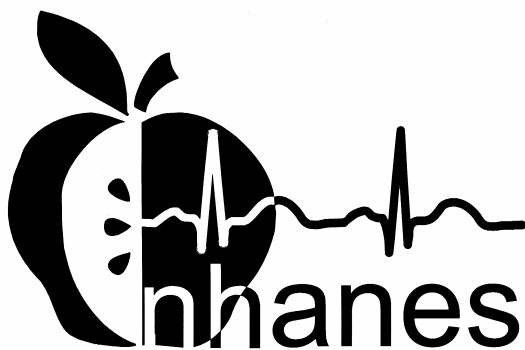


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National Health  
and Nutrition  
Examination Survey

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DENTAL  
EXAMINERS  
PROCEDURES  
MANUAL



Revised January 2004

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# **1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY**

This chapter provides a general description of the health examination surveys conducted by the National Center for Health Statistics (NCHS) and the current National Health and Nutrition Examination Survey (NHANES). It also provides an overview of the tasks that staff perform during the survey.

## **1.1 History of the National Health and Nutrition Examination Programs**

This NHANES is the eighth in a series of national examination studies conducted in the United States since 1960.

The National Health Survey Act, passed in 1956, gave the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. In order to fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) the people themselves by direct interview; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, between 1960 and 1984, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data.

The first three national health examination surveys were conducted in the 1960s:

1. 1960-62 – National Health Examination Survey I (NHES I)
2. 1963-65 – National Health Examination Survey II (NHES II)
3. 1966-70 – National Health Examination Survey III (NHES III)

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11, while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.

Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status had become increasingly important as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and monitor nutritional changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Four surveys of this type have been conducted since 1970:

1. 1971-75 – National Health and Nutrition Examination Survey I (NHANES I)
2. 1976-80 – National Health and Nutrition Examination Survey II (NHANES II)
3. 1982-84 – Hispanic Health and Nutrition Examination Survey (HHANES)
4. 1988-94 – National Health and Nutrition Examination Survey (NHANES III)

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months to 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many of the ethnic groups within the United States. Hispanic HANES (HHANES), conducted from 1982 to 1984, produced estimates of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, the health status of minority groups is often different than the health status and characteristics of nonminority groups, so black Americans and Mexican Americans were selected in large proportions for NHANES III. Each group comprised 30 percent of the sample. NHANES III was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. To obtain generalizable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate than previously. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure levels of pesticide exposure, presence of certain trace elements in the blood, and amounts of carbon monoxide present in the blood. A home examination was incorporated for those persons who were unable or unwilling to come to the exam center but would agree to an abbreviated examination in their homes.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiologic Follow-up Survey, a multiphase survey conducting follow-up interviews with the NHANES I population in order to provide longitudinal data on the health of the U.S. population.

## **1.2 Overview of the Current NHANES**

This NHANES follows in the tradition of past NHANES surveys, continuing to be a keystone in providing critical information on the health and nutritional status of the U.S. population.

The major difference between the current NHANES and previous surveys is that the current NHANES is conducted as a **continuous, annual survey**. Each single year and any combination of consecutive years of data collection comprises a nationally representative sample of the U.S. population. This new design allows annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period will be about the same as in previous NHANES, about 5,000 a year from 15 different locations across the nation. The data from the NHANES are used by government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

### **1.2.1 Data Collection**

Data collected on the current NHANES survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. The survey was preceded by a pretest in the spring of 1998 and a dress rehearsal was conducted in early 1999.

Approximately 40,000 individuals of all ages in households across the U.S. will be randomly selected to participate in the survey. The study respondents include whites as well as an oversample of blacks and Mexican-Americans. The study design also includes a representative sample of these groups by age, sex, and income level. Adolescents, older people, and pregnant women are also oversampled in the current NHANES.

The overall goals of the NHANES are to:

- Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factor;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposure;
- Analyze risk factors for selected diseases;

- Study the relationships between diet, nutrition, and health; and
- Explore emerging public health issues and new technologies.

Selected persons are invited to take part in the survey by first being interviewed in their homes. Household interview data are collected via computer-assisted personal interviewing (CAPI) and include demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents are asked to participate in a physical examination. The examination is conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses the state-of-the-art exam equipment and is divided into rooms to assure the privacy of each study participant during the exams and interviews. The examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, a variety of physical measurements, and other health interviews conducted by highly trained medical personnel.

The household interviews and MEC exam combined will collect data in the following important health-related areas:

- Cardiovascular and respiratory disease;
- Vision;
- Hearing;
- Mental illness;
- Growth;
- Infectious diseases and immunization status in children;
- Obesity;
- Dietary intake and behavior;
- Nutritional status;
- Disability;
- Skin diseases;
- Environmental exposures;
- Physical fitness; and
- Other health-related topics.

### **1.3 Sample Selection**

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the U.S. for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, gender, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the MEC examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent Form. An additional consent form is required for consent to future general research for both adults (ages 18+) and parents of children under 18 years. This consent form gives permission to store a small sample of blood and urine for future specimen testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

## 1.4 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat** – Project staff from Westat are responsible for overseeing the field teams and field work.
- **Field Office (FO) Staff** – For this survey, an office will be opened at every survey location (stand). Each field office will have a Study Manager (SM), Office Manager (OM), a Field Manager (FM), and one Assistant Office Manager (AOM).
  - The **Study Manager (SM)** is responsible for the overall management of operations at a stand.
  - The **Office Manager (OM)** is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. S/he will supervise one or more local office clerks hired to assist with office activities. The OM reports to the SM.
  - The **Field Manager (FM)** has primary responsibility for the supervision of the household interviewers. The FM also assists the SM and supervises the activities of the Assistant Office Managers. S/he will deal with administrative issues, ISIS problems, and preparations for the next stand.
  - The **Assistant Office Managers (AOMs)** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. The AOMs report to the FM and also work closely with the OM.
- **Household Interviewers** – This staff is primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, household interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, household interviewers visit the field office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- **MEC Staff** – This staff of health professionals conducts the health exams. The survey includes two exam teams.



There are 16 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technologists, 2 MEC interviewers, 2 dietary interviewers, and 1 phlebotomist. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff. A data manager also travels with each team.

The following section describes the steps that are always completed prior to the opening of a stand and an overview of the tasks that interviewers are expected to perform. Highlighted items are basic concepts critical to the conduct of the study.

Steps completed prior to interviewing include:

- Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
- Twelve weeks before data collection begins, NHANES staff list the segments. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
- A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
- Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter briefly describes the study and inform the household that an interviewer will contact them in the near future.

The tasks interviewers perform when they arrive at a stand include:

1. After the successful completion of training, interviewers are given an assignment of sampled dwelling units to contact. Each assignment consists of pre-labeled Household Folders, pre-labeled Neighbor Information Forms, and the appropriate Segment Folder.
2. Using addresses on the Household Folders and listing/mapping materials in the Segment Folder, interviewers locate these dwelling units.
3. If a selected address is not a dwelling unit or is not occupied, interviewers complete the “Vacant/Not a DU Section” on the Screener Non-Interview Form.
4. In an occupied residential dwelling unit, interviewers contact an adult who lives in the selected household and administer the Screener using a laptop computer.

The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.

All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.

5. If all persons in a household are ineligible, no further work is done with the case. When eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
6. In eligible households, the interviewer obtains a signed interview consent form prior to completing the medical history and/or the family questionnaire.
7. Next, the appropriate medical history CAPI interview is administered to eligible respondents. The questions asked depend on the age of the SP.
8. In each household containing children aged 1-5, floor and window sill dust samples are obtained. These samples provide information on lead levels in the household environment.
9. A Family questionnaire is also administered to one adult family member from each eligible family in the household.
10. Next, an appointment is scheduled for each SP, coordinating the MEC schedule and the SP schedule.
11. Interviewers then obtain signed consent form(s) for each SP for the examination, call the field office to confirm the examination appointment(s), and give each SP an appointment slip.
12. If there is more than one eligible family in a household, this process is repeated with each additional family.
13. Interviewers record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.
14. Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments.
15. If an interviewer is unable to complete any of the questionnaires or procedures for any SP, an SP Card is completed. This card documents the problems encountered in completing one or more tasks.
16. Interviewers check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures is implemented and appropriate forms will be completed.

17. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility.
18. Interviewers report in person to the FM at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.
19. To insure the accuracy and completeness of the survey, all interviewer work is edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors provide interviewers with feedback concerning the quality of the work.
20. At the end of each stand field period, interviewers return all interviewing materials to the supervisor.

## **1.5 Exams and Interviews in the Mobile Examination Center (MEC)**

Examinations and interviews are conducted in a mobile examination center (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 48 feet long and 8 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows the locations of the various exams within the MEC.

### **1.5.1 Exam Sessions**

The MEC operates 5 days a week and includes weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10-12 SPs per session. During a stand, work weeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exhibit 1-1. Floor plan of the MEC

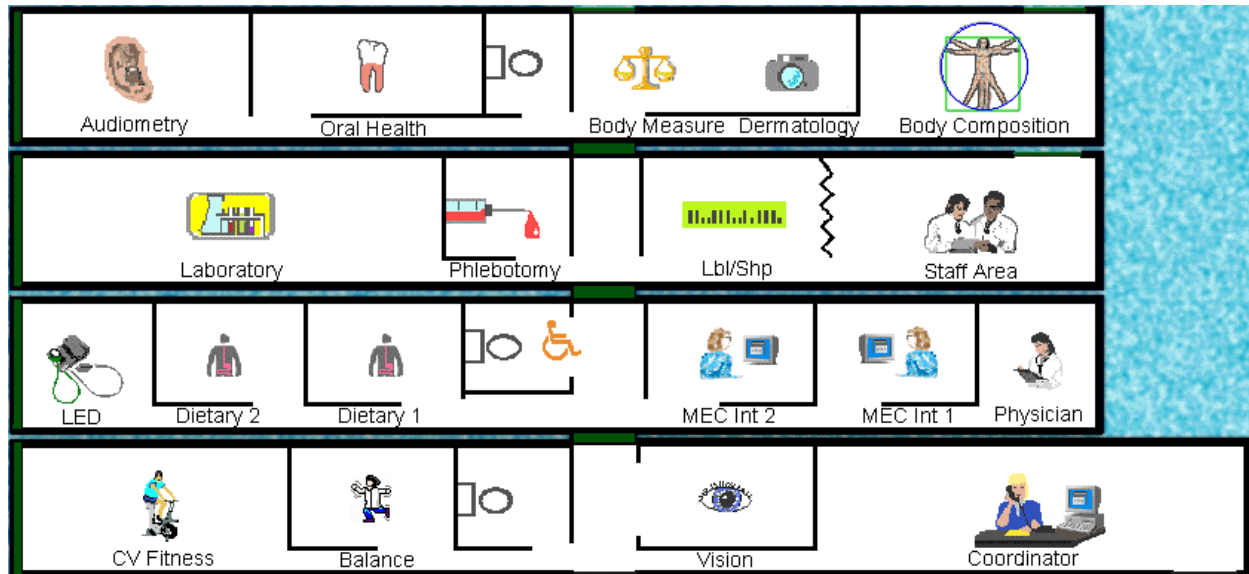


Exhibit 1-2. MEC exams and rooms

<u>Trailer</u>	<u>Room</u>	<u>Room Use</u>
Trailer 1	Reception area Vision room Balance Fitness	Welcoming and waiting area for SPs Vision tests Balance test Cardiovascular fitness
Trailer 2	Physician MEC Interview MEC Interview Dietary Interview Dietary Interview Lower Extremity Disease	Physical examination Health interview Health interview Dietary interview Dietary interview Testing for lower extremity pulses and sensitivity
Trailer 3	Venipuncture  Laboratory Label/shipping area Staff lounge	Drawing of blood samples, MRSA collection and physical activity monitor Processing of urine and blood samples Lab area for labeling and shipping specimens Staff area that houses main computer system
Trailer 4	Total Body Composition  Body Measures Dental Audiometry/Tympanometry	Total body composition scans and bioimpedance Body measurements and dermatology Dental exam Hearing tests

## 1.5.2 Exam Team Responsibilities

There are 16 individuals on each exam team. In addition, a local assistant will be hired to assist the staff in managing examinee flow. One data manager also travels with each team. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, manages the facility, and supports exam operations.
- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood count and pregnancy test, and serves as the safety officer for the MEC.
- One dentist conducts the dental exam and calls the results to a health technologist who records the findings.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours.
- Four health technologists with radiologic technology or other health training take and record body measurements, perform balance tests, vision tests, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA) tests, administer hearing tests, and collect skin images. In addition, the technologists record findings for the dental examiner.
- Three medical technologists conduct clinical laboratory tests on biological and environmental specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist administers the phlebotomy questionnaire draws blood from SPs, and recruits SPs for special studies.
- The data manager (DM) assists in the setup and testing of computer systems and telecommunications hookups at the FO and MEC. S/he also coordinates the maintenance and repair of computer systems at the FO and MEC with the home office and external vendors and acts as the FO and MEC systems “help desk” person. The data manager reports to the SM on administrative matters and the HO for ISIS-related matters.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

### **1.5.3 Examination Components**

The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP's age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3:

- **Anthropometry**

The purpose of the anthropometry component is to provide: (1) nationally representative data on selected body measures, (2) estimates of the prevalence of overweight and obesity, (3) data to study the association between body measures and such health conditions and risk factors as cardiovascular disease, diabetes, hypertension, and activity and dietary patterns, and (4) data to monitor growth and development in children. A total of 11 body measurements are collected, but the number and type of measures varies with the age groups.

- **Balance**

Balance disorders, disequilibrium, and dizziness from vestibular disorders constitute a major public health problem. Primary disorders may be hidden by their consequences, such as falls, while subtle dysfunction may underlie difficulties in learning, writing, reading, and in everyday activities. The main objectives of the balance test are to obtain prevalence data, examine the relationship between balance disorders and other factors, and to characterize normal and disordered balance and spatial orientation. The standard Romberg test is used to measure postural sway.

- **Bioelectrical Impedance Analysis (BIA)**

The purpose of the BIA exam is to monitor secular trends in overweight prevalence, describe the prevalence of obesity, and examine the relationship between overweight and obesity and other examination measures. BIA measures the electrical impedance of body tissues and is used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

Exhibit 1-3. Examination components

<b>Component</b>	<b>Ages</b>
Anthropometry	All
Audiometry/Tympanometry	20-69 (half-sample)
Balance	40+
Bioimpedance (BIA)	8-49
Cardiovascular Fitness	12-49
Dermatology	20-59
Dietary Interview	All
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years (also includes parents of 8-15-year-olds); 20-39 years (half-sample)
MRSA sample collection	1+
Oral Health	2+
Physical Activity Monitor	6+
Physician Exam	All
Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
Volatile Organic Compounds (VOC)	20-59 (random subsample)

■ **Cardiovascular Fitness**

Evaluation of physical fitness provides nationally representative data on measures of physical fitness, and estimates of the prevalence of persons at risk due to sedentary habit and poor physical fitness. Cardiovascular fitness is assessed with a submaximal treadmill test on examinees aged 12 through 49 years.

■ **Dermatology (Skin Disorders)**

The specific aims of this component are: (1) to monitor the prevalence, secular trends and impact of selected skin conditions that were last assessed in NHANES I (1971-75); (2) to identify risk factors for selected skin conditions that can be used to increase understanding of disease etiology and prevention; and (3) to create a data resource that can be used to develop a CDC National Skin Cancer Prevention and Control Agenda. The MEC dermatology exam involves standardized photography of selected sites on the body. This component will focus on two specific skin diseases: psoriasis and hand dermatitis. The major goal is to determine the prevalence of these two conditions.

- **Dietary Interview**

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data is obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system. A second 24-hour recall will be conducted on all SPs by telephone through a phone center operation at the home office. In 2003, a self-administered form, the Food Frequency Questionnaire, will be offered to SPs who complete the MEC dietary interview. It will be mailed from and returned to the home office.

- **Hearing**

The goals of the hearing exam are to obtain normative data on the hearing status of the adult U.S. population, and to evaluate certain covariates that may be related to hearing loss, such as occupational exposure. The hearing component tests adults by performing pure tone audiometry and tympanometry. Because pure tone screening by itself may not be sensitive enough to detect middle ear disease, tympanometry is conducted to provide an estimate of tympanic membrane compliance.

- **Laboratory**

The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, urine for subjects 6 years and older. On-site pregnancy testing excludes pregnant women from other examination components such as DEXA, BIA, and cardiovascular fitness testing. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

- **Lower Extremity Disease (LED)**

The purpose of this component is to determine the prevalence of LED and its risk factors. Simple and reproducible measures of lower extremity arterial disease are obtained. Peripheral neuropathy is evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities permit the estimation of prevalence of those at high risk for the late-stage complications of LED.

- **MEC Interview**

The MEC Interview consists of questionnaire sections designed to obtain information on health behaviors, specific conditions, medical history, and risk factors. The information collected in the interview is intended to assist researchers in analyzing the data collected in the other examination components. The interview is administered to all age-eligible subjects, or a suitable proxy, using computer-assisted interviewing software.



- **Mental Health**

The mental health assessment is used to estimate the prevalence of selected disorders in the U.S. and to describe the degree of comorbidity between mental health disorders and other medical conditions and biological risk factors. Assessments are made during the MEC Interview using relevant portions of the Diagnostic Interview Schedule for Children (DISC) and the Composite International Diagnostic Interview (CIDI) for adults.

- **Methicillin-Resistant *S. Aureus* (MRSA) Sample Collection**

A nasal swab specimen collection for Methicillin-Resistant *Staphylococcus aureus* (*S. aureus*) is obtained on SPs aged 1+ years for the purpose of estimating the prevalence of MRSA in the population. Antimicrobial resistance to *S. aureus* has increased so dramatically, particularly in the hospital setting, that currently only one treatment option exists for this organism. NHANES is the first population-based prevalence study of MRSA. No other population-based studies or national surveillance efforts are available to provide reliable national estimates for this problem.

- **Oral Health**

This component monitors oral health status, risk factors for disease, and access to preventive and treatment services. The exam consists of a series of subcomponents which assess dentition and periodontal disease.

- **Physical Activity Monitor**

The purpose of physical activity monitor component (PAM) is to assess the physical activity levels of NHANES examinees 6+ years of age. NHANES examinees wear a physical activity monitor (PAM) to examine physical activity patterns over a 7-day monitoring period and then mail it back to the home office. The monitors detect locomotion-type activities such as walking or jogging. The monitors provide a means of capturing non-structured activities that are often difficult for survey respondents (SPs) to self-report. Physical activity data are linked to other household interview and health component data and are used to track changes that occur in body weight, functional status, bone status, and health status over time.

- **Physician Exam**

Blood pressure assessment and discussion of testing for sexually transmitted disease are the primary elements of the physician's exam. The purpose of assessment of blood pressure is to monitor prevalence and trends in major cardiovascular conditions and risk factors and to evaluate prevention and treatment programs targeting cardiovascular disease. The physician discusses the purpose of STD testing and arranges for SPs to select a unique password with which to phone NCHS and obtain test results.

- **Total Body Composition**

This component is composed of the BIA and Dual Energy X-ray Absorptiometry (DEXA). The purpose of the DEXA scan is to gain insights into age, gender, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity. A total body scan using dual energy X-rays is performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.

- **Vision**

The vision examination consists of a near vision acuity test, a distance vision acuity test, an eyeglass prescription determination (when appropriate), and an automated refraction measurement. Information from the component may be used to estimate the prevalence of visual acuity impairment and distribution of refractive error in the U.S. population. Data are also used to evaluate screening strategies for visual impairment and eye disease, and evaluate functional impairment related to vision.

- **Volatile Organic Compounds (VOC)**

Information on levels of exposure to a selected group of volatile organic compounds is collected on a subsample of the survey population to assist in determining whether regulatory mechanisms are needed to reduce the levels of hazardous air pollutants to which the general population is exposed.

#### **1.5.4 Sample Person Remuneration**

All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and includes an extra incentive if the SP fasts prior to the exam. SPs who complete the physical activity monitoring component also receive an incentive. In addition, remunerations are offered to SPs who complete the dietary phone interview and the Food Frequency Questionnaire.

#### **1.5.5 Report of Exam Findings**

Examinees receive the results of many of the tests and exams conducted in the MEC, though some results are used only for research and are not reported.

One report, a Preliminary Report of Findings, is produced for the SP on the day of their examination and includes results that are immediately available and require no further evaluation or

interpretation. Just prior to the examinee's departure from the MEC, the coordinator prints a report that includes height, weight, and body mass index, complete blood count, blood pressure, and results from the audiometry, cardiovascular fitness, lower extremity disease, vision, and dental exams. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or their parent). The dentist also discusses the dental recommendations with the SP. Approximately 12-16 weeks after the exam, NCHS mails the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed.

Certain tests, such as those for sexually transmitted diseases (chlamydia, gonorrhea, syphilis, Herpes simplex 1 and 2, bacterial vaginosis, and Trichomoniasis) and human immunodeficiency virus (HIV) are released only to the sample person using a specially devised procedure requiring a unique password.

To further assist sample persons, an in-house NCHS survey response team is available to answer calls from NHANES participants regarding the results from the Report of Finding System. The response team effort works both as a triage mechanism and a surveillance system. A receipt and control record is kept on all sample person inquiries. Also available at no cost to sample persons is an 800 toll-free telephone number which can be accessed during regular scheduled business hours. The response team members include a physician, a nurse with a doctorate degree, and other staff who are trained to answer specific questions.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician offers to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad may be summoned or the SP will be advised to seek immediate medical treatment.

### **1.5.6 Dry Run Day**

At the beginning of the examination period, one-half day is devoted to calibrating instruments, practicing MEC procedures, and collecting biological specimens that serve as blind quality control samples. A dry run day is scheduled immediately prior to the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. Any problems are corrected quickly before the “real” examinations begin. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the examinees are actual volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

### **1.6 Integrated Survey Information System (ISIS)**

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. With a collection of customized subsystems, the ISIS links the Field Office, Mobile Examination Center, Westat home office, and NCHS during field operations. Each component in NHANES such as Dietary Interview has a computer application for direct data entry. Data collected in the Dietary Interview room of the mobile examination center is directly entered in the ISIS system computers. In addition, data from biomedical equipment such as the blood pressure monitor in the CV Fitness room is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

### **1.7 Confidentiality and Professional Ethics**

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey to encourage continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently staff must be discreet in speech and action. Personal appearance and behavior must be governed by these same considerations. Please be aware of the audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

Staff will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that they are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that they agree to abide by the contractor's Assurance of Confidentiality.

## **2. OVERVIEW TO THE ORAL HEALTH COMPONENT**

### **2.1 Introduction**

The oral health component of NHANES is sponsored by the following organizations:

- National Institute of Dental and Craniofacial Research (NIDCR);
- The Division of Oral Health of the Center for Chronic Disease Prevention and Health Promotion of the Centers for Disease Control and Prevention (CDC); and
- The National Center for Health Statistics (NCHS).

The component was developed by the NIDCR, the Division of Oral Health, and the NCHS, with input from nationally recognized research scientists intramurally and extramurally, and public health leaders from the NIDCR, CDC, other U.S. Public Health Service agencies, universities, and state health departments.

The purpose of the NHANES oral health component is to assess the prevalence of oral diseases and conditions, such as dental caries, periodontal disease, edentulism, denture use, sealants, fluorosis, and traumatic injury in a national sample. The periodic assessment includes evaluation of tooth wear, functional occlusal contacts, and perceived overall quality of oral health.

Over the past four decades, oral and dental health characteristics collected in national surveys supported by the Federal Government have been critical for monitoring health status, risk factors for disease, access to preventive and treatment services, and other health characteristics among the general population and special subpopulations. These studies include the National Health and Nutrition Examination Surveys (NHANES), National Health Interview Surveys (NHIS), National Medical Expenditure Surveys (NMES), and special surveys such as the Hispanic Health and Nutrition Examination Survey.

Oral and dental diseases affect many in the United States and constitute a major burden on the Nation. Dental caries, periodontal disease, and tooth loss are significant problems affecting the Nation's oral health. Although average dental caries scores for school-aged children have declined, 50 percent of children still have caries. In addition, 94 percent of adults in the United States have

experienced caries. Dental sealants, an effective means of preventing caries, are underutilized in the United States, with only 19 percent of children aged 5-17 having them. In addition to caries, 15 percent of Americans have severe periodontal destruction and 11 percent have lost all their teeth.

The oral health component of the current NHANES will meet a critical need by accomplishing the objectives listed below. The NHANES oral health component will:

- Evaluate trends in oral and dental diseases;
- Evaluate trends in tooth retention and replacement;
- Estimate the burden of oral and dental diseases in the population as a whole;
- Estimate the burden of oral and dental diseases in subgroups of the population; and
- Assess progress in meeting national health objectives.

This section provides a general overview of the oral health component and the Mobile Examination Center (MEC) operations. Specific procedures for conducting the oral examination are described in Chapter 4 of the *Dental Examiners Procedures Manual* while specific procedures for recording data are described in Chapter 4 of the *Dental Recorders Procedures Manual*.

## **2.2 Data Collection**

The MEC contains an automated computer system referred to as ISIS, the Integrated Survey and Information System. This automated system is used to:

- Direct the flow of SPs through the MEC, keeping track of which parts of the examination have been completed;
- Record interview and examination data;
- Perform edits on collected data; and
- Enter quality control data for each component.

The dental examiner “calls” his/her observations (codes for oral health indices) during the oral examination and the recorder enters these calls into ISIS.

## 2.3 Operations Overview

This section summarizes the flow in the MEC and the responsibilities of the dental examiner and dental recorder.

- The dental examiner arrives at the MEC prior to the session start. He/she needs to arrive early enough to complete the following tasks prior to the start of session:
  - Print and post the session schedule for the number of study participants (SPs) and their ages;
  - Set up the oral health work area (details will be provided later in this chapter);
  - Check all equipment;
  - Make sure enough supplies are available for the session. A full session is quite busy and there will be no time to resupply;
  - Complete the quality control for set-up in ISIS (details will be provided later); and
- At the start of the session, each SP will check in with the coordinator at the workstation, just inside the MEC entrance. The coordinator will provide each SP with a bracelet with the SPs name, ID number, and corresponding bar code.
- The examiner notifies the coordinator that the room set-up is complete and the examiner is ready to receive SPs.
- The examiner or recorder checks the daily appointment schedule and goes to the coordinator station to meet the SP and bring him/her to the oral health room.
- The recorder opens the SP's record in ISIS and wands the bar code on the SP's bracelet.
- The examiner asks SPs 16 years and older medical exclusion questions, and responds to SP questions. SPs aged 13 to 15 years will have a proxy form that the MEC manager completed with the SP's parent or guardian.
- The examiner completes the oral health subcomponents while the recorder enters the data in the ISIS system.
- The SP is escorted to the reception area or next examination by the dental examiner or recorder.
- The examiner sets up the room for the next SP.



- At the end of a session, the examiner does the following:
  - Cleans the oral health room;
  - Takes the biohazard trash bag to the collection area; and
  - Completes the End of Session quality control in ISIS.

## **2.4 Conducting the Oral Examination and Recording Oral Examination Data**

Data for this component will be collected using a visual-tactile examination. This examination has several sections. The specific section a study participant receives is dependent on their age and medical exclusions. The specific examinations, with the appropriate age range are listed below.

### **Medical Exclusions and Dental Condition Questions**

- Medical exclusion questions (13 years and older); and
- Dental condition questions (16 years and older).

### **Dentition**

- Denture questions (25 years and older);
- Tooth count (2 years and older);
- Coronal caries (2 years and older);
- Root caries (18 years and older);
- Dental sealants (2 to 34 years old);
- Dental fluorosis (6 to 49 years);
- Incisor trauma (6 to 29 years old)
- Tooth wear (13 years and older); and
- Functional occlusal contacts (25 years and older).

### **Periodontal Assessment**

- Loss of attachment (13 years and older)
- Bleeding from probing (13 years and older)

### **Recommendation for Care**

- Report of Findings (2 years and older); and
- Referral letter (as needed).

#### **2.4.1 Exclusion for Medical Conditions**

SPs with certain medical conditions will not be permitted to participate in some components of the dental exam. The examiner must ask each SP 16 years or older if he/she has any of the conditions listed on the Medical Exclusion screen. The MEC manager obtains medical exclusion information for SPs 13 to 15 years old from the SP's parent or guardian. The MEC manager records the answers on a hard copy proxy questionnaire. The questionnaire accompanies the SP to the oral health room and is reviewed by the dental examiner. This information is then entered in ISIS by the dental recorder at the beginning of the examination. The responses to the medical exclusion questions along with the SP's age determine which dental examination components can be performed.

#### **2.4.2 Documenting Incomplete and Omitted Examinations**

If a scheduled examination is partially completed or not done at all, the reason must be recorded in ISIS. The NHANES dental examination has several subcomponents and not every SP receives every subcomponent. The primary reasons SPs do not receive certain subcomponents relate to age and medical exclusions. However, there may be occasions when SPs are prevented from receiving the dental examination, or the dental examination begins but must be terminated prior to completion. Medical exclusions and these other unusual circumstances are recorded in ISIS. The age-dependent components are already accounted for by the system.

Medical exclusions are recorded by a "yes" response to any of the medical conditions or circumstances listed in ISIS. This causes the system to automatically skip the excluded subcomponents.

Specific reasons for terminating an examination or a subcomponent of an examination are recorded in ISIS, on the status screen for the whole examination or for the particular section of the examination. Section status screens are summary screens that appear at the end of each subcomponent section: medical exclusions and dental conditions, dentition, periodontal, and recommendation for care. If

the subcomponent is partially complete or not done, the following reasons are programmed into the ISIS system and appear at the status screen:

- **SP refused or uncooperative.** An “uncooperative” SP is one who is unwilling to cooperate, e.g., an infant or small child who cannot be persuaded to get through the examination.
- **No time.**
- **Physical limitation.** An SP may complete part of the examination because of a physical limitation, e.g., the examiner may not be able to do part of an examination because an SP has braces.
- **SP unable to comply.** SP who is willing but faces a barrier in complying with the protocol, e.g., a person who cannot sit in a position conducive to conducting the examination.
- **Equipment failure.** A piece of equipment is not working, or the examiner does not have the supplies necessary to complete an exam.
- **Medical reasons.** A circumstance where the SP’s safety or medical condition is of concern to the examiner due to pain, fainting, seizure, bleeding, etc.

For example, if the SP experienced pain or fainted and the examiner elected not to complete certain exam portions, this would be treated as an aborted exam for medical reasons.

- **Safety Reasons.** If an SP is excluded from certain subcomponents because of a medical exclusion question, but has otherwise gone through the exam, it is recorded as a partially completed exam for safety reasons **not** a termination for medical reasons.
- **Room not available.**
- **Other reason.** A reason not programmed in the ISIS system requires a comment.

### 2.4.3 Report of Dental Exam Findings and Referral Letters

The last portion of the examination is the Recommendation for Care screen. The information on this screen is used to create the Report of Oral Exam Findings and an Oral Health Referral Letter, if needed. The information on this screen is partially automated – based on the examination data, and partially examiner driven – based on information the examiner gives the recorder. The Report of Findings will be handed to the SP when he/she leaves the MEC. It will indicate whether the SP should continue his/her usual dental care, see a dentist at his/her earliest convenience, see a dentist within 2 weeks, or see

a dentist immediately. The Referral Letter is handed to those SPs whose oral health warranted a concern that they see a dentist within the next 2 weeks or earlier. The report, Referral Letter, and related procedures will be discussed in depth in Chapter 5.

#### **2.4.4 Returning the SP to the Coordinator's Area**

After examination data are recorded and the examiner completes the Recommendation for Care screen, the examiner or recorder will escort the SP to the coordinator station or to another examination room. The examiner will then prepare the oral health room for the next SP.

### **3. EQUIPMENT AND SUPPLIES**

#### **3.1 Dental Examination Area in MEC**

The oral health room is located in Trailer #4 of the mobile examination center (MEC). This room contains the equipment and supplies necessary to conduct the dental examinations. This 9' by 4' 9" room includes cabinets for storage, a counter top, and a sink with running water. (See Exhibit 3-1.)

#### **3.2 Description of Equipment and Supplies**

Exhibit 3-2 shows a list of equipment and supplies and the anticipated quantities for each of these items. The specific manuals for each piece of equipment are located in the bottom drawer of the oral health room. It is located in a blue folder labeled Oral Health Equipment. Use these as necessary if a problem arises.

Each MEC was loaded with equipment and supplies necessary to perform examinations for the first stand. The home office ships supplies to the field prior to the start of each stand, and as needed. Remember to use older items first.

The dental examiner should inform the MEC manager **immediately** if there is a problem with any dental equipment or supply. The home office will arrange to have the equipment repaired or replaced, if necessary.

##### **3.2.1 Inventory Procedures**

There are two inventories completed per stand. The first is done at the Start of Stand and requires verifying the End of Stand count from the previous MEC inventory and the amount shipped to the stand at the Start of Stand. The total for each item should be at par or above par. The second type of inventory is completed at the End of Stand. This inventory requires counting all supplies for your component. Remember to include everything in the oral health room and in the belly compartment.

Exhibit 3-1. Dental examination room

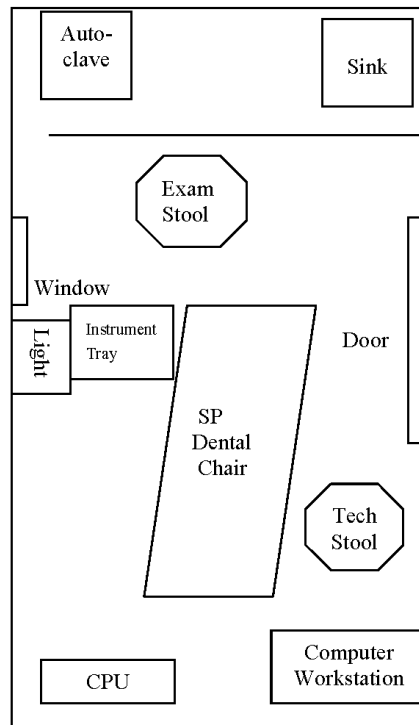


Exhibit 3-2. Equipment and supplies for dental component

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
<b>Examination</b>			
Dental Porta-Chair	1		
Back-up dental chair (kept in belly compartment of MEC)	1		
Adeck set screws	1 set		
Adjustable Deltube stools (for examiner and recorder)	2		
Air compressor	1		
Back-up air compressor (kept in belly of MEC)	1		
Air syringe	1		
Air compressor gasket (o-ring) 1/8"	5		
Air compressor gasket (o-ring) 1/16"	5		
Filter element replacement (cotton roll – spare)	1		
Cotton applicators	1 bag		
Halogen light (with bulb and adapter)	1		
Replacement halogen light bulb	1		
Back-up light and replacement light bulb	1		
Replacement fuse for halogen light	2		
2x2 gauze, non-sterile (NuGauze)			2
Denture adhesive	1 tube		
Pillow (for elderly)	1		
Pillow covers	25		
Instrument set-up tray	1		
One-quart bottle (to mix Restore solution)	1		
Half-gallon bottle (to mix Speed Clean solution)	1		
Rubbermaid container, rectangle #10 (to soak instruments)	4		
Dental Release Forms	10 English/ 5 Spanish		
Stickers (assorted cartoon for children)	4 rolls		
<b>Instruments</b>			
#23 Explorer	60		1
Hu Friedy PCP-2 periodontal probe	60		1 (SP 13+)
Mirrors (handles and heads)	60		1
Endodontic ruler, 65 mm	60		1 (SP 25+)
Curettes	5		
<b>Sterilization</b>			
Ritter SpeedClave Steam Sterilizer	1		
SpeedClean solution		8 oz	
Attest incubator	1		
Attest (spore tests)		12 vials	
Peelvue sterilizing pouches			1
Sterigage indicator strips		12-18	
Door gasket (spare)	1		

Exhibit 3-2. Equipment and supplies for dental component (continued)

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
<b>Sterilization (continued)</b>			
Instrument brush with holder	1		
Utility gloves	1 pr		
Hot pad mitt	1		
Distilled water		3 gal	
<b>Infection Control</b>			
Safe-tips EZ, disposable			1
Syringe covers			1
Barrier chair covers			2
Coverall barrier with dispenser			2 sheets
Disposable lab jackets		6	
Latex examination gloves, powder free			1 pr
Latex free examination gloves, powder free		4 boxes	
Face masks, ear loop and molded		60	
Safety glasses, plexiglas	1		
Side shields, disposable (for eyeglasses)			
Restore (to soak instruments)		60 quarts	
Germicidal wipes, disposable		5 cans	
Liquid hand soap dispenser	1 bottle		
Waterless hand cleaner	1 bottle		
Waste basket, biohazard	1		
Trash bags, biohazard		60	
Sharps disposal container		2	
<b>Non-Dental</b>			
Containers, various (to hold miscellaneous items)	6		
Hand cream	As needed		
Small toothbrush	1		
Washcloth	1		
Sponge	1		
Scissors	1		
Masking tape	2 rolls		
Scotch tape	1 roll		
Cleaning supplies: 409, window cleaner, softscrub	1 bottle each		
Felt tip pens	2		
Clipboard	1		
Paper towels	As needed		
Clock	1		
CPR mask	1		
Liquid dish detergent (Dove only)	1 bottle		
Hand mirror	1		
Tool kit (screwdrivers, Allen wrenches, wrench, pliers)	1		
Cotton pliers	1		



The following procedures should be followed when counting supplies for either inventory.

- Verify that you are counting in the correct units (e.g., box, bottle, case).
- Enter only one name in the “Counted By” field. This is the person responsible for taking and verifying the inventory count.
- Do not write any notes, comments, etc. on the count sheet. Only write your name in the “Counted By” field and place a number in the “Count” box. Do not redefine or reiterate the Unit of Measure. If you have any comments or concerns on the count sheets see your MEC manager.
- Do not count partial units. Record whole numbers only in the “Count” field.
- If the PAR for an item is more than 1 and the box or container is open, do not count that container (e.g., gloves – 12 boxes have not been opened, 1 box is opened, the count is 12).
- If the PAR for an item is only 1 unit – if it is more than ½ empty place a 0 in the count unit. Another way to look at it is can the next stand get by without needing more? If not, put a 0.
- Lot #'s and expiration dates – all active lot #'s and expiration dates show up on the count sheets if they are applicable for that item. If you see a lot # and expiration date you must put a count (even if it is 0) in this field. Please also remember to use items with older expiration dates first.
- Restocking Supplies – remember to use items you have on hand in the rooms and items in the belly compartment first. Do not restock your rooms unless necessary with items that were just shipped to the stand. Many items such as gloves, alcohol prep pads, electrodes, etc. deteriorate over time.

### **3.2.1.1 Consumables vs. Non-Consumables**

Inventory items are broken out into two categories – consumable and non-consumable. Inventory both types of items at the end of each stand. The definition for a consumable item is anything that is typically consumed during an examination. Whereas some items may be used (consumed) in case of emergency, these are still considered non-consumables since they are not typically consumed during the course of an exam.

### **3.2.1.2 Shipping Excess Inventory Back to the Warehouse**

When shipping excess inventory back to the warehouse, please use the “Transfer Inventory to Warehouse Manifest” which is found on the IntraWeb and can be printed by your MEC manager or data manager. This form will look similar to the “End of Stand Count Sheets.” Please enter your name in the “Count By” field and indicate next to each item how many units are being shipped back to the warehouse. This information will be entered into the system by the warehouse manager and will be used to adjust your stand inventory and usage information as well as increase the warehouse inventory counts.

### **3.2.1.3 Tracking of Expired and Broken Inventory**

The “Delete Expired/Broken Inventory Report” should be completed whenever you have inventory that has expired and must be destroyed or has broken and is no longer usable. This report is also found on the IntraWeb and should be completed and forwarded to the warehouse manager so that the expired or broken inventory can be removed from the stand inventory.

Do not borrow any supplies from any other components. The warehouse tracks usage by stand and by component. You are responsible for ensuring that you have enough supplies to complete exams, notify you MEC manager as soon as possible when your supplies run low.

## **3.3 Equipment Procedures and Maintenance**

The procedures for set-up and maintenance of equipment at the beginning of a stand, daily, weekly, mid-stand, and at the end of a stand will be listed below. Then this chapter will review specific procedures for use of equipment and supplies.

### **3.3.1 Start of Stand**

It is very important the dental equipment and supplies are checked and set-up properly at the start of a stand. The specific directions for the equipment may seem complicated, but they will be

reviewed, demonstrated, and practiced during training sessions. The examiner has primary responsibility for setting up and taking down the dental equipment and supplies.

The following is a list of all tasks the dental examiner completes at set-up or start-of-stand:

- Complete inventory of supplies – Add new/additional items and check to make sure all items listed are present and in good working condition.
- Clean the oral health room with 409 and/or soft scrub. Use the washcloth, then throw it out. Counters, blinds, cabinets, walls, and window should be cleaned. Disinfect the inside of the instrument drawers.
- Clean and disinfect the biohazard can.
- Check to make sure all equipment arrived without damage.
- Check the back-up compressor to make sure it is in working order.
- Stock cabinets with supplies per instructions in Chapter 6.
- Pack excess supplies in the belly.
- Hang clock and CPR mask.
- Clean and set-up Porta-Chair.
- Clean and set-up dental light.
- Clean and set-up dental stools.
- Set-up air compressor.
- Check air syringe filter to make sure it is dry.
- Clean and set-up Speedclave.
- Check Speedclave gasket.
- Make sure the dental reference sheets are secured on the wall.

### 3.3.2 Start of Exam Session

There are a number of specific tasks the dental examiner needs to complete at the beginning of each exam session. These are listed below.

- Wash hands;
- Turn dental light on; and
- Visually check the following pieces of equipment:
  - The light;
  - The air compressor and air tank valves;
  - The sterilizer;
- Turn the air compressor on and close valve;
- Check airflow from air syringe; and
- Prepare the room for the examination – complete all infection control procedures;
  - Wipe all counters and chairs with sani-cloths;
  - Mix Restore solution **daily** (start of first session);
  - Place Restore solution in Rubbermaid containers to place used instruments. These should be on counter with lids on; and

### 3.3.3 End of Exam Session

There are a number of procedures the dental examiner will complete at the end of each session. These are as follows:

- Turn the dental light off;
- Purge the air tank (only needed at the last session of the day or after the AM session if the sessions are split – morning and evening) and turn the air compressor off; and

- If instruments were sterilized, complete the information required in ISIS utilities for this (instruments must be washed and bagged with 1 mirror, explorer, perio-probe, ruler, and 2 gauze squares prior to sterilizing. One sterigage must be placed with each load). See instructions for proper sterilizing procedures later in this chapter.
- Clean room;
- Take biohazardous waste to the storage facility in the MEC taking the following steps:
  1. Seal the biohazard bag with tape;
  2. Wear gloves to transport the bag to the inside rear bay doors of the laboratory in Trailer #3; open the bay doors and drop the bag to the ground;
  3. Remove the gloves and discard them in a biohazard bag in the laboratory;
  4. Take a new pair of clean gloves from the laboratory and walk outside to the back of trailer #3;
  5. Open the belly compartment;
  6. Put on the clean gloves;
  7. Place the biohazard bag into the belly compartment;
  8. Remove the gloves and place them in the belly compartment; and
  9. Lock the belly compartment.
- Exit the ISIS system.

### **3.3.4 Weekly**

There are a number of procedures the dental examiner will complete each week during a stand. These are as follows:

- Conduct a spore test;
- Clean the exterior of the sterilizer;
- Check water reservoir in the sterilizer; and
- Check supply levels in cabinets; restock if necessary.

### **3.3.5 Mid-Stand**

The following items need to be completed by the dental examiner during the middle of each stand:

- Drain and clean the sterilizer chamber; and
- Refill sterilizer chamber with distilled water.

### **3.3.6 End of Stand**

Equipment and supplies must be packed at the end of each stand. Since the MEC may be moving long distances, the equipment must be packed and stored for distance travel.

- Disassemble the Porta-Chair and pack it in the carrying case. Place on the exam room floor in a flat position.
- Remove the light and light assembly from the wall. The light assembly should be placed in the specified plastic case lined with bubble wrap. Secure the case on the exam room floor.
- Turn the air compressor off and bleed the tank. Move the compressor to the back of the cabinet and secure it using the U hooks and bungee cord provided. Wrap the air syringe in bubble wrap, secure on the wall either with tape and velcro strips to the metal holder or in velcro strip on the wall.
- Flush the SpeedClave with SpeedClean, then flush 2 times with distilled water as per directions. Pack it and the Attest biological monitoring kit in the designated carrying case and secure on the floor.
- Remove the clock from the wall. Remove the batteries and tape to the back of the clock. Wrap in bubble wrap and place in bottom drawer.
- Remove the CPR mask from the wall. Wrap in bubble wrap and place in bottom drawer.
- Secure supplies in the cabinets. Bring supplies from upper cabinet shelves down to lower shelves. Pack securely on bottom shelf with heavier items on the bottom. Secure the cabinets, doors, and storage drawers with the designated Velcro strips and wood bars.
- Contact the data manager to secure the computer equipment and telephone.

- Close the window.
- Close and secure the window blind.
- Use the recorder and examiner stools, biohazardous containers, and other items not packed in carrying cases to secure the equipment and boxes in the room to prevent sliding and shifting during transport (refer to Appendix G).
- Secure the door to the oral health room in the open position.
- Pack supplies in the belly compartment in water resistant containers. Any items that are breakable or not stored in water resistant containers should be moved to the oral health room.
- The back-up dental chair, soft cases for the primary and back-up dental chairs, and the plastic containers with supplies should remain in the belly compartment.
- The back-up light and back-up compressor should be moved to the oral health room.

### **3.4 Equipment**

#### **3.4.1 Porta-Chair**

The Porta-Chair is the chair in which the SP will sit during the dental examination. Exhibit 3-3 on p. 3-12 shows the steps used in setting up the Porta-Chair.

**NOTE: The chair must be placed on its side when raising, collapsing, or adjusting the legs. Raising, collapsing, or adjusting the chair while it is upright could result in severe injury to the hands and wrists.**

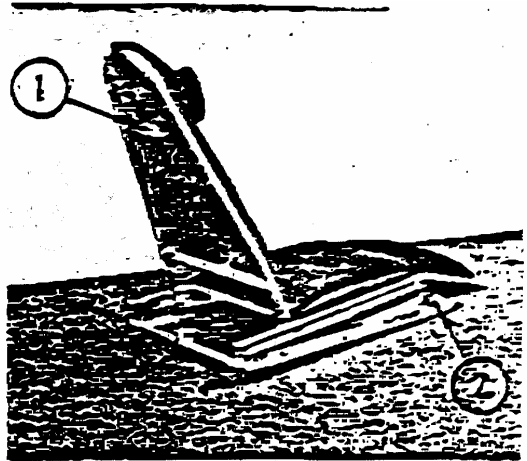
##### **3.4.1.1 Set-up**

1. Carefully place the chair on its side. The scissored legs have two screw knobs on each side which fasten into one of several notches underneath the base of the chair. The height of the base of the chair is determined by which notch is chosen. When determining the height, remember that it is difficult to change the height between SPs.

Exhibit 3-3. Illustration of Porta-Chair

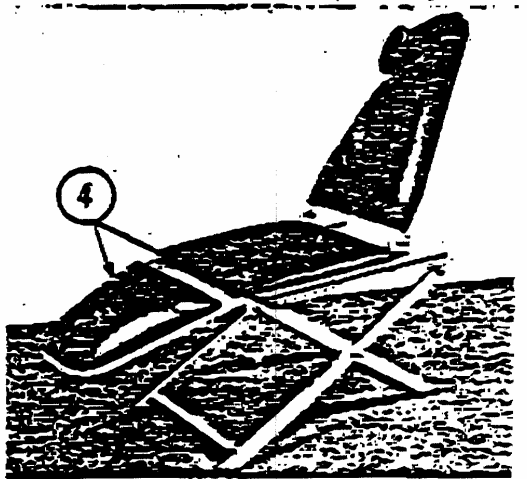
1 Connect adjustable back support with attached quick release pin.

2 Loosen height adjustment knobs.



3 Place right foot on bottom portion of right chair leg.

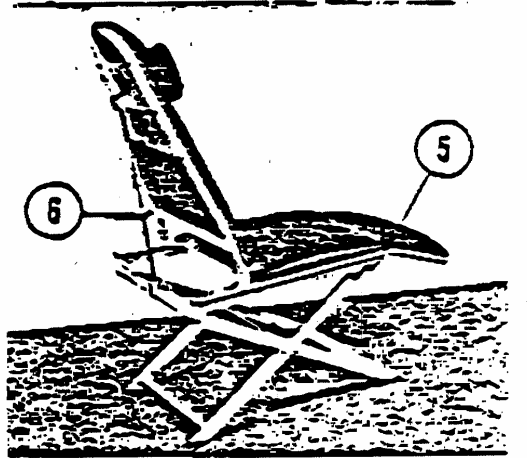
4 Raise toe board of chair with left hand while lifting chair leg with height adjustment knobs up into slots on chair frame.



5 Tighten height adjustment knobs securely before using chair.

6 Adjust chair back to desired position. Push back forward to raise; pull adjusting knob out to lower.

7 Fold chair by reversing above steps.





2. The adjustable rod attaches to the chair in two places. The rod should be attached to the small assembly on the horizontal rod just underneath the chair. There is a small screw that secures the rod into the assembly. (It is often stripped because it is frequently forcibly removed.) It is important that this is secure as it can loosen and the chair back will fall. This is especially important if you intend to adjust the back of the chair during an examination. The rod can easily be connected and reconnected by depressing the button on the side of the T-pin, which fits into the bracket on the upper part of the backside of the chair. To assemble, align the holes of the assembly and the rod, then insert the T-pin.
3. If using the backup Rolux light, the chair will have to be set-up with the light post bracket on the right side due to the layout of the dental room. To install the 25-inch light post, insert the post in the mounting bracket on the side of the chair and tighten the two screws with the supplied Allen wrench.

#### **3.4.1.2 Breakdown**

1. To detach the adjustable rod, remove the connecting T-pin from the upper portion rod that is attached into the bracket on the upper portion of the backside of the chair. Leave the rod attached to the assembly on the horizontal rod underneath the seat of the chair. Lower the rod and fold the chair back over the seat.
2. Turn the chair on its side and loosen the screw knobs on the sides of the base of the chair to disconnect the scissored legs.
3. The chair should be laid flat for storage.

#### **3.4.1.3 Cleaning**

A mild soap or foam-type upholstery cleaner (e.g., 409) may be used on the vinyl. All external metal surfaces may be cleaned using a detergent solution. Never use abrasive cleaners or scrubbing pads; they will damage the finishes. Be sure to clean the chair before returning it to its carrying bag.

#### **3.4.2 Dental Stool**

Since the examinations will be conducted with the examiner seated, the stool must be positioned next to the Porta-Chair. The dental stool can be raised to a comfortable height by using the

release lever under the seat. The stool is also equipped with a backrest that can be added for additional comfort.

### **3.4.3 ProBrite Halogen Dental Light (Model HEINE HL 1200)**

The ProBrite Halogen dental light is pre-assembled and only needs to be mounted on the wall support in the oral health room and plugged into an electrical outlet.

#### **3.4.3.1 Set-up**

Remove the light from the plastic packing container and bubble wrap. Leave the bubble wrap in the container for tear down. The light mounting should be attached to the pole above the stainless steel tray and then the mounting screws should be tightened.

#### **3.4.3.2 Use**

The ProBrite Halogen light has a power switch to activate/deactivate the light and the distance to the SP controls the illumination area. For optimum use, turn the light off between exams. At the start of an exam, turn the light on and position the light head for maximum illumination of the area.

#### **3.4.3.3 Maintenance**

The following visual check should be performed at the start of each session:

- Look for cracks on the power cable;
- Look for cracks or splits on the bulb cowling and cover;
- Look for cracks or scratches on the lens; and
- Look for loose or missing items such as screws, nuts, or bolts.

#### **3.4.3.4 Cleaning**

To clean the unit, first disconnect the power cord from the electrical source and wait until the unit is cool. Then clean the light with a soft cloth and soapy water or non-abrasive soap solution.

#### **3.4.3.5 Replacement of Light Bulb**

To replace the light bulb:

1. Turn the light off and disconnect the power cable from the electrical source.
2. Allow the bulb to cool.
3. With thumb and forefinger, press the cap together at the two white marks and ease the cap off.
4. When inserting the new bulb, ensure that the contact pins are not bent.
5. To replace the cap, engage the clip in the opening marked (\*) in the illumination head and press the cap until the second cap clicks in place.

#### **3.4.3.6 Changing the Fuse**

In order to change the fuse, first disconnect the power cord from the electrical source. The fuses are located in the fuse compartment next to the male outlet in the light assembly. Use a small screwdriver to open the fuse compartment.

#### **3.4.3.7 Pack-up**

To pack up the light, first disconnect the power cord from the electrical source and the light assembly. Then remove the light from the pole above the stainless steel tray. Re-tighten the screws so they do not get lost during transport. Wrap the light in bubble wrap and place in the long plastic storage container. The light must be kept in the oral health room during transport.

### **3.4.4 Air Compressor**

The ProAir Portable Air Compressor used in the current NHANES has been modified slightly to meet study-specific requirements. It is a 1/3 horsepower, oil-free, rocking piston compressor with sealed bearings.

#### **3.4.4.1 Set-up**

While travelling, the air compressor is secured to the back of the cabinet with U-hooks and a bungee cord. During set-up, move the air compressor back into position. Make sure the air compressor is sitting on a rug in the cabinet, the door is padded, and the air compressor is not resting against any of the cabinet walls. Then, check it for signs of mechanical damage such as split air lines, loose electrical wires, or connections, loose handles, and loose or missing nuts, bolts, and screws.

#### **3.4.4.2 Use**

Turn power source on. To turn the compressor on, there is a switch in the form of a knob. It is at the top of the compressor on the left. The air compressor will run until the air reservoir is filled and then automatically turn off. It will then cycle on and off to keep the reservoir charged at the appropriate pressure as air is used.

#### **3.4.4.3 Daily Maintenance**

**Visual checks:** Check for signs of mechanical damage such as split air lines, loose electrical wires, loose connections, loose handles, and loose or missing screws, nuts, or bolts.

**Purge/bleed air tank:** Turn the air compressor off and open the screw valve on the bottom of the tank (it is a brass nut) at the end of each day. If there is a split session day, then purge the tank at the end of the morning session as well. Make sure the valves are closed and the compressor has been turned on before operating the compressor again.

#### **3.4.4.4 Pack-up**

Turn the power source off and bleed the tank. Move the compressor to the back of the cabinet and secure with the U-hooks and bungee cord provided.

#### **3.4.5 Air Syringe**

##### **3.4.5.1 Set-up**

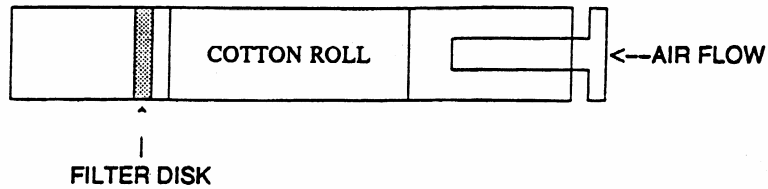
Unwrap the air syringe (should be wrapped in bubble wrap), and check the connection with the air compressor. Visually check to make sure there has been no damage (cylinder is intact) and the cotton roll (filter element) is not damp. If needed, replace the cotton roll, filter, or filter tube.

##### **3.4.5.2 Changing the filter element (cotton roll)**

The filter element of the air syringe should be changed annually and also if it becomes damp.

1. Turn off the air to the compressor and bleed off any air in the syringe by pressing the air button on the syringe until no air flows through it.
2. Unscrew the handle of the syringe.
3. Push on the supply tubing so that the clear filter tube containing the filter element is ejected from within the aluminum handle.
4. Remove the used cotton roll from the tube using cotton pliers.
5. Inspect the clear tube for any debris or moisture. If present, clean with soap and water and dry thoroughly.
6. Install a clean cotton roll into the clear tube and position as shown below.
7. Install a filter disc into the tube above the cotton roll.
8. Apply silicone lube to the o-ring on the syringe head.

9. Reassemble the syringe handle to the head.
10. Turn on the air and test the syringe.



### 3.4.5.3 Pack-up

Turn off the air to the compressor and bleed off any air in the syringe. Wrap the syringe in bubble wrap, and secure it to the air syringe holder using tape and velcro.

### 3.4.6 Replacing Instruments

The MEC will be equipped with 60 sets of dental instruments. One set of instruments will be used per SP. We are assuming about 20 SPs per day; so, the examiner will use about 20 sets each day.

Since mirrors become scratched and explorers and probes become worn over time, defective instruments will be replaced annually during the field period. Mirror handles are not replaced during the study unless the need arises.

New instruments will be shipped to the MEC as needed. Old instruments are to be sent back to the home office if they are in need of replacement.

**NOTE: Examiners should inspect instruments, equipment, and supplies daily. Damaged instruments, such as scratched mirrors should be returned to the home office and replaced. Completely unusable instruments, such as broken mirrors should be discarded in the sharps container. Remember: Instruments must be sterilized and the pointed edges carefully wrapped prior to sending back to the home office or disposing of them.**

### 3.5 Examination Environment

The instruments and dental supplies must be checked and organized at the start of each session. General guidelines for maintaining safety and efficiency in the dental examination room are:

- Arrange equipment so that SPs can move easily and safely into and out of the room.
- Electric cords must be under or behind the dental chair.
- The SpeedClave is set up so as not to interfere with dental examinations.
- Disinfecting solutions and other liquids must be covered and out of reach of SPs, particularly children.
- The dental examination room must be kept clean.
- The instrument sterilization packets are impervious to fluids and should be opened and placed in such a position that the packet becomes the instrument tray for the SP on which they are used.
- Two plastic containers with lids for used instruments must be placed out of the examination environment. Used mirrors will be placed in one plastic container and used explorers, probes, rulers, and curettes in the other container. **Other instruments must not be placed with the mirrors because they may scratch the mirrors.**
- The hazardous waste container lid must be closed except when depositing wastes.

### 3.6 Infection Control

The examiner is responsible for the infection control procedures described in this section; the recorder will not help with cleaning, sterilizing, or handling used instruments. The procedures for handling and sterilizing instruments and maintaining a safe examination environment are in compliance with regulations and recommendations of the Centers for Disease Control, U.S. Public Health Service, and the National Institute of Occupational Safety and Health.

Appendix B presents infection control practices recommended for dentistry by the Centers for Disease Control and Prevention (CDC). The dentist is responsible for ensuring proper infection control practices in the dental examination room.

### 3.6.1 Prior to the Examination

The following must be completed prior to the start of each session:

- Counter tops must be disinfected with an appropriate solution before arranging the instruments and supplies for daily use.
- Disposable barriers must be placed on the following items: chair cover, syringe, light head and controls, and mounted instrument tray.
- The examiner must wear a facemask, safety glasses with side shields, and a new pair of powder-free exam gloves for each SP examination.

**NOTE: If the examiner adjusts the dental stool or the mask or touches any object, other than ones that have been covered or disinfected during an examination, he or she must rescrub and put on a new pair of gloves.**

- Examiners and recorders must wear neat and clean lab jackets or gowns in the MEC. Examiners are provided with disposable lab jacket which should be changed weekly, or more frequently if needed. Dental examiners should remove lab jackets before entering the staff lounge.
- Only properly sterilized instruments are to be used for dental examinations.
- The Restore holding solution should be prepared daily.

### 3.6.2 After Each Examination

The sequence of procedures for maintaining infection control between SP examinations is as follows:

- Used instruments will be deposited in the used instrument containers partially filled with the appropriately diluted solution of Restore.
- Soiled adhesive covers, syringe covers, chair covers, and instrument sterilization packets must be removed and thrown in the hazardous waste container prior to degloving.
- Disposable air tips must be disposed of in the sharps container.
- Gloves should be turned inside out as they are removed and thrown into the hazardous waste container.



- A disinfecting solution must be used on any surface that could have been contaminated during the examination.
- A disinfecting solution must also be used on the air syringe holder and the air syringe tubing.
- Hands must be washed with soap and water, and then be regloved.
- A clean chair cover should be placed on the mounted instrument tray with a new instrument packet. Do not set up the new instruments until the SP arrives in the room as the instruments may become contaminated if left out for a period of time.
- When not in use, instrument containers, utility gloves, instrument brushes, and any other supplies that come in contact with used instruments should be stored on the bottom shelf under the sink away from noncontaminated items.
- Examiners must remove their lab jackets when leaving the work area; lab jackets may not be worn in the staff lounge.

### **3.6.3 After Each Session**

The biohazard bag needs to be taken to the MEC storage facility in the following manner:

1. Seal the biohazard bag with tape;
2. Wear gloves to transport the bag to the inside rear bay doors of the laboratory in trailer three;
3. Open the bay doors and drop the bag to the ground;
4. Remove the gloves and discard them in a biohazard bag in the laboratory;
5. Take a new pair of clean gloves from the laboratory and walk outside to the back of trailer three;
6. Open the belly compartment;
7. Put on the clean gloves;
8. Place the biohazard bag into the belly compartment;
9. Remove the gloves and place them in the biohazard box in the belly compartment; and
10. Lock the belly compartment.

The chief medical technologist can address any questions about opening the inside rear bay doors in trailer three.

### **3.6.4 Infection Control Supplies**

The infection control supplies and their specific uses are discussed in this section. This includes chemical solutions, disposable barriers, sterilization supplies, personal protection, and miscellaneous items.

#### **3.6.4.1 Chemical Solutions**

- Surface disinfectants: Sani-cloths (1- to 5-minute exposure time); and
- Holding solution: Restore (10-minute exposure time; concentration of 1/4 oz. to 1 qt. water).

#### **3.6.4.2 Disposable Barriers**

- Disposable air syringe tips;
- Chair covers;
- Instrument tray covers;
- Syringe covers; and
- Coverall adhesive barriers.

#### **3.6.4.3 Sterilization Supplies**

- Peelvue autoclave pouch;
- Sterigage indicator;
- Attest Biological Indicator Monitoring Kit;
- SpeedClean autoclave cleaner;

- Distilled water;
- Instrument brush; and
- Dishwashing detergent.

#### **3.6.4.4 Personal Protection**

- Disposable lab jackets;
- Masks;
- Protective eyewear with side shields;
- Gloves, latex or non-latex, one time use; and
- Utility gloves (handling used instruments).

#### **3.6.4.5 Containers**

- Biohazardous waste container; and
- Biohazardous sharps containers.

#### **3.6.4.6 Hand Washing**

- Paper towels; and
- Liquid hand soap and/or waterless hand cleaner.

The following list summarizes infection control supplies for use in the dental examination room:

- **Air syringe:** plastic covers for syringe; disposable air tips; surface disinfectant for plastic tubing and the syringe holder;
- **Porta-Chair:** plastic cover; surface disinfectant;
- **Light:** adhesive barrier on head and controls; surface disinfectant;
- **Instrument tray:** plastic chair cover; surface disinfectant;

- **Counter:** surface disinfectant;
- **Instruments:** Restore holding solution; instrument brush; utility gloves; dishwashing detergent; paper towels;
- **Sterilization:** Peelvue autoclave pouches with sterigage indicator; spore test kit; SpeedClean;
- **Waste:** biohazard containers (waste and sharps); and
- **Examiner:** disposable lab jacket; mask; protective eyewear with side shields; single use gloves.

### 3.6.5 Instruments

All mirrors, explorers, probes, and endodontic rulers must be sterilized prior to first use and after each use. Having a sufficient number of sterilized instruments available for each examination session is the responsibility of the dental examiner. The examiner must wear Nitrile utility gloves whenever handling used instruments.

To prepare instruments for sterilization:

- Remove the instruments from the holding solution. Discard the holding solution and rinse instruments in their container. Fill the containers with soapy water, using liquid dish soap. Place lids on containers and agitate. Scrub with a brush to remove any remaining blood or debris. Be careful to prevent cutting your hands while scrubbing contaminated instruments.
- Rinse instruments thoroughly to remove all foreign debris and soap.
- Pat instruments dry with paper towels. Thoroughly dry rulers and mirror heads with paper towels. Then set all instruments on the stainless steel tray to air dry overnight for complete drying before placing them in the Peelvue pouches. Endodontic rulers and mirror heads must be completely dry to prevent undue damage.

### 3.6.6 SpeedClave

Used instruments will be sterilized with a portable SpeedClave in the MEC. If the SpeedClave is not working properly, the examiner must inform the MEC manager immediately and, if necessary, a replacement SpeedClave will be sent to the field.

### **3.6.6.1 Storage and Handling of Used Instruments**

- Used instruments should be handled carefully to prevent transfer of microorganisms from the SP to the dental examiner.
- Immediately after instruments have been used, place them in a plastic container containing Restore. Keep the instruments in solution until you are ready to scrub them for sterilization.
- Instruments must be scrubbed and dried before they are packaged for sterilization in the SpeedClave. Extra care must be taken with the mirror heads and rulers.

### **3.6.6.2 SpeedClave Set-up**

The SpeedClave should be placed on a level surface to ensure proper filling of water in the chamber. The far-left side of the counter in the dental room has been configured to properly hold the SpeedClave as follows:

- A minimum of a 2½" space must be available behind and on either side of the unit for proper air circulation.
- The wall cabinets have been built at least 25" above the top of the unit to provide space for filling the reservoir with water as well as for cooling processed trays.

### **3.6.6.3 General Operation Information**

- The pilot light blinks ON and OFF when the heater is in operation. If the light does not blink, check to make sure the timer is in the ON position. You may also need to check the electrical power supply line and the thermostat reset.
- The sterilizer is protected by an automatic low-water control, which will prevent the unit from operating without sufficient water. To return to operating conditions, add water and press the reset button.

#### 3.6.6.4 Weekly Checks

- Check the water reservoir weekly. If the water level is below the FULL mark, fill the reservoir to this mark with distilled water.
- Adjust the temperature regulator during the setup operation by turning the temperature regulator knob fully counter-clockwise. This will give a maximum temperature of 270° F.

#### 3.6.6.5 Placing Instruments in SpeedClave

- Self-seal paper bags for sterilizing the instruments will be used. **Place one set of instruments and two pieces of gauze in each bag.** Mirror heads and sharp points of instrument are placed at opposite ends of the bag, so that pointed instruments will not scratch the mirror head. By using this procedure you will keep sets of instruments sterile and can open bags of instruments as needed for the next day's examinations. Gloves must be worn when handling sterilized instruments.
- Place bags on their sides on the tray. This will maximize steam circulation and facilitate drying. The diamond-shaped symbol on the paper bag changes color from blue to black to indicate that the sterilization process has been completed.
- Place one sterigage indicator strip on top of the instrument packs.

**NOTE: Several bags of instruments can be sterilized at once. Do not pack the bags too tightly on the tray since air circulation around each object is required for proper sterilization.**

#### 3.6.6.6 Sterilization

**NOTE: The SpeedClave must never be left unattended while sterilization is in progress.**

- With the door open, press the FILL/VENT lever down until the water level in the chamber is within ½" of the front rim.
- Place tray with the prepackaged instruments and the separate Sterigage indicator strip in the chamber.
- Close and latch door: swing the door assembly to the left until it stops in the almost closed position, then push the entire door to the right so that the right edge is fitted inside the chamber rim. The left side will follow. Swing the door handle all the way to the right to latch the door.

- Set the timer for 15 minutes to heat the water in the chamber.
- When the pilot light goes out, and the gauge indicates that the sterilizing temperature has been met, reset the timer for 15 minutes.
- An automatic timer will shut off the heater and a buzzer will sound for 1 minute when the cycle is complete.
- Turn the timer knob counterclockwise to zero to turn the buzzer off.
- Pull the door handle to the vent position, then hold the FILL/VENT lever down until the door pops inward and steam escapes. Release the FILL/VENT lever when the door pops inward.
- Allow the sterilizer to remain in this position for 15 minutes to allow the instruments to dry thoroughly.
- Open the door. **NOTE: The instruments may require further drying at this point. They may be unloaded or kept in the chamber for further drying.**
- Allow at least 15 minutes before beginning the next cycle.

### 3.6.6.7 Termination of Cycle Prior to Completion

If the cycle is terminated before normal completion of the cycle, the red pilot light will go out and the temperature will drop. Usual causes for termination are (1) insufficient water in the chamber; (2) the door is opened during the cycle; (3) the proper temperature is not maintained; or (4) the circuit breaker is tripped. To correct the problem, test the system as follows:

- Swing the door handle to the vent position and wait 15 minutes for the steam to dissipate.
- Remove the load of instruments.
- Check the water reservoir and fill it if necessary.
- Check the water level in the chamber and fill it to ½" of the front rim, if necessary.
- Close the door and press the reset button.

If the test cycle completes without a malfunction, you can begin again to sterilize using new monitors and biologic indicator strips.

If the test cycle does not complete without a malfunction, rotate the timer to zero, which is the OFF position. Unplug the power cord. Do not open the door or attempt any other procedures. Inform the MEC manager.

### **3.6.6.8 Maintenance**

#### **3.6.6.8.1 Weekly**

Wipe all external surfaces with a soft, dry cloth. Wash them occasionally with a damp cloth and mild soap or detergent. Clean the door gasket and mating surface with a damp cloth. Examine the door gasket for possible damage that would prevent a good sealing surface.

#### **3.6.6.8.2 Mid-Stand**

Clean the sterilizing chamber. Drain the water from the reservoir. A petcock is located at the bottom of the unit to facilitate draining. Wash the inside of the chamber with mild soap and distilled water. Do not use abrasives or bleaching agents. Rinse with distilled water. Refill the reservoir with distilled water.

#### **3.6.6.8.3 End-of-Stand**

The system must be flushed at the end of each stand with SpeedClean Sterilizer Cleaner as follows:

- Mix 4 ounces of SpeedClean with 2 quarts of distilled water.
- Drain the reservoir and fill with the diluted cleaning solution.
- Run one 15-minute cycle at 250 degrees F. Instruments should not be sterilized at this time.
- Drain the cleaning solution from the chamber and reservoir. Fill the reservoir with clean distilled water and run two 15-minute cycles at 250 degrees F.



- Drain the reservoir and allow the sterilizer to cool to room temperature. Remove the tray rack. Wipe out the inside of the chamber being careful not to damage the heating element. Wipe off the tray rack itself and replace in the chamber.
- Clean the gasket and channel. You may find a small brush helpful during this procedure. Clean and inspect the gasket for damage and replace if necessary.
- The gasket may need to be lubricated at the end of each stand. If this is necessary, the supplies and instructions will be forwarded to the examiners.
- Gaskets will be replaced twice a year.

#### **3.6.6.9 Repair**

If the SpeedClave needs repair, inform the MEC manager immediately.

### 3.6.6.10 Documentation

Sterilization of instruments and maintenance of the autoclave must be documented in the ISIS quality control system. This is located in utilities. The information required is under the end of session QC. It should be filled out the day the instruments are sterilized.

QC Check	Done	Result	Comment
Instruments Sterilized Exposure (minutes)	<input type="checkbox"/>		
Instruments Sterilized Temperature (F)	<input type="checkbox"/>		
Purge Air Tank (not needed after AM session)	<input type="checkbox"/>		
Sterilizer exterior cleaned?	<input type="checkbox"/>		

### 3.7 Spore Tests

The dental examiner must conduct a spore test on the SpeedClave weekly using the Attest biological indicators. These indicators contain bacillus steraotherophilus spores, which are especially resistant to the steam sterilization process. Following the sterilization cycle, the vial is crushed which provides media to promote growth of any spores not killed during the sterilization. A color change on the

indicator will inform you whether the sterilization process was successful. Gloves and safety glasses should be used at all times when handling these indicators. Complete the weekly test by using the following procedures:

### **3.7.1 Processing**

- Place one Attest steam biological indicator in the center of an empty “test” Peelvue instrument bag.
- Place this test pack on a tray loaded with instruments. Placement should be in the most difficult area for steam to reach in the load; i.e., the middle of the tray.
- Process the load according to routine sterilization procedures.
- After the cycle is completed, wait a minimum of 5 minutes after the sterilizer door has been opened fully before removing the test pack.
- Remove the test pack from the sterilizer. Open it and allow the heat to dissipate prior to removing the biological indicator.
- Allow the biological indicator to cool outside the test pack for 10 minutes.
- Check the biological indicator label for a color change from rose to brown. Check the chemical integrator for an ACCEPT result. (An incomplete color change on the biological indicator label or a REJECT result on the chemical integrator may indicate an inadequate sterilization process.)
- Incubate the sterilized biological indicator along with the control indicator (see Section III) as soon as possible. Place the bottom of the indicator vial into the incubator at a 45-degree angle. Then push the vial straight back. This crushes the vial and activates the indicator. Push the “activated” indicator vial down until it is firmly set in the incubator. The cap should remain above the metal block.

### **3.7.2 Interpretation**

- Examine the biological indicator at the following intervals: 8, 12, 24, and 48 hours. A yellow color indicates an inadequate sterilization process. No color change indicates an adequate sterilization process.

- The final determination of successful sterilization can be made at the 48-hour incubation mark. Be sure to time the incubation so that you are in the MEC at the 48-hour time period.
- Record the results in the ISIS quality control system.

### 3.7.3 Use of Controls

- Place a nonsterilized Attest biological indicator in the incubator at the same time you place the sterilized indicator into the incubator. This nonsterilized indicator acts as a “positive” control.
- Examine the positive control at the same intervals as the test indicator. In this case, a yellow color indicates correct incubation, viability of spores, and capability of the media to support rapid growth.
- Record the results in the ISIS quality control system.
- Dispose of used positive indicators by sterilizing them for at least 10 minutes at 270 degrees and then discarding them in the biohazardous waste container.

### 3.7.4 Reporting Results

Results of the “test indicator” and the “positive control” incubations are to be recorded in the ISIS quality control system under the weekly tab. Include the following information:

- **Load:** Since the spore tests are done on a weekly basis but you will be sterilizing more than once per week, you must indicate the load in which the test was done. For example, if you performed the spore test on the first load that was sterilized that week, record “1”; if you performed the spore test on the second load that was sterilized that week, record “2”; and so on.
- **Start Date:** Record the day you began the test, which is the day you sterilized the test indicator.
- **Start Time:** Record the time of day you began the test in hours and minutes. Be sure to specify “a.m.” or “p.m.” Do not use military time.
- **End Date:** Record the day you ended the test, that is 48 hours after the test was completed OR the day the test indicator first indicated a problem.
- **End Time:** Record the time of day you ended the test in hours and minutes. Be sure to specify “a.m.” or “p.m.” Do not use military time.

- **Control:** Record whether the result was “+” (yellow) or “-” (no color change) or “NA” (indeterminate-problem with the test).
- **Test:** Record whether the result was “+” (yellow) or “-” (no color change) or “NA” (indeterminate-problem with the test).
- **Lot #:** Record the lot number of the spore vials used during the test.
- **Comments:** Use this space to record any unusual circumstances, such as a problem with the test (i.e., the biological indicator on the test strip indicates that the test was rejected).

**NOTE: You must have a “+” control result and “-” test result to continue using the autoclave to sterilize instruments.**

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

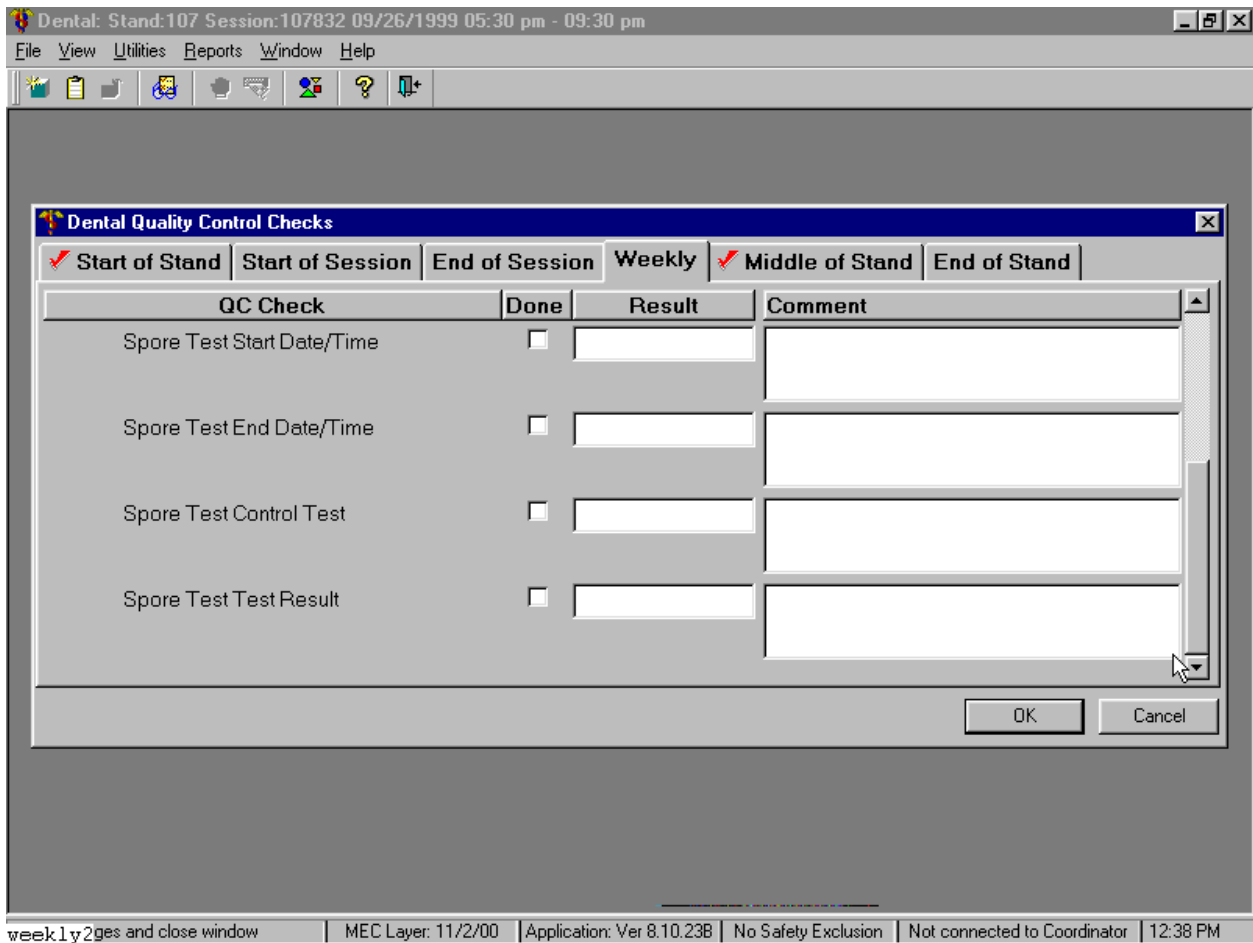
Dental Quality Control Checks

Start of Stand Start of Session End of Session Weekly Middle of Stand End of Stand

QC Check	Done	Result	Comment
Sterilizer water reservoir checked?	<input type="checkbox"/>		
Spore Test Lot #	<input type="checkbox"/>		
Spore Test Load #	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 12:38 PM



Inform the MEC manager **immediately** if the test indicator results are positive. Perform a second spore test if there is any problem with the initial test, i.e. the control indicator results are negative, using two control vials, one from the same lot and one from a different lot. This will help isolate whether there is a problem with the autoclave, incubator, or vials. Inform the MEC manager **immediately** if you are unable to obtain an acceptable test result, either negative or positive, after the second spore test.

### 3.8 Unusual Occurrence

Whenever an action is taken that is not documented elsewhere, it should be reported in the unusual occurrence log. This is a Word document on the computer. This document should be completed in the event of an unusual occurrence. Once completed, two copies will be printed—one to be left on the

MEC and the other sent by facsimile to Westat. Examples of actions requiring the use of the unusual occurrence log include the following:

- Maintenance or repair of dental instruments;
- Maintenance or repair of dental equipment;
- Replacement of dental instruments;
- Replacement of dental equipment; and
- Anything not recorded or reported elsewhere.

## 4. ORAL EXAMINATION METHODS

The oral examination component consists of a questionnaire and clinical examination sub-components. The dentist examiner and dental recorder work as a team in conducting this examination for each study participant (SP).

Questionnaire and clinical examination data are entered by keyboard directly into computer terminals at the examination site. The procedures for recording into the Integrated Survey and Information System (ISIS) are discussed in the *Dental Recorders Procedures Manual*.

### 4.1 Sequence of Oral Examination Components

All SPs aged 2 years and older are eligible for some part of the examination.

Exhibit 4-1 lists the oral examination subcomponents in the order they are conducted. Included on the table are the eligible ages of the SP for each examination component and whether the component triggers a referral for care. The examination procedures and methods are discussed in the following sections.

The assessment sequences of the examination follow the sequences shown on the ISIS screen. Each examination component has its own sequence.

### 4.2 Pre-examination Procedures

1. The examiner or recorder will select the Dental Examination icon from the introductory window on the automated system at the start of a session.
2. The examiner will enter his/her password when prompted.
3. The recorder will open a new examination when a SP has been assigned to the room.
4. The recorder will enter his/her tech password when prompted.
5. The recorder will pass the optical scan wand across the SP's identification bracelet and then verify the SP's name and identification number displayed on the screen.



Exhibit 4-1. Guide to oral examination components

<b>Assessment</b>	<b>Age</b>	<b>Referral Match</b>
<b><u>1- ELIGIBILITY AND DENTAL CONDITION</u></b>		
Medical Exclusion Questions	13+	No
Dental Condition Questions	16+	No
<b><u>2 – DENTITION</u></b>		
Denture Questions	25+	No
Tooth Count	2+	No
Caries: Coronal Surface	2+	Yes
Caries: Root Surface*	18+	Yes
Sealants	2-34	No
Fluorosis - Dean's Index	6-49	Yes
Incisor Trauma	6-29	Yes
Tooth Wear Scores	13+	No
Functional Occlusal Contacts Index	25+	No
<b><u>3 – PERIODONTAL</u></b>		
Loss of Attachment*	13+	Yes
Bleeding on Probing*	13+	Yes
<b><u>4 – RECOMMENDATION FOR CARE</u></b>		
<b>Instrument Packs</b>		
#5 Reflecting Mirror		
#23 Explorer		
Hu Friedy PCP-2 (2-4-6-8-10-12) Periodontal Probe		
Endodontic Ruler		

\* Not to be performed if there is a medical exclusion.

6. The examiner will explain the process to the SP in his/her own words and include the following facts:
  - This dental examination is not a substitute for examinations performed by the SP's dentist.
  - You will be looking at and lightly touching the SP's teeth.
  - You will be calling numbers and letters to the technologist that only have meaning for this research project.
  - Some general results will be provided when the SP leaves the MEC.

In conducting the examinations, each SP will be examined in the same manner. An examiner will avoid the temptation of examining an SP who appears to be highly susceptible to a condition more thoroughly than an SP who appears less susceptible.

### 4.3 Answering Study Participant Questions

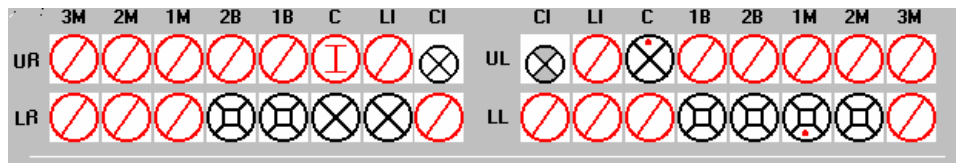
It is very important that the dental examiner answer questions raised by the SPs. Some of their concerns about the dental exam and appropriate responses might be:

- **Treatment.** If the SP asks, assure him/her that the exam will not include treatment, X-rays, a drill, or anesthesia. The dentist will use only a mirror and dental hand instruments to examine the mouth.
- **Qualifications of the examiner.** The examiner is a licensed dentist.
- **Existing dental work.** The exam will not interfere with any existing dental work such as fillings, bridges, sealants, or orthodontic bands. The examiner may ask the SP to remove any complete or partial dentures for intra-oral inspection.
- **AIDS (Acquired Immune Deficiency Syndrome).** The Centers for Disease Control, part of the Public Health Service, has set up standard practices (universal precautions) for dentists to use to prevent the spread of diseases, viruses, and bacteria, and these procedures are strictly observed by the dentists on this study. The dentist will wear sterile gloves and a mask, and the dental instruments will be sterilized before examinations are performed. The precautions used in the survey are the same as those maintained in dental offices.

#### 4.4 Guide to the Integrated Survey and Information System (ISIS)

The dental recorder is responsible for entering dental “calls” directly into ISIS during the examination. Detailed instructions for proceeding through each screen are provided in the Recorder’s Manual. The ISIS screens are organized as follows:

- **Demographic Information:** On the bar located at the top of the screen, the SP ID, name, age, gender, and the examination date and session time are displayed.
- **Heads Up Display:** This is a summary screen that is displayed in the upper portion of the screen after the Tooth Count is completed.



Space for each surface of each tooth is provided and conditions, such as caries and restorations, are indicated with different symbols as entered by the recorder. The mouth diagram is shown as if the examiner is facing the SP with the central incisors of each quadrant in the middle of the diagram and the third molars at each end. Tooth surfaces are displayed in the pattern commonly used in diagnostic charts and are defined as follows:

- Occlusal - top or biting surface;
- Lingual - surface toward the tongue;
- Facial (Buccal)- surface outside, toward the lips and cheeks;
- Mesial - interproximal surface towards the midline of the arch; and
- Distal - interproximal surface away from the midline of the arch.

Tooth condition symbols are as follows:

Circle, black	=	Permanent tooth
Circle, small, black	=	Primary tooth
Circle with slash, red	=	Missing tooth
Circle with “I”, red	=	Implant

Surface condition symbols are:

Bullet, red	=	Caries
Shading, gray	=	Restoration

- **Examination Data Entry:** The various examination data entry screens have the following similarities:

- Each row represents a quadrant or portion of a quadrant.
- The quadrants are displayed in the following order: upper right, upper left, lower left, and lower right.
- The data entry spaces correspond to the teeth being examined in that quadrant for that assessment.
- The teeth are identified with codes along the top of the row to identify the teeth as follows:

CI	=	Permanent Central Incisor/Primary Central Incisor
LI	=	Permanent Lateral Incisor/Primary Lateral Incisor
C	=	Permanent Cuspid/Primary Cuspid
1B/1PM	=	1st Bicuspid/1st Primary Molar
2B/2PM	=	2nd Bicuspid/2nd Primary Molar
1M	=	1st Permanent Molar
2M	=	2nd Permanent Molar
3M	=	3rd Permanent Molar

#### 4.4.1 General Data Entry Guidelines

This section summarizes key data entry guidelines. Detailed instructions are available in the MEC Subsystem Overview Manual (see Appendix E). Directions regarding allowable codes, acceptable ways to move through a screen, allowable shortcuts, and mandatory QC checks by screen are provided in this chapter.

Movement within the dental examination program can be accomplished by using the mouse or the keyboard. In most instances, using the keyboard is easier and more efficient. The keys are to be used in the program as follows:

TAB	Use this key to move <b>forward</b> from data entry field to data entry field within a screen whenever the program does not automatically move from field to field for you.
Shift TAB	Use this key to move <b>backwards</b> from data entry field to data entry field within a screen.
Backspace	Use this key within a data entry field to erase an entry backwards, one digit at a time.
Enter	Use this key to move to the next screen after all allowable entries are made on the current screen.
F2	Use this key as a shortcut on two assessments, dental sealants and fluorosis.
F11	Use this key to clear data on a screen and restart the assessment.
F12	The F12 key allows you to skip one or more assessments but still complete the “Recommendation for Care” section.  It is to be used only when you cannot collect data for a certain screen. It can be used for the following assessments; coronal caries, sealants, fluorosis, trauma, tooth wear, functional occlusal contacts, and periodontal assessment.

The mouse is used in a variety of ways as follows:

- To move the cursor to any data entry field within a screen;
- To display a list of allowable responses on a “pick list” by clicking on the down arrow (∇) to the right of the data entry field;
- To activate shortcuts by clicking on a box which will trigger fields to be filled or shaded, as appropriate;
- To move to the next screen after all allowable entries are made on a screen by clicking on the right arrow button on the lower right portion of the screen.

Improper entries will cause the system to beep, display an error message in the lower left portion of the screen, and prohibit movement within the screen until a valid response is entered. If necessary, the recorder should provide the examiner with the explanation of the error as defined in the error message.

In some instances, a “9” will appear in one or more shaded data entry fields on a screen when the screen is initially displayed. This code is termed a “hard 9” and is triggered by specific codes entered on the Tooth Count screen. The program does not allow the recorder to overwrite the “9” with any other code. ISIS will skip these fields and the cursor will move to the first blank field on the screen. To change this hard “9,” the tooth count code for that tooth must be changed on the Tooth Count Screen.

#### 4.4.2 Editing the Examination Record

ISIS automatically edits responses as the recorder enters them. Below are a few of the edits that the system provides.

- **Range Edit Checks:** The system checks to make sure that the value entered by the recorder is valid.
- **Tooth Count Edit Checks:** The system checks against the tooth count calls during all subsequent assessments. This ensures calls are consistent across assessments, i.e., teeth coded as missing in the tooth count are not assessed in most of the subsequent assessments, and primary teeth are not assessed in subsequent assessments that only look at permanent teeth (i.e., incisor trauma).

When the system determines that a tooth should not be assessed for a particular component based on the tooth count results, the tooth space on the screen is shaded and “hard coded” with a “9” (cannot be assessed) code.

- **“Hard” 9 Checks:** The system does not allow the recorder to overwrite a “hard” 9 code with another code. “Hard” 9 codes are determined by the system as a result of the tooth count.

#### 4.4.3 Section Status Screens

After each component section (medical exclusions and dental conditions, dentition, periodontal, and recommendation for care), a status screen is displayed which is used to document the outcome of the section. The screen consists of two parts: The first one is used to record an overall completion code and the second is used to record the reasons for incomplete exams.

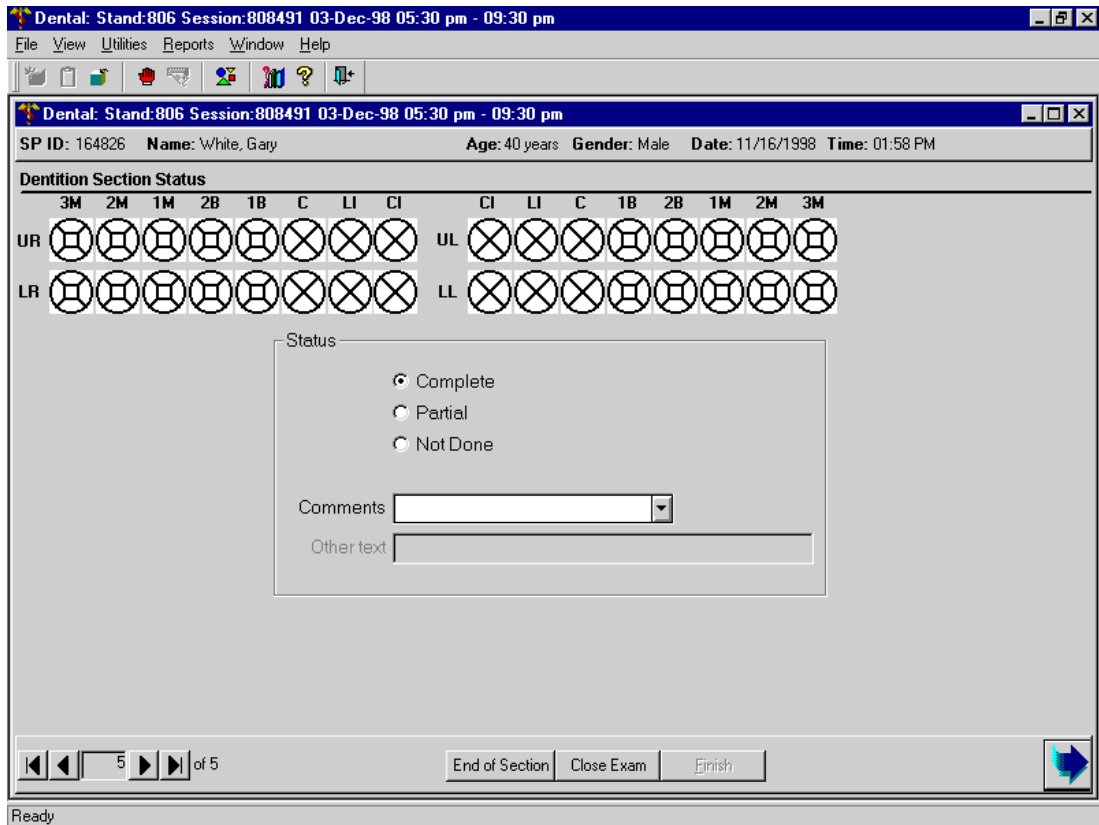
The overall completion code is automatically assigned by the system based on the data entered during the course of the dental examination. One of three outcomes is selected:

- Complete;
- Partial complete; and
- Not done.

Whenever a “partial complete” or “not done” outcome is assigned, ISIS prompts the recorder to enter a reason for the incomplete exam. There are nine choices the recorder can select from. These choices are standard throughout the survey and are listed below.

1. Safety exclusion
2. SP refusal
3. No time
4. Physical limitation
5. Communication problem
6. Equipment failure;
7. SP ill/emergency;
8. Interrupted; and
9. Other (Specify) - If “Other specify” is chosen, the “Other text” field is enabled and the recorder must enter a comment in order to continue.

### 4.4.3.1 Sample Section Startup Screen



### 4.4.4 Examination Break-offs

There are several types of examination break-offs. In the first scenario, you may need to clear an assessment and restart it. In the second scenario, you may need to break-off during a particular assessment and still continue with the examination. In the third scenario, you may need to break-off during a particular assessment and cancel the rest of the examination. The procedures to be followed for these situations are provided in this section.

#### 4.4.4.1 Clearing a Screen

There are various reasons for clearing a screen. For example, the examiner inadvertently calls the codes for one assessment while the recorder is entering data on another screen, or the examiner is



calling assessments for a particular tooth and the recorder is entering that call for a different tooth. If the situation cannot easily be resolved, the screen is cleared and the assessment is restarted using the F11 key.

If the F11 key is used on any screen other than the Tooth Count screen, only the data on the selected screen is cleared. However, if the F11 key is used on the Tooth Count screen, all data on the Tooth Count screen as well as data on the following screens are cleared. This is because the tooth count calls drive subsequent assessments.

#### **4.4.4.2 Canceling an Assessment**

There are times when an assessment must be interrupted before it is completed but the examination can continue (for example, the SP experiences pain in gingival bleeding but is still eligible for loss of attachment). In these situations the recorder presses the F12 key to end the assessment, regardless of how much has been completed, and continues with the next assessment. All data entered on the screen prior to the use of the F12 key are saved. Specifications for using the F12 key are provided in the Recorders Manual (Section 3.3.1).

#### **4.4.4.3 Canceling an Examination**

There may be situations when an examination is terminated early i.e., the SP faints, the session ends, or the MEC shuts down for weather reasons. To cancel an examination before it is finished, the recorder uses the <CLOSE EXAM> button on the navigation bar as specified in the Recorders Manual.

**Note: All data entered up until the point you exited is saved. The “Open an Existing Examination” icon on the toolbar is used to reenter the examination. The Medical Exclusion Questionnaire is displayed to remind you of the pertinent exclusion information. Then the program requires the user to scroll forward through the screens until the first blank screen or partially blank screen, depending on how you exited, is displayed. The examination is continued from this point forward.**

#### 4.4.5 Exiting an Examination

The <FINISH> button on the navigation bar is used to exit an examination once the SP specific assessments are completed. This button is only enabled when the Recommendation For Care status screen is completed; it is not enabled on any other screen. To exit the examination on any other screen, the <CLOSE EXAM> button is used as specified in the previous section.

#### 4.5 Medical Exclusion Questionnaire

The medical exclusion questions will be asked of all SPs aged 13 years and older. The purpose of this questionnaire is to identify SPs who should be excluded from portions of the oral health examination for their personal safety.

The Medical Exclusion Questionnaire (Exhibit 4-2) asks about medical conditions that may preclude the SP from participating in some components of the oral exam. If there are no medical exclusions for the SP, all questions were answered “No,” then all age-appropriate assessments are performed. However, if there is at least one “yes” answer to a medical condition that leads to a medical exclusion, then all of the age appropriate assessments are performed **except the root caries and periodontal assessment**. ISIS is designed to skip these assessments as appropriate.

It is the examiner’s responsibility to ask the medical exclusion questions directly of all SPs aged 16 years and older. Medical exclusion information will be obtained from SPs aged 13-15 years via proxy interviews conducted by the MEC manager. The hard copy Proxy Questionnaire will accompany the SP to the dental room for the dental examiner to review and the recorder to enter in ISIS.

Answers of “Don’t know” will be coded as “No” whenever “Don’t know” is prohibited as a valid data entry response. Answers of “Refused” will not be accepted. Probe all “Refused” responses until an acceptable answer (“Yes” or “No”) is obtained.

**NOTE: A positive response to Q2 does not indicate a medical exclusion; rather it indicates that Q3-Q6 must be asked. A positive response to any of the specific conditions asked about in Q3-Q6 will generate a medical exclusion based on a heart condition.**

Exhibit 4-2. Medical Exclusion Questionnaire

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107030 07/08/1999 08:30 am - 12:30 pm

SP ID: Name: Age: 15 years Gender: Male Date: 11/09/2000 Time: 11:22 AM

**Medical Exclusion Questionnaire**

All Exclusion Questions are No

Q1. Has a doctor or dentist ever told you that you must ALWAYS take antibiotics (e.g. penicillin) before you get a dental check up or care?

Before we begin, I would like to read you a list of health conditions that some people have. As I read off each condition, please tell me whether or not a doctor has ever told you that you have the condition. Has a doctor ever told you that you have...

Q2. A heart problem?

**Was the heart problem due to:**

Q3. Congenital heart murmurs?

Q4. Heart valve problem?

Q5. Congenital heart disease?

Q6. Bacterial endocarditis?

Q7. Rheumatic fever?

Q8. Kidney disease requiring renal dialysis?

**Do you have:**

Q9. Hemophilia?

Q10. A pacemaker or automatic defibrillator?

Q11. Other artificial material in your heart, veins, or arteries?

Q12. A hip, bone, or joint replacement?

1 of 6

End of Section Close Exam Finish

med gif action Status Screen | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 11:25 AM

**NOTE:** The remainder of the Medical Exclusion Questionnaire is not asked once a positive response to a medical exclusion item is given. For example, if the SP answers “yes” to Q6, do not ask Q7-Q11.

**NOTE:** The questions on hemophilia (Q9) and pacemakers (Q10) will not be asked here if the information is obtained elsewhere, such as in the household interview or other exam components. Answers provided elsewhere will appear on the screen when the screen is initially displayed. Therefore, only ask these questions if they are highlighted on the screen as this indicates that the information is still pending. Because these are “shared” medical exclusion items and “Don’t Know” responses are accepted in other components, acceptable answers for these items are “Yes,” “No,” and “Don’t Know.” Answers of “Don’t Know” will be treated as “No” by ISIS.

## 4.6 Dental Condition Questions

Understanding the determinants that promote underutilization of dental care is important for promoting a community's oral health status. This brief module of questions will provide information from perceived overall oral health status to ascertain existing dental conditions or problems to allow for future comparative research with clinical oral health status.

### 4.6.1 Examination Procedure

This Dental Condition Questionnaire is administered to all SPs aged 16 years or greater by the dental examiner. The purpose of this questionnaire is to ascertain a perceived general assessment of the condition of the mouth and reasons associated with utilization of dental care. A "good" or "poor" or "fair" response to the perceived overall condition of the mouth will lead to a question about perceived problems/reasons. A positive response to the inability to access care when needed leads to a question about reasons why care was not accessed. The dental examiner will read the questions to the SP and will relay the appropriate codes to the dental recorder. The sequence of the questions is as follows:

The dental examiner states:

**"Now I have some questions about your teeth."**

**(Q1)** How would you describe the condition of your teeth? Would you say...

- 1 – Excellent,
- 2 – Very Good,
- 3 – Good,
- 4 – Fair, or
- 5 – Poor?
- 7 – Refused
- 9 – Don't Know

{If response is "good" or "fair" or "poor" to Q1, go to Q2; if not skip to tooth count.}

(Q2) What specific problems do you have with your teeth?

- 1 – Toothache
- 2 – Sensitivity
- 3 – Cavities / Caries
- 4 – Broken / Missing Fillings or Restorations
- 5 – Broken / Fractured Teeth
- 6 – Staining / Discoloration of Teeth
- 7 – Crooked Teeth / Need Braces
- 8 – Teeth Needing Extractions
- 9 – Missing Teeth
- 10 – Denture Problems
- 11 – Periodontal Related Problems
- 12 – Unsatisfactory Prior Dental Experience
- 13 – None / No Specific Problem
- 14 – Other
- 77 – Refused
- 99 – Don't Know

#### **4.6.2 Recording Procedures**

The dental examiner uses the Dental Condition Questionnaire crib sheet to read the questions to the SP. The dental examiner receives the SP responses and dictates the appropriate codes to the dental recorder for the questionnaire. The examiner will obtain this information directly from the SP.

## Screen shots:

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 592301 Name: TEST, TEST Age: 39 years Gender: Female Date: 10/28/2002 Time: 02:53 PM

**Dental Health Status Questions**

Now I have some questions about your teeth.  
How would you describe the condition of your teeth?  
Would you say...

2 of 4

End of Section Close Exam Finish

Ready No Safety Exclusion Not connected to Coordinator 02:53 PM

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 592301 Name: TEST, TEST Age: 39 years Gender: Female Date: 10/28/2002 Time: 02:53 PM

**Dental Health Status Questions**

What specific problems do you have with your teeth?

1.  Toothache
2.  Sensitivity
3.  Cavities/Caries
4.  Broken/Missing Fillings or Restorations
5.  Broken Fractured Teeth
6.  Staining/Discoloration of Teeth
7.  Crooked Teeth/Need Braces
8.  Teeth Needing Extractions
9.  Missing Teeth
10.  Denture Problems
11.  Periodontal Problems
12.  Unsatisfactory Prior Dental Experience
13.  None/No Specific Problem
14.  Other
15.  Refused
16.  Don't Know

3 of 4

End of Section Close Exam Finish

Ready No Safety Exclusion Not connected to Coordinator 02:54 PM

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## 4.7 Denture Questions

SPs aged 25 years and older receive the denture questionnaire subcomponent. This component consists of a series of questions asked by the examiner to the SP regarding complete or partial denture use. Two questions relate to maxillary denture use and two questions relate to mandibular denture use. The objectives of the subcomponent are to:

- Determine the prevalence of complete and partial dentures among adults including important sociodemographic subgroups.
- Determine type of replacement with tooth loss patterns (in conjunction with the coronal caries assessment).
- Determine the percentage of people who routinely use complete and partial dentures.
- Provide a basis for comparisons with past and future national estimates for denture use in the United States.
- Provide useful information for training programs specializing in dental prosthetics.

With minor modifications, these denture questions have been used in several surveys, including NHANES III. Data were collected in NHANES III on complete denture prevalence, their conditions and their use.

### 4.7.1 Examination Procedure

After administering the dental condition questions, the examiner will read the following introductory text to the SP:

*“I am now going to ask you some questions about full and/or partial removable denture (i.e. plate or false teeth) use. A full denture (plate) is a replacement for either all of your upper or lower teeth. A partial denture replaces only some of your upper or lower teeth. Both a partial or a full (plate) denture can be removed from the mouth or placed in the mouth by yourself.”*

The examiner will then ask up to a series of four questions based upon the presence or history of denture wear. The first question (Q1) that the examiner will ask is “do you have an upper removable partial or full denture?” If the SP responds affirmatively, the examiner dictates a call of “yes”



to the recorder and asks the second question. If the SP responds with a “no,” the examiner dictates a call of “no” to the recorder and proceeds to the third question, skipping the second question. The second question (Q2) to be asked is “Do you usually wear it during the day?”

The third question (Q3) that the examiner will ask is “Do you have a lower removable partial or full denture?” If the SP responds “yes,” the examiner dictates a call of “yes” to the recorder and asks the fourth question. If the SP responds with a “no,” the examiner dictates a call of “no,” and the denture question section is completed. The fourth question (Q4) to be asked is “Do you usually wear it during the day?”

#### **4.7.2 Scoring Codes**

The codes for each of the four denture questions are the same and are as follows:

Y = Yes

N = No

R = Refused

D = Don’t know

#### **4.7.3 Guide to Referral and Follow-up**

The examiner is to use his/her own professional judgment about referring SPs with apparent removable prosthetic needs. A recommendation for dental prosthetic referral is provided as a category (E) in the level of care and recommendation section, which is later described in this chapter.

#### **4.7.4 Recording Procedures**

The recorder uses the Denture Questionnaire screen to record the examiner’s calls as the SP responds to the questions. There may be two to four questions asked depending on previous answers provided by the SP to the examiner.

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 867742 Name: GUEST, GUEST Age: 38 years Gender: Male Date: 10/23/2001 Time: 01:44 PM

### Denture Questionnaire

I am now going to ask you some questions about full and/or partial removable denture (plate or false teeth) use. A full denture (plate) is a replacement for either all of your upper or lower teeth. A partial denture replaces only some of your lower or upper teeth. Both a partial or a full (plate) denture can be removed from the mouth or placed in the mouth by yourself.

Do you have an upper removable partial or full denture?

Do you usually wear it during the day?

Do you have a lower removable partial or full denture?

Do you usually wear it during the day?

1 of 6

End of Section Close Exam Finish

Close the exam MEC Layer: 6/15/01 Application: Ver 9.10.18B No Safety Exclusion Not connected to Coordinator 01:51 PM

denture queu... C:\WINDOWS\DESKTOP... Dental: Stand:107 Se... Snagl/32 Catalog Browse... 1:51 PM

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## **4.8 Tooth Count**

### **4.8.1 Examination Procedures**

SPs 2 years and older receive this examination which assesses the number of primary and permanent teeth, and the presence of surgical implants. Information on surgical implants is obtained from preliminary questions asked by the examiner. The dentist examines the SP utilizing any guidance provided during the questioning.

The Tooth Count Assessment involves examining the maxillary arch and the mandibular arch to identify the presence or absence of permanent and/or primary teeth as well as the presence of permanent dental roots in each tooth position of the mouth. There are 32 tooth positions in the mouth, including the third molars. The maximum number of permanent tooth spaces that can be indicated is 32. The maximum number of primary tooth spaces that can be indicated is 20. Tooth spaces must be examined in the following order: Maxillary right quadrant, maxillary left quadrant, mandibular left quadrant, and mandibular right quadrant. Within each quadrant, the examiner should begin with the central incisor space and move posteriorly in order to the third molar space using the surface reflecting mirror and the #23 explorer.

The codes used for the tooth count calls are listed below. Only one code per tooth is to be entered.

1 = Primary tooth (deciduous)

2 = Permanent tooth

3 = Implant

4 = Tooth not present

5 = Permanent tooth root

#### **4.8.1.1 Surgical Implants**

Surgical implants are posts surgically placed through the gingival tissue into the jawbone and are typically capped by a prosthetic tooth. Implants may replace a single tooth or may replace

multiple teeth in longer segments of a dental arch. There may be more missing teeth restored with pontics than there are implants, similar to a traditional fixed bridge. The surgical implant question will be asked for SPs age 10 and older.

Surgical implants may be used to replace specific teeth or to support fixed or removable appliances. Surgical implants may be difficult to detect without suitable radiographs. Therefore, in addition to the clinical assessment, questions must be posed to all SPs to determine whether implants are present. Information for children may be obtained from an adult responsible for the child being examined. The examiner should ask the question in the following way:

**“Do you/does does (SP name) have one or more teeth that are missing, or were removed, and have been replaced with a surgical implant?”**

If the SP responds, “Don’t know,” repeat the question and define implants as follows:

**“Surgical implants have a post surgically placed through your gum and into the bone and are often capped by an artificial tooth or bridge.”**

The answer to this question must be called to the recorder. If the SP’s, or responsible adult’s response to this question is “Yes,” the following questions will be asked:

- Do you know how many surgical implants you/SP’s name have/has in your/his/her mouth?
- Can you point to the area of your/(SP’s name) mouth where the surgical implant(s) was/were placed?

The SP may be able to indicate the exact tooth position or the general location of the implant. If the SP or responsible adult indicates a “Yes” response, encourage the SP or responsible adult to indicate where in the mouth the surgical implants are. The dental examiner should then examine the whole mouth for implants.

If the SP does not know whether they received a surgical implant or not, go over the fact that this is a procedure where the implant is surgically (emphasis on surgically) implanted into the bone. If they still do not know, then answer NO, and the Dental Examiner should do a thorough examination of the mouth with verbal probing to see if there is an implant. The implant box can be checked and

unchecked at any point in the tooth count. The Recorder cannot proceed if the implant box is checked and there is not at least one “3”.

The location of the implant is called during the tooth count assessment along with the other codes. If a tooth space has been replaced with a surgical implant, a code of “3” is assigned for that space; otherwise, a code of “1,” “2,” or “4” is assigned to the tooth space, as appropriate.

If through the examination the examiner determines no implants are present, then he/she should tell the recorder to uncheck the implant box on the tooth count screen.

#### **4.8.2 Guidelines for Scoring**

To assist with the guidelines listed below, the codes used in the tooth count are listed below, again.

1 = Primary tooth (deciduous)

2 = Permanent tooth

3 = Implant

4 = Tooth not present

5 = Permanent tooth root

1. A tooth is considered to be present if any part of its crown projects through the gum.
2. If a permanent and a primary tooth are visible in the same tooth space, the permanent tooth is assigned to the tooth space.
3. In instances of supernumerary teeth, the examiner must decide which tooth is the “legitimate” occupant of the space.
4. Orthodontic extractions - First bicuspid are often extracted as part of orthodontic treatment. These teeth are coded as missing (“4”). For the sake of uniformity, all bicuspid extracted for

orthodontics are scored as first bicuspid. The examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to detect because of the symmetric pattern of orthodontic extractions. The examiner should confirm this with the SP prior to coding the teeth.

5. When the primary tooth crown is destroyed by caries and only the roots remain, score the tooth as present (“1”).

6. When the permanent tooth crown is destroyed by caries or trauma and only the roots remain, score the tooth as permanent root present (“5”). A permanent tooth that has a replacement for the appropriate coronal structure or serves as a support structure for an overdenture will also be scored as “5.”

### **4.8.3 Recording Procedures**

The recorder first enters the code called by the examiner for the question about surgical implants. The recorder then uses the next screen, the Tooth Count screen, to enter the tooth count calls made by the examiner.

**NOTE: It is extremely important that the correct calls be made by the examiner and entered correctly by the recorder on this screen, as the outcome of this assessment determines how other assessments are performed and coded. For example, root caries, dental fluorosis, and traumatic injuries are assessed only on permanent teeth as defined in the tooth count.**

Whenever a call in the Tooth Count precludes a later assessment, such as primary teeth not eligible for The Incisor Trauma assessment, the program automatically shades the affected tooth in the subsequent assessment. A “Cannot be assessed” code is also automatically displayed in the shaded data entry space. This code is “9” and the shaded “9” code is termed a “hard 9.” The program does not allow the recorder to overwrite the “9” with any other code. In subsequent assessments, ISIS will skip these tooth positions and the cursor will move to the first blank tooth space. To change this hard “9,” the Tooth Count code for that tooth must be changed on the Tooth Count Screen.

In addition, the following apply to SPs who are edentulous or have implants:

1. There is a variable on the screen labeled “Implant” which must be checked if the SP reports an implant. Simply recording a “3” on the tooth spaces will not suffice for coding the SP as having an implant.
2. There is a variable on the screen labeled “Edentulous” which must be checked if the SP is edentulous. Simply recording all “3s” and “4s” in the tooth spaces will not suffice for coding the SP as edentulous.
3. If an edentulous SP has an appliance supported by implants, the implant box and edentulous box must be checked on the screen. When the edentulous box is checked on a SP who answered yes to the implant question, the system will automatically enter “4” in all tooth spaces. Prompt the recorder to change the mandibular cuspids to “3” to record the presence of implants, regardless of the placement of the implants.
4. Natural teeth used as an overdenture abutment would be coded as a “5” followed by a “T” for the coronal caries assessment.

Root tips are classified as any permanent residual tooth structure that is predominately composed of dental root structure with less than 90 percent of the CEJ visible, with less than 90 percent of the coronal structure visible, and occupies a dental position within the dental arch. Because multi-rooted posterior teeth may present as multiple root tips, examiners will assign multiple root tips to the appropriate dental position in the arch and code accordingly.



Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

SP ID: 880482 Name: Sanchez, Miguel Age: 8 years Gender: Male Date: 11/25/1998 Time: 02:10 PM

**Tooth Count**

Permanent	CI	LI	C	1B	2B	1M	2M	3M	
<b>Primary</b>				<b>1PM</b>	<b>2PM</b>				
UR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Implant
UL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Edentulous
LL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

1 of 6

End of Section Close Exam Finish

Ready

## 4.9 Dental Caries

The objectives of the dental caries component of the survey are to:

- Establish age-specific data for the prevalence of dental caries, both coronal and root, in a national sample;
- Provide a basis for comparisons with past and future national dental caries surveys;
- Provide baseline data for possible follow-up of selected subsamples;
- Provide a basis for the development of estimates of treatment needs; and
- Provide a basis for studying the association between the prevalence of dental caries and risk factors.

There are two parts to the dental caries assessment: coronal caries and root caries. With certain exceptions, diagnostic criteria for the coronal caries examinations are those developed by Radike, et al., as published in the Proceedings of the Conference on Clinical Testing of Cariostatic Agents, sponsored by the American Dental Association in 1968. With minor modifications, the diagnostic criteria for coronal caries have been used in several statewide surveys and in the following national surveys:

- National Health and Nutrition Examination Survey I (NHANES I) (1970-74);
- National Institute of Dental Research (NIDR) National Dental Caries Prevalence Survey in U.S. School Children (1979-80);
- Hispanic Health and Nutrition Examination Survey (Hispanic HANES);
- NIDR National Survey of Oral Health in U.S. Employed Adults and Seniors (1985-86);
- NIDR National Survey of Oral Health in School Children (1986-87); and
- National Health and Nutrition Examination Survey III (NHANES III) (1988-1994).

The diagnostic criteria for root caries were used in the following surveys:

- NIDR National Survey of Oral Health in U.S. Employed Adults and Seniors (1985-86); and
- NHANES III.

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#### **4.9.1 Coronal Caries Assessment**

Each SP aged 2 years and older receives the coronal caries assessment. All teeth except the third molars are assessed.

##### **4.9.1.1 Examination Procedures**

Each quadrant is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The examiner begins the assessment in the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants. Tooth surfaces are examined in the following order: lingual, facial (buccal), mesial, and distal for anterior teeth, and lingual, occlusal, facial, mesial, and distal for posterior teeth. It is not advisable to call out the individual tooth surface codes until the surfaces of the whole tooth are examined, as this can be confusing to the recorder. Thus, the examiner will mentally accumulate surface calls for a given tooth, then dictate the calls to the recorder.

##### **4.9.1.2 Scoring Codes**

The codes characterizing a whole tooth condition are referred to as “tooth calls.” The allowable codes are as follows:

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

U = Unerupted tooth

E = Missing due to dental disease (caries/periodontal disease)

M = Missing due to other causes (orthodontic/traumatic or other nondisease)

R = Missing due to dental disease but replaced by a fixed restoration

X = Missing due to other causes but replaced by a fixed restoration

P = Missing due to dental disease but replaced by a removable restoration

Q = Missing due to other causes but replaced by a removable restoration

J = Permanent root tip is present but no restorative replacement is present

T = Permanent root tip is present but a restorative replacement is present

Y = Tooth present, condition cannot be assessed

The codes characterizing the surface condition are referred to as “surface codes.” The allowable codes are as follows:

For caries, the allowable codes are as follows:

0 = Lingual caries

1 = Occlusal caries

2 = Facial caries

3 = Mesial caries

4 = Distal caries

For filled teeth or restorations, the allowable surface codes are as follows:

5 = Lingual restoration

6 = Occlusal restoration

7 = Facial restoration

8 = Mesial restoration

9 = Distal restoration

C = Crown (short call for both primary and permanent teeth)

#### 4.9.1.3 Assessment Diagnostic Criteria: Decayed, Missing, and Filled Surface Index (DMFS)

##### 4.9.1.3.1 Decayed Tooth Surfaces (the D Component of the DMFS Index)

Frank lesions are detected as gross cavitation and thus present few problems in diagnosis. Incipient lesions captured in this survey, on the other hand, are more difficult to diagnose consistently. Incipient lesions may be subdivided into three categories according to location, each with the following special diagnostic considerations:

#### 1. Pits and fissures on occlusal, facial, and lingual surfaces

These areas are classified as carious when the explorer catches after insertion with moderate, firm pressure, accompanied by either a softness at the base of the area **and/or** an opacity adjacent to the area providing evidence of undermining or demineralization. In other words, a deep pit or fissure in which the explorer catches is not sufficient evidence of decay without **one or both** of the following:

- Softness at the base of the area;
- Opacity adjacent to the area providing evidence of undermining or demineralization.

#### 2. Smooth areas on facial (labial or buccal) or lingual surfaces

These areas are carious if they are (1) either decalcified **or** if there is a white spot as evidence of subsurface demineralization **and** (2) if the area is found to be soft by:

- Penetration with the explorer, or
- Scraping the area with the explorer.

Visual evidence of demineralization is not enough to diagnose caries.

#### 3. Proximal surfaces

- When areas are accessible to direct visual and tactile examination, i.e., when there is no adjacent tooth, the same criteria as that used for smooth areas on facial or lingual surfaces are used.

(Revised February 2003)

- When areas are not available to direct examination, other criteria must be applied.
  - On anterior teeth, trans-illumination can serve as a useful aid in discovering proximal lesions. Trans-illumination is achieved by placing a mirror lingually and positioning the examining light so that it passes through the teeth and reflects into the mirror. If a characteristic shadow or loss of translucency is seen on the proximal surface, then this is indicative of caries on the surface. Ideally, the actual diagnosis should be confirmed by detecting a break in the enamel surface with the explorer; however, clear visualization of a lesion by trans-illumination can justify a positive diagnosis.
  - On posterior teeth, however, visual evidence alone, such as undermining under a marginal ridge, is not sufficient proof for diagnosing a proximal lesion. **A positive diagnosis is made only if a break in the enamel surface can be detected with the explorer.**

#### 4.9.1.3.2 Missing Teeth (the M Component of the DMFS Index)

This criterion traditionally represented permanent teeth extracted only as a result of caries. However, because of the difficulty of correctly distinguishing between teeth extracted due to caries and those extracted for periodontal reasons, no attempt is made at the time of the examination to differentiate between these two causes of tooth loss. It is essential, however, to distinguish between teeth extracted because of caries or periodontal disease and those extracted or missing for other reasons.

- The code “E” is used to indicate teeth extracted because of caries or periodontal disease,
- The code “M” is used for teeth missing due to trauma, orthodontic treatment, or other nondisease related causes.
- The code “U” is used to identify unerupted or congenitally missing teeth.

In order to determine whether an “E,” “M,” or “U” is called, the examiner will ask the SP about the reason for tooth loss. Separate codes are used when a missing tooth has been replaced by a fixed or removable prosthesis.

- “R” is used to designate a tooth that is missing due to dental disease, but has been replaced by a fixed restoration.
- “P” is used to designate a tooth that is missing due to dental disease, but has been replaced by a removable restoration.

- “X” is used to designate a tooth that is missing due to other causes, but has been replaced by a fixed restoration.
- “Q” is used to designate a tooth that is missing due to other causes, but has been replaced by a removable restoration.

A fixed or removable prosthetic replacement is considered to exist when it is visible in the mouth. If an appliance is not visible, the examiner should ask the SP if one exists. If the SP reports the existence of a removable appliance, the replacement is considered to exist if the SP reports he/she wears the appliance, no matter how infrequently.

When a replacement exists, the examiner does not consider its condition or adequacy when making the call. When a replacement does not exist, the examiner does not attempt a clinical judgment of the need or adequacy of space for a replacement, even if tooth movement has closed the space.

When more than one tooth has been replaced by a single pontic, each tooth space is scored as replaced.

	Not Replaced	Replaced
Disease	E	R, P
Nondisease	M	X, Q

When an implant is identified in Tooth Count, a code of “3,” the appropriate restorative codes for Coronal Caries would either be “R,” “X,” “P,” or “Q.” The correct code is based on restorative replacement type and the self-reported reason for permanent tooth loss.

#### **4.9.1.3.3 Filled Tooth Surfaces (the F Component of the DMFS Index)**

The F component represents a tooth surface that has been filled with either a permanent or a temporary restoration as a result of caries. It is necessary to distinguish between surfaces restored because of caries and those restored for other reasons, such as trauma, hypoplasia, malformation, or bridge abutment. The examiner may question the SP as necessary to make the correct call.



#### **4.9.1.4 Scoring Permanent Teeth**

Sound permanent teeth (“S”) are distinguished from permanent teeth with restorations or caries (“Z”). The “Z” code precedes any other legitimate diagnostic call for decayed or filled surfaces. For example, if a permanent molar has occlusal caries and is otherwise sound, the “Z” code is combined with the code for occlusal caries, i.e., “Z1.” If the permanent tooth is sound, the “S” code is used alone. For permanent teeth coded as a “5” in the tooth count, the “T” or “J” codes must be used. ISIS will not accept any other coronal caries codes.

Any permanent root tip that has had a replacement made for the appropriate coronal structure or serves as a supporting structure for an overdenture will be coded as a “T.” This includes visible residual roots present under any type of removable complete or partial denture. If a visible residual root is present and no replacement has been made, the correct code will be a “J.”

The specific codes for permanent teeth are listed below:

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

J = Permanent root tip is present but no restorative replacement is present

T = Permanent root tip is present but a restorative replacement is present

#### **4.9.1.5 Scoring Primary Teeth**

Decayed or filled surfaces of primary teeth are scored in the same manner as permanent teeth, using the same diagnostic criteria. However, because this survey is concerned with both primary and permanent teeth, it is necessary to call sound primary teeth with a “deciduous” score (“D”) to distinguish them from sound permanent teeth (“S”). The “K” code is used for primary teeth with restorations or caries to distinguish them from permanent teeth with restorations or caries (“Z”). The “K” code precedes any other legitimate diagnostic call for decayed or filled surfaces on primary teeth. For example, if a primary molar has occlusal caries and is otherwise sound, the “K” code is combined with the code for occlusal caries (i.e., “K1”). If the primary tooth is sound, the “D” code is used alone.

Missing primary teeth present potential problems in scoring because it is often not possible to distinguish exfoliated teeth from those extracted due to caries, especially during the period of mixed dentition. To avoid this problem, at the time of examination, all missing primary teeth are scored as unerupted permanent teeth (“U”). When data are analyzed, the age of the SPs can be used to determine the most likely reason for tooth loss.

The specific codes for primary teeth are listed below:

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

**Note again if both a permanent and a primary tooth are visible in the same tooth space, only the status of the permanent tooth is described and no score is assigned for the primary tooth.**

#### **4.9.1.6 General Guidelines for Scoring**

The tooth and surface codes are listed again here for convenience. They are as follows:

##### Tooth Codes

S = Sound permanent tooth (no decay or filling on any surface)

Z = Permanent tooth with surface condition

D = Sound primary (deciduous) tooth

K = Primary tooth with surface condition

U = Unerupted tooth

E = Missing due to dental disease (caries/periodontal disease)

M = Missing due to other causes (orthodontic/traumatic or other non-disease)

R = Missing due to dental disease but replaced by a fixed restoration

X = Missing due to other causes but replaced by a fixed restoration

P = Missing due to dental disease but replaced by a removable restoration

Q = Missing due to other causes but replaced by a removable restoration

J = Permanent root tip is present but no restorative replacement is present

T = Permanent root tip is present but a restorative replacement is present

Y = Tooth present, condition cannot be assessed

##### Surface Codes

For caries, the allowable codes are as follows:

0 = Lingual caries

1 = Occlusal caries

2 = Facial caries

3 = Mesial caries

4 = Distal caries

For filled teeth or restorations, the allowable surface codes are as follows:

- 5 = Lingual restoration
- 6 = Occlusal restoration
- 7 = Facial restoration
- 8 = Mesial restoration
- 9 = Distal restoration
- C = Crown (short call for both primary and permanent teeth)

The following conventions have been adopted in the interest of achieving diagnostic consistency:

1. Only **one entry** can be made for each tooth surface. In the event that a surface has both decay and a filling, only the decay is called. If the examiner gives two calls for the same surface, the ISIS system will beep and a message will be displayed in the lower right portion of the screen. Data entry is prohibited until an allowable response is entered. The recorder should bring this to the examiner's attention immediately.
2. If a tooth has rotated, surface calls should be assigned to the anatomical surface not to the current position of the surface.
3. Incisal edges of anterior teeth are not considered to be separate surfaces. If a lesion or restoration is confined solely to the incisal edge, its score should be assigned to the nearest adjacent surface. If the lesion is equidistant from the surfaces, code lingual.
4. Anterior teeth have four surfaces that are coded - facial, lingual, mesial, and distal.
5. Posterior teeth have five surfaces that are coded – facial, lingual, mesial, distal, and occlusal.
6. When a caries lesion extends beyond the line angle onto another surface, that surface is also scored as carious. For restorations, however, the following **rules** apply:
  - On anterior teeth, a proximal filling is not considered to involve the adjacent facial or lingual surface unless it extends at least one-third of the distance to the opposite proximal surface. The reason for this criterion is that the tooth structure on facial or lingual surfaces of anterior teeth must often be removed to provide access for the proximal restoration.
  - On posterior teeth, to guard against a similar possibility of overcalling, a proximal restoration should extend more than a millimeter past the line angle before it is considered to involve the adjacent facial or lingual surface.
7. If a tooth has a full crown restoration placed because of caries, the tooth will be coded as "C," which represents the maximum number of surfaces for the tooth type, i.e., four surfaces on anterior teeth and five surfaces on posterior teeth.

The following conventions apply:

- All full crowns on posterior teeth, including abutment teeth for fixed or removable prostheses, will be considered to have been placed due to caries.
- On anterior teeth, however, the examiner should make a determination of the reason for crown placement. If it can be determined that the crown was placed solely for a reason other than caries, such as fracture, malformation, or bridge abutment, the tooth is coded “Y.”

For three-quarter crowns, the following rules apply:

- In general, if a tooth has been restored with less than full coverage, each surface is examined and scored in the usual manner. However, when the crown coverage extends onto the facial (labial or buccal) or lingual surface for cusp protection, the surface is not scored as restored unless the coverage extends more than two millimeters cervically from the cusp tip or incisal edge.
  - For three-quarter crowns used as abutment teeth, all surfaces are scored in the usual manner if the abutment is a posterior tooth. On anterior teeth, if it can be determined that the crown was placed solely for purposes of abutment and not for caries, the restoration is not scored, but surfaces without crown coverage are examined and scored in the usual manner.
8. Teeth that are banded or bracketed for orthodontic treatment are examined in the usual manner and all visible surfaces are scored.
  9. Certain teeth, notably first bicuspid, may have been extracted as part of orthodontic treatment. These teeth are coded “missing due to other causes” “M” and will be excluded from the DMFS analysis. The examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to determine because of the typically symmetric pattern of these extractions. For the sake of uniformity, all orthodontically extracted bicuspid are scored as first bicuspid. Teeth other than bicuspid may also be extracted for orthodontic reasons. In many cases the SP will have good recall of the reason for the extractions and can help in making the correct determination.
  10. Nonvital teeth are scored in the same manner as vital teeth. If, however, a restoration on a nonvital tooth was placed solely to seal a root canal and not for caries, that restoration is not scored. If no other lesions or restorations are present, the tooth will be called sound (“S”).
  11. Hypoplastic teeth are scored in the usual manner. However, if it can be determined that a restoration was placed solely for esthetic reasons and not for caries, that restoration is not scored. If a hypoplastic tooth is restored with a full crown, it is to be coded “Y”.
  12. Malformed teeth are scored in the usual manner except when they have been restored with a full crown for esthetic reasons, in which case they are coded “Y”.

13. When the primary tooth crown is destroyed by caries and only the roots remain, score all surfaces carious (5 surfaces on the posterior teeth – 0,1,2,3,4; and 4 surfaces on the anterior teeth – 0,2,3,4).
14. When the same tooth surface is both carious and filled, only the caries is scored.
15. Fractured or missing restorations are scored as if the restoration was intact unless caries is found to be present. In that case, the involved surface is scored as carious rather than restored.
16. In the case of supernumerary teeth, only one tooth is scored for the tooth space. The examiner must decide which tooth is the “legitimate” occupant of the space.
17. If both a deciduous and a permanent tooth occupy the same tooth space, only the permanent tooth is scored.
18. Third molars are not scored. When examining second molars it is important to note that a drifted third molar may occupy the space of a missing second molar. In such cases, the diagnosis and score must relate to the status of the missing second molar, not the third molar. If the second molar, for example, was extracted due to caries and a sound third molar now occupies the space, the second molar is scored as extracted (“E”) and the third molar is not scored.
19. A tooth is considered to be in eruption when any part of its crown projects through the gum. This criterion is easier to standardize than one based on a more advanced stage of eruption.
20. Stain and pigmentation alone should not be regarded as evidence of caries as either can occur on sound teeth.

If the tooth is permanent with no decay or filling on any surface, the examiner calls “S.” If the tooth is permanent and is not sound, the examiner calls “Z” **and** the appropriate surface condition codes as described below. “D” is entered for all sound primary calls while “K” **and** the appropriate surface condition codes are entered if the primary tooth has surface conditions (caries, restoration). If the tooth is missing and characterized by one of the other “tooth” calls, the examiner calls out the appropriate letter (U, E, M, R, X, P, or Q).

The recorder records the appropriate tooth condition code in the first space for the tooth. After this first space, there is a separate block of data entry spaces to accommodate the surface calls for that tooth as necessary.

If the tooth is permanent with decay or restorations on one or more surfaces (Z), the examiner calls the number(s) which correspond(s) to the surface(s) having decay or a restoration. Some examples are listed below.

- If the examiner calls 0, 1, 2, 3, or 4, it means that there is decay on the surfaces of the tooth represented by those numbers.
- If the examiner calls 5, 6, 7, 8, or 9, it means that there is a filling on the surface(s) represented by the number(s) called.
- If the examiner calls “C,” it means that there is a crown on that tooth.
- Combinations of caries and restorations on **different** surfaces are allowed. For example, if the examiner calls “1, 8, 9” it means that there is a caries on the occlusal surface and a restoration on the mesial and distal surfaces.

This procedure continues to the second molar for each of the four quadrants of the mouth.

#### **4.9.1.7 Guide for Referral and Followup**

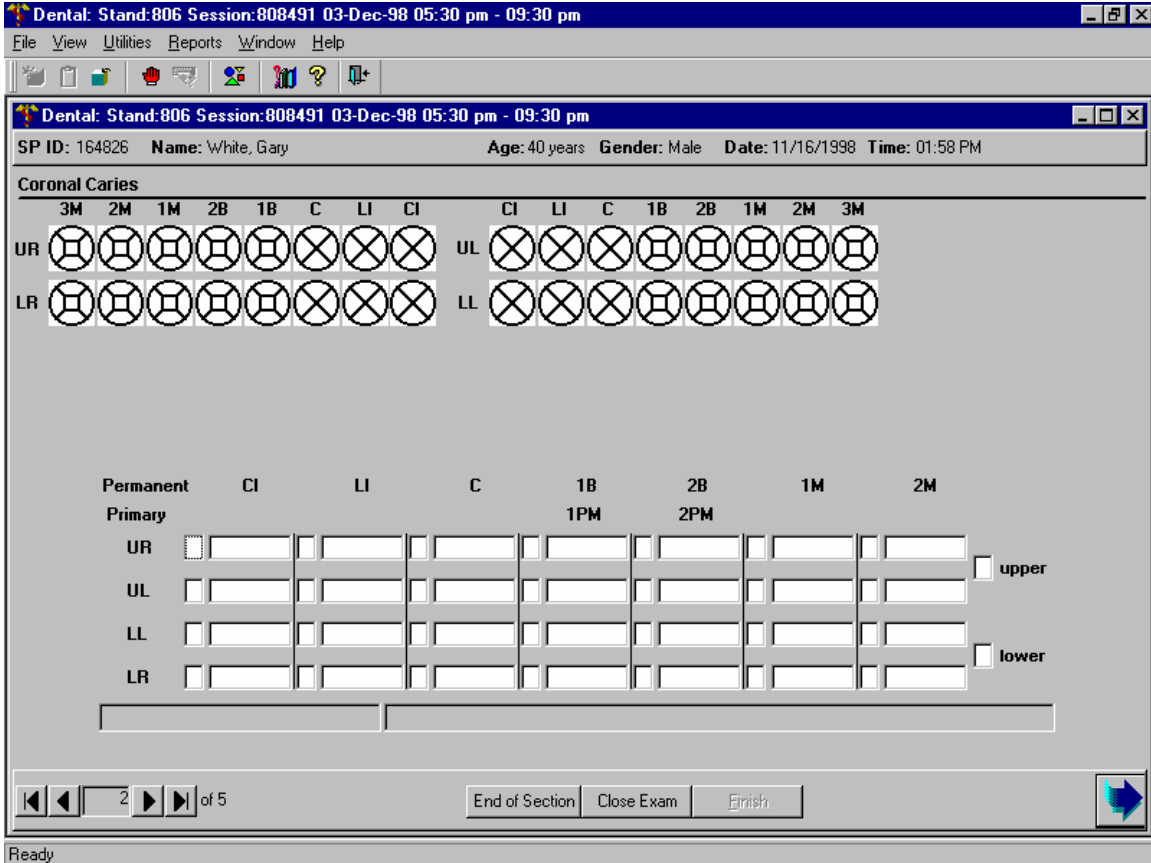
Any caries call (0, 1, 2, 3, or 4) flags an ISIS recommendation telling the SP to see a dentist at his/her earliest convenience (Level 3 recommendation). Levels of recommendation are discussed in detail later in this chapter.

#### **4.9.1.8 Recording Procedures**

The Coronal Caries screen is divided into four rows, which correspond to the four quadrants of the mouth: upper right, upper left, lower left, and lower right. These quadrants are labeled on the left portion of the screen. The teeth are labeled across the top. Space to enter the overall caries tooth call and the individual surface caries is provided for each tooth except the third molars. There is space to enter codes for seven teeth per quadrant. No more than 28 permanent teeth can be scored for each SP. Third molars, or wisdom teeth, are not scored for dental caries.

**NOTE: The examiner and recorder are both responsible for making sure that the calls the examiner makes are being recorded in the correct tooth space on the screen. In order to do this consistently, each tooth position is to be referred to by its quadrant location and tooth location. For example, whenever a new quadrant is started or there is a long silence between calls, the recorder will prompt the examiner with the next blank tooth space, such as “upper left central incisor” (noted as “UL CI” on the screen).**

**NOTE:** In instances where all teeth in the upper and/or lower jaws are missing for the same reason, it is imperative that the examiner prompt the recorder to use the “Upper” and “Lower” fields to indicate the caries code. By doing so, the system will fill all teeth in that half mouth with the same code and the SP will be scored with the appropriate half-mouth calls.



#### 4.9.1.9 Interaction with Heads-Up Display Screen

As condition codes are entered on the Coronal Caries screen, the corresponding condition symbols are displayed on the Heads-Up Display screen. As mentioned earlier, red bullets symbolize caries, while restorations are symbolized by shading. No changes are made to implants (red circle with “I”) or missing teeth (red circle with slash) based on calls entered on this or subsequent screens.

## **4.9.2 Root Caries Assessment**

SPs aged 18 years and older receive this assessment to determine the prevalence of root caries and root restorations.

### **4.9.2.1 Examination Procedures**

Only teeth that have recession should be assessed for the presence of root caries and root-restorations. If recession is present but the root surfaces are sound, then the score is “2.” If recession is not present, the score is also a “2”. All exposed portions of a tooth’s root surface should be examined carefully in the following sequence: the examiner begins with the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants.

Each quadrant with recession is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The most difficult areas to examine are approximal surfaces in posterior teeth, particularly those that contain approximal restorations. Subgingival inspection is not recommended because few lesions are confined subgingivally and it may produce bleeding. Data are captured as overall presence or absence of root caries and overall presence or absence of root restorations.

### **4.9.2.2 Scoring Codes**

For this assessment, the presence of any root caries and any restorations will be recorded as “whole mouth” calls. Therefore, the exposed surfaces of individual teeth will be assessed, but not recorded as individual surfaces. The allowable “whole mouth” codes for root caries are as follows:

- 1 = Root caries detected
- 2 = No root caries detected
- 9 = Cannot be assessed



The allowable “whole mouth” codes for root restorations are as follows:

- 1 = Root restoration detected
- 2 = No root restoration detected
- 9 = Cannot be assessed

#### **4.9.2.3 Diagnostic Criteria**

Caries occur on root surfaces of teeth only where there has been loss of normal gingival attachment, apical recession from the cemento-enamel junction (CEJ). Generally, caries on root surfaces occurs coronal to the present gingival margin but apical to the CEJ; very few lesions exist solely in the gingival pocket. Although all exposed root surfaces are susceptible, it has been reported that root caries predominantly occurs in approximal and facial aspects.

Root caries starts at or just below the cemento-enamel junction. Most commonly, early root caries lesions are small and round. However, they may spread laterally along the cervical junction, sometimes coalescing with neighboring lesions to produce a collar of caries around the root. Caries that begins in a root surface does not tend to affect the adjacent coronal enamel surface directly. Rather, they may undermine the cervical enamel and invade coronal dentin, leaving a cervical enamel spur or ledge. If the carious process continues, pieces of this ledge may fracture, making it appear as if the caries had originated in the enamel as well as the cementum. The opposite sequence can occur as well, with cervical coronal caries spreading apically to involve the CEJ and then the root surface. Some scoring guidelines are listed below.

- When a single caries lesion that extends at least 1 mm past the CEJ in both incisal and apical directions affects both the coronal and root surfaces, both surfaces should be considered decayed, thus this lesion would be assessed for root and coronal caries.
- A lesion affecting both crown and root surfaces that extends less than 1 mm in either direction, the surface on the side of the CEJ that involves more than 50 percent of the area of the lesion should be scored.
- When it is impossible to apply the “>50 percent rule,” i.e., both coronal and root surfaces appear equally affected, both surfaces should be considered “decayed.” For restorations, the same rules apply.

Defective margins of fillings with suspicious carious areas should be checked with an explorer for recurrent decay and the criteria for assessing “decayed and filled” root surfaces should be the same as for coronal surfaces, that is, decay takes precedence over a filling. Full crown coverage is considered to have been placed for coronal caries even if the margin of the crown extends on to the root surface. Thus, a root surface with a crown margin free of recurrent decay should be considered sound.

Areas of abrasion or erosion in root surfaces rarely become carious because they are generally kept clean and are free of plaque. Root caries frequently occur beneath plaque, but rarely beneath calculus. Accumulations of plaque, which obstruct the examination procedure, should be removed. **Surfaces covered entirely by calculus are considered sound.**

Active caries lesions in root surfaces are yellow/orange, tan, or light brown in color. Lesions in remission may or may not be cavitated. They are hardened and tend to be darker, sometimes almost black. When root caries are covered by small amounts of plaque, the discoloration of the lesions usually shows through.

In some incipient lesions the carious area of the root surface may merely be discolored without cavitation, but the area will be soft to exploration. Cavitation with jagged margins and a roughened, but soft floor or base usually occurs in advanced lesions. Normal cementum is softer than enamel, and frequently will yield to pressure from the tip of an explorer. Areas of root caries, however, are softer than surrounding cementum; therefore, it is possible to differentiate sound cementum from carious cementum based on tactile sense. In the presence of root caries, an explorer penetrates the tissue but usually can be removed easily. However, if the explorer penetrates but resists withdrawal or “sticks,” the surface is usually sound cementum. With experience and training, it is possible to develop a tactile sense to differentiate sound from carious cementum. Note that for areas without gross cavitation, visual criteria related to location, shape, and discoloration of the suspected area do not, in themselves, define root caries. The tactile criteria of softness to an explorer tip must be met for a definitive diagnosis of root caries to be made.

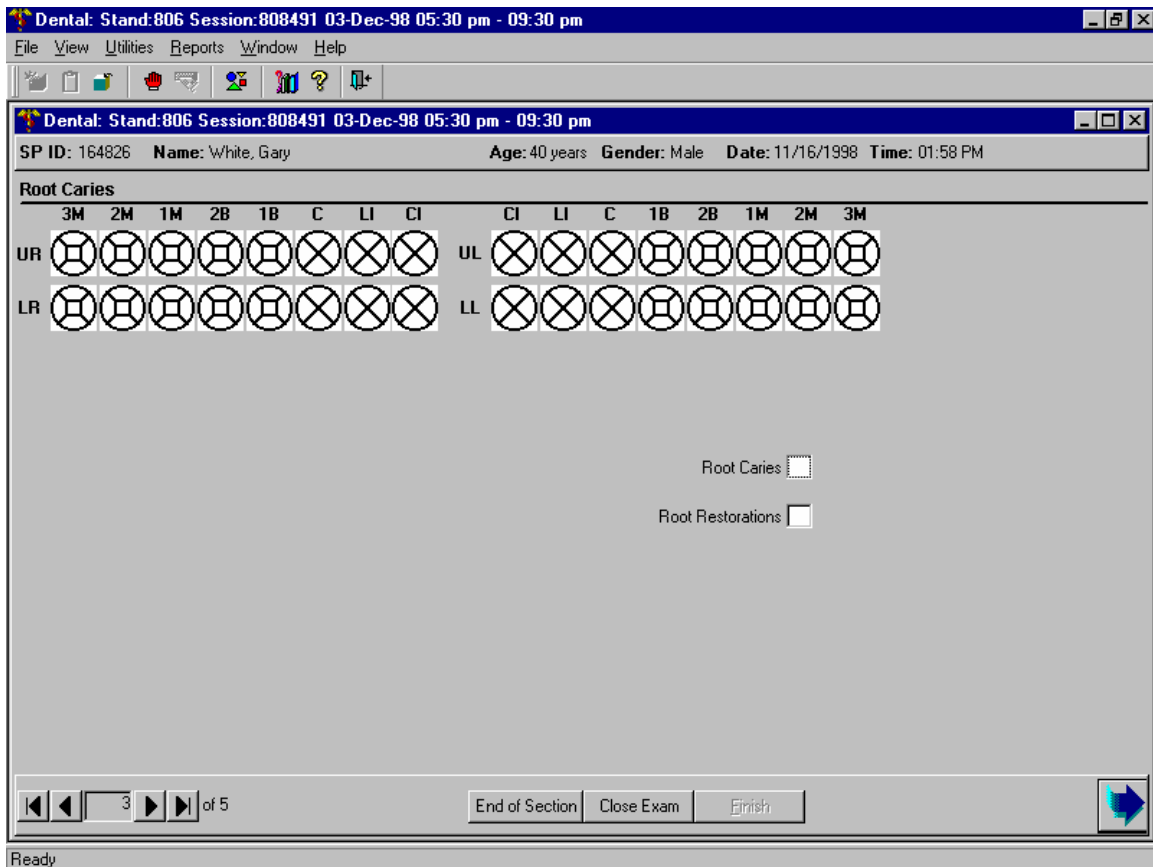
#### 4.9.2.4 Guide for Referral and Follow-up

Presence of any root caries flags an ISIS recommendation telling the SP to see a dentist at his/her earliest convenience (Level 3 recommendation). Levels of recommendation are discussed in detail later in this chapter.

#### 4.9.2.5 Recording Procedures

A maximum of 28 permanent teeth will be examined for each SP. Third molars, or wisdom teeth, are not examined for root caries.

The Root Caries screen consists of two “whole mouth” variables. Space has been provided to indicate whether **any** root caries or root restorations exist in the SP’s mouth.



## **4.10 Sealant Assessment**

### **4.10.1 Examination Procedures**

SPs aged 2-34 years receive the sealant assessment. The sequence of the exam is the same as that of the tooth count. However, only the pitted or grooved surfaces of the first and second bicuspid/primary molars, first and second molars, and the permanent maxillary lateral incisors are to be scored for the assessment. These surfaces in each quadrant are dried with air and examined with a surface reflecting mirror and a No. 23 explorer for the presence of sealant.

Sealants are professionally applied plastic films used to occlude the pits and fissures on occlusal, facial (buccal), and lingual surfaces of teeth. Sealants are applied to the teeth as viscous liquids and polymerize (or “cure”) in a short period of time. The purpose of sealants is to provide a physical barrier to the collection of substrate for cariogenic bacteria in the pits and fissures, and thus prevent dental caries from initiating or developing further. It is important to be aware that sealant products may vary in appearance, from clear to colored, or white. Sealant should be scored as present on a surface when any part of the surface remains covered. If it appears that sealant material was used as a restoration rather than as a preventive procedure, score the surface as filled in the coronal caries section and do not record the presence of sealant on this screen.

### **4.10.2 Scoring Codes**

The calls for the sealant assessment are as follows:

0 = Sealant not present

1 = Occlusal sealant present on permanent tooth

2 = Facial sealant present on permanent tooth (mandibular only)

3 = Lingual sealant present on permanent tooth (maxillary only)

4 = Occlusal sealant present on primary tooth

9 = Cannot be assessed

### 4.10.3 Scoring Guidelines

- “0”, “4,” and “9” are mutually exclusive calls.
- Combinations of “1, 2” and “1, 3” are allowed for permanent molars since more than one surface of these teeth may be sealed.
- Only “0,” “3,” or “9” are allowable codes for lateral incisors.
- Only “0,” “1,” “3,” or “9” are allowable codes for upper permanent molars.
- Only “0,” “1,” “2,” or “9” are allowable codes for lower permanent molars.

### 4.10.4 Recording Procedures

Sealant codes can be entered for the bicuspids/primary molars, first and second molars, and the permanent maxillary lateral incisors only. One code is permitted for primary teeth, bicuspids and permanent lateral incisors, while multiple codes are permitted for permanent molar teeth. Refer to the previous section for allowable codes.

The recorder may use a designated shortcut key to record all “0s” if the SP has no sealants on the teeth to be assessed. In these instances, the examiner calls “All 0’s” instead of calling “0” for each individual tooth assessed. The recorder presses the F2 key to automatically fill “0” in all blank tooth spaces in each quadrant, thus pressing the F2 key four times will fill all four quadrants with “0s.” **The examiner will call “All 0’s” by quadrant, or will call “All 0’s” for all four quadrants. The examiner will let the recorder know which he/she is doing.**

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

SP ID: 614640 Name: Sanchez, Maria Age: 8 years Gender: Female Date: 12/03/1998 Time: 02:37 PM

**Dental Sealant**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR																	
LR																	

	Permanent	LI	1B	2B	1M	2M
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UL		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
LL		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
LR		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

3 of 6

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#### **4.11 Dental Fluorosis Assessment**

Dental fluorosis is a condition of tooth enamel and dentine that results from receiving excessive amounts of fluoride during the period of tooth development. Both primary and permanent teeth may have dental fluorosis, although the former generally is affected to a lesser extent. The degree of dental fluorosis can range from barely noticeable whitish opacities to confluent pitting of the enamel surface and unsightly dark brown staining, depending upon the amount of fluoride ingested and duration of exposure during tooth development. Enamel opacities in dental fluorosis are bilaterally symmetrical and affect multiple teeth. Staining, loss of enamel, and attrition are post-eruptive phenomena, therefore they may not be strictly bilateral.

##### **4.11.1 Classification and Scoring (Dean's Fluorosis Index Criteria)**

The criteria for classifying and scoring dental fluorosis are modified from the system described by Dean in 1942. Each tooth is examined and assigned to one of six categories according to its degree of dental fluorosis. For analysis, classification of a person is based on the two teeth most affected by fluorosis. If the two teeth are not equally affected, the classification given to the person is the score for the less involved tooth. For the purpose of the dental examination in this study, each tooth is classified. The modified criteria and the corresponding scores described by Dean are provided in Exhibit 4-3.

#### **REFERENCES**

- Dean H.T. (1942). The investigation of psychological effects by the epidemiological method. In: *Fluorine and Dental Health*, F.R. Moulton, (Ed.), AAAS, Pub. No. 19, Washington, DC, pp. 23-31.
- Rozier, R.G. (1994). Epidemiologic indices for measuring the clinical manifestations of dental fluorosis: Overview and critique. *Advances in Dental Research*, 8(1), 39-55.



Exhibit 4-3. Dean's Fluorosis Index criteria (Modified for NHANES)

Dean's Classification (Score*)	Criteria	Operational Definition
Normal - (0)	The enamel presents the usual translucent semi-vitriform type of structures. The surface is smooth, glossy, and usually of a pale creamy white color.	Criteria that do not meet definitions below.
Questionable- (0.5)	The enamel shows slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilized in those instances where a definite diagnosis of the very mild form of fluorosis is not warranted and a classification of "normal" is not justified.	Occasional white spots.
Very Mild - (1)	Small, opaque, paper white areas scattered irregularly over the enamel but involving less than 25 percent of the total surface area. Included in this category are teeth that show no more than 1-2 mm of white opacity at the cusp tips of posterior teeth or incisal edges of anterior teeth.	Paper white areas, scattered over 25 percent of the tooth surface or less. One should be confident of the diagnosis of fluorosis based on the pattern in the mouth and the type of lesions. The lesions are bilaterally symmetrical and the margin of lesion blends or is not clearly defined. Otherwise call it questionable.
Mild - (2)	The white opaque areas are more extensive but involve less than 50 percent of the total surface area.	Greater than 25 percent, but less than 50 percent of any tooth surface is affected.
Moderate - (3)	50 percent or greater of the tooth surface area is affected. All enamel surfaces of the teeth are affected, and surfaces subject to attrition show marked wear. Brown stain is frequently a disfiguring feature.	50 percent or greater of the tooth is affected. All visible surfaces (occlusal, buccal, and lingual of posterior teeth; or facial and lingual surfaces of anterior teeth) must be involved. Posterior teeth typically show attrition because fluorosed surfaces wear easily. The area that has undergone attrition is considered as fluorosed for scoring purposes. If there is marked attrition, this has to be considered when determining the extent of involvement (consider this area as fluorosed). Anterior teeth out of occlusion may not show attrition.
Severe - (4)	All enamel surfaces are affected. The diagnostic sign required for this classification is discrete or confluent pitting of the enamel. With marked confluent pitting, the tooth often presents a corroded-like appearance. Brown stains of intact enamel are often present.	A fluorosed tooth with discrete or confluent pitting. General form of the tooth may be affected.

\* NOTE: These are the scoring codes as defined by Dean. NHANES scoring codes are provided later in this chapter.

#### 4.11.1.1 Special Diagnostic Considerations

- It is not uncommon to observe bilateral hypoplastic teeth especially with first molars. These should be distinguished from dental fluorosis. In dental fluorosis, all enamel surfaces are affected when pitting is present. In non-fluorosed hypoplastic teeth, part of the unaffected enamel will appear free of enamel opacities.
- A tooth is not scored if one-half or more of the visible enamel area is replaced with a restoration, is destroyed by caries, or is covered with an orthodontic band. For posterior teeth the visible enamel is composed of the buccal and lingual surfaces, extending from embrasure to embrasure, and the occlusal surface. For the anterior teeth, the visible area is composed of the labial and lingual surfaces, extending from embrasure to embrasure.
- Dental fluorosis in the milder classifications may be confined to particular areas of the enamel, or may occur irregularly over the entire enamel surface. The area affected is derived by visually coalescing all areas of the fluorosis and relating that area to the total area of all visible enamel.
- Staining of intact enamel is not a diagnostic criterion specific to any of the classifications and is not taken into consideration in scoring a tooth.
- A pit is defined as a discrete, focal loss of outermost enamel. Initially, the enamel wall is usually intact. With wear, however, the enamel wall can be abraded away, so that often only part of the wall can be detected. In contrast to intact enamel on which the explorer tip can be moved easily across the smooth surface, pitted areas demonstrate a definite physical defect in which the base of the defective area may be either carious or sound. If it is sound, the base of the pit is rough and offers resistance to the lateral movement of the explorer tip, and a scratchy sound is detected when the explorer is moved across it. If the base is carious, it demonstrates softness upon being probed with moderate pressure. The pitted area is usually stained or demonstrates a different color compared with the surrounding intact enamel.
- Confluent pitting of the enamel results from the coalescence of two or more discrete pits. The walls of pits at the occlusal or incisal edges can be abraded, so that only the walls on the gingival aspect remain intact, often leading to an irregular “ledging” effect. In some cases, confluent pitting may advance to a point where such large areas of enamel are corroded such that the anatomy of the tooth is altered.
- If the lingual and buccal surfaces of a posterior tooth have fluorosis from the occlusal surface to the middle third, but the occlusal surface shows marked attrition, call it moderate.
- If the lingual and buccal surfaces of a posterior tooth have fluorosis involving 25 percent of each surface, but the occlusal surface shows attrition only on the cuspal tips and the rest of the occlusal surface appears normal, the call would be mild. This is because the total will not add up to 50 percent and there is no marked attrition.

- If the lingual and buccal surfaces of a posterior tooth have fluorosis from the occlusal surface to the middle 3<sup>rd</sup>, and 100 percent of the occlusal surface has white opacities, it would be moderate. This is because 50 percent of the tooth is affected and the tooth probably has not been subjected to attrition.
- If the labial surface of an anterior tooth has fluorosis from incisal to cervical but the lingual is free, the code is mild because not all surfaces are affected.

#### 4.11.1.2 Differentiating Between Dental Fluorosis and Nonfluoride Opacities

Opacities occurring in enamel may be due to a multitude of etiological factors in addition to excessive fluoride intake. In studies of dental fluorosis it is necessary to distinguish between fluoride and nonfluoride enamel changes. This distinction is generally most difficult when examining for the milder forms of fluorosis. To aid the examiner in making an appropriate decision, the set of criteria developed by Russell (Exhibit 4-4) are used.

Exhibit 4-4. The differential diagnosis of fluoride and nonfluoride enamel opacities

Characteristic	Milder Forms of Fluorosis	Nonfluoride Enamel Opacities
Area affected	Usually seen on or near tips of cusps or incisal edges.	Usually centered on smooth surface; may affect entire crown.
Shape of lesion	Resembles line shading in pencil sketch; lines follow incremental lines in enamel, form irregular caps on cusps.	Often round or oval.
Demarcation	Shades off imperceptibly into surrounding normal enamel.	Clearly differentiated from adjacent normal enamel.
Color	Slightly more opaque than normal enamel; "paper-white." Incisal edges, tips of cusps may have frosted appearance. Does not show stain at time of eruption (in these milder degrees, rarely at any time).	Usually pigmented at time of eruption; often creamy yellow to dark reddish-orange.
Gross hypoplasia	None. Pitting of enamel does not occur in the milder forms. Enamel surface has glazed appearance, is smooth to point of explorer.	Absent to severe. Enamel surface may seem etched, be rough to explorer.
Detection	Often invisible under strong light; most easily detected by line of sight tangential to tooth crown.	Seen most easily under strong light on line of sight perpendicular to tooth surface.

## REFERENCE

Russell, A.L. (1961). The differential diagnosis of fluoride and non-fluoride enamel opacities. *Pub Health Dent*, 21, 143-146.

### 4.11.2 Examination Procedures

All SPs aged 6-49 years old receive the dental fluorosis assessment, which utilizes a slightly modified Dean's Fluorosis Index to assess the condition of the enamel. The index scores the entire tooth and is used for assessing fully erupted permanent teeth only (excluding third molars). Deciduous teeth, permanent teeth **not** in full eruption, and teeth in which more than one-half of the visible surface area is obscured by a restoration, caries, or an orthodontic appliance are not assessed. Code these teeth/spaces as cannot be assessed ("9").

Each tooth is examined using a surface reflecting mirror and a No. 23 explorer. **No air is used for this assessment.** Each tooth is scored as a unit according to Dean's Fluorosis Index as follows:

- 0 = Normal (no fluorosis detected)
- 1 = Very mild (opaque, paper white areas involving less than  $\frac{1}{4}$  of the tooth surface)
- 2 = Mild (opaque, paper white areas involving  $\frac{1}{4}$  to less than  $\frac{1}{2}$  of the tooth surface)
- 3 = Moderate (opaque paper white areas involving  $\frac{1}{2}$  or more of the tooth surface)
- 4 = Severe (discrete or confluent pitting in involved areas)
- 5 = Questionable (slight aberration of normal enamel appearance including white flecks)
- 8 = Nonfluoride opacity
- 9 = Cannot be assessed

The fluorosis assessment is conducted in the following order:

1. As the exam proceeds tooth by tooth in the same convention as the caries examination, observe the enamel condition of the corresponding bilateral tooth. For example, if initially examining tooth #3, then #14 would be the examined bilateral tooth.
2. If the bilateral tooth relatively exhibits comparable enamel opacities and/or anomalies, then a fluorosis score is appropriately called to the recorder for the initially examined tooth. The extent of fluorosis cannot vary widely from the initially examined tooth to the examined bilateral tooth.
3. Proceed tooth by tooth until each quadrant is scored in the same order and sequence as in the caries examination
4. Important notes:
  - Because fluorosis always occurs bilaterally in the same arch, dental fluorosis must be established bilaterally before scoring teeth individually.
  - There is only one score per tooth.
  - If the corresponding bilateral tooth cannot be assessed, then the initially examined tooth is scored as cannot be assessed (“9”).
  - If the corresponding bilateral tooth is normal, then the initially examined tooth is scored either as normal (“0”), or nonfluoride opacity (“8”), or could not be assessed (“9”).
  - This survey will use a score of “5” for Dean’s “0.5” score as noted in Exhibit 4-3. Codes for nonfluoride opacity (“8”) and nonassessment (“9”) have also been added.

#### **4.11.2.1 Scoring Guidelines**

These guidelines promote diagnostic consistency. Note that fluorosis is a condition that is generally bilateral.

1. Only fully erupted permanent teeth are scored.
2. Teeth are NOT dried with air prior to examination.
3. A tooth is scored as “9” if it is crowned, missing, not fully erupted, or if one-half or more of the visible enamel is replaced with a restoration, covered with an orthodontic band, or destroyed by caries.

4. If fluorosis occurs irregularly on areas of the enamel surface, determination of the area affected is derived by visually coalescing all areas of fluorosis and relating that amount of area to the total visible surface area.
5. For anterior teeth the visible enamel area is the labial and lingual surfaces extending from embrasure to embrasure. For posterior teeth, the visible enamel area is the facial and lingual surfaces extending from embrasure to embrasure and the occlusal surface.
6. Scoring is based on the extent of fluoride opacities, attrition, and pitting.
7. Staining of intact enamel is not a diagnostic criterion for any of the fluorosis classifications. Note that an area of severe fluorosis may not be stained, whereas, an area of moderate fluorosis may become stained.
8. All nonfluoride opacities are to be scored as code “8” regardless of the suspected etiology.
9. Mild nonfluoride opacities are difficult to distinguish from mild fluoride opacities.

Mild nonfluoride opacities are more likely to be:

- Centered on the surface;
  - Round or oval;
  - Clearly differentiated from adjacent enamel; and
  - Pigmented and/or glassy.
10. Mild fluorosis is more difficult to detect under strong light than mild nonfluoride opacities. Tangential viewing improves the likelihood of detecting fluorosis.

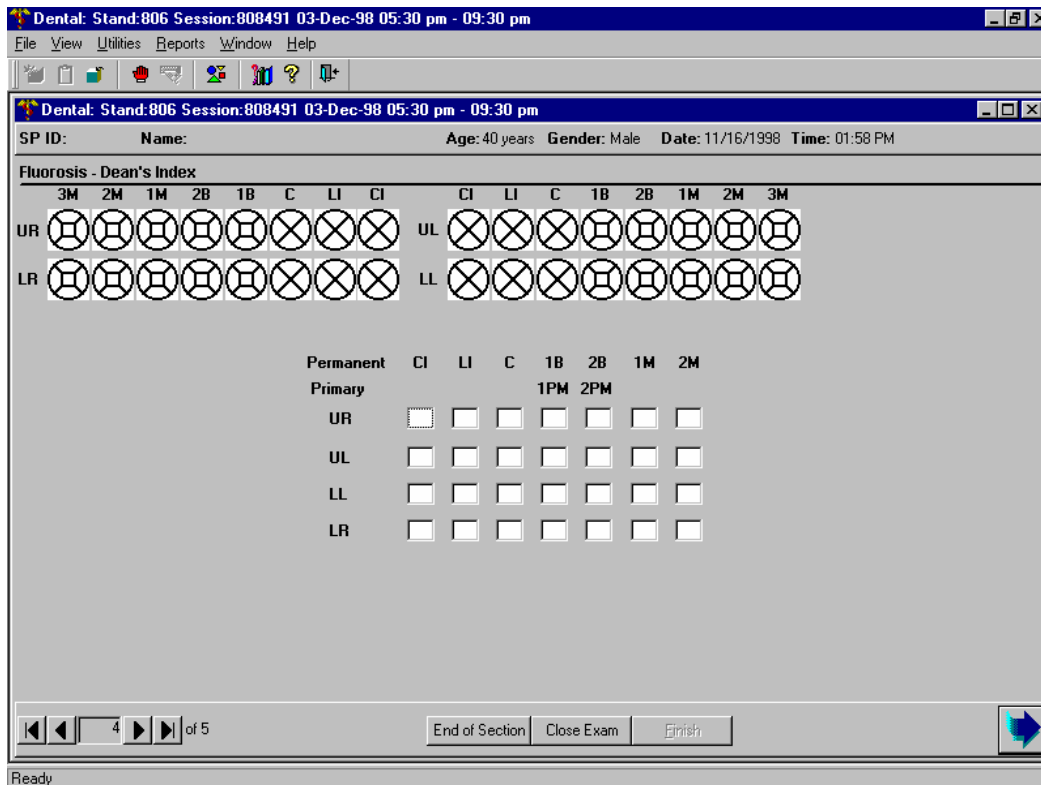
### **4.11.3 Guide for Referral and Followup**

A code of “4” in the Dean’s Index triggers a Level 3 recommendation for care flag in ISIS. This recommendation is telling the SP to see a dentist at his/her earliest convenience. Levels of recommendation are discussed in detail later in this chapter.

#### 4.11.4 Recording Procedures

The scores called by the examiner are entered in the appropriate fields for the Dean's Index using the codes listed above.

The recorder may use a designated shortcut key (F2 key) to record all "0s" whenever the SP has no fluorosis. In these instances, the examiner calls "All 0's" instead of "0" for each individual tooth assessed. The recorder presses the F2 key to automatically fill "0" in each blank tooth space of a quadrant. Pressing the F2 four times will fill all four quadrants with "0's." **The examiner will call "All 0's" by quadrant, or "All 0's" for all quadrants. The examiner will let the recorder know which he/she is calling.**



#### 4.11.5 Fluorosis Review: Questions and Answers\*

Questions:

1. How do I score if #3 is affected but not #14?
  - **There is no fluorosis. Usually many pairs of teeth are affected.**
2. Is the occurrence of fluorosis always bilateral or can one arch have it and another arch not have it?
  - **Yes, always bilateral. Upper incisors can have fluorosis but not lower incisors.**
3. Can the degree of fluorosis vary considerably from arch to arch and bilaterally?
  - **Can be very mild on #3 and mild on #14 but not very mild on #3 and moderate/severe on #14.**
4. Should the dentition with the fluorosis that has heavy staining and wear, but no pits, be classified always as moderate and not severe?
  - **Yes. Confluent pitting is characteristic of severe.**
5. How do I score if the lingual and the buccal of tooth #14 has fluorosis from the occlusal to middle 3<sup>rd</sup> but the occlusal shows marked attrition.
  - **Call it moderate.**
6. How do I score if the lingual and buccal of tooth #14 has fluorosis involving 25 percent of each surface but the occlusal shows attrition only on the cuspal tips but the rest of the occlusal surfaces appears normal.
  - **Call it mild because the total will not add up to 50 percent and there is no marked attrition.**
7. How do I score if the lingual and buccal of tooth #14 has fluorosis from occlusal to middle 3<sup>rd</sup> and 100 percent of the occlusal show as white opacities?
  - **Call it moderate. Because 50 percent of the tooth is affected and probably the tooth has not been subjected to attrition.**
8. How do I score if the labial of tooth #8 has fluorosis from incisal to cervical but the lingual is normal?
  - **Call it mild. Not all surfaces are affected (I have never seen a case like this).**

---

\* Questions & answers have been provided by Dr. Kumar.



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## 4.12 Incisor Trauma Assessment

The objectives of the Incisor Trauma subcomponent of the survey are to:

- Determine the prevalence of traumatic injuries to permanent incisor teeth in a national sample;
- Provide a basis for comparison with past and future surveys;
- Provide a basis for developing estimates of treatment needs; and
- Provide a basis for developing strategies for the prevention of traumatic injuries to teeth.

### REFERENCES

Andreason, J.O. (1972). *Traumatic injuries to teeth*. St. Louis: C.V. Mosby.

Basrani, E. (1985). *Fractures of the teeth*. Philadelphia: Lea & Febiger.

Ferguson, F.S., and Ripa, L.W. (Fall 1979). Prevalency and type of traumatic injuries in the anterior teeth of preschool children. *J Pedodont*, 4(1), 3-8.

### 4.12.1 Examination Procedures

All SPs aged 6-29 years receive the Incisor Trauma assessment for the maxillary and mandibular permanent incisors only. The clinical assessment is described in this section.

Ask the SP or a responsible adult, the following question:

**“Have you (SP name) ever had an injury to your (his/her) front teeth?”**

If the SP indicates that one or more injuries have occurred, ask the following question:

**“Can you point to the area of your (SP name) mouth where the trauma occurred?”**

The SP or responsible adult may be able to indicate the quadrant of the mouth in which the trauma occurred, or the exact tooth positions where the trauma occurred.

If the SP indicates where in the mouth the trauma occurred, this should be used for information only. Regardless of the answer, proceed to examine the SP.

The eight permanent incisors should be examined carefully for evidence of traumatic injury. The teeth should be examined in the same sequence as for the caries examination. A positive history of trauma is required for codes “1” through “6.” One of the following scores is to be assigned for each permanent incisor tooth:

- 0 A score of “0” indicates that a permanent tooth has no evidence of traumatic injury.
- 1 A score of “1” indicates that an unrestored enamel fracture is present in a permanent tooth that does not involve the dentine.
- 2 A score of “2” indicates an unrestored fracture in a permanent tooth that involves the dentine.
- 3 A score of “3” indicates untreated pulpal damage to a permanent tooth as evidenced by one of the following:
  - dark discoloration, as compared with other teeth—a discoloration of one tooth, or adjacent teeth, that are otherwise healthy is considered a sign of pulpal injury or
  - swelling or a fistula in the labial or lingual vestibule adjacent to an otherwise healthy tooth.
- 4 A score of “4” indicates that a fracture has been restored in a permanent tooth, either with a full crown or a less extensive restoration. It may be necessary to question the SP or responsible adult to ascertain the reason for the restoration.
- 5 A score of “5” indicates the presence of a lingual restoration in a permanent tooth as a sign of endodontic therapy, **and** a positive history from the SP or responsible adult of root canal therapy following traumatic injury.
- 6 A score of “6” indicates that a permanent tooth is missing due to trauma.

- 9 A score of “9” is assigned to any tooth or space that does not fall within the preceding categories; for example, a missing tooth due to a reason(s) other than trauma, a tooth having a full crown restoration as a treatment for dental caries, or a primary tooth.

#### **4.12.2 Guide for Referral and Follow-up**

The following codes trigger a recommendation for care flag:

- Code “2” on this assessment has ISIS flag a recommendation that says the SP should see a dentist within the next 2 weeks (Level 2 Recommendation).
- Code “3” on this assessment has ISIS flag a recommendation that says the SP should see a dentist immediately (Level 1 Recommendation).
- Code “6” on this assessment has ISIS flag a recommendation that says the SP should see a dentist at his/her earliest convenience (Level 3 Recommendation).

#### **4.12.3 Recording Procedures**

Findings for the traumatic injuries of permanent incisor teeth are recorded on the Incisor Trauma Injuries screen. Allowable codes range from “0” to “6” and “9” as listed above. Missing or implanted teeth are restricted to “6” and “9.”

Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

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Dental: Stand:806 Session:808469 12/01/1998 08:30 am - 12:30 pm

SP ID: 880482 Name: Sanchez, Miguel Age: 8 years Gender: Male Date: 11/25/1998 Time: 02:10 PM

**Incisor Trauma**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR									UL								
LR									LL								

Permanent CI LI

UR	<input checked="" type="checkbox"/>	<input type="checkbox"/>
UL	<input type="checkbox"/>	<input type="checkbox"/>
LL	<input type="checkbox"/>	<input type="checkbox"/>
LR	<input type="checkbox"/>	<input type="checkbox"/>

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## **4.13 Tooth Wear**

NHANES provides a unique opportunity to assess the prevalence of dental erosion and tooth wear across the lifespan and amongst varied population groups to discern if health disparities exist. In addition, many of the suggested etiologies of dental erosion including dietary factors, medications, health conditions, and socioeconomic status can be explored while adjusting for potential confounders. No other survey in the United States provides such an excellent opportunity to address the much discussed but little researched issue of dental erosion and tooth wear. The Tooth Wear Index is proposed for use in the NHANES because the index will allow for comparisons to be made with recently published reports from other countries.

### **4.13.1 Description**

The exam is conducted on all SPs aged 13 years or greater. The dental examiner performs the exam with a surface-reflecting mirror.

The Tooth Wear Index of Smith and Knight (1984), with modifications by Millward et al. (1994), has been used in the assessment of dental erosion in epidemiological surveys and studies. The Tooth Wear Index as described for use in the 1998 Adult Dental Health Survey conducted by the Social Survey Division of the Office of National Statistics, United Kingdom, will be used in the NHANES.

#### **4.13.1.1 Description of Index and Scoring System**

Visual examination of the facial, lingual, and incisal surfaces of the maxillary central and lateral incisors, and cuspids; the mandibular central and lateral incisors, and cuspids; and occlusal surfaces of the maxillary and mandibular first molars should be conducted using an examining light and a surface reflecting mirror with each tooth surface being dried.

For purposes of this assessment, the mouth is divided into segments as follows:

*Upper Right Segment*

Central Incisor, Lateral Incisor, Cuspid, and First Molar

*Upper Left Segment*

Central Incisor, Lateral Incisor, Cuspid, and First Molar

*Lower Left Segment*

Central Incisor, Lateral Incisor, Cuspid, and First Molar

*Lower Right Segment*

Central Incisor, Lateral Incisor, Cuspid, and First Molar

**4.13.1.2 Tooth Wear Scoring System**

Exhibit 4-5 presents the criteria for assessment for tooth wear.

Exhibit 4-5. Criteria for assessment of tooth wear

Score	Surface	Criteria
0	All	Sound natural tooth surface. Any wear is restricted to the enamel and does not extend into dentin.
1	All	Loss of enamel just exposing dentin.
2	B, L	Loss of enamel exposing dentin for more than an estimated one-third of the individual surface area (B,L).
	O, I	Loss of enamel and extensive loss of dentin, but not exposing secondary dentin or pulp. On occlusal/incisal surfaces exposed dentin facets with a buccal-lingual dimension of 2mm or greater at the widest point will be seen.
3	B, L	Complete loss of enamel on a surface, pulp exposure or exposure of secondary dentin where the pulp used to be. Frank pulp exposure is most unlikely.
	O, I	Pulp exposure or exposure of secondary dentin.
8	All	Fractured tooth. Clear evidence of traumatic loss of tooth substance rather than wear.
9	All	Cannot assess. More than 75% of surface is obscured and no remaining incisal edge/tip which can be coded. Includes missing teeth, crowns, and abutments.

B = Buccal; L = Lingual; I – Incisal; O = Occlusal

#### **4.13.2 Examination Procedures**

The general sequence of the exam is similar to the Tooth Count Exam. Each eligible tooth should be assessed looking at each coronal surface. The assessment begins with the upper right central incisor (#8) lingual surface, proceeds to the incisal surface, and concludes with the facial surface. The lateral incisor (#7) is examined next and is followed by the cuspid (#6). The Upper Right Segment is concluded with the examination of the upper right first maxillary molar occlusal surface (#3).

Upon completion of the Upper Right Segment, the exam proceeds to the Upper Left Segment, then the Lower Left Segment, and concludes with the Lower Right Segment.

#### **4.13.3 Scoring Guidelines**

- Only natural teeth surfaces are examined. If a crown, abutment, pontic, or other restorative materials cover a surface of the tooth eligible for examination, a “9” will be called.
- Partially erupted teeth will be excluded from all surface assessments and a “9” will be called.
- Teeth sustaining traumatic damage will be excluded from all surface assessments and an “8” will be called. The examiner should probe for a history of trauma to confirm a call of “8.”
- Missing teeth identified in the Tooth Count will be hard coded with a “9.”
- Code “2” is the most difficult one to judge. Use the periodontal probe (2mm band) to measure the diameter of any exposed dentin facet if necessary.
- Where wear is severe, it can often be contiguous from palatal onto incisal, such that it is difficult to distinguish the surfaces. In these instances, code both the same.
- Frank pulpal exposure is very rare, but exposure of secondary dentin (where the pulp used to be), usually appearing as a small translucent area in the center of a wide area of dentin exposure, is not uncommon in older people.
- Assess only the indexed permanent teeth. Retained primary teeth are not scored.

(Revised February 2003)



#### **4.13.4 Recording Procedures**

A Tooth Wear Score (TWS) can be entered for the central incisors, lateral incisors, cuspids, and first molars only. One code is permitted for each surface and each tooth has three surfaces. Allowable codes are listed in Table 2-1. The dental examiner will dictate codes to the dental recorder.

If a code of “1,” “3,” “4,” or “5” from the Tooth Count has been recorded, a “9” is hard-coded for the appropriate tooth for the TWS.

#### **4.13.5 References**

Al-Dlaigan, Y.H., Shaw, L., and Smith, A. (2001). Dietary erosion in a group of British 14-year-old school children Part II: Influence of dietary intake. *British Dental Journal*, 190, 258-261.

Hinds, K., and Gregory, J.R. (1995). *National Diet and Nutrition Survey: Children age 1.5 To 4.5 years, Vol 2: Report of the Dental Survey*. London: HMSO.

Millward, A., Shaw, L., Smith, A.J., Rippin, J.W., and Harrington, E. (1994). The distribution and severity of tooth wear and the relationship between erosion and dietary constituents in a group of children. *International Journal of Paediatric Dentistry*, 151-157.

Smith, B.G.N., and Knight, J.K. (1984). An index for measuring the wear of teeth. *British Dental Journal*, 156, 435-438.

Kelly, M., Steele, J., Nuttall, N., Bradnock, G., Morris, J., Nunn, J., Pine, C., Pitts, N., Treasure, E., and White, D. (1998). *Adult Dental Health Survey: Oral health in the United Kingdom*. London: Office for National Statistics.

Screen shot:

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

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Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 592301 Name: TEST, TEST Age: 39 years Gender: Female Date: 10/28/2002 Time: 02:53 PM

**Tooth Wear Score (TWS)**

	3M	2M	1M	2B	1B	C	LI	CI		CI	LI	C	1B	2B	1M	2M	3M
UR									UL								
LR									LL								

**TWS: Upper Segment**

	CI	LI	C	1M
UR	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Occlusal <input type="checkbox"/>
UL	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Occlusal <input type="checkbox"/>

**TWS: Lower Segment**

	CI	LI	C	1M
LL	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Occlusal <input type="checkbox"/>
LR	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Lingual <input type="checkbox"/> Incisal <input type="checkbox"/> Facial <input type="checkbox"/>	Occlusal <input type="checkbox"/>

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#### **4.14 Functional Occlusal Contacts Index (FOCI)**

National epidemiological surveys conducted in the United States have historically focused on descriptions of the oral craniofacial complex largely from a disease perspective by quantifying such conditions as carious lesions, periodontal attachment loss, and oral mucosal pathologies. This supplement to the NHANES dental examination component would further enhance the dentition examination by adding a count of the numbers of functional occlusal contacts of teeth as quantified by an index of the same name (FOCI). The functional occlusal contacts supplement would respond to the need that dental researchers have identified for assessments that more fully describe the functional capacities of the dentition. Having a greater understanding of this feature of the functional capacity of the oral craniofacial complex is of importance to research related to the relationship of oral health status and general health, e.g., diet and nutritional status to health services research. It is integral to answering questions regarding the impact of dental status on oral health-related quality of life.

Given that the range of incisal opening is a contributory factor to a functional occlusion, a maximal incisal opening measure also will be collected.

##### **4.14.1 Description**

The exam is conducted on all SPs aged 25 years or older. The dental examiner performs the exam with a surface-reflecting mirror.

This exam will count the number of functional occlusal contacts in such a way to quantify an important aspect of the functional status of the dentition that simple counts of teeth and prostheses alone cannot provide. This is a visual examination that goes beyond counting the number of teeth to count how many of the teeth oppose each other and can function properly when eating.

##### **4.14.1.1 Description of Index and Scoring System**

For the purposes of this examination the participant closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. If a contact is present for a natural tooth to natural tooth contact, a

code “1” is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses is present, a code “1” is also called. For purposes of this assessment, a code of “1” is reflective of “tooth-borne” contacts. If a contact is present for a natural tooth or a fixed prosthesis and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called.

#### **4.14.1.2 Methods and Scoring System**

The Functional Occlusal Contacts Index (FOCI) consists of (1) an assessment of the posterior (premolar and molar) regions, and then (2) a similar assessment for the sum of anterior tooth contacts. The right and then left posterior regions are assessed for (1) the number of contacts between natural teeth, (2) natural teeth and pontics of fixed prostheses, (3) natural teeth and removable prostheses, and (4) the number of contacts between denture teeth. As there are few anterior teeth missing without prostheses in the U.S. adult population, the anterior assessment is limited to a single assessment requiring at least one anterior mandibular tooth in contact with an opposing anterior tooth irrespective of the type of teeth involved.

A contact is the same as an occlusal stop. For the purposes of this examination, the SP closes together normally on the back teeth. Using a mouth mirror to hold back the cheek, the examiner looks at the lower arch from the side and records the distribution of contacts. In a complete quadrant, there will be 8 possible zones of contact in the posterior region (see diagrams in Section 4.14.4). Each of the premolars is a single zone, and each of the molars is about twice as wide, so they are counted as two zones each.

#### **4.14.1.3 Codes and Criteria of Occlusal Contact Zones**

##### **Posterior functional occlusal contact zones:**

0 = No posterior functional contact

1 = “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

9 = Cannot assess

(Revised February 2003)

**Anterior functional occlusal contact zone:**

0 = No anterior functional contact

1 = “Tooth-borne” functional contact present

2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis

3 = Functional contact between two removable prostheses

9 = Cannot assess

**4.14.2 Examination Procedures**

The Functional Occlusal Contact Exam begins with the **Maximal Incisal Opening**.

With the SP lying down, in the position required for the intraoral exam, ask the SP to position his/her mandible in a comfortable position and open his/her mouth as wide as possible, even if pain is felt. Do not prompt the SP to “open wider” again.

Examiners will ask the SP to:

*“Please rest your lower jaw into a comfortable position and open your mouth as wide as possible.”*

**There is to be no additional prompting of the SP to open wider.** Using the endodontic ruler, measure from the incisal edge of the most vertically oriented maxillary central incisor to the labio-incisal edge of the opposing mandibular incisor. Place the edge of the endodontic ruler against the labio-incisal edge of the mandibular central incisor and measure to the incisal edge of the most vertically oriented maxillary central incisor. Call the measurement to the recorder in whole millimeters. Fractional measurements are rounded down to the lower whole number. The allowable calls are as follows:

0 – 65 = Measurement in mm (where 65 = 65 mm or greater)

99 = Cannot be assessed.

If a prosthetic device has replaced central incisors, measure from the incisal edge of the replacement tooth. If the SP is edentulous and does not have a prosthetic device, “99” for cannot be assessed is recorded. The completion code would then be partial, physical limitation.

Following Maximal Incisal Opening measurement, the **Functional Occlusal Contact Index** exam is implemented. Scoring begins with the right side, distal to the canine, and counting the number of occlusal contacts distally. The left posterior region is scored next. If a contact is present for a natural tooth to natural tooth contact, a code “1” is called. If a contact is present for a natural tooth to a fixed prosthesis or between two fixed prostheses, a code “1” is also called. If a contact is present for a natural tooth or a fixed prostheses and a removable prosthesis, a code “2” is called. If a contact between two removable prostheses is present, a code “3” is called. If however there is no contact, a code “0” (zero) is called. The calls are made irrespective of which teeth are in contact. For example, if a first premolar has been lost and the second premolar has moved forward, the mesial cusp of the first molar may have taken up the second premolar position, and the second premolar may have taken the first premolar position. However, although it is the second premolar and the first molar that are making the contacts, the contacts will be scored as being in the zones that (in a full dentition) would be occupied by the first and second premolars. Several examples are provided in Section 4.14.4.

For the assessment of anterior contacts, the examiner looks at the six lower anterior teeth and selects the one mandibular incisor and its opposing maxillary anterior tooth (either incisor or canine) that represents the following hierarchical relationship:

- 1 = “Tooth-borne” functional contact present
- 2 = Functional contact present between a natural tooth or a fixed prosthesis and a removable prosthesis
- 3 = Functional contact between two removable prostheses
- 0 = No anterior functional contact

When people have a deep overbite, they may have difficulty in protrusively producing a true “end-to-end” contact. If so, then it may be difficult to observe a contact even in a more centric relation. Nevertheless, the assumption should be made that a contact exists. Where there is severe anterior open bite, or where lower teeth are missing, there clearly cannot be a contact. Nevertheless, an attempt should be made to assess for the potential of a functional occlusal contact in an anterior open bite condition.

(Revised February 2003)

#### 4.14.3 Scoring Guidelines

- A posterior functional contact is classified as present where the contact forms a vertical occlusal stop. This is recorded according to the lower even if the area of contact is small. In rare cases where there is contact but no occlusal stop (e.g., a scissors bite), a zero is recorded. Clearly there can be no contact if there is no lower tooth in the zone.
- In some cases it may be difficult to tell whether the teeth actually touch or not; if in doubt, the assumption should be made that the contact is present.
- Where there are small spaces in the lower arch and you cannot decide whether you should consider it as a whole zone, count the space as a full zone if the space is wider than a half a tooth; otherwise ignore it.
- Removable prosthesis contact must be a contact involving a denture tooth and not contact to an acrylic base plate alone.
- If contact is observed involving gross cavitation and caries, this type of contact is not considered to be “functional” and should be coded as “0.”
- If the SP presents with having left his/her removable denture(s) at home, the examiner cannot assess for functional contacts and the code of “9” should be used where appropriate.



#### 4.14.4 Examples of Scoring Contacts

**Right side:** Several lower teeth are present but do not make contact, and the two molars have drifted forward into the distal half of the space where the first molar was. Starting distal to the canine and working back, the call for all natural teeth would be:

0.1.0.1.1. 0.0.0

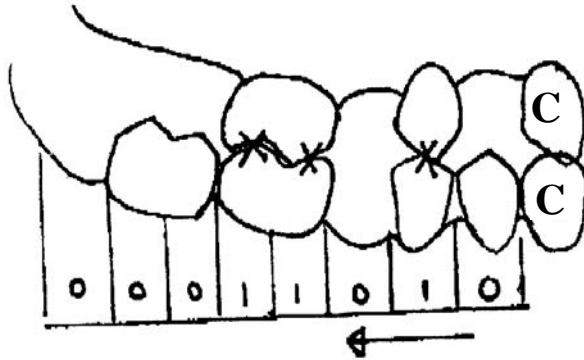


Figure 4-1. Example 1 – Right side

**Left side:** On this side there has been a fair amount of drifting, but this isn't relevant to the numbers of functional occlusal contacts. The calls from the distal of the canine towards the distal of the left side of the mouth are:

0.0.1.1.1.0.0.0

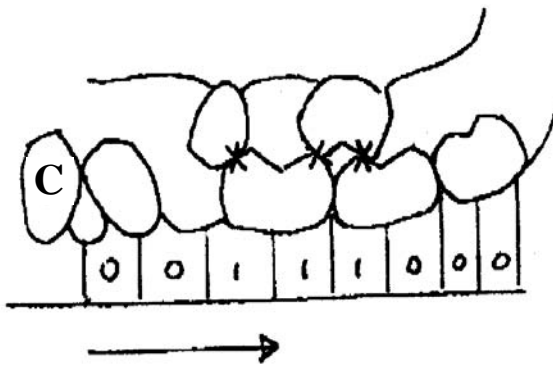


Figure 4-2. Example 2 – Left side

**Left side:** All but one maxillary tooth has been lost and the one remaining tooth has drifted and tipped forward and makes a contact in about the fifth zone back (roughly where the mesial half of the second molar would be). Sometimes this position can be difficult to judge accurately. Whether the contact is actually in that position or one zone, either side is not critical. What is important is that it is in the middle of the molar region. The calls are:

**0.0.0.0.1.0.0.0**

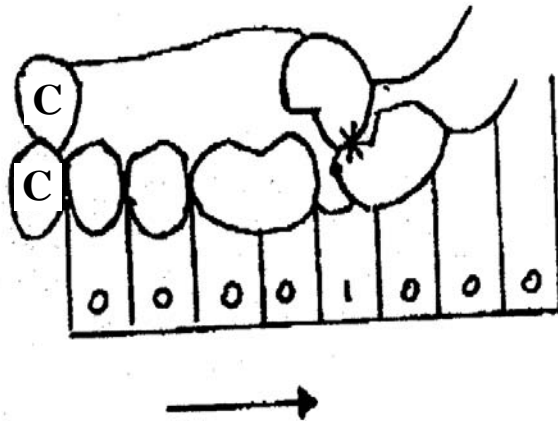


Figure 4-3. Example 3 – Left side

**Right side:** There are posterior teeth but they all miss each other. The upper first premolar has slipped down into the lower premolar space and although there may be contact between the lower molar and the upper premolar it is on the side of the tooth and does not constitute an occlusal stop. These are called out as:

**0.0.0.0.0.0.0.0**

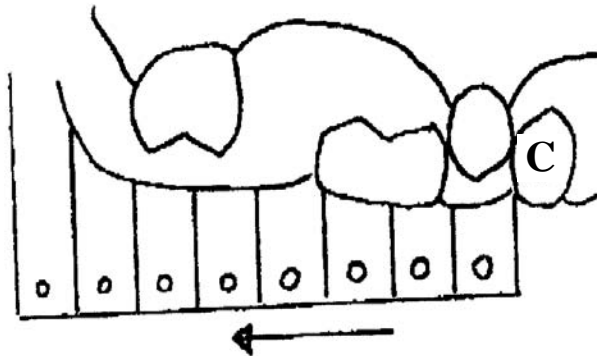


Figure 4-4. Example 4 – Right side

**Right side:** This is a common situation where single upper and lower premolars have been removed for orthodontic purposes and all spaces have been closed. Once again it does not matter that there are no second premolars. What matters is that there is a contact in that position. The calls are:

1.1.1.1.1.1.0

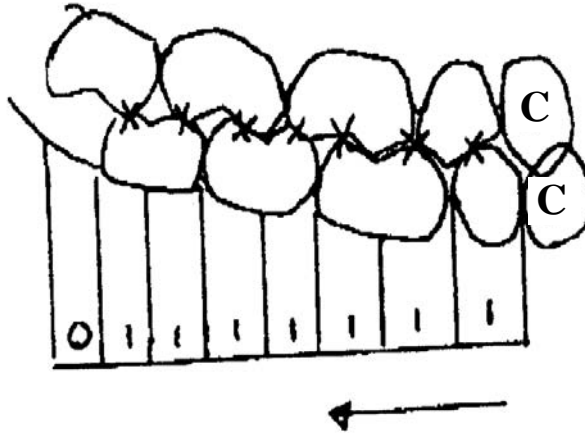


Figure 4-5. Example 5 – Right side

**Right side:** Maxillary and Mandibular partial tooth loss is present; however, only a Maxillary Removable Partial Denture (denture teeth are shaded) is worn at the time of the exam. Contact in Zone 1 is between the first premolars is defined as a lower natural tooth and an upper denture tooth to yield a call of a “2.” The calls are:

2.1.0.1.1.2.2.0

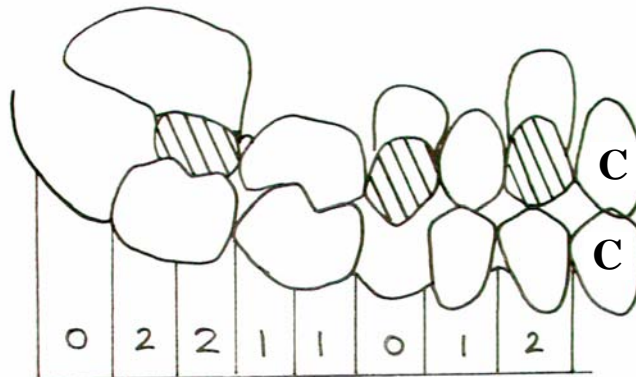


Figure 4-6. Example 6 – Right side

**Left side:** Maxillary and Mandibular Partial Dentures are worn (denture teeth are shaded). Contact in Zone 1 is between a forward drifted lower second premolar and Maxillary denture teeth. The correct call would be a “2.” Contact in Zone 3 involves a lower partial denture tooth (premolar) and the mesial of an upper molar denture tooth. The correct call here is a “3.” The calls are:

2.3.3.2.2.0.0.0

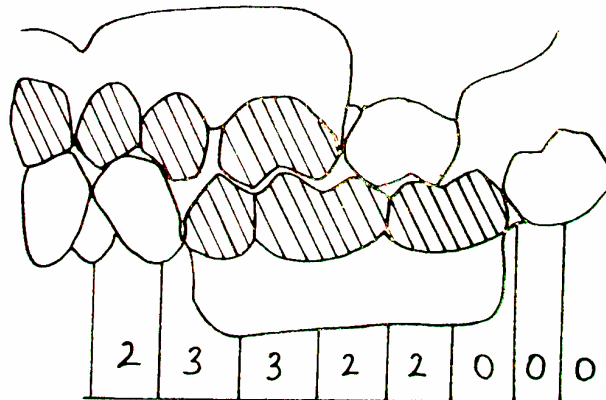


Figure 4-7. Example 7 – Left side

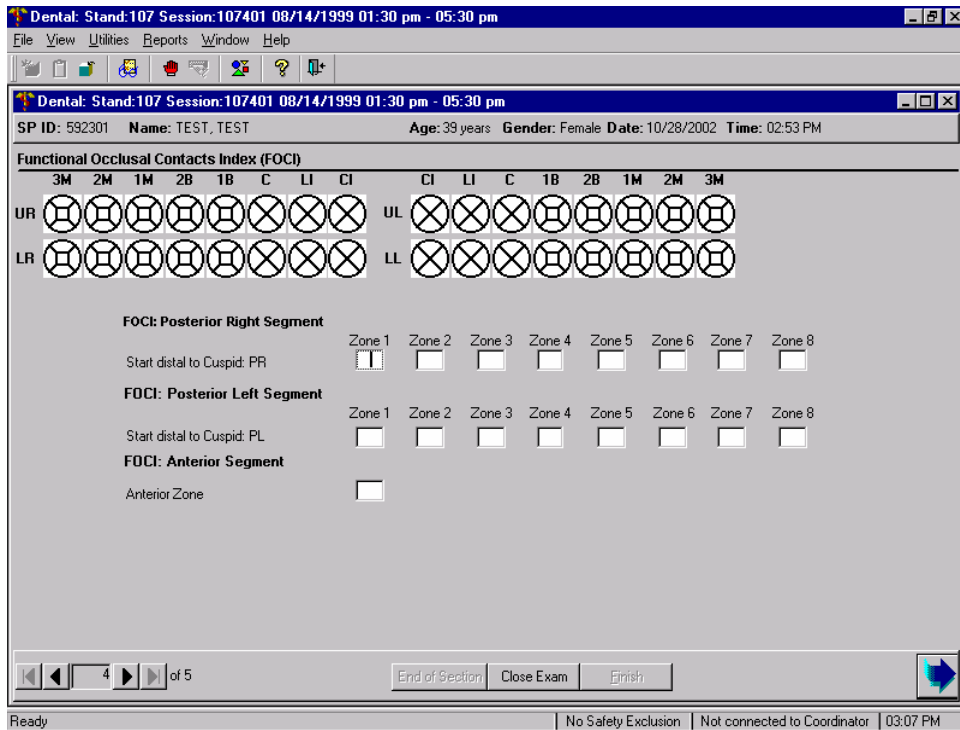
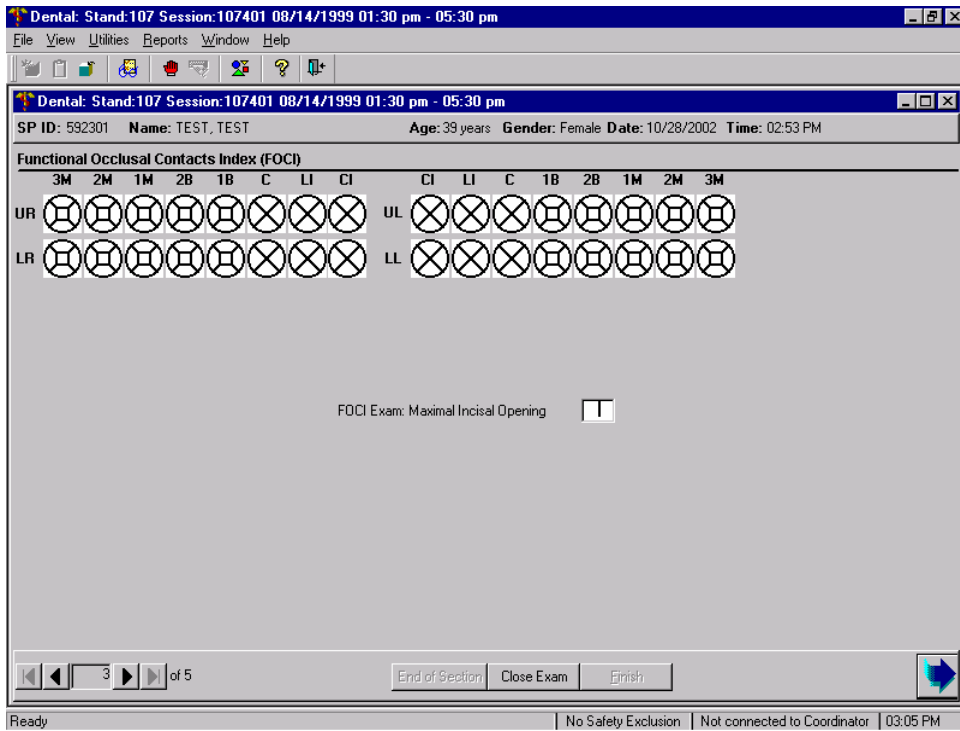
#### 4.14.5 Recording Procedures

One code is permitted for each posterior zone (16 zones in total) and one code is permitted for the anterior segment assessment. Allowable codes are listed in Section 4.14.1.3. The dental examiner will dictate codes to the dental recorder.

#### 4.14.6 References

Steele, J.G., Sheiham, A., Marcenes, W., and Walls, A.W.G. (1998). *National Diet and Nutrition Survey: People Aged 65 Years and Over. Volume 2: Report of the Oral Health Survey*. London: The Stationery Office, 1-124.

Screen shots:



#### 4.15 Periodontal Assessments

The periodontal section includes two parts: measurements to determine the loss of attachment and the identification of bleeding from probing. The objectives of the periodontal disease component of the survey are to:

- Establish age-specific data for the prevalence of periodontal diseases in a national sample;
- Provide a basis for comparisons with past and future national surveys;
- Provide baseline data for possible followup of selected subsamples;
- Provide a basis for the future development of estimates of treatment needs; and
- Provide a basis for studying the association between periodontal diseases prevalence and risk factors.

Periodontal assessments are conducted from posterior to anterior, beginning with the most distal tooth in a quadrant (excluding third molars) and proceeding toward the midline. With minor modifications, current diagnostic criteria were used in the following surveys:

- NIDR National Survey of Oral Health in Employed Adults and Seniors (1985-86)
- NIDR National Survey of Oral Health in School Children (1986-87)
- NHANES III
- Several statewide surveys.

#### REFERENCES

- Löe, H. and Silness, J. (1963). Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odont Scand*, 21, 533.
- Ramfjord, S.P. (1967). Periodontal disease index (PDI). *J Periodont*, 38, 585.
- Ramfjord, S.P. and Ash, M.N. (1979). *Periodontology and Periodontics*. Philadelphia: W.B. Saunders Co.

#### **4.15.1 Participant Eligibility for the Periodontal Assessment**

The periodontal assessment is performed on all SPs aged 13 and older. Periodontal attachment losses and bleeding from probing are assessed in the same randomly selected quadrants—one maxillary and one mandibular. Only fully erupted permanent teeth are scored. Three sites from each tooth are assessed: the distal, the mid-facial, and the mesial.

#### **4.15.2 Selection of Quadrants to be Assessed**

The computer program automatically identifies the two random quadrants (one random upper quadrant and one random lower quadrant) to be selected for the periodontal assessment. The recorder tells the examiner which quadrants to examine. The computer program uses the following system to determine the two quadrants:

- The fifth digit of the ID number is used to select the upper quadrant. If this number is even, the right side is used. If this number is odd, the left side is used.
- Similarly, the sixth digit of the ID number is used to select the lower quadrant for the periodontal examination. If this number is even, the right side is used. If this number is odd, the left side is used.
- For example, if the SP's ID number is 123456, this would represent a left upper (5) and right lower (6) designation for the SP.

#### **4.15.3 Examination Procedure**

Clinically and quantitatively the loss of attachment is the distance in millimeters (mm) from the cemento-enamel junction (CEJ) to the bottom of the sulcus. The computer program calculates loss of attachment. The examiner takes two measurements per site for use in this calculation. Bleeding on Probing (BOP) is the clinical observation of the presence of blood after a site has been probed to produce a sulcus (pocket) depth measurement.

Each quadrant is dried with air and then each site in the quadrant is examined with a surface reflecting mirror and a periodontal probe. The periodontal probe is used to measure the distal-facial interproximal (D), mid-facial (B), and mesial-facial interproximal (M) sites. For each site, the distance

from the free gingival margin (FGM) to the CEJ is measured first, and then the distance from the FGM to the bottom of the pocket is measured. Where the gingival margin is subject to recession and the CEJ is exposed, the distance from the CEJ to the gingival margin is called a negative value.

The periodontal probe is color coded and graduated at 2, 4, 6, 8, 10, and 12 millimeters. The periodontal probe is to be held with a light grasp and pointed toward the apex of the tooth. Each measurement is rounded to the lowest whole millimeter. The probe is inserted from the facial aspect to measure all three sites – the distal interproximal, the mid-facial, and the mesial interproximal.

For the interproximal sites, (M) and (D), the probe should be placed parallel to the long axis of the tooth and facially adjacent to the dental contact area. Angulating the probe into the interproximal area under the dental contact is not permitted. For the maxillary and mandibular molars the mid-facial assessment is always made mid-buccally at the location of mid-facial furcation area, keeping the probe parallel to the long axis of the tooth.

The allowable range for the FGM to CEJ measurement is:

-9 to 9 = Measurement in millimeters  
±A = Measurement is ±10 millimeters  
±B = Measurement is ±11 millimeters  
±C = Measurement is ±12 millimeters  
Y = Cannot be assessed

The allowable range for the FGM to sulcus base measurement (pocket depth) is:

0 - 9 = Measurement in millimeters  
A = Measurement is 10 millimeters  
B = Measurement is 11 millimeters  
C = Measurement is 12 millimeters  
Y = Cannot be assessed

The presence of bleeding is assessed after the probing measurements are made. The (D), (B), and (M) sites for each tooth are examined for bleeding points, and the appropriate score is called for each site at each tooth as follows:

1 = Bleeding from probing detected  
2 = No evidence of bleeding  
9 = Cannot assess



The periodontal assessment is conducted in the following order:

- The examiner will identify the most distal tooth that is eligible in the appropriate quadrant and proceed tooth-by-tooth in a posterior to anterior direction. The examiner will make the distal FGM-CEJ measurement first followed by the distal FGM-pocket depth measurement. The examiner will proceed to the mid-facial aspect of the tooth and will make the FGM-CEJ measurement followed by the FGM-pocket depth measurement. The examiner will proceed to the mesial site of the same tooth and measure accordingly. The examiner will then proceed to the next tooth toward the anterior and repeat the same measures for attachment loss. This process continues until measurements are made and recorded for all teeth in the quadrant.
- Once the quadrant's (D), (B), and (M) sites are probed for a tooth's loss of attachment measurement, the dental examiner will assess for bleeding from probing. Following probing and recording of the (M) site of the most anterior tooth in that quadrant, the examiner will return to the most posterior tooth in the quadrant and will observe the distal site for any presence of blood. If blood is seen, the examiner calls a "1." If the site is blood-free, the examiner calls a "2." If the site cannot be assessed, the examiner calls a "9." The examiner proceeds to the mid-facial aspect of the same tooth and repeats the procedure and makes the appropriate call. Then the examiner proceeds to the mesial site of the same tooth and records accordingly. The examiner will then proceed to the next tooth toward the anterior and repeat the same observations for bleeding from probing. This process continues until all the teeth in the quadrant are observed and recorded. This now completes the periodontal assessment for the first quadrant and the examiner moves on to the next quadrant for assessment.
- Therefore, the pattern of recording will be the (D), (B), and (M) loss of attachment measurements tooth-by-tooth for the quadrant, then the (D), (B), and (M) bleeding observations tooth-by-tooth for the same quadrant. Once the maxillary quadrant has been periodontally assessed, the recorder identifies the appropriate mandibular quadrant and the examiner repeats the periodontal assessment procedures.

#### **4.15.4 Special Considerations**

1. Calculus at mesiofacial or midfacial sites that obscures the CEJ or interferes with the correct placement of the probe is removed (using a curette, if necessary).
2. When the margin of a restoration is below the CEJ, the position of the CEJ will be estimated using adjacent landmarks and dental anatomy.
3. When the CEJ cannot be estimated, the examiner codes "Y" to exclude the site.
4. When the natural tooth is missing, (i.e., space maintainers, implants, partial denture, or pontics), the tooth sites are automatically scored "Y" by the ISIS program.
5. Mobile teeth should be examined with care. The CEJ should be estimated if possible.

6. Orthodontically banded teeth, splinted teeth, and hemisected teeth will be considered on an individual basis and should be examined if possible.
7. Partially erupted teeth are excluded from all periodontal assessments. Retained roots are also excluded if the CEJ and part of the clinical crown are not present. The code of “Y” should be used for mesiofacial and midfacial sites of the excluded tooth. If the entire quadrant cannot be scored, the single code of “NS” (no score) should be called and the recorder will enter “Y” for each tooth present in that quadrant.
8. Although bleeding from probing is a site-specific call, if blood has pooled from a previously probed site and covered any other site of the same tooth, that site is scored a “1” as well.
9. When teeth are rotated or positioned out of arch alignment, eligible probing sites are to be determined by anatomical positioning. If a tooth is rotated distally 90 degrees and the mid-facial is in a position of relative contact with the mesial of the posterior tooth, the distal probing measure will be made at the anatomical distal of the rotated tooth and not the anatomical mid-facial location. The anatomical mid-facial of the rotated tooth in this example would most likely be coded as “YY.” The appropriate probe insertion site to ascertain a measure will always be relative to the anatomical location of the tooth.

#### **4.15.5 Guide to Referral and Follow-up**

A Level 3 (see your dentist at earliest convenience) recommendation for care flag is identified by the system under the following conditions:

- More than 2 sites have a sulcus depth  $>4\text{mm}$ ; or
- More than 2 sites have a depth from FGM to CEJ  $\leq -4\text{mm}$ ; or
- More than 1 site has a level of attachment loss  $> 4\text{mm}$ .

If suppuration occurs as a result of the periodontal probing or if a periodontal abscess is observed during the clinical examination, the examiner must recommend a level 1 or 2 recommendation for care, based on the examiner’s professional judgement, and generate a referral letter for the SP.

(Revised February 2003)

#### **4.15.6 Recording Procedures**

Findings for the periodontal assessment are recorded on the Periodontal Assessment screen. Each screen view is reserved for one quadrant.

**NOTE: The second periodontal measurement must be equal to or greater than the first periodontal measurement and if one measurement cannot be assessed, then the other measurement must also be coded as a “Y” for cannot be assessed.**

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID: Name: Age: 35 years Gender: Female Date: 11/07/2000 Time: 03:17 PM

**Periodontal Assessment - Upper**

3M 2M 1M 2B 1B C LI CI CI LI C 1B 2B 1M 2M 3M

UR UL

LR LL

**Loss of Attachment - UR**

2M Dis Mid Mesio 1M Dis Mid Mesio 2B Dis Mid Mesio 1B Dis Mid Mesio

C Dis Mid Mesio LI Dis Mid Mesio CI Dis Mid Mesio

**Bleeding on Probing**

2M Dis Mid Mesio 1M Dis Mid Mesio 2B Dis Mid Mesio 1B Dis Mid Mesio

C Dis Mid Mesio LI Dis Mid Mesio CI Dis Mid Mesio

1 of 3 End of Section Close Exam Finish

Go to the Section Status Screen MEC Layer: 9/21/00 Application: Ver 8.10.23B No Safety Exclusion Not connected to Coordinator 03:19 PM

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID: Name: Age: 35 years Gender: Female Date: 11/07/2000 Time: 03:17 PM

**Periodontal Assessment - Lower**

3M 2M 1M 2B 1B C LI CI CI LI C 1B 2B 1M 2M 3M

UR UL

LR LL

**Loss of Attachment - LR**

2M Dis Mid Mesio 1M Dis Mid Mesio 2B Dis Mid Mesio 1B Dis Mid Mesio

C Dis Mid Mesio LI Dis Mid Mesio CI Dis Mid Mesio

**Bleeding on Probing**

2M Dis Mid Mesio 1M Dis Mid Mesio 2B Dis Mid Mesio 1B Dis Mid Mesio

C Dis Mid Mesio LI Dis Mid Mesio CI Dis Mid Mesio

2 of 3 End of Section Close Exam Finish

Ready MEC Layer: 9/21/00 Application: Ver 8.10.23B No Safety Exclusion Not connected to Coordinator 03:24 PM

This page intentionally left blank.

#### **4.16 Recommendation For Care and Referrals**

The computer system generates a list of specific recommendations for follow-up care based on subcomponent evaluation. There are four levels of referrals defined in the system as follows:

- Level 1 - SP should see a dentist immediately
- Level 2 - SP should see a dentist within the next 2 weeks
- Level 3 - SP should see a dentist at his/her earliest convenience
- Level 4 - SP should continue with his/her regular routine dental care

Recommendations for care levels are flagged for specific conditions. The dental examiner assigns an overall recommendation for the SP based on the care levels assigned to each subcomponent and his/her clinical judgement.

An examination recommendation for care level must be assigned to each and every SP by the examiner. If the SP does not have a condition that triggers a Level 1, Level 2, or Level 3 recommendation for any assessment, he/she will be flagged as a Level 4 recommendation for care referral. If the examiner finds any condition that warrants a different level of referral, he/she will override the system's referral.

##### **4.16.1 Recommendation For Care Recording Procedure**

This section is comprised of two screens. The first screen is used to document the care level assigned by the examiner. The second screen is used to create the SP Referral Letter, if needed.

##### **4.16.2 Recommendation For Care Screen**

The Recommendation For Care screen is a multipart screen with a list of the assessments that may trigger a referral on the upper left side of the screen and a choice of referral levels on the upper right side of the screen. The system automatically pulls data from the assessments performed to aid the

examiner in determining which level of care should be recommended. The lower portion of the screen is an open-ended comment section used by the examiner to clarify the reason for the recommendation.

The “Assessments” section will be prefilled by the system. If the codes entered for an assessment do not trigger a recommendation for care flag as defined in this chapter, the system automatically assigns a Level 4 to that assessment. If the codes entered for an assessment trigger a predetermined care level, the system automatically assigns that level. In the event that multiple codes are assigned within the assessment, the system automatically displays the code for the more severe recommendation. **NOTE: Preassigned levels are provided as a guide for the examiner only.**

The “Overall Recommendation” section is to be based on the level of care determined by the examiner and entered by the recorder. **It is the examiner’s responsibility to assign an overall examination recommendation for care level based on his/her best professional judgment and calls the level to the recorder.**

The “Other Conditions” section is located just below the “Overall Recommendation” section. The dental examiner will choose one or more of the following conditions to be printed on the Referral Letter and Report of Findings as follows.

- A = Decayed teeth
- B = Gum problems/disease
- C = Oral hygiene
- D = Clinical impression of soft tissue condition
- E = Denture/partial denture/plates
- F = No significant findings
- G = Other Finding (see comment)

**NOTE: “F” is mutually exclusive with all other calls and no other condition will be listed if selected.**

Section G is only used when a referral letter needs to be generated. The “Comments” section is for the examiner to write any open-ended comment up to 75 characters long. The purpose of this comment is to clarify the reason for the Level 1 or Level 2 referral, if necessary. The information recorded in this space is printed on the Referral Letter the SP receives.

Specific requirements for determining the recommendation of care level and recording conditions for the SP Referral Letter with regard to professional and ethical considerations are provided in Chapter 5.

The “Referral Refused” and “Generate Referral Letter” buttons are enabled whenever a Level 1 or Level 2 overall recommendation for care level is assigned.

When the “Referral Refused” button is selected, a comment must be entered in order to move on. This comment is the examiner’s assessment of the reason the referral was refused and any other important information he/she feels may need to be documented. The system will then proceed directly to the Recommendation For Care Status Screen without creating the SP Referral Letter.

When the “Generate Referral Letter” button is selected, the system will proceed to the SP Referral Information Screen to create a SP Referral Letter as discussed in the next section.

#### **4.16.3 SP Referral Information Screen Recording Procedures**

The SP Referral Information screen is used to record the information necessary to create the SP Referral Letter. It is displayed whenever the “Generate Referral Letter” button is selected on the Recommendation For Care screen.

To complete this screen, the examiner will obtain the name and address of the SP’s dentist or clinic to which the letter should be addressed. In addition, the examiner will inform the recorder of any statements that should be added regarding the nature of the explanation or the SP’s response. Then the screen is used to document to whom the referral was actually given—the SP or the SP’s guardian.

If the SP does not have a specific dentist or clinic to whom the letter should be sent, the Clinic Pickup feature on the upper right hand portion of the screen is used to select one of the NHANES referral dentists/clinics. The examiner asks the SP to choose one of the facilities listed and that is the health care provider to whom the SP Referral Letter will be addressed. If the name of the clinic is very long, this will not appear on the referral letter screen. The recorder will need to type the name in.



All comments to be added in the “Description of Explanation” and “SP Response” dialog boxes are to be recorded verbatim by the recorder as the examiner dictates. In sensitive cases, the examiner may ask the recorder to leave the room and complete the screen him/herself with the SP still present. The examiner will then complete the examination or ask the recorder to come back and close the examination.

After completing the SP Referral Information screen, the following functions may be performed by choosing the menu options on the lower right hand portion of the screen. Use the mouse to click on the appropriate button as follows:

- |         |   |
|---------|---|
| Print   | This button will trigger the referral letter to be printed in the Shipping Room. Only use this function when the examiner needs to review a hardcopy of this letter with the SP. <b>However, do not provide the SP with a copy of this letter.</b> He/she will receive a copy of the letter along with other related documents when he/she leaves the MEC.  |
| Preview | This button is used to view the letter on the computer screen. You will be able to scroll through the letter to verify all items have been inserted properly: The dentist name and address, the SP name, and the conditions entered on the Recommendation For Care screen. Any changes that need to be made must be made on the appropriate referral screen; changes cannot be made on this preview screen. |
| Save    | This button saves the letter. This must be done, so the letter will be printed and given to the SP at the coordinator stand when the SP leaves the MEC. It then closes the SP Referral Screen and returns the user to the Recommendation for Care Screen.   |
| Cancel  | This button is used to cancel the creation of the SP Referral Letter and returns to the Recommendation For Care Screen.   |

After the SP Referral Screen is completed, the program returns to the Recommendation for Care screen. The <Enter> key is used to proceed with the rest of the examination; that is, the Recommendation For Care Section Status screen.

**NOTE: If an examination is not completed, for whatever reason (SP ill, MEC closes, equipment malfunction, etc.), but the examiner felt that an SP Referral Letter should be generated, the <CLOSE EXAM> button, not the <FINISH> button, must be selected on the section status screen.**

## Recommendation For Care Screens

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107401 01:30 pm - 05:30 pm

SP ID: 867742 Name: GUEST, GUEST Age: 38 years Gender: Male Date: 10/23/2001 Time: 01:44 PM

### Recommendation For Care

Assessments	Overall recommendation for care
Recomm. for care for Coronal caries: 4	
Recomm. for care for Root caries: 4	
Recomm. for care for Deans Index: 4	
Recomm. for care for Incisor Trauma: 4	
Recomm. for care Bleeding on Probing: 3	
Recomm. for care for LOA: 4	

Other Referral Comments

Referral Refuse

Generate Referral Letter

Other Conditions

- A. Decayed teeth
- B. Gum disease/problem
- C. Oral hygiene
- D. Clinical impression of soft tissue condition
- E. Dental/Partial Denture/Plates
- F. No significant findings
- G. Some other finding (specify w/referral letter)

Ready MEC Layer: 6/15/01 Application: Ver 9.10.188 No Safety Exclusion Not connected to Coordinator 02:23 PM

Dental: Stand:806 Session:808599 12/14/1998 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Dental: Stand:806 Session:808599 12/14/1998 08:30 am - 12:30 pm

SP ID: 478777 Name: Jennings, Keith Age: 53 years Gender: Male Date: 02/04/1999 Time: 08:56 AM

### SP Referral Information

Clinic/Dentist Name:

Addr. 1:

Addr. 2:

City, State, Zip:

Contact Name:

Phone: ( ) -

Fax: ( ) -

Clinic  Dentist

Clinic Pickup

Explained to SP

Explained to Guardian

Explanation declined

Description of Explanation:

SP Response:

Print

Preview

Save

Cancel

Ready Not connected to Coordinator 08:56 AM

#### **4.16.4 Post-examination Procedures**

1. Complete the Dental Examination Screens.
2. Return the SP to the coordinator for assignment to another component.
3. Set the room up for the next SP.

## **5. RECOMMENDATION FOR CARE, REFERRALS, AND MISCELLANEOUS**

As stated earlier, each SP will receive some general results about the dental examination he/she received in the MEC. These general oral health results will be combined with general results from the other MEC examination components to create an overall Report of Findings for each SP. In addition, SPs who require immediate dental care will receive a separate Oral Health Referral Letter. Both these documents are discussed in this section.

Some SPs may not be able to physically complete the oral health assessments in a recumbent position (i.e., lying down in the dental exam chair.) These individuals may be wheel-chair-bound and experience difficulty in transferring to the dental exam chair, or they may be very frail. Consequently, individuals who do not receive the entire oral health exam lying down in the dental chair are identified with a special tracking code.

### **5.1 SP Exam Position Tracking Code**

Before the recommendation of care screen appears, ISIS displays a screen asking if the SP was in a recumbent (lying down) position for all eligible assessments of the oral health exam (including tooth count through loss of attachment measures.) The examiner will dictate a “yes” to the recorder if a “yes” is applicable. If not, the examiner will dictate a “no” to the recorder. Final discretion as to whether a SP should be examined on the dental chair in a recumbent position is left to the examiner’s professional judgment and the abilities/wishes of the SP.

#### **5.1.1 Scoring Codes**

The allowable codes for the SP exam position tracking variable are as follows:

Y = Yes

N = No

C = Cannot assess

### **5.1.2 Guidelines for Scoring**

If a child was held by a parent or guardian during the exam, the child will be coded as a “no.” If the child was lying down on the dental exam chair with a parent or guardian sitting on the chair as well, the child will be coded as a “yes.” If, at any part during the oral health exam, a SP must sit up to complete any portion of an exam or to quit any exam component, the SP will be coded as a “no.”

### **5.2 Report of Findings**

A Report of Findings document is printed for each SP who is examined in the MEC. The general results from each component completed by that SP are provided on the report. The oral health section of the report includes the level of recommendation for care assigned by the examiner and a list of the problem area(s) identified by the examiner. A Sample Report of Findings is provided in Exhibit 5-1.

### **5.3 Completing the Recommendations for Dental Care**

The oral examination included in this survey does not take the place of a dental checkup, treatment by the SP’s own dentist, or routine dental care since no radiographs are taken and the SP’s history is not available to the examiner. Rather, the exam is designed to achieve the research objectives. Therefore, a procedure has been developed for alerting SPs to the need for followup care or the need to continue regular routine dental care that takes the limits of the exam into consideration.

The report of dental findings called Recommendation For Care (Exhibit 5-2) should be completed for each SP. This report makes recommendations about the SP’s need for dental care. At the conclusion of the examination, the examiner determines which of four levels should be recorded on the Recommendations For Care screen. These boxes indicate whether the SP should:

1. See a dentist immediately;
2. See his/her dentist within 2 weeks;

Exhibit 5-1. SP Report of Findings



## National Health and Nutrition Examination Survey

These measurements were obtained as part of a survey and do not represent a medical diagnosis.  
Interpretation of these measurements must be made by a physician.

**Date of Examination:**  
**Participant Name:**  
**Participant Age:**  
**Participant Gender:**  
**SP ID:**

### SAMPLE REPORT #1

#### Dental

The dental examination of the National Health and Nutrition Examination Survey is not, and is not intended to be, a substitute for the examination usually given to persons seeking care from their own dentists. Neither a dental history nor x-rays are taken, and therefore the findings are solely the result of what can be seen at the time of the examination.

The examining dentist recommends that you continue your regular routine care.

- No findings

### SAMPLE REPORT #2

#### Dental

The dental examination of the National Health and Nutrition Examination Survey is not, and is not intended to be, a substitute for the examination usually given to persons seeking care from their own dentists. Neither a dental history nor x-rays are taken, and therefore the findings are solely the result of what can be seen at the time of the examination.

The examining dentist recommends that you see a dentist within the next two weeks because of the following conditions:

- Clinical impression of a soft tissue condition
- Other findings (see referral letter)

Exhibit 5-2. Recommendation For Care screen

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107401 08/14/1999 01:30 pm - 05:30 pm

SP ID: 867742 Name: GUEST, GUEST Age: 38 years Gender: Male Date: 10/23/2001 Time: 01:44 PM

### Recommendation For Care

**Assessments**

Recomm. for care for Coronal caries: 4

Recomm. for care for Root caries: 4

Recomm. for care for Deans Index: 4

Recomm. for care for Incisor Trauma: 4

Recomm. for care Bleeding on Probing: 3

Recomm. for care for LOA: 4

**Overall recommendation for care**

**Other Conditions**

A. Decayed teeth

B. Gum disease/problem

C. Oral hygiene

D. Clinical impression of soft tissue condition

E. Dental/Partial Denture/Plates

F. No significant findings

G. Some other finding (specify w/referral letter)

Other Referral Comments

Referral Refuse

Generate Referral Letter

2 of 3

End of Section Close Exam Finish

Ready MEC Layer: 6/15/01 Application: Ver 9.10.18B No Safety Exclusion Not connected to Coordinator 02:23 PM

See his/her dentist at the earliest convenience; or

3. Continue his/her regular routine dental care.

The Recommendation For Care screen will trigger the printing of a referral letter (Exhibit 5-3) each time a Level 1 or Level 2 recommendation of care is given. The referral letter will print in the coordinator area and will be given to the SP when he/she leaves the MEC.

When the SP requires immediate care or care within the next 2 weeks, several items enable on the Recommendation For Care screen which will allow the examiner to indicate the main reason for the referral. Select one of the approved descriptions and/or include a brief comment in the space allocated. Remember that any description provided will be printed on the Referral Letter the SP receives. The comments should not provide a detailed diagnosis. Avoid descriptions which are references to specific tooth surface, specific treatment needs, or statements indicating a specific diagnostic classification. The approved descriptions include:

A. Decayed teeth (this is listed as cavities on the Report of Findings);

B. Gum problem/disease;

C. Oral hygiene problem;

D. Clinical impression of soft tissue conditions;

E. Denture/Partial Denture/Plates

F. No significant findings, and

G. Some other finding (see referral letter);

#### **5.4 Criteria for Referral**

This section is provided to help the examiner choose the appropriate level (Level 1, 2, 3, or 4) on the “Recommendation For Care” screen. The guidelines in Exhibit 5-4 are offered to assist examiners with their choice of the appropriate recommendation for care level.



Exhibit 5-3. Oral health referral letter

**National Health and Nutrition Examination Survey IV  
Notification of Dental Examination Findings**

Dentist/Clinic Name  
Address  
Phone Number

Dear Doctor:

On <exam date>, <SP's Name> was among those who had a voluntary examination at special mobile facilities operated by the U.S. Public Health Service. The oral examination of the National Health and Nutrition Examination Survey is not and is not intended to be a substitute for the examination usually given to persons seeking care from their own dentists. Our examination does not include a dental history or x-rays; therefore, the findings are solely the result of a limited oral examination.

<SP's Name> was referred to your office for immediate evaluation or followup in the following areas:

- Other condition 1
- Other condition 2
- Etc.

If you have any questions about the survey, please call Kathryn S. Porter, MD at <NCHS 800#> between 9:00 AM and 6:00 PM EST, Monday – Friday.

Cordially,

<NHANES Dentist Name>

Exhibit 5-4. Guidelines for dental referral

**GUIDELINES FOR DENTAL REFERRAL**

- Level 1**    Emergency dental condition: In the opinion of the examiner, a dental or oral condition exists which may require immediate services for the relief of symptoms and stabilization of the condition. Such conditions include but are not limited to: severe tooth pain, hemorrhage of the oral tissues, acute infectious processes of the oral cavity, traumatic injury to the teeth and surrounding tissues, unusual swelling of the face, gums, or other oral tissue, or oral conditions that obstruct the airway.
- Level 2**    Urgent dental condition: In the opinion of the examiner, a dental or oral lesion or condition exists for which the SP should seek medical/dental services within a few week period for diagnosis, relief of symptoms and/or stabilization of the condition, counseling about the condition or other appropriate followup. Such conditions may include but are not limited to: tooth fracture, oral lesion or condition visible to the examiner or SP, lost restoration, chronic pain, or other condition that is unlikely to resolve without professional intervention.
- Level 3**    Earliest convenience: In the opinion of the examiner, a need for oral hygiene services or nonemergency conditions exist which should be addressed prior to the next scheduled visit. Such nonemergency conditions may include incipient/early caries lesions or mild gingivitis.
- Level 4**    Continue regular care: Applies when none of the above conditions exist.

It is widely recognized by the American public that susceptibility to plaque-induced carious and/or periodontal lesions is both universal and continuous throughout the life of the dentition. A periodic examination by a professional is an effective means of averting the serious sequelae, which may develop due to failure to treat these lesions at the appropriate time. It is therefore justified, following any research-oriented oral examination, to advise that SPs “continue regular routine dental check-ups” when nothing unusual is found. There is, however, a considerable proportion of our population that does not receive appropriate treatment at an appropriate time. It is the examiner’s ethical responsibility to advise these SPs to “see the dentist at their earliest convenience” when such advice is warranted. There will be a small number of SPs who should seek treatment immediately, and it is the examiner’s responsibility to inform the appropriate individuals about the urgency of the situation.

The choice of referral for “routine care” or “within 2 weeks” or “at the earliest convenience” or “immediate care” requires careful consideration based first on the SP’s welfare but tempered by the

realities of dental practice. For example, it is inappropriate to refer SPs for care at “the earliest convenience” for decayed primary teeth if it is likely that those teeth will exfoliate before developing into sources of pain or infection. **An inquiry about current or pending treatment status should be made to avoid the inappropriate referral of SPs currently under care or scheduled for examination in the near future.**

The examiner should not identify the specific teeth or surfaces of concern, nor is it necessary to list the specific condition provided in the guidelines in Exhibit 5-4 on the Recommendation For Care screen. By doing so the examiner may inadvertently misdirect the SP’s dentist’s attention away from another problem. Since the NHANES exam is not diagnostic, the examiner does not want to discourage the SP’s dentist from making an independent evaluation.

Recommendations for care for young children should be based on the recommendations of the American Dental Association and other organizations. These organizations recommend that children have their first dental visit by age 2. Children over 2 years who have never had a check-up should be encouraged to have one; children with no problems who have seen a dentist should be encouraged to “continue regular routine care.”

If the situation warrants it, the examiner may ask the MEC physician to assume responsibility for the SP. This would be especially appropriate if an oral condition is discovered with significant medical ramifications (e.g., hairy cell leukoplakia).

As mentioned above, the realities of dental practice must be kept in mind in making the final choice.

## **5.5 SP Refusal of Referral Letter**

There may be times when an SP refuses to accept the referral for dental care the examiner has provided. These instances are documented manually using a Dental Release Form and documented electronically using the Recommendation For Care screen in the ISIS system.

Exhibit 5-5. Dental Release Form



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Centers for Disease Control

National Center for Health Statistics  
6525 Belcrest Road  
Hyattsville, MD 20782

**NHANES  
DENTAL RELEASE FORM**

Date: \_\_\_\_\_

Stand: \_\_\_\_\_

This is to certify that against the advice of the staff dentist, I choose no further dental referral or immediate follow-up. By so doing, I assume all responsibilities for my act.

Signed \_\_\_\_\_

Relationships \_\_\_\_\_

Witness \_\_\_\_\_

Whenever an SP refuses the referral, the examiner is to obtain the reason for the refusal. The dental examiner must also have the SP complete the Dental Manual Release Form (Exhibit 5-5). The examiner should fill out the date and the stand in the SP's presence. The SP or SP's guardian is then asked to sign the form and indicate the relationship to the SP if the SP is a minor. The examiner then must sign as the witness. The form is printed on 3-part NCR paper. The SP's copy of the form (pink copy) should be handed to the coordinator when the SP is returned to the coordinator area for distribution to the SP when he/she leaves the MEC. The original form and the yellow copy (for NCHS) should be sent to Westat with the next mail delivery.

The Recommendation For Care screen has a box that is checked if the SP refuses the referral. If this box is checked, the ISIS system will require a comment. This comment is the examiner's assessment of the reason the referral was refused and any other important information he/she feels may need to be documented. This comment section may also be used to indicate the examiner's response to the refusal and/or any pertinent information that may be useful for the examiner or someone at NCHS who is contacted about the SP.

## **6. QUALITY CONTROL FOR ORAL HEALTH EQUIPMENT**

This chapter reviews the tasks required of the dental examiner during a stand. Some of these tasks require documentation in the quality control program in the ISIS system. All of the ISIS screens are printed at the end of the chapter. The ISIS QC system replaces the hard copy logs used at the beginning of the current NHANES. The data entered on the ISIS QC screens is accessible to Westat and NCHS staff daily. Maintenance of the oral health equipment and room is the responsibility of the dental examiner. Completing the quality control checks in ISIS is also the responsibility of the dental examiner. If the quality control checks are not completed in the ISIS system, a pop-up error message will appear prior to each examination. Quality control checks will be completed at the following intervals:

- Start of stand
- Start of session
- End of session
- Weekly
- Mid-stand
- End of stand

### **6.1 ISIS Quality Control System**

#### **6.1.1 Accessing the System**

- The dental examiner will select the dental icon from the introductory window on the computer screen.
- The dental examiner will enter his or her password when prompted.
- The dental examiner will go to utilities at the top of the screen.
- Under utilities, the examiner will select the quality control option and the dental quality control checks, Exhibit 6-1, will appear on the screen.

## 6.1.2 Entering the Data

The examiner will choose the correct tab (Start of Stand, Start of Session, End of Session, Weekly, Middle of Stand, End of Stand) and enter the required information. If a required item is not done, the reason should be listed in the Comment section. There are several items on the list that may not be required every time (e.g., instrument sterilization not done every session). These items still require a check, but ND should be added to the Comment section.

Exhibit 6-1. Dental quality control checks

The screenshot shows a software window titled "Dental: Stand:703 Session:703061 03/10/1999 01:30 pm - 05:30 pm". Inside the window is a dialog box titled "Dental Quality Control Checks". The dialog box has six tabs: "Start of Stand", "Start of Session", "End of Session", "Weekly", "Middle of Stand", and "End of Stand". The "Start of Session" tab is selected. The dialog box contains a table with four columns: "QC Check", "Done", "Result", and "Comment". There are four rows of data:

QC Check	Done	Result	Comment
Room cleaned?	<input type="checkbox"/>		
Chair setup?	<input type="checkbox"/>		
Chair cleaned?	<input type="checkbox"/>		
Light setup?	<input type="checkbox"/>		

At the bottom right of the dialog box are "OK" and "Cancel" buttons. The Windows taskbar at the bottom shows the system tray with "Ready", "Not connected to Coordinator", and "10:42 AM".

There are four columns for each QC check. The columns are as follows:

- The first column lists the QC check.
- The second column requires a check (✓). The examiner should use the left button of the mouse. The check is inserted by clicking the left button while the cursor is over

the box. If the examiner needs to uncheck an item, then he or she needs to click the left button again, while the cursor is over the box.

- The third column is the Result column. This is not necessary for every item in the QC list. Each item is listed later in the chapter with the required information.
- The fourth column is the Comment section. This should be used if an item is not completed or if there is a problem with the equipment/supplies.

## **6.2 Start of Stand Procedures**

You will note that a great deal of detail is provided. Examiners are switching MECs approximately every 6 weeks. If each examiner stores dental equipment and supplies in different places, it will be difficult locating equipment and supplies when he or she arrives at a different MEC. Occasionally, back-up examiners are sent to the field. Because the back-up staff are not as familiar with the room set-up and location of specific items, it is particularly beneficial for the back-ups if all examiners follow the same procedures for storing supplies.

### **6.2.1 Inventory**

- Inventory the dental room and belly compartment. Be sure to add newly shipped items to the existing list before taking the inventory.
- Remove the dental equipment from the cases and unpack the supplies needed for the first few weeks of exams.
- Store all empty cases, back up equipment, and extra supplies in the belly compartment. Place those supplies needed during the stand towards the front of the compartment. When possible, store the extra supplies in the waterproof case provided.
- Check all waterproof containers and covers for cracks or breakage. Report problems to the home office so that arrangements can be made to send replacements.

### **6.2.2 Cleaning and Disinfecting**

- Clean cabinet shelves and doors, drawers, counter tops, walls, shelves, and computer area.



- Disinfect the top drawer where the sterile instruments are stored. Disinfect all handles and any area that is used for supplies that come into contact with SPs during the examination.
- Clean and disinfect the biohazardous waste container. Insert a biohazardous waste bag into the container. Bags are stored in the third drawer.

### 6.2.3 Set Up

Set up the dental equipment using the specifications provided in Chapter 3. Exhibit 6-2 lists the QC checks that need to be completed in the ISIS system. The following tasks need to be completed as well.

- Set up the counter top as follows:
  - Place the sharps container above the sink.
  - Place miscellaneous non-SP supplies, such as pens, pencils, tape, and scissors in bin on the shelf located above the counter.
- The drawers should be organized as follows:
  - **Drawer 1:** Sterilized instrument sets
  - **Drawer 2:** Syringe covers; disposable air tips; stickers; denture adhesive; cotton tip applicators; alcohol squares
  - **Drawer 3:** Biohazard bags, masking tape, etc.
  - **Drawer 4:** Manuals; paper work; miscellaneous non-SP supplies; and tool kit
- The cabinets should be organized as follows:
  - **Upper left cabinet:** Tissues and the spore test kit are located on the top shelves; adhesive coverings and sterilization supplies are located on the bottom shelf.
  - **Upper right cabinet:** Gloves and masks are located on the bottom shelf; extra gloves and masks are located on the top shelves along with the pillow and pillow cases.
  - **Lower left cabinet:** This cabinet houses the compressor.

- **Lower right cabinet:** Bottled cleaning and disinfecting supplies are located on the bottom shelf; all contaminated supplies, such as the used instrument containers, are located on the top shelf.
- All computer equipment should have been set up prior to your arrival. If there is a problem with the keyboard, monitor, or wand, contact the data manager.

Exhibit 6-2. Quality control checks

Check	Done	Result	Comment
Room cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Stool cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor set-up	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue

### 6.3 Within Stand Tasks

#### 6.3.1 Start of Session Tasks

- Open the ISIS dental program after the coordinator has opened the system for the session.
- Complete all tasks necessary for the start of session quality control as listed in Exhibit 6-3.
- Prepare fresh holding solutions.
- Clean and disinfect the dental area as needed.
- Place the adhesive coverings on the light-head arm and the light controls.
- Place plastic coverings on the instrument tray, the chair, and the air syringe. Place a new disposable air tip on the air syringe.

Exhibit 6-3. Start of session quality control checks

QC check	Done	Result	Comment
Visual light check	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor visual check	<input type="checkbox"/>	No required entry	Comment on problem or issue
Close air tank valves	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer exterior cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket and mating surface cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket visual check	<input type="checkbox"/>	No required entry	Comment on problem or issue

### 6.3.2 Between SPs

- Place the used instruments and mirrors into the containers with the appropriately diluted Restore holding solution.
- Dispose of air tips into the sharps container.
- Throw all other used disposable items and barriers into the biohazardous waste container.
- Replace all disposable barriers, including the headrest covers on the pillow if used.
- Wipe instrument tray, counter top, light head, air tip holder, chair head, etc., with disinfectant.

### 6.3.3 End of Session

- Complete all tasks necessary for the end of session quality control as listed in Exhibit 6-4.
- Discard holding solutions at the end of the last session for the day. Fill instrument containers with soapy water and scrub instruments with the instrument brush. Dry instruments and prepare for packaging and sterilizing.
- Clean and disinfect dental area as needed.
- Bag the biohazardous waste and replace with a clean bag at the end of each session. Check with the lab for specific pickup dates.
- Close ISIS.

Exhibit 6-4. End of session quality control checks

QC check	Done	Result	Comment
Purge air tank (not needed after AM session)	<input type="checkbox"/>	No required entry	Comment on problem or issue
Instrument sterilized exposure time (if sterilized instruments )	<input type="checkbox"/>	Enter time	Comment on problem or issue
Instrument sterilized temperature (if sterilized instruments)	<input type="checkbox"/>	Enter temperature	Comment on problem or issue

### 6.3.4 Weekly Tasks

- Complete all tasks necessary for the weekly quality control as listed in Exhibit 6-5.
- Clean the inside of the SpeedClave with mild soap and distilled water and then rinse with distilled water. Drain the water from the reservoir and refill with fresh, distilled water.
- Clean those areas not maintained on a daily basis (e.g., countertop under the autoclave; exterior of autoclave, computer; screen; walls; shelves), as needed.
- Stock supplies, as needed.

Exhibit 6-5. Weekly quality control checks

QC check	Done	Result	Comment
Sterilizer water reservoir checked	<input type="checkbox"/>	No required entry	Comment on problem or issue
Spore Test (see below)	<input type="checkbox"/>	No required entry	Comment on problem or issue
Spore Test start time	<input type="checkbox"/>	Enter time	Comment on problem or issue
Spore Test end time	<input type="checkbox"/>	Enter time	Comment on problem or issue
Spore Test - control result	<input type="checkbox"/>	Enter result	Comment on problem or issue
Spore Test – test result	<input type="checkbox"/>	Enter result	Comment on problem or issue
Lot #	<input type="checkbox"/>	Enter lot #	Comment on problem or issue
Load #	<input type="checkbox"/>	Enter load #	Comment on problem or issue

### 6.3.5 Mid-Stand Procedures

- Complete all tasks necessary for the mid-stand quality control as listed in Exhibit 6-6.

Exhibit 6-6. Mid-stand quality control checks

QC Check	Done	Result	Comment
Sterilizer drained and refilled with distilled water	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer chamber cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue

### 6.3.6 End-of-Stand Pack-Up Procedures

- Review end of stand QC prior to pack-up.
- Open ISIS system prior to the coordinator shutting down. Enter information as it is completed.
- Complete all tasks necessary for the end of stand quality control as listed in Exhibit 6-7.
- Flush the SpeedClave with SpeedClean solution as described in Chapter 3.
- Inventory the dental room and belly compartment using the inventory form provided by the MEC manager. An inventory worksheet developed for the dental component is available to assist and track the stand inventories.
- Pack the equipment and supplies as specified in Chapter 3.
- Close ISIS QC session.

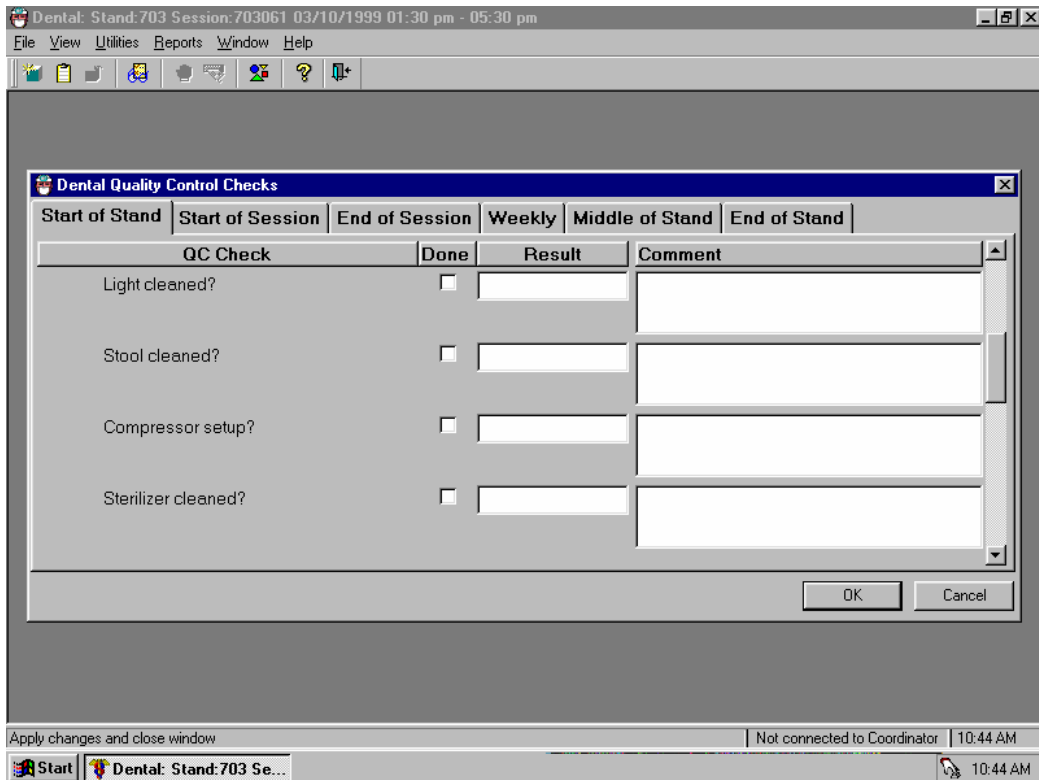
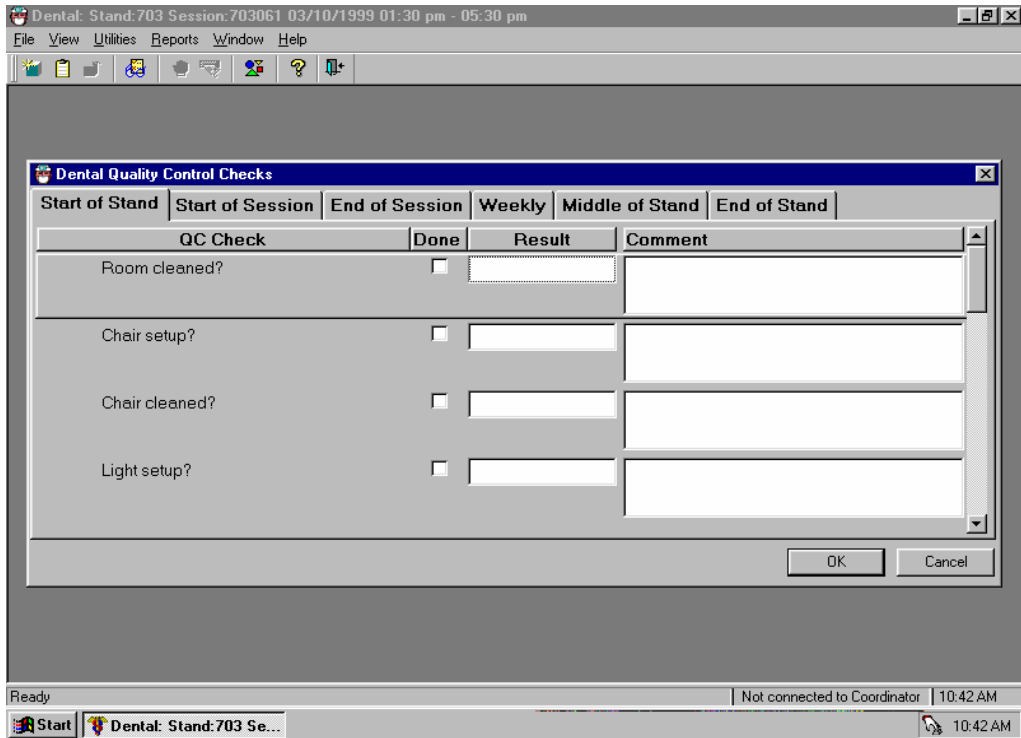
Exhibit 6-7. End of stand quality control checks

QC Check	Done	Result	Comment
Chair cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Chair packed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Light cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Stool cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer flushed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer chamber cleaned	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer interior tray wiped and replaced	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer gasket cleaned and inspected	<input type="checkbox"/>	No required entry	Comment on problem or issue
Sterilizer packed	<input type="checkbox"/>	No required entry	Comment on problem or issue
Air tank bled	<input type="checkbox"/>	No required entry	Comment on problem or issue
Compressor secured	<input type="checkbox"/>	No required entry	Comment on problem or issue
Replace instruments	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Replace light bulb	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Change fuses	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Change syringe cotton roll (if wet or if annual replacement required)	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Sterilizer gasket replaced	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced

#### 6.4 Shipping

Instruments or supplies that are broken, defective, or no longer used can be shipped back to the NHANES warehouse manager at the Home Office. Place the instruments in a padded envelope and ask the MEC manager to ship directly to the warehouse. When shipping obsolete or broken inventory back to the warehouse, please complete the “Delete Expired/Broken Inventory Report” which is found on the IntraWeb and can be printed by your MEC manager or Data Manager.

## Start of Stand ISIS Screen



## Start of Session ISIS Screen

Dental: Stand:506 Session:506351 12/19/2000 01:30 pm - 05:30 pm

SP ID: 249463 Name: HERBER1, MELISSA Age: 26 years Gender: Female Date: 12/13/2002 Time: 11:33 AM

**Dental Quality Control Checks**

Start of Stand
  Start of Session
  End of Session
  Weekly
  Middle of Stand
  End of Stand

QC Check	Done	Result	Comment
Room cleaned?	<input checked="" type="checkbox"/>		
Biohazard can cleared?	<input checked="" type="checkbox"/>		
Chair setup?	<input checked="" type="checkbox"/>		
Chair cleaned?	<input checked="" type="checkbox"/>		

OK Cancel

Ready | No Safety Exclusion | Not connected to Coordinator | 11:48 AM



## End of Session ISIS Screens

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

Start of Stand  
  Start of Session  
  End of Session  
  Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Instruments Sterilized Exposure (minutes)	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
Instruments Sterilized Temperature (F)	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
Purge Air Tank (not needed after AM session)	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
Sterilizer exterior cleaned?	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>

End of session | MEC Layer: 11/2/00 | Application: Ver 8.10.23B | No Safety Exclusion | Not connected to Coordinator | 12:27 PM

## Weekly ISIS Screens

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand  
  Start of Session  
  End of Session  
 Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Sterilizer water reservoir checked?	<input type="checkbox"/>		
Spore Test Lot #	<input type="checkbox"/>		
Spore Test Load #	<input type="checkbox"/>		

OK Cancel

Apply changes and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:38 PM

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand  
  Start of Session  
  End of Session  
 Weekly  
  Middle of Stand  
  End of Stand

QC Check	Done	Result	Comment
Spore Test Start Date/Time	<input type="checkbox"/>		
Spore Test End Date/Time	<input type="checkbox"/>		
Spore Test Control Test	<input type="checkbox"/>		
Spore Test Test Result	<input type="checkbox"/>		

OK Cancel

week 1 y 2 ges and close window   MEC Layer: 11/2/00   Application: Ver 8.10.23B   No Safety Exclusion   Not connected to Coordinator   12:38 PM

## Middle of Stand ISIS Screen

Dental: Stand:703 Session:703061 03/10/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental Quality Control Checks

Start of Stand Start of Session End of Session Weekly Middle of Stand End of Stand

QC Check	Done	Result	Comment
Sterilizer chamber cleaned?	<input type="checkbox"/>		
Sterilizer drained and refilled with distilled water?	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | Not connected to Coordinator | 10:49 AM

Start | Dental: Stand:703 Se... | 10:50 AM

## End of Stand ISIS Screens

Dental: Stand:703 Session:703061 03/10/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

**Dental Quality Control Checks**

Start of Stand | Start of Session | End of Session | Weekly | Middle of Stand | End of Stand

QC Check	Done	Result	Comment
Chair cleaned?	<input type="checkbox"/>		
Chair packed?	<input type="checkbox"/>		
Light cleaned?	<input type="checkbox"/>		
Stool cleaned?	<input type="checkbox"/>		

OK Cancel

Apply changes and close window | Not connected to Coordinator | 10:50 AM

Start Dental: Stand:703 Se... 10:50 AM

Dental: Stand:107 Session:107832 09/26/1999 05:30 pm - 09:30 pm

File View Utilities Reports Window Help

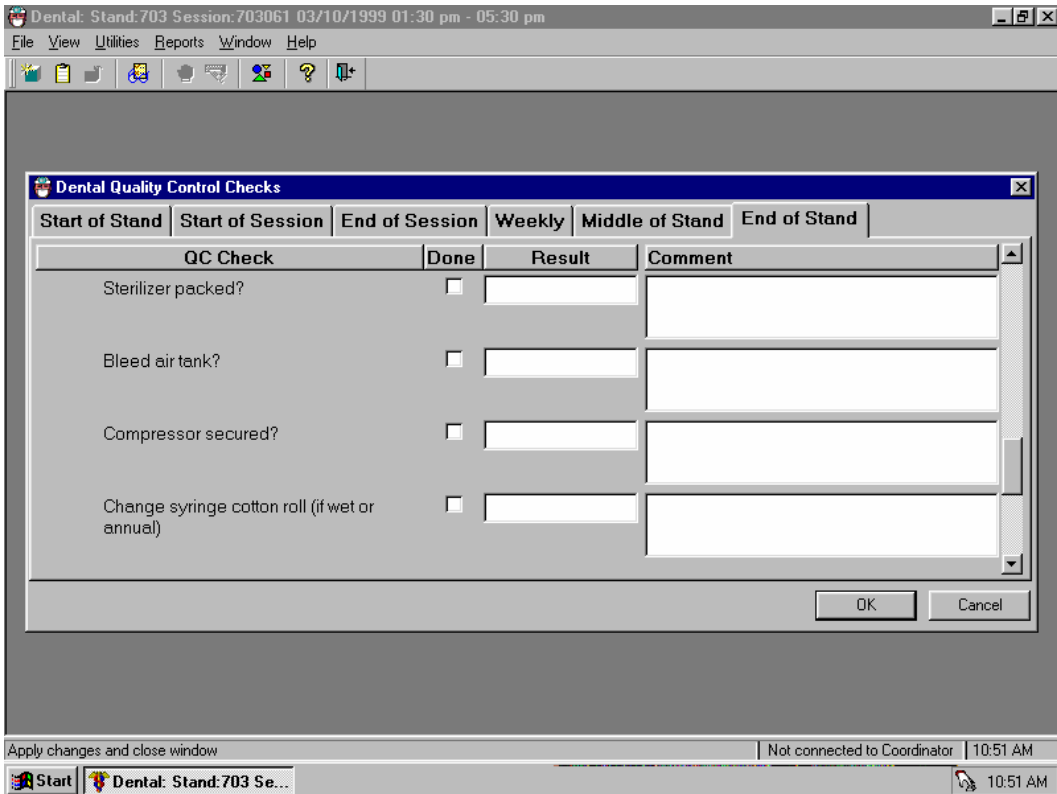
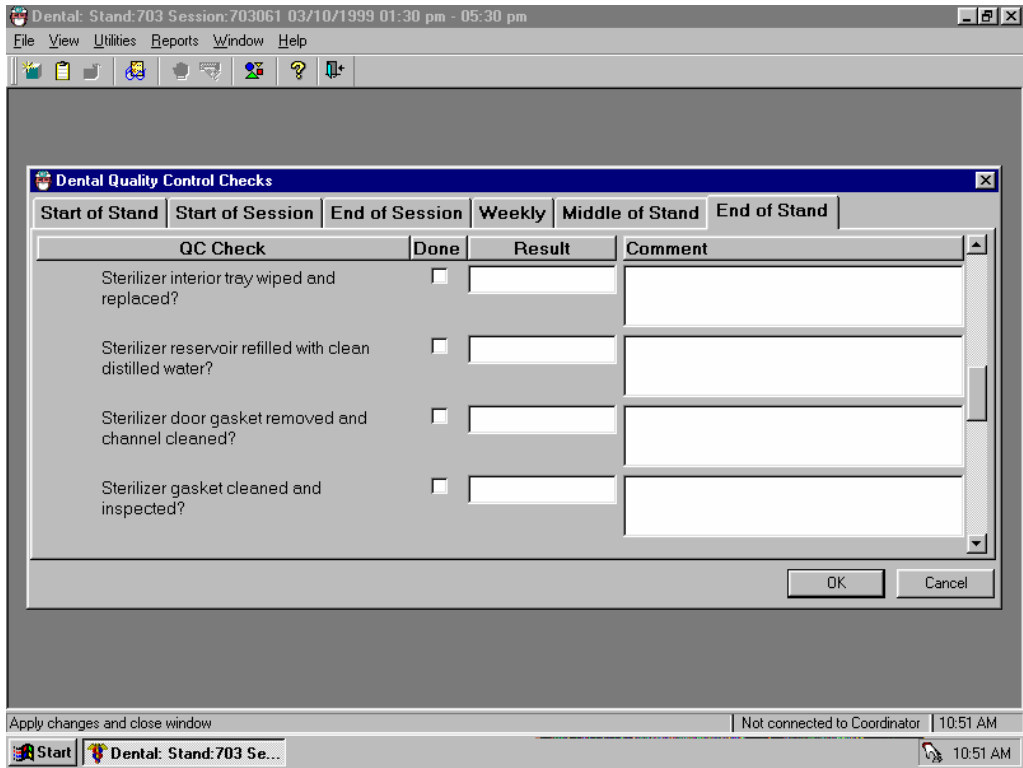
**Dental Quality Control Checks**

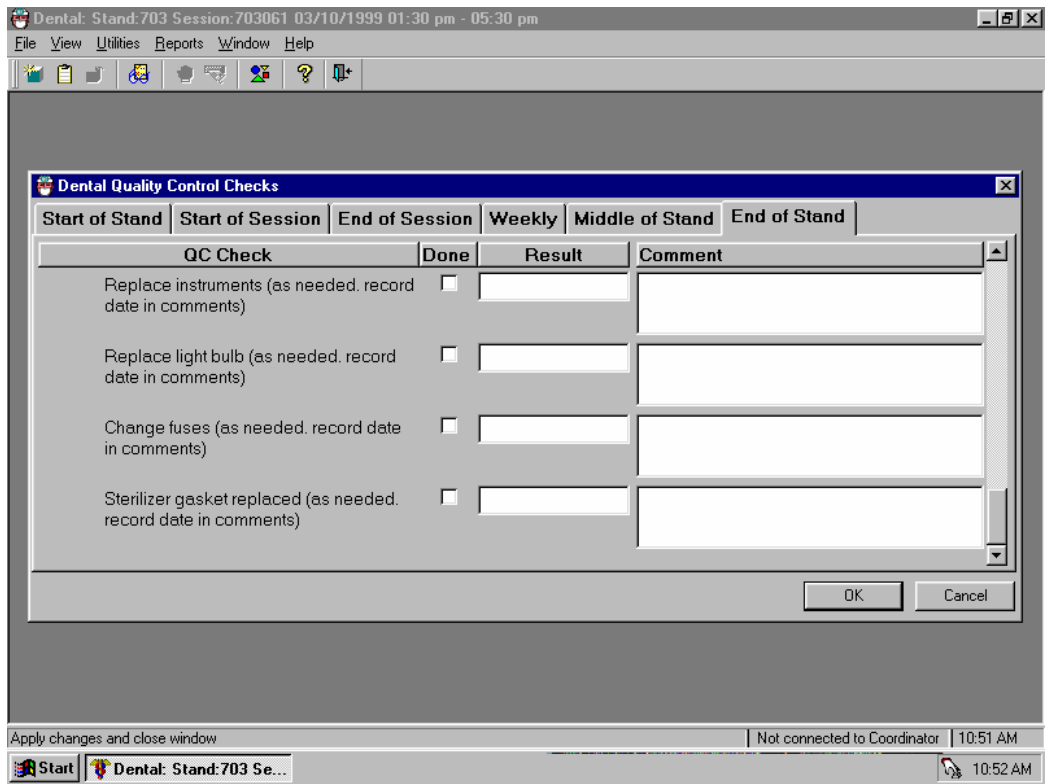
Start of Stand | Start of Session | End of Session | Weekly | Middle of Stand | End of Stand

QC Check	Done	Result	Comment
Sterilizer flushed?	<input type="checkbox"/>		
Sterilizer chamber cleaned?	<input type="checkbox"/>		

OK Cancel

end of stand2lose window | MEC Layer: 11/2/00 | Application: Ver 8.11.9B | No Safety Exclusion | Not connected to Coordinator | 11:38 AM





## **7. QUALITY CONTROL PROCEDURES**

Two primary concerns in all epidemiological surveys are to protect the survey from errors that may compromise the representativeness of the sample and from errors in measurement of the phenomena being studied. Dental teams and support staff in NHANES are responsible for protecting the accuracy and precision of the dental component of this survey by promoting maximum response rates and assuring the quality of data collected from the sample.

This section of the manual presents a brief summary of quality control procedures for which the dental team and support staff will be accountable.

### **7.1 Response Rates**

The precision of the sample design in this survey is based on a very small number of persons selected to represent very large numbers of people. Therefore, the examination team's responsibility to achieve the highest possible examination response rate is a very important one. The examination response rate is actually a product of response rates achieved at three stages: (1) the screener response rates, (2) the interview response rates, and (3) the examination response rates.

Obviously, the dental team is directly involved in only the third stage of developing high examination response rates. Appearance, demeanor, and attitude of professional personnel shape SPs' feelings about the survey and help determine the degree to which they will be cooperative during the examination. SPs' feelings toward project personnel also affect what they say about the survey after they leave the MEC and interact with other people in the community. Individual members of the dental team and support staff are to treat all SPs with respect and courtesy. Special attention must be devoted toward relieving fear in children and apprehensive adults. In addition to being pleasant and displaying a caring attitude toward the SPs, examiners must exercise great care in performing the assessments so that the SPs are comfortable during the examination.

Although it is only the third stage of response rate development in which the dental team is directly involved, every effort should be made to cooperate with advance arrangement teams and interview teams to assist them in developing high response rates. Examiners must be willing to provide

them with information and advice on how to alleviate fear that the examination may be painful or embarrassing so they can deal with apprehension among SPs who are reluctant to make an appointment for the examination.

## **7.2 Data Quality**

Each individual staff member is the first and best guarantor of the quality of the data being collected. Data quality is affected by every step of the survey including nonexam procedures leading to the examination, and nonexam procedures following the examination. The quality of data in this survey is controlled by (1) an intense training period for the dental teams with calibration of dental examiners prior to the beginning of the survey, (2) periodic monitoring and recalibration of dental examiners, and (3) periodic retraining of dental teams.

### **7.2.1 Training and Calibration**

Training is divided into three phases as follows:

- **The instructional phase** in which examination team members are familiarized with research examination procedures and criteria for research assessments.
- **The standardization phase** in which they are trained to use standard procedures and apply standard criteria for the oral health assessments.
- **The calibration phase** in which the degree of correlation among the examiners and the standard examiner is measured.

#### **Instruction**

The instructional phase of the training sequence is conducted by nationally recognized research science experts in each type of oral health assessment and survey procedure with support and assistance from the standard examiner. The standard examiner is a specially trained dentist with a high level of experience in conducting oral health protocols in national surveys. The expert trainers present lectures on criteria for each of the oral health assessments to be used in the survey. Lectures are accompanied by slides depicting a wide variety of possible observations and illustrating application of



assessment criteria to those observations. The lecture-slide presentations on each assessment are followed by instructions on data recording and editing for that assessment. Although the instructional phase consists primarily of lectures and slide presentations, some demonstrations of examination technique and equipment use are conducted.

### **Standardization**

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews examination procedures and techniques and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between a research examination and a diagnostic examination are discussed and professional ethics of research examinations reviewed. A demonstration of the examination by the standard examiner and practice examinations by the examiners being trained is among the salient features of this phase. Standardization of all examiners is achieved by using replicate examinations with detailed discussion of observations. NIDCR scientists, project consultants, and the standard examiner monitor and referee examinations and discussion of observations during these sessions.

### **Calibration**

The reliability of the assessments is measured by determining the degree to which examiners can produce uniform and consistent results when performing independent replicate examinations without discussion. In this phase of training, the standard examiner and all examiners in training perform components of the examination on a specified number of SPs while NIDCR examiners monitor the calibration session without discussing observations with any of the examiners or the standard examiner. Data from the calibration sessions are analyzed to measure correlation between each examiner and the standard examiner. If correlations between each of the examiners and the standard examiner are not within acceptable ranges, additional training sessions will be scheduled.

## **7.2.2 Monitoring and Recalibration**

Continual gathering of clean, reliable data in a consistent and uniform manner is the primary objective of the survey. Several quality control procedures will be carried out periodically to assure continuing quality of data gathered by the dental teams throughout the duration of the survey.

### **Expert Replication and Monitoring Field Operations**

During the field operations, examiners and recorders should periodically review their training manuals to prevent deviation, or “drift” from the standards achieved during the training period. Particular attention should be devoted to uniform adherence to the criteria for making correct decisions about observations. Strict compliance with infection control procedures is another important consideration for dental teams. In order to help the dental teams maintain their standards, NIDCR and CDC Division of Oral Health scientists and various other project personnel will make periodic visits to field personnel to observe their performance and offer feedback on the results of their examinations.

The standard examiner will visit each team three times per year to observe field operations and to replicate 20 to 25 dental examinations during each visit. The purpose of these so called “expert replications” is to determine whether the examiners are maintaining the examination standards achieved during training, and to measure the degree of deviation, if any, from those standards. If correlation between the standard examiner and the field examiner is not within acceptable limits, retraining will be conducted on site.

### **Annual Retraining**

The long duration of the study (6 years) mandates the need for regularly scheduled retraining periods. In addition to the regularly scheduled recalibration sessions with the standard examiner, there will be an annual retraining session for each dental examiner, also conducted by the standard examiner.

Appendix A  
Backup Equipment

## **APPENDIX A. BACKUP EQUIPMENT**

Backup equipment will be provided for the dental chair, dental light, air compressor, and SpeedClave. Procedures for the setup, care, and maintenance of the backup equipment are provided in this appendix.

### **1. Porta-Chair**

The back up Porta-Chair is the same as the original. Procedures for set up, care and maintenance are provided in Section 3.3.1

### **2. Light**

The ProBrite light is a portable light that is partially preassembled and needs only to be connected to the wall support and plugged into an electrical outlet.

#### **■ Set-up**

The wall mount ProBrite light comes assembled with a horizontal supporting arm and a bushing designed for the light post. After unpacking, the male plug extending past the bushing is connected to the female receptacle in the light post and then the ProBrite Light is lowered to the light post until the bushing properly seats in the light post. Connect the power cord.

#### **■ Use**

The ProBrite light is equipped with two intensity control systems. The infinitely variable selection switch regulates intensity from no illumination to maximum illumination. The lens system located at the end of the arm regulates focus from a wide to a narrow light beam. As the beam is narrowed, the light energy is concentrated for greater illumination. A few minutes of experimentation will

establish the optimum intensity and focus for each operator. To ensure maximum lamp life, the minimum intensity position should not be left on all day but used only for short durations when needed during an exam.

The light is also designed to minimize the need to reposition SPs for the dental procedures. The light is equipped with a fully flexible arm that may be moved freely to eliminate shadows and to illuminate areas impossible to illuminate with conventional lights. The optimum distance from the light lens to the operating area is 8-12 inches. Certain dental procedures may require higher light intensity that can be accomplished, in part, by moving the light lens to within 4 inches of the operating area.

Correct adjustment is accomplished when all arm angles are about equal. **Do not straighten the arm more than 90° at any flexible joint** or broken glass fibers may result in reduction of light transmission.

#### ■ Maintenance

Perform a visual check at the start of each session, before using the equipment. Be sure to look for mechanical damage such as cracks on the power cord or cable, cracks or splits on the bulb cowl and cover, and cracks or scratching of the lens. Also look for loose or missing items such as screws, nuts, and bolts.

#### ■ Cleaning

Always wear nonpowdered gloves when cleaning the light and be sure to disconnect the power cable from the power source before you begin.

The light may be cleaned using a soft cloth and a mild soap solution as needed. The mirror and lenses may be cleaned using a cotton applicator in a circular motion. Do not spray disinfectant directly into the light adapter as this may cause damage to the bulb and reduce light transmission.

- **Replace Light Bulb**

To replace the high-intensity light bulb, disconnect the power cable from the electrical source. Allow the projector to cool down. Open the side-flap and expose the bulb holder, which easily swings out of the compartment. Using a small screwdriver, pry the bulb from its socket. Insert the new bulb (without touching the glass) into the holder as far as it will go. The metal contacts of the bulb should not be bent. Close the flap. The bulb holder automatically returns to the correct working position. Be aware, the light bulb fits tightly in the socket and can be difficult to remove and replace.

- **Change Fuses**

Replacement fuses are found in the fuse compartment next to the male outlet in the light assembly. This is located underneath the projector. A screw driver is needed to open and close the fuse compartment. **Be sure to disconnect the power cable from the electric source.**

- **Pack-up**

The arm of the light is made of glass fibers, which transmit the light. If the fibers are broken, there will be less light transmission. For this reason, care must be taken with the light. At the end of a stand, the light head and light box must be packed in their designated storage boxes, and the light head should be wrapped in bubble wrap.

### **3. Gomco Air Compressor**

The backup air compressor is the Gomco Air Compressor.

- **Operating Principle**

The negative and positive pressures of a diaphragm pump are developed by the reciprocating motion of the diaphragm inside the pump head. These pressures are maintained by the motion of the diaphragm and the pressure and suction flapper valves. On the up stroke, the pressure valve will open to allow air to flow through to the exhaust or pressure port. On the down stroke, the pressure valve closes and the

suction valve opens which draws a vacuum or creates a negative pressure at the suction side.

#### ■ **Assembly**

The Gomco Air Compressor is used only for air drying the mouth and not for suction, therefore only three assembly items are applicable.

1. The black cord tubing for blowing air will already be attached to the air pressure valve and does not need to be removed when moving the equipment.
2. Check all tubing to make sure that connections are secure.
3. Plug the electrical cord into a three-pronged outlet. If the outlet is two-pronged, use a three-pronged adapter.

#### ■ **Safety Overflow Valve**

The valve operates on the principle that a chamois disc permits the flow of air through it when dry. Any fluid striking and saturating the chamois causes the pores to swell and, thereby, stops the passage of air. When the chamois becomes moist (restricting the air flow), the vacuum of the pump causes the chamois to push against the formed spring which shuts off the air flow through the pump. The unit may be used without a chamois disc in emergencies, but there will be no overflow protection.

When the valve closes, the pump should immediately be shut off and the felt filter and chamois disc replaced.

The felt filter is replaced into the head of the safety overflow valve to collect any moisture droplets that may get drawn into the intake tube.

#### ■ **To Replace the Felt Filter**

1. Shut off pump.
2. Remove cover on valve back.
3. Take out three screws and filter window.
4. Remove gasket.
5. Remove felt filter and discard.
6. Wipe clean and dry all parts.
7. Put in new filter and attach gasket and window making sure that the window is tight.

■ **To Replace Chamois Disc**

1. Remove cover of valve while pump is running.
2. With chamois removed and spring in closed position, wipe out the moisture from valve back.
3. Shut off pump and note that the spring releases from valve back.
4. Press spring to back of valve and remove any moisture in lower portion of valve back.
5. Start pump and note that the spring will remain open permitting air to enter pump.
6. Gently insert new chamois in place of the old one with pump running and fasten on overflow valve cover.
7. Remove moisture from vacuum regulating valve and tubing attached to overflow valve.
8. Attach tubing from short bottle tube to valve and check to make sure suction is present. NOTE: The valve function should be checked in the collection bottle and in the vacuum system or premature shutoff may occur.

If the valve closes after reassembly when the motor is running, this is an indication that moisture may be reaching the chamois disc. The valve should be disassembled and dried more thoroughly or replaced. Replace chamois disc. There is a chance that the valve may close by itself if the tubing is compressed and released suddenly--stop the pump for three seconds and it will reopen.

If no moisture is reaching the valve and it still closes, the difficulty may be that the spring has been bent in a convex condition or the legs of the spring may have been bent too flat. Should this condition occur, the spring must be replaced. Refer servicing to qualified personnel.

**CAUTION:** If flooding occurs, do not attempt to operate the pump. Refer servicing to qualified personnel. Do not at any time lubricate any of the parts with oil, grease, or petroleum products. The pump and motor are permanently lubricated and require no oiling or greasing.

**4. SpeedClave**

Problems with the SpeedClave should be reported to your MEC manager who will notify the Home Office of the need for a replacement as necessary.



**Appendix B**  
**Recommended Infection-Control**  
**Practice for Dentistry**



# MMWR<sup>TM</sup>

## Morbidity and Mortality Weekly Report

Recommendations and Reports

December 19, 2003 / Vol. 52 / No. RR-17

### Guidelines for Infection Control in Dental Health-Care Settings — 2003



**INSIDE: Continuing Education Examination**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION**

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\*For Continuing Dental Education (CDE), see <http://www.ada.org>.

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#### Disclosure of Relationship

Our subject matter experts wish to disclose they have no financial interests or other relationships with the manufacture of commercial products, providers of commercial services, or commercial supporters. This report does not include any discussion of the unlabeled use of commercial products or products for investigational use.

# Guidelines for Infection Control in Dental Health-Care Settings — 2003

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## Summary

*This report consolidates previous recommendations and adds new ones for infection control in dental settings. Recommendations are provided regarding 1) educating and protecting dental health-care personnel; 2) preventing transmission of bloodborne pathogens; 3) hand hygiene; 4) personal protective equipment; 5) contact dermatitis and latex hypersensitivity; 6) sterilization and disinfection of patient-care items; 7) environmental infection control; 8) dental unit waterlines, biofilm, and water quality; and 9) special considerations (e.g., dental handpieces and other devices, radiology, parenteral medications, oral surgical procedures, and dental laboratories). These recommendations were developed in collaboration with and after review by authorities on infection control from CDC and other public agencies, academia, and private and professional organizations.*

## Introduction

This report consolidates recommendations for preventing and controlling infectious diseases and managing personnel health and safety concerns related to infection control in dental settings. This report 1) updates and revises previous CDC recommendations regarding infection control in dental settings (1,2); 2) incorporates relevant infection-control measures from other CDC guidelines; and 3) discusses concerns not addressed in previous recommendations for dentistry. These updates and additional topics include the following:

- application of standard precautions rather than universal precautions;
- work restrictions for health-care personnel (HCP) infected with or occupationally exposed to infectious diseases;
- management of occupational exposures to bloodborne pathogens, including postexposure prophylaxis (PEP) for work exposures to hepatitis B virus (HBV), hepatitis C virus (HCV); and human immunodeficiency virus (HIV);
- selection and use of devices with features designed to prevent sharps injury;

- hand-hygiene products and surgical hand antisepsis;
- contact dermatitis and latex hypersensitivity;
- sterilization of unwrapped instruments;
- dental water-quality concerns (e.g., dental unit waterline biofilms; delivery of water of acceptable biological quality for patient care; usefulness of flushing waterlines; use of sterile irrigating solutions for oral surgical procedures; handling of community boil-water advisories);
- dental radiology;
- aseptic technique for parenteral medications;
- preprocedural mouth rinsing for patients;
- oral surgical procedures;
- laser/electrosurgery plumes;
- tuberculosis (TB);
- Creutzfeldt-Jakob disease (CJD) and other prion-related diseases;
- infection-control program evaluation; and
- research considerations.

These guidelines were developed by CDC staff members in collaboration with other authorities on infection control. Draft documents were reviewed by other federal agencies and professional organizations from the fields of dental health care, public health, and hospital epidemiology and infection control. A *Federal Register* notice elicited public comments that were considered in the decision-making process. Existing guidelines and published research pertinent to dental infection-control prin-

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ciples and practices were reviewed. Wherever possible, recommendations are based on data from well-designed scientific studies. However, only a limited number of studies have characterized risk factors and the effectiveness of prevention measures for infections associated with dental health-care practices.

Some infection-control practices routinely used by health-care practitioners cannot be rigorously examined for ethical or logistical reasons. In the absence of scientific evidence for such practices, certain recommendations are based on strong theoretical rationale, suggestive evidence, or opinions of respected authorities based on clinical experience, descriptive studies, or committee reports. In addition, some recommendations are derived from federal regulations. No recommendations are offered for practices for which insufficient scientific evidence or lack of consensus supporting their effectiveness exists.

## Background

In the United States, an estimated 9 million persons work in health-care professions, including approximately 168,000 dentists, 112,000 registered dental hygienists, 218,000 dental assistants (3), and 53,000 dental laboratory technicians (4). In this report, dental health-care personnel (DHCP) refers to all paid and unpaid personnel in the dental health-care setting who might be occupationally exposed to infectious materials, including body substances and contaminated supplies, equipment, environmental surfaces, water, or air. DHCP include dentists, dental hygienists, dental assistants, dental laboratory technicians (in-office and commercial), students and trainees, contractual personnel, and other persons not directly involved in patient care but potentially exposed to infectious agents (e.g., administrative, clerical, housekeeping, maintenance, or volunteer personnel). Recommendations in this report are designed to prevent or reduce potential for disease transmission from patient to DHCP, from DHCP to patient, and from patient to patient. Although these guidelines focus mainly on outpatient, ambulatory dental health-care settings, the recommended infection-control practices are applicable to all settings in which dental treatment is provided.

Dental patients and DHCP can be exposed to pathogenic microorganisms including cytomegalovirus (CMV), HBV, HCV, herpes simplex virus types 1 and 2, HIV, *Mycobacterium tuberculosis*, staphylococci, streptococci, and other viruses and bacteria that colonize or infect the oral cavity and respiratory tract. These organisms can be transmitted in dental settings through 1) direct contact with blood, oral fluids, or other patient materials; 2) indirect contact with contaminated objects (e.g., instruments, equipment, or environmental surfaces); 3) contact of conjunctival, nasal, or oral mucosa with

droplets (e.g., spatter) containing microorganisms generated from an infected person and propelled a short distance (e.g., by coughing, sneezing, or talking); and 4) inhalation of airborne microorganisms that can remain suspended in the air for long periods (5).

Infection through any of these routes requires that all of the following conditions be present:

- a pathogenic organism of sufficient virulence and in adequate numbers to cause disease;
- a reservoir or source that allows the pathogen to survive and multiply (e.g., blood);
- a mode of transmission from the source to the host;
- a portal of entry through which the pathogen can enter the host; and
- a susceptible host (i.e., one who is not immune).

Occurrence of these events provides the chain of infection (6). Effective infection-control strategies prevent disease transmission by interrupting one or more links in the chain.

Previous CDC recommendations regarding infection control for dentistry focused primarily on the risk of transmission of bloodborne pathogens among DHCP and patients and use of universal precautions to reduce that risk (1,2,7,8). Universal precautions were based on the concept that all blood and body fluids that might be contaminated with blood should be treated as infectious because patients with bloodborne infections can be asymptomatic or unaware they are infected (9,10). Preventive practices used to reduce blood exposures, particularly percutaneous exposures, include 1) careful handling of sharp instruments, 2) use of rubber dams to minimize blood spattering; 3) handwashing; and 4) use of protective barriers (e.g., gloves, masks, protective eyewear, and gowns).

The relevance of universal precautions to other aspects of disease transmission was recognized, and in 1996, CDC expanded the concept and changed the term to *standard precautions*. Standard precautions integrate and expand the elements of universal precautions into a standard of care designed to protect HCP and patients from pathogens that can be spread by blood or any other body fluid, excretion, or secretion (11). Standard precautions apply to contact with 1) blood; 2) all body fluids, secretions, and excretions (except sweat), regardless of whether they contain blood; 3) nonintact skin; and 4) mucous membranes. Saliva has always been considered a potentially infectious material in dental infection control; thus, no operational difference exists in clinical dental practice between universal precautions and standard precautions.

In addition to standard precautions, other measures (e.g., expanded or transmission-based precautions) might be necessary to prevent potential spread of certain diseases (e.g., TB, influenza, and varicella) that are transmitted through airborne,



droplet, or contact transmission (e.g., sneezing, coughing, and contact with skin) (11). When acutely ill with these diseases, patients do not usually seek routine dental outpatient care. Nonetheless, a general understanding of precautions for diseases transmitted by all routes is critical because 1) some DHCP are hospital-based or work part-time in hospital settings; 2) patients infected with these diseases might seek urgent treatment at outpatient dental offices; and 3) DHCP might become infected with these diseases. Necessary transmission-based precautions might include patient placement (e.g., isolation), adequate room ventilation, respiratory protection (e.g., N-95 masks) for DHCP, or postponement of nonemergency dental procedures.

DHCP should be familiar also with the hierarchy of controls that categorizes and prioritizes prevention strategies (12). For bloodborne pathogens, engineering controls that eliminate or isolate the hazard (e.g., puncture-resistant sharps containers or needle-retraction devices) are the primary strategies for protecting DHCP and patients. Where engineering controls are not available or appropriate, work-practice controls that result in safer behaviors (e.g., one-hand needle recapping or not using fingers for cheek retraction while using sharp instruments or suturing), and use of personal protective equipment (PPE) (e.g., protective eyewear, gloves, and mask) can prevent exposure (13). In addition, administrative controls (e.g., policies, procedures, and enforcement measures targeted at reducing the risk of exposure to infectious persons) are a priority for certain pathogens (e.g., *M. tuberculosis*), particularly those spread by airborne or droplet routes.

Dental practices should develop a written infection-control program to prevent or reduce the risk of disease transmission. Such a program should include establishment and implementation of policies, procedures, and practices (in conjunction with selection and use of technologies and products) to prevent work-related injuries and illnesses among DHCP as well as health-care-associated infections among patients. The program should embody principles of infection control and occupational health, reflect current science, and adhere to relevant federal, state, and local regulations and statutes. An infection-control coordinator (e.g., dentist or other DHCP) knowledgeable or willing to be trained should be assigned responsibility for coordinating the program. The effectiveness of the infection-control program should be evaluated on a day-to-day basis and over time to help ensure that policies, procedures, and practices are useful, efficient, and successful (see Program Evaluation).

Although the infection-control coordinator remains responsible for overall management of the program, creating and maintaining a safe work environment ultimately requires the

commitment and accountability of all DHCP. This report is designed to provide guidance to DHCP for preventing disease transmission in dental health-care settings, for promoting a safe working environment, and for assisting dental practices in developing and implementing infection-control programs. These programs should be followed in addition to practices and procedures for worker protection required by the Occupational Safety and Health Administration's (OSHA) standards for occupational exposure to bloodborne pathogens (13), including instituting controls to protect employees from exposure to blood or other potentially infectious materials (OPIM), and requiring implementation of a written exposure-control plan, annual employee training, HBV vaccinations, and postexposure follow-up (13). Interpretations and enforcement procedures are available to help DHCP apply this OSHA standard in practice (14). Also, manufacturer's Material Safety Data Sheets (MSDS) should be consulted regarding correct procedures for handling or working with hazardous chemicals (15).

## Previous Recommendations

This report includes relevant infection-control measures from the following previously published CDC guidelines and recommendations:

- CDC. Guideline for disinfection and sterilization in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR (in press).
- CDC. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52(No. RR-10).
- CDC. Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51(No. RR-10).
- CDC. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR-16).
- CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. MMWR 2001;50(No. RR-11).
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## Selected Definitions

*Alcohol-based hand rub:* An alcohol-containing preparation designed for reducing the number of viable microorganisms on the hands.

*Antimicrobial soap:* A detergent containing an antiseptic agent.

*Antiseptic:* A germicide used on skin or living tissue for the purpose of inhibiting or destroying microorganisms (e.g., alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol [PCMX], quaternary ammonium compounds, and triclosan).

*Bead sterilizer:* A device using glass beads 1.2–1.5 mm diameter and temperatures 217°C–232°C for brief exposures (e.g., 45 seconds) to inactivate microorganisms. (This term is actually a misnomer because it has not been cleared by the Food and Drug Administration [FDA] as a sterilizer).

*Bioburden:* Microbiological load (i.e., number of viable organisms in or on an object or surface) or organic material on a surface or object before decontamination, or sterilization. Also known as *bioload* or *microbial load*.

*Colony-forming unit (CFU):* The minimum number (i.e., tens of millions) of separable cells on the surface of or in semi-solid agar medium that give rise to a visible colony of progeny. CFUs can consist of pairs, chains, clusters, or as single cells and are often expressed as colony-forming units per milliliter (CFUs/mL).

*Decontamination:* Use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item so that they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

*Dental treatment water:* Nonsterile water used during dental treatment, including irrigation of nonsurgical operative sites and cooling of high-speed rotary and ultrasonic instruments.

*Disinfectant:* A chemical agent used on inanimate objects (e.g., floors, walls, or sinks) to destroy virtually all recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial endospores). The U.S. Environmental Protection Agency (EPA) groups disinfectants on the basis of whether the product label claims limited, general, or hospital disinfectant capabilities.

*Disinfection:* Destruction of pathogenic and other kinds of microorganisms by physical or chemical means. Disinfection is less lethal than sterilization, because it destroys the majority of recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g., bacterial spores). Disinfection does not ensure the degree of safety associated with sterilization processes.

*Droplet nuclei:* Particles  $\leq 5 \mu\text{m}$  in diameter formed by dehydration of airborne droplets containing microorganisms that can remain suspended in the air for long periods of time.

*Droplets:* Small particles of moisture (e.g., spatter) generated when a person coughs or sneezes, or when water is converted to a fine mist by an aerator or shower head. These particles, intermediate in size between drops and droplet nuclei, can contain infectious microorganisms and tend to quickly settle from the air such that risk of disease transmission is usually limited to persons in close proximity to the droplet source.

*Endotoxin:* The lipopolysaccharide of gram-negative bacteria, the toxic character of which resides in the lipid protein. Endotoxins can produce pyrogenic reactions in persons exposed to their bacterial component.

*Germicide:* An agent that destroys microorganisms, especially pathogenic organisms. Terms with the same suffix (e.g., *virucide*, *fungicide*, *bactericide*, *tuberculocide*, and *sporicide*) indi-

cate agents that destroy the specific microorganism identified by the prefix. Germicides can be used to inactivate microorganisms in or on living tissue (i.e., antiseptics) or on environmental surfaces (i.e., disinfectants).

*Hand hygiene:* General term that applies to handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antiseptics.

*Health-care-associated infection:* Any infection associated with a medical or surgical intervention. The term *health-care-associated* replaces *nosocomial*, which is limited to adverse infectious outcomes occurring in hospitals.

*Hepatitis B immune globulin (HBIG):* Product used for prophylaxis against HBV infection. HBIG is prepared from plasma containing high titers of hepatitis B surface antibody (anti-HBs) and provides protection for 3–6 mos.

*Hepatitis B surface antigen (HBsAg):* Serologic marker on the surface of HBV detected in high levels during acute or chronic hepatitis. The body normally produces antibodies to surface antigen as a normal immune response to infection.

*Hepatitis B e antigen (HBeAg):* Secreted product of the nucleocapsid gene of HBV found in serum during acute and chronic HBV infection. Its presence indicates that the virus is replicating and serves as a marker of increased infectivity.

*Hepatitis B surface antibody (anti-HBs):* Protective antibody against HBsAg. Presence in the blood can indicate past infection with, and immunity to, HBV, or immune response from hepatitis B vaccine.

*Heterotrophic bacteria:* Those bacteria requiring an organic carbon source for growth (i.e., deriving energy and carbon from organic compounds).

*High-level disinfection:* Disinfection process that inactivates vegetative bacteria, mycobacteria, fungi, and viruses but not necessarily high numbers of bacterial spores. FDA further defines a high-level disinfectant as a sterilant used for a shorter contact time.

*Hospital disinfectant:* Germicide registered by EPA for use on inanimate objects in hospitals, clinics, dental offices, and other medical-related facilities. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

*Iatrogenic:* Induced inadvertently by HCP, medical (including dental) treatment, or diagnostic procedures. Used particularly in reference to an infectious disease or other complication of treatment.

*Immunization:* Process by which a person becomes immune, or protected against a disease. Vaccination is defined as the process of administering a killed or weakened infectious organism or a toxoid; however, vaccination does not always result in immunity.

*Implantable device:* Device placed into a surgically or naturally formed cavity of the human body and intended to remain there for  $\geq 30$  days.

*Independent water reservoir:* Container used to hold water or other solutions and supply it to handpieces and air and water syringes attached to a dental unit. The independent reservoir, which isolates the unit from the public water system, can be provided as original equipment or as a retrofitted device.

*Intermediate-level disinfection:* Disinfection process that inactivates vegetative bacteria, the majority of fungi, mycobacteria, and the majority of viruses (particularly enveloped viruses) but not bacterial spores.

*Intermediate-level disinfectant:* Liquid chemical germicide registered with EPA as a hospital disinfectant and with a label claim of potency as tuberculocidal (Appendix A).

*Latex:* Milky white fluid extracted from the rubber tree *Hevea brasiliensis* that contains the rubber material cis-1,4 polyisoprene.

*Low-level disinfection:* Process that inactivates the majority of vegetative bacteria, certain fungi, and certain viruses, but cannot be relied on to inactivate resistant microorganisms (e.g., mycobacteria or bacterial spores).

*Low-level disinfectant:* Liquid chemical germicide registered with EPA as a hospital disinfectant. OSHA requires low-level hospital disinfectants also to have a label claim for potency against HIV and HBV if used for disinfecting clinical contact surfaces (Appendix A).

*Microfilter:* Membrane filter used to trap microorganisms suspended in water. Filters are usually installed on dental unit waterlines as a retrofit device. Microfiltration commonly occurs at a filter pore size of 0.03–10  $\mu\text{m}$ . Sediment filters commonly found in dental unit water regulators have pore sizes of 20–90  $\mu\text{m}$  and do not function as microbiological filters.

*Nosocomial:* Infection acquired in a hospital as a result of medical care.

*Occupational exposure:* Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM that can result from the performance of an employee's duties.

*OPIM:* Other potentially infectious materials. OPIM is an OSHA term that refers to 1) body fluids including semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid visibly contaminated with blood; and all body fluids in situations where differentiating between body fluids is difficult or impossible; 2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and 3) HIV-containing cell or tissue cultures, organ



cultures; HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

*Parenteral:* Means of piercing mucous membranes or skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

*Persistent activity:* Prolonged or extended activity that prevents or inhibits proliferation or survival of microorganisms after application of a product. This activity can be demonstrated by sampling a site minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. Previously, this property was sometimes termed *residual activity*.

*Prion:* Protein particle lacking nucleic acid that has been implicated as the cause of certain neurodegenerative diseases (e.g., scrapie, CJD, and bovine spongiform encephalopathy [BSE]).

*Retraction:* Entry of oral fluids and microorganisms into waterlines through negative water pressure.

*Seroconversion:* The change of a serological test from negative to positive indicating the development of antibodies in response to infection or immunization.

*Sterile:* Free from all living microorganisms; usually described as a probability (e.g., the probability of a surviving microorganism being 1 in 1 million).

*Sterilization:* Use of a physical or chemical procedure to destroy all microorganisms including substantial numbers of resistant bacterial spores.

*Surfactants:* Surface-active agents that reduce surface tension and help cleaning by loosening, emulsifying, and holding soil in suspension, to be more readily rinsed away.

*Ultrasonic cleaner:* Device that removes debris by a process called cavitation, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces.

*Vaccination:* See immunization.

*Vaccine:* Product that induces immunity, therefore protecting the body from the disease. Vaccines are administered through needle injections, by mouth, and by aerosol.

*Washer-disinfecter:* Automatic unit that cleans and thermally disinfects instruments, by using a high-temperature cycle rather than a chemical bath.

*Wicking:* Absorption of a liquid by capillary action along a thread or through the material (e.g., penetration of liquids through undetected holes in a glove).

## Review of Science Related to Dental Infection Control

### Personnel Health Elements of an Infection-Control Program

A protective health component for DHCP is an integral part of a dental practice infection-control program. The objectives are to educate DHCP regarding the principles of infection control, identify work-related infection risks, institute preventive measures, and ensure prompt exposure management and medical follow-up. Coordination between the dental practice's infection-control coordinator and other qualified health-care professionals is necessary to provide DHCP with appropriate services. Dental programs in institutional settings, (e.g., hospitals, health centers, and educational institutions) can coordinate with departments that provide personnel health services. However, the majority of dental practices are in ambulatory, private settings that do not have licensed medical staff and facilities to provide complete on-site health service programs. In such settings, the infection-control coordinator should establish programs that arrange for site-specific infection-control services from external health-care facilities and providers before DHCP are placed at risk for exposure. Referral arrangements can be made with qualified health-care professionals in an occupational health program of a hospital, with educational institutions, or with health-care facilities that offer personnel health services.

### Education and Training

Personnel are more likely to comply with an infection-control program and exposure-control plan if they understand its rationale (5,13,16). Clearly written policies, procedures, and guidelines can help ensure consistency, efficiency, and effective coordination of activities. Personnel subject to occupational exposure should receive infection-control training on initial assignment, when new tasks or procedures affect their occupational exposure, and at a minimum, annually (13). Education and training should be appropriate to the assigned duties of specific DHCP (e.g., techniques to prevent cross-contamination or instrument sterilization). For DHCP who perform tasks or procedures likely to result in occupational exposure to infectious agents, training should include 1) a description of their exposure risks; 2) review of prevention strategies and infection-control policies and procedures; 3) discussion regarding how to manage work-related illness and injuries, including PEP; and 4) review of work restrictions for the exposure or infection. Inclusion of DHCP with minimal exposure risks (e.g., administrative employees) in education and training programs might enhance facilitywide understand-

ing of infection-control principles and the importance of the program. Educational materials should be appropriate in content and vocabulary for each person's educational level, literacy, and language, as well as be consistent with existing federal, state, and local regulations (5,13).

### Immunization Programs

DHCP are at risk for exposure to, and possible infection with, infectious organisms. Immunizations substantially reduce both the number of DHCP susceptible to these diseases and the potential for disease transmission to other DHCP and patients (5,17). Thus, immunizations are an essential part of prevention and infection-control programs for DHCP, and a comprehensive immunization policy should be implemented for all dental health-care facilities (17,18). The Advisory Committee on Immunization Practices (ACIP) provides national guidelines for immunization of HCP, which includes DHCP (17). Dental practice immunization policies should incorporate current state and federal regulations as well as recommendations from the U.S. Public Health Service and professional organizations (17) (Appendix B).

On the basis of documented health-care-associated transmission, HCP are considered to be at substantial risk for acquiring or transmitting hepatitis B, influenza, measles, mumps, rubella, and varicella. All of these diseases are vaccine-preventable. ACIP recommends that all HCP be vaccinated or have documented immunity to these diseases (5,17). ACIP does not recommend routine immunization of HCP against TB (i.e., inoculation with bacille Calmette-Guérin vaccine) or hepatitis A (17). No vaccine exists for HCV. ACIP guidelines also provide recommendations regarding immunization of HCP with special conditions (e.g., pregnancy, HIV infection, or diabetes) (5,17).

Immunization of DHCP before they are placed at risk for exposure remains the most efficient and effective use of vaccines in health-care settings. Some educational institutions and infection-control programs provide immunization schedules for students and DHCP. OSHA requires that employers make hepatitis B vaccination available to all employees who have potential contact with blood or OPIM. Employers are also required to follow CDC recommendations for vaccinations, evaluation, and follow-up procedures (13). Nonpatient-care staff (e.g., administrative or housekeeping) might be included, depending on their potential risk of coming into contact with blood or OPIM. Employers are also required to ensure that employees who decline to accept hepatitis B vaccination sign an appropriate declination statement (13). DHCP unable or unwilling to be vaccinated as required or recommended should be educated regarding their exposure risks, infection-control policies and procedures for the facility, and the management

of work-related illness and work restrictions (if appropriate) for exposed or infected DHCP.

### Exposure Prevention and Postexposure Management

Avoiding exposure to blood and OPIM, as well as protection by immunization, remain primary strategies for reducing occupationally acquired infections, but occupational exposures can still occur (19). A combination of standard precautions, engineering, work practice, and administrative controls is the best means to minimize occupational exposures. Written policies and procedures to facilitate prompt reporting, evaluation, counseling, treatment, and medical follow-up of all occupational exposures should be available to all DHCP. Written policies and procedures should be consistent with federal, state, and local requirements addressing education and training, postexposure management, and exposure reporting (see Preventing Transmission of Bloodborne Pathogens).

DHCP who have contact with patients can also be exposed to persons with infectious TB, and should have a baseline tuberculin skin test (TST), preferably by using a two-step test, at the beginning of employment (20). Thus, if an unprotected occupational exposure occurs, TST conversions can be distinguished from positive TST results caused by previous exposures (20,21). The facility's level of TB risk will determine the need for routine follow-up TSTs (see Special Considerations).

### Medical Conditions, Work-Related Illness, and Work Restrictions

DHCP are responsible for monitoring their own health status. DHCP who have acute or chronic medical conditions that render them susceptible to opportunistic infection should discuss with their personal physicians or other qualified authority whether the condition might affect their ability to safely perform their duties. However, under certain circumstances, health-care facility managers might need to exclude DHCP from work or patient contact to prevent further transmission of infection (22). Decisions concerning work restrictions are based on the mode of transmission and the period of infectivity of the disease (5) (Table 1). Exclusion policies should 1) be written, 2) include a statement of authority that defines who can exclude DHCP (e.g., personal physicians), and 3) be clearly communicated through education and training. Policies should also encourage DHCP to report illnesses or exposures without jeopardizing wages, benefits, or job status.

With increasing concerns regarding bloodborne pathogens and introduction of universal precautions, use of latex gloves among HCP has increased markedly (7,23). Increased use of these gloves has been accompanied by increased reports of allergic reactions to natural rubber latex among HCP, DHCP, and patients

**TABLE 1. Suggested work restrictions for health-care personnel infected with or exposed to major infectious diseases in health-care settings, in the absence of state and local regulations\***

Disease/problem	Work restriction	Duration
Conjunctivitis	Restrict from patient contact and contact with patient's environment.	Until discharge ceases
Cytomegalovirus infection	No restriction	
Diarrheal disease		
Acute stage (diarrhea with other symptoms)	Restrict from patient contact, contact with patient's environment, and food-handling.	Until symptoms resolve
Convalescent stage, <i>Salmonella</i> species	Restrict from care of patients at high risk.	Until symptoms resolve; consult with local and state health authorities regarding need for negative stool cultures
Enteroviral infection	Restrict from care of infants, neonates, and immunocompromised patients and their environments.	Until symptoms resolve
Hepatitis A	Restrict from patient contact, contact with patient's environment, and food-handling.	Until 7 days after onset of jaundice
Hepatitis B		
Personnel with acute or chronic hepatitis B surface antigenemia who do not perform exposure-prone procedures	No restriction <sup>†</sup> ; refer to state regulations. Standard precautions should always be followed.	
Personnel with acute or chronic hepatitis B e antigenemia who perform exposure-prone procedures	Do not perform exposure-prone invasive procedures until counsel from a review panel has been sought; panel should review and recommend procedures that personnel can perform, taking into account specific procedures as well as skill and technique. Standard precautions should always be observed. Refer to state and local regulations or recommendations.	Until hepatitis B e antigen is negative
Hepatitis C	No restrictions on professional activity. <sup>†</sup> HCV-positive health-care personnel should follow aseptic technique and standard precautions.	
Herpes simplex		
Genital	No restriction	
Hands (herpetic whitlow)	Restrict from patient contact and contact with patient's environment.	Until lesions heal
Orofacial	Evaluate need to restrict from care of patients at high risk.	
Human immunodeficiency virus; personnel who perform exposure-prone procedures	Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures that personnel can perform, taking into account specific procedures as well as skill and technique. Standard precautions should always be observed. Refer to state and local regulations or recommendations.	
Measles		
Active	Exclude from duty	Until 7 days after the rash appears
Postexposure (susceptible personnel)	Exclude from duty	From fifth day after first exposure through twenty-first day after last exposure, or 4 days after rash appears
Meningococcal infection	Exclude from duty	Until 24 hours after start of effective therapy
Mumps		
Active	Exclude from duty	Until 9 days after onset of parotitis
Postexposure (susceptible personnel)	Exclude from duty	From twelfth day after first exposure through twenty-sixth day after last exposure, or until 9 days after onset of parotitis

**Source:** Adapted from Bolyard EA, Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. *Am J Infect Control* 1998;26:289-354.

\* Modified from recommendations of the Advisory Committee on Immunization Practices (ACIP).

† Unless epidemiologically linked to transmission of infection.

§ Those susceptible to varicella and who are at increased risk of complications of varicella (e.g., neonates and immunocompromised persons of any age).

¶ Patients at high risk as defined by ACIP for complications of influenza.

**TABLE 1. (Continued) Suggested work restrictions for health-care personnel infected with or exposed to major infectious diseases in health-care settings, in the absence of state and local regulations\***

Disease/problem	Work restriction	Duration
Pediculosis	Restrict from patient contact	Until treated and observed to be free of adult and immature lice
Pertussis		
Active	Exclude from duty	From beginning of catarrhal stage through third week after onset of paroxysms, or until 5 days after start of effective antibiotic therapy
Postexposure (asymptomatic personnel)	No restriction, prophylaxis recommended	
Postexposure (symptomatic personnel)	Exclude from duty	Until 5 days after start of effective antibiotic therapy
Rubella		
Active	Exclude from duty	Until 5 days after rash appears
Postexposure (susceptible personnel)	Exclude from duty	From seventh day after first exposure through twenty-first day after last exposure
<i>Staphylococcus aureus</i> infection		
Active, draining skin lesions	Restrict from contact with patients and patient's environment or food handling.	Until lesions have resolved
Carrier state	No restriction unless personnel are epidemiologically linked to transmission of the organism	
Streptococcal infection, group A	Restrict from patient care, contact with patient's environment, and food-handling.	Until 24 hours after adequate treatment started
Tuberculosis		
Active disease	Exclude from duty	Until proved noninfectious
PPD converter	No restriction	
Varicella (chicken pox)		
Active	Exclude from duty	Until all lesions dry and crust
Postexposure (susceptible personnel)	Exclude from duty	From tenth day after first exposure through twenty-first day (twenty-eighth day if varicella-zoster immune globulin [VZIG] administered) after last exposure.
Zoster (shingles)		
Localized, in healthy person	Cover lesions, restrict from care of patients <sup>§</sup> at high risk	Until all lesions dry and crust
Generalized or localized in immunosuppressed person	Restrict from patient contact	Until all lesions dry and crust
Postexposure (susceptible personnel)	Restrict from patient contact	From tenth day after first exposure through twenty-first day (twenty-eighth day if VZIG administered) after last exposure; or, if varicella occurs, when lesions crust and dry
Viral respiratory infection, acute febrile	Consider excluding from the care of patients at high risk <sup>¶</sup> or contact with such patients' environments during community outbreak of respiratory syncytial virus and influenza	Until acute symptoms resolve

**Source:** Adapted from Bolyard EA, Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. *Am J Infect Control* 1998;26:289–354.

\* Modified from recommendations of the Advisory Committee on Immunization Practices (ACIP).

† Unless epidemiologically linked to transmission of infection.

§ Those susceptible to varicella and who are at increased risk of complications of varicella (e.g., neonates and immunocompromised persons of any age).

¶ Patients at high risk as defined by ACIP for complications of influenza.

(24–30), as well as increased reports of irritant and allergic contact dermatitis from frequent and repeated use of hand-hygiene products, exposure to chemicals, and glove use.

DHCP should be familiar with the signs and symptoms of latex sensitivity (5,31–33). A physician should evaluate DHCP exhibiting symptoms of latex allergy, because further exposure could result in a serious allergic reaction. A diagnosis is made through medical history, physical examination, and diagnostic tests. Procedures should be in place for minimizing latex-related health problems among DHCP and patients while protecting them from infectious materials. These procedures should include 1) reducing exposures to latex-containing materials by using appropriate work practices, 2) training and educating DHCP, 3) monitoring symptoms, and 4) substituting nonlatex products where appropriate (32) (see Contact Dermatitis and Latex Hypersensitivity).

### **Maintenance of Records, Data Management, and Confidentiality**

The health status of DHCP can be monitored by maintaining records of work-related medical evaluations, screening tests, immunizations, exposures, and postexposure management. Such records must be kept in accordance with all applicable state and federal laws. Examples of laws that might apply include the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 45 CFR 160 and 164, and the OSHA Occupational Exposure to Bloodborne Pathogens; Final Rule 29 CFR 1910.1030(h)(1)(i–iv) (34,13). The HIPAA Privacy Rule applies to covered entities, including certain defined health providers, health-care clearinghouses, and health plans. OSHA requires employers to ensure that certain information contained in employee medical records is 1) kept confidential; 2) not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by the OSHA standard; and 3) maintained by the employer for at least the duration of employment plus 30 years. Dental practices that coordinate their infection-control program with off-site providers might consult OSHA's Bloodborne Pathogen standard and employee Access to Medical and Exposure Records standard, as well as other applicable local, state, and federal laws, to determine a location for storing health records (13,35).

### **Preventing Transmission of Bloodborne Pathogens**

Although transmission of bloodborne pathogens (e.g., HBV, HCV, and HIV) in dental health-care settings can have serious consequences, such transmission is rare. Exposure to

infected blood can result in transmission from patient to DHCP, from DHCP to patient, and from one patient to another. The opportunity for transmission is greatest from patient to DHCP, who frequently encounter patient blood and blood-contaminated saliva during dental procedures.

Since 1992, no HIV transmission from DHCP to patients has been reported, and the last HBV transmission from DHCP to patients was reported in 1987. HCV transmission from DHCP to patients has not been reported. The majority of DHCP infected with a bloodborne virus do not pose a risk to patients because they do not perform activities meeting the necessary conditions for transmission. For DHCP to pose a risk for bloodborne virus transmission to patients, DHCP must 1) be viremic (i.e., have infectious virus circulating in the bloodstream); 2) be injured or have a condition (e.g., weeping dermatitis) that allows direct exposure to their blood or other infectious body fluids; and 3) enable their blood or infectious body fluid to gain direct access to a patient's wound, traumatized tissue, mucous membranes, or similar portal of entry. Although an infected DHCP might be viremic, unless the second and third conditions are also met, transmission cannot occur.

The risk of occupational exposure to bloodborne viruses is largely determined by their prevalence in the patient population and the nature and frequency of contact with blood and body fluids through percutaneous or permucosal routes of exposure. The risk of infection after exposure to a bloodborne virus is influenced by inoculum size, route of exposure, and susceptibility of the exposed HCP (12). The majority of attention has been placed on the bloodborne pathogens HBV, HCV, and HIV, and these pathogens present different levels of risk to DHCP.

### **Hepatitis B Virus**

HBV is a well-recognized occupational risk for HCP (36,37). HBV is transmitted by percutaneous or mucosal exposure to blood or body fluids of a person with either acute or chronic HBV infection. Persons infected with HBV can transmit the virus for as long as they are HBsAg-positive. The risk of HBV transmission is highly related to the HBeAg status of the source person. In studies of HCP who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis if the blood was positive for both HBsAg and HBeAg was 22%–31%; the risk of developing serologic evidence of HBV infection was 37%–62% (19). By comparison, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was 1%–6%, and the risk of developing serologic evidence of HBV infection, 23%–37% (38).



Blood contains the greatest proportion of HBV infectious particle titers of all body fluids and is the most critical vehicle of transmission in the health-care setting. HBsAg is also found in multiple other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid. However, the majority of body fluids are not efficient vehicles for transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg (19). The concentration of HBsAg in body fluids can be 100–1,000-fold greater than the concentration of infectious HBV particles (39).

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among HCP. In multiple investigations of nosocomial hepatitis B outbreaks, the majority of infected HCP could not recall an overt percutaneous injury (40,41), although in certain studies, approximately one third of infected HCP recalled caring for a patient who was HBsAg-positive (42,43). In addition, HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for  $\leq 1$  week (44). Thus, HBV infections that occur in HCP with no history of nonoccupational exposure or occupational percutaneous injury might have resulted from direct or indirect blood or body fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (45–47). The potential for HBV transmission through contact with environmental surfaces has been demonstrated in investigations of HBV outbreaks among patients and HCP in hemodialysis units (48–50).

Since the early 1980s, occupational infections among HCP have declined because of vaccine use and adherence to universal precautions (51). Among U.S. dentists, >90% have been vaccinated, and serologic evidence of past HBV infection decreased from prevaccine levels of 14% in 1972 to approximately 9% in 1992 (52). During 1993–2001, levels remained relatively unchanged (Chakwan Siew, Ph.D., American Dental Association, Chicago, Illinois, personal communication, June 2003). Infection rates can be expected to decline further as vaccination rates remain high among young dentists and as older dentists with lower vaccination rates and higher rates of infection retire.

Although the potential for transmission of bloodborne infections from DHCP to patients is considered limited (53–55), precise risks have not been quantified by carefully designed epidemiologic studies (53,56,57). Reports published during 1970–1987 describe nine clusters in which patients were thought to be infected with HBV through treatment by an infected DHCP (58–67). However, transmission of HBV

from dentist to patient has not been reported since 1987, possibly reflecting such factors as 1) adoption of universal precautions, 2) routine glove use, 3) increased levels of immunity as a result of hepatitis B vaccination of DHCP, 4) implementation of the 1991 OSHA bloodborne pathogen standard (68), and 5) incomplete ascertainment and reporting. Only one case of patient-to-patient transmission of HBV in the dental setting has been documented (CDC, unpublished data, 2003). In this case, appropriate office infection-control procedures were being followed, and the exact mechanism of transmission was undetermined.

Because of the high risk of HBV infection among HCP, DHCP who perform tasks that might involve contact with blood, blood-contaminated body substances, other body fluids, or sharps should be vaccinated (2,13,17,19,69). Vaccination can protect both DHCP and patients from HBV infection and, whenever possible, should be completed when dentists or other DHCP are in training and before they have contact with blood.

Prevaccination serological testing for previous infection is not indicated, although it can be cost-effective where prevalence of infection is expected to be high in a group of potential vaccinees (e.g., persons who have emigrated from areas with high rates of HBV infection). DHCP should be tested for anti-HBs 1–2 months after completion of the 3-dose vaccination series (17). DHCP who do not develop an adequate antibody response (i.e., anti-HBs <10 mIU/mL) to the primary vaccine series should complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAg-positive (17). Revaccinated persons should be retested for anti-HBs at the completion of the second vaccine series. Approximately half of nonresponders to the primary series will respond to a second 3-dose series. If no antibody response occurs after the second series, testing for HBsAg should be performed (17). Persons who prove to be HBsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation. Nonresponders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood.

Vaccine-induced antibodies decline gradually over time, and 60% of persons who initially respond to vaccination will lose detectable antibodies over 12 years. Even so, immunity continues to prevent clinical disease or detectable viral infection (17). Booster doses of vaccine and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series are not necessary for vaccine responders (17).

## Hepatitis D Virus

An estimated 4% of persons with acute HBV infection are also infected with hepatitis Delta virus (HDV). Discovered in 1977, HDV is a defective bloodborne virus requiring the presence of HBV to replicate. Patients coinfecting with HBV and HDV have substantially higher mortality rates than those infected with HBV alone. Because HDV infection is dependent on HBV for replication, immunization to prevent HBV infection, through either pre- or postexposure prophylaxis, can also prevent HDV infection (70).

## Hepatitis C Virus

Hepatitis C virus appears not to be transmitted efficiently through occupational exposures to blood. Follow-up studies of HCP exposed to HCV-infected blood through percutaneous or other sharps injuries have determined a low incidence of seroconversion (mean: 1.8%; range, 0%–7%) (71–74). One study determined transmission occurred from hollow-bore needles but not other sharps (72). Although these studies have not documented seroconversion associated with mucous membrane or nonintact skin exposure, at least two cases of HCV transmission from a blood splash to the conjunctiva (75,76) and one case of simultaneous transmission of HCV and HIV after nonintact skin exposure have been reported (77).

Data are insufficient to estimate the occupational risk of HCV infection among HCP, but the majority of studies indicate the prevalence of HCV infection among dentists, surgeons, and hospital-based HCP is similar to that among the general population, approximately 1%–2% (78–86). In a study that evaluated risk factors for infection, a history of unintentional needlesticks was the only occupational risk factor independently associated with HCV infection (80).

No studies of transmission from HCV-infected DHCP to patients have been reported, and the risk for such transmission appears limited. Multiple reports have been published describing transmission from HCV-infected surgeons, which apparently occurred during performance of invasive procedures; the overall risk for infection averaged 0.17% (87–90).

## Human Immunodeficiency Virus

In the United States, the risk of HIV transmission in dental settings is extremely low. As of December 2001, a total of 57 cases of HIV seroconversion had been documented among HCP, but none among DHCP, after occupational exposure to a known HIV-infected source (91). Transmission of HIV to six patients of a single dentist with AIDS has been reported, but the mode of transmission could not be determined (2,92,93). As of September 30, 1993, CDC had information regarding test results of >22,000 patients of 63 HIV-infected

HCP, including 33 dentists or dental students (55,93). No additional cases of transmission were documented.

Prospective studies worldwide indicate the average risk of HIV infection after a single percutaneous exposure to HIV-infected blood is 0.3% (range: 0.2%–0.5%) (94). After an exposure of mucous membranes in the eye, nose, or mouth, the risk is approximately 0.1% (76). The precise risk of transmission after skin exposure remains unknown but is believed to be even smaller than that for mucous membrane exposure.

Certain factors affect the risk of HIV transmission after an occupational exposure. Laboratory studies have determined if needles that pass through latex gloves are solid rather than hollow-bore, or are of small gauge (e.g., anesthetic needles commonly used in dentistry), they transfer less blood (36). In a retrospective case-control study of HCP, an increased risk for HIV infection was associated with exposure to a relatively large volume of blood, as indicated by a deep injury with a device that was visibly contaminated with the patient's blood, or a procedure that involved a needle placed in a vein or artery (95). The risk was also increased if the exposure was to blood from patients with terminal illnesses, possibly reflecting the higher titer of HIV in late-stage AIDS.

## Exposure Prevention Methods

Avoiding occupational exposures to blood is the primary way to prevent transmission of HBV, HCV, and HIV, to HCP in health-care settings (19,96,97). Exposures occur through percutaneous injury (e.g., a needlestick or cut with a sharp object), as well as through contact between potentially infectious blood, tissues, or other body fluids and mucous membranes of the eye, nose, mouth, or nonintact skin (e.g., exposed skin that is chapped, abraded, or shows signs of dermatitis).

Observational studies and surveys indicate that percutaneous injuries among general dentists and oral surgeons occur less frequently than among general and orthopedic surgeons and have decreased in frequency since the mid-1980s (98–102). This decline has been attributed to safer work practices, safer instrumentation or design, and continued DHCP education (103,104). Percutaneous injuries among DHCP usually 1) occur outside the patient's mouth, thereby posing less risk for recontact with patient tissues; 2) involve limited amounts of blood; and 3) are caused by burs, syringe needles, laboratory knives, and other sharp instruments (99–102,105,106). Injuries among oral surgeons might occur more frequently during fracture reductions using wires (104,107). Experience, as measured by years in practice, does not appear to affect the risk of injury among general dentists or oral surgeons (100,104,107).

The majority of exposures in dentistry are preventable, and methods to reduce the risk of blood contacts have included use of standard precautions, use of devices with features engineered to prevent sharp injuries, and modifications of work practices. These approaches might have contributed to the decrease in percutaneous injuries among dentists during recent years (98–100,103). However, needlesticks and other blood contacts continue to occur, which is a concern because percutaneous injuries pose the greatest risk of transmission.

Standard precautions include use of PPE (e.g., gloves, masks, protective eyewear or face shield, and gowns) intended to prevent skin and mucous membrane exposures. Other protective equipment (e.g., finger guards while suturing) might also reduce injuries during dental procedures (104).

Engineering controls are the primary method to reduce exposures to blood and OPIM from sharp instruments and needles. These controls are frequently technology-based and often incorporate safer designs of instruments and devices (e.g., self-sheathing anesthetic needles and dental units designed to shield burs in handpieces) to reduce percutaneous injuries (101,103,108).

Work-practice controls establish practices to protect DHCP whose responsibilities include handling, using, assembling, or processing sharp devices (e.g., needles, scalers, laboratory utility knives, burs, explorers, and endodontic files) or sharps disposal containers. Work-practice controls can include removing burs before disassembling the handpiece from the dental unit, restricting use of fingers in tissue retraction or palpation during suturing and administration of anesthesia, and minimizing potentially uncontrolled movements of such instruments as scalers or laboratory knives (101,105).

As indicated, needles are a substantial source of percutaneous injury in dental practice, and engineering and work-practice controls for needle handling are of particular importance. In 2001, revisions to OSHA's bloodborne pathogens standard as mandated by the Needlestick Safety and Prevention Act of 2000 became effective. These revisions clarify the need for employers to consider safer needle devices as they become available and to involve employees directly responsible for patient care (e.g., dentists, hygienists, and dental assistants) in identifying and choosing such devices (109). Safer versions of sharp devices used in hospital settings have become available (e.g., blunt suture needles, phlebotomy devices, and butterfly needles), and their impact on reducing injuries has been documented (110–112). Aspirating anesthetic syringes that incorporate safety features have been developed for dental procedures, but the low injury rates in dentistry limit assessment of their effect on reducing injuries among DHCP.

Work-practice controls for needles and other sharps include placing used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to where the items were used (2,7,13,113–115). In addition, used needles should never be recapped or otherwise manipulated by using both hands, or any other technique that involves directing the point of a needle toward any part of the body (2,7,13,97,113,114). A one-handed scoop technique, a mechanical device designed for holding the needle cap to facilitate one-handed recapping, or an engineered sharps injury protection device (e.g., needles with resheathing mechanisms) should be employed for recapping needles between uses and before disposal (2,7,13,113,114). DHCP should never bend or break needles before disposal because this practice requires unnecessary manipulation. Before attempting to remove needles from nondisposable aspirating syringes, DHCP should recap them to prevent injuries. For procedures involving multiple injections with a single needle, the practitioner should recap the needle between injections by using a one-handed technique or use a device with a needle-resheathing mechanism. Passing a syringe with an unsheathed needle should be avoided because of the potential for injury.

Additional information for developing a safety program and for identifying and evaluating safer dental devices is available at

- <http://www.cdc.gov/OralHealth/infectioncontrol/forms.htm> (forms for screening and evaluating safer dental devices), and
- <http://www.cdc.gov/niosh/topics/bbp> (state legislation on needlestick safety).

### Postexposure Management and Prophylaxis

Postexposure management is an integral component of a complete program to prevent infection after an occupational exposure to blood. During dental procedures, saliva is predictably contaminated with blood (7,114). Even when blood is not visible, it can still be present in limited quantities and therefore is considered a potentially infectious material by OSHA (13,19). A qualified health-care professional should evaluate any occupational exposure incident to blood or OPIM, including saliva, regardless of whether blood is visible, in dental settings (13).

Dental practices and laboratories should establish written, comprehensive programs that include hepatitis B vaccination and postexposure management protocols that 1) describe the types of contact with blood or OPIM that can place DHCP at risk for infection; 2) describe procedures for promptly reporting and evaluating such exposures; and 3) identify a health-



care professional who is qualified to provide counseling and perform all medical evaluations and procedures in accordance with current recommendations of the U.S. Public Health Service (PHS), including PEP with chemotherapeutic drugs when indicated. DHCP, including students, who might reasonably be considered at risk for occupational exposure to blood or OPIM should be taught strategies to prevent contact with blood or OPIM and the principles of postexposure management, including PEP options, as part of their job orientation and training. Educational programs for DHCP and students should emphasize reporting all exposures to blood or OPIM as soon as possible, because certain interventions have to be initiated promptly to be effective. Policies should be consistent with the practices and procedures for worker protection required by OSHA and with current PHS recommendations for managing occupational exposures to blood (13,19).

After an occupational blood exposure, first aid should be administered as necessary. Puncture wounds and other injuries to the skin should be washed with soap and water; mucous membranes should be flushed with water. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended (19). Exposed DHCP should immediately report the exposure to the infection-control coordinator or other designated person, who should initiate referral to the qualified health-care professional and complete necessary reports. Because multiple factors contribute to the risk of infection after an occupational exposure to blood, the following information should be included in the exposure report, recorded in the exposed person's confidential medical record, and provided to the qualified health-care professional:

- Date and time of exposure.
- Details of the procedure being performed, including where and how the exposure occurred and whether the exposure involved a sharp device, the type and brand of device, and how and when during its handling the exposure occurred.
- Details of the exposure, including its severity and the type and amount of fluid or material. For a percutaneous injury, severity might be measured by the depth of the wound, gauge of the needle, and whether fluid was injected; for a skin or mucous membrane exposure, the estimated volume of material, duration of contact, and the condition of the skin (e.g., chapped, abraded, or intact) should be noted.
- Details regarding whether the source material was known to contain HIV or other bloodborne pathogens, and, if

the source was infected with HIV, the stage of disease, history of antiretroviral therapy, and viral load, if known.

- Details regarding the exposed person (e.g., hepatitis B vaccination and vaccine-response status).
- Details regarding counseling, postexposure management, and follow-up.

Each occupational exposure should be evaluated individually for its potential to transmit HBV, HCV, and HIV, based on the following:

- The type and amount of body substance involved.
- The type of exposure (e.g., percutaneous injury, mucous membrane or nonintact skin exposure, or bites resulting in blood exposure to either person involved).
- The infection status of the source.
- The susceptibility of the exposed person (19).

All of these factors should be considered in assessing the risk for infection and the need for further follow-up (e.g., PEP).

During 1990–1998, PHS published guidelines for PEP and other management of health-care worker exposures to HBV, HCV, or HIV (69,116–119). In 2001, these recommendations were updated and consolidated into one set of PHS guidelines (19). The new guidelines reflect the availability of new antiretroviral agents, new information regarding the use and safety of HIV PEP, and considerations regarding employing HIV PEP when resistance of the source patient's virus to antiretroviral agents is known or suspected. In addition, the 2001 guidelines provide guidance to clinicians and exposed HCP regarding when to consider HIV PEP and recommendations for PEP regimens (19).

## Hand Hygiene

Hand hygiene (e.g., handwashing, hand antisepsis, or surgical hand antisepsis) substantially reduces potential pathogens on the hands and is considered the single most critical measure for reducing the risk of transmitting organisms to patients and HCP (120–123). Hospital-based studies have demonstrated that noncompliance with hand hygiene practices is associated with health-care-associated infections and the spread of multiresistant organisms. Noncompliance also has been a major contributor to outbreaks (123). The prevalence of health-care-associated infections decreases as adherence of HCP to recommended hand hygiene measures improves (124–126).

The microbial flora of the skin, first described in 1938, consist of transient and resident microorganisms (127). Transient flora, which colonize the superficial layers of the skin, are easier to remove by routine handwashing. They are often acquired by HCP during direct contact with patients or contaminated environmental surfaces; these organisms are most frequently

associated with health-care-associated infections. Resident flora attached to deeper layers of the skin are more resistant to removal and less likely to be associated with such infections.

The preferred method for hand hygiene depends on the type of procedure, the degree of contamination, and the desired persistence of antimicrobial action on the skin (Table 2). For routine dental examinations and nonsurgical procedures, handwashing and hand antisepsis is achieved by using either a plain or antimicrobial soap and water. If the hands are not visibly soiled, an alcohol-based hand rub is adequate.

The purpose of surgical hand antisepsis is to eliminate transient flora and reduce resident flora for the duration of a procedure to prevent introduction of organisms in the operative wound, if gloves become punctured or torn. Skin bacteria can rapidly multiply under surgical gloves if hands are washed with soap that is not antimicrobial (127,128). Thus, an antimicrobial soap or alcohol hand rub with persistent activity should be used before surgical procedures (129–131).

Agents used for surgical hand antisepsis should substantially reduce microorganisms on intact skin, contain a nonirritating antimicrobial preparation, have a broad spectrum of activity, be fast-acting, and have a persistent effect (121,132–135). Persistence (i.e., extended antimicrobial activity that prevents or inhibits survival of microorganisms after the product is

applied) is critical because microorganisms can colonize on hands in the moist environment underneath gloves (122).

Alcohol hand rubs are rapidly germicidal when applied to the skin but should include such antiseptics as chlorhexidine, quaternary ammonium compounds, octenidine, or triclosan to achieve persistent activity (130). Factors that can influence the effectiveness of the surgical hand antisepsis in addition to the choice of antiseptic agent include duration and technique of scrubbing, as well as condition of the hands, and techniques used for drying and gloving. CDC's 2002 guideline on hand hygiene in health-care settings provides more complete information (123).

### Selection of Antiseptic Agents

Selecting the most appropriate antiseptic agent for hand hygiene requires consideration of multiple factors. Essential performance characteristics of a product (e.g., the spectrum and persistence of activity and whether or not the agent is fast-acting) should be determined before selecting a product. Delivery system, cost per use, reliable vendor support and supply are also considerations. Because HCP acceptance is a major factor regarding compliance with recommended hand hygiene protocols (122,123,147,148), considering DHCP needs is critical and should include possible chemical allergies,

**TABLE 2. Hand-hygiene methods and indications**

Method	Agent	Purpose	Duration (minimum)	Indication*
Routine handwash	Water and nonantimicrobial soap (e.g., plain soap <sup>†</sup> )	Remove soil and transient microorganisms	15 seconds <sup>§</sup>	Before and after treating each patient (e.g., before glove placement and after glove removal). After barehanded touching of inanimate objects likely to be contaminated by blood or saliva. Before leaving the dental operatory or the dental laboratory. When visibly soiled, <sup>¶</sup> Before regloving after removing gloves that are torn, cut, or punctured.
Antiseptic handwash	Water and antimicrobial soap (e.g., chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan)	Remove or destroy transient microorganisms and reduce resident flora	15 seconds <sup>§</sup>	
Antiseptic hand rub	Alcohol-based hand rub <sup>¶</sup>	Remove or destroy transient microorganisms and reduce resident flora	Rub hands until the agent is dry <sup>¶</sup>	
Surgical antisepsis	Water and antimicrobial soap (e.g., chlorhexidine, iodine and iodophors, chloroxylenol [PCMX], triclosan)	Remove or destroy transient microorganisms and reduce resident flora (persistent effect)	2–6 minutes	Before donning sterile surgeon's gloves for surgical procedures <sup>††</sup>
	Water and non-antimicrobial soap (e.g., plain soap <sup>†</sup> ) followed by an alcohol-based surgical hand-scrub product with persistent activity		Follow manufacturer instructions for surgical hand-scrub product with persistent activity <sup>¶**</sup>	

\* (7,9,11,13,113,120–123,125,126,136–138).

<sup>†</sup> Pathogenic organisms have been found on or around bar soap during and after use (139). Use of liquid soap with hands-free dispensing controls is preferable.

<sup>§</sup> Time reported as effective in removing most transient flora from the skin. For most procedures, a vigorous rubbing together of all surfaces of premoistened lathered hands and fingers for  $\geq 15$  seconds, followed by rinsing under a stream of cool or tepid water is recommended (9,120,123,140,141). Hands should always be dried thoroughly before donning gloves.

<sup>¶</sup> Alcohol-based hand rubs should contain 60%–95% ethanol or isopropanol and should not be used in the presence of visible soil or organic material. If using an alcohol-based hand rub, apply adequate amount to palm of one hand and rub hands together, covering all surfaces of the hands and fingers, until hands are dry. Follow manufacturer's recommendations regarding the volume of product to use. If hands feel dry after rubbing them together for 10–15 seconds, an insufficient volume of product likely was applied. The drying effect of alcohol can be reduced or eliminated by adding 1%–3% glycerol or other skin-conditioning agents (123).

<sup>\*\*</sup> After application of alcohol-based surgical hand-scrub product with persistent activity as recommended, allow hands and forearms to dry thoroughly and immediately don sterile surgeon's gloves (144,145). Follow manufacturer instructions (122,123,137,146).

<sup>††</sup> Before beginning surgical hand scrub, remove all arm jewelry and any hand jewelry that may make donning gloves more difficult, cause gloves to tear more readily (142,143), or interfere with glove usage (e.g., ability to wear the correct-sized glove or altered glove integrity).

skin integrity after repeated use, compatibility with lotions used, and offensive agent ingredients (e.g., scent). Discussing specific preparations or ingredients used for hand antisepsis is beyond the scope of this report. DHCP should choose from commercially available HCP handwashes when selecting agents for hand antisepsis or surgical hand antisepsis.

### **Storage and Dispensing of Hand Care Products**

Handwashing products, including plain (i.e., non-antimicrobial) soap and antiseptic products, can become contaminated or support the growth of microorganisms (122). Liquid products should be stored in closed containers and dispensed from either disposable containers or containers that are washed and dried thoroughly before refilling. Soap should not be added to a partially empty dispenser, because this practice of topping off might lead to bacterial contamination (149,150). Store and dispense products according to manufacturers' directions.

### **Lotions**

The primary defense against infection and transmission of pathogens is healthy, unbroken skin. Frequent handwashing with soaps and antiseptic agents can cause chronic irritant contact dermatitis among DHCP. Damage to the skin changes skin flora, resulting in more frequent colonization by staphylococci and gram-negative bacteria (151,152). The potential of detergents to cause skin irritation varies considerably, but can be reduced by adding emollients. Lotions are often recommended to ease the dryness resulting from frequent handwashing and to prevent dermatitis from glove use (153,154). However, petroleum-based lotion formulations can weaken latex gloves and increase permeability. For that reason, lotions that contain petroleum or other oil emollients should only be used at the end of the work day (122,155). Dental practitioners should obtain information from lotion manufacturers regarding interaction between lotions, gloves, dental materials, and antimicrobial products.

### **Fingernails and Artificial Nails**

Although the relationship between fingernail length and wound infection is unknown, keeping nails short is considered key because the majority of flora on the hands are found under and around the fingernails (156). Fingernails should be short enough to allow DHCP to thoroughly clean underneath them and prevent glove tears (122). Sharp nail edges or broken nails are also likely to increase glove failure. Long artificial or natural nails can make donning gloves more difficult and can cause gloves to tear more readily. Hand carriage of gram-negative organisms has been determined to be greater among

wearers of artificial nails than among nonwearers, both before and after handwashing (157–160). In addition, artificial fingernails or extenders have been epidemiologically implicated in multiple outbreaks involving fungal and bacterial infections in hospital intensive-care units and operating rooms (161–164). Freshly applied nail polish on natural nails does not increase the microbial load from periungual skin if fingernails are short; however, chipped nail polish can harbor added bacteria (165,166).

### **Jewelry**

Studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (167–170). In a study of intensive-care nurses, multivariable analysis determined rings were the only substantial risk factor for carriage of gram-negative bacilli and *Staphylococcus aureus*, and the concentration of organisms correlated with the number of rings worn (170). However, two other studies demonstrated that mean bacterial colony counts on hands after handwashing were similar among persons wearing rings and those not wearing rings (169,171). Whether wearing rings increases the likelihood of transmitting a pathogen is unknown; further studies are needed to establish whether rings result in higher transmission of pathogens in health-care settings. However, rings and decorative nail jewelry can make donning gloves more difficult and cause gloves to tear more readily (142,143). Thus, jewelry should not interfere with glove use (e.g., impair ability to wear the correct-sized glove or alter glove integrity).

### **Personal Protective Equipment**

PPE is designed to protect the skin and the mucous membranes of the eyes, nose, and mouth of DHCP from exposure to blood or OPIM. Use of rotary dental and surgical instruments (e.g., handpieces or ultrasonic scalers) and air-water syringes creates a visible spray that contains primarily large-particle droplets of water, saliva, blood, microorganisms, and other debris. This spatter travels only a short distance and settles out quickly, landing on the floor, nearby operatory surfaces, DHCP, or the patient. The spray also might contain certain aerosols (i.e., particles of respirable size, <10 µm). Aerosols can remain airborne for extended periods and can be inhaled. However, they should not be confused with the large-particle spatter that makes up the bulk of the spray from handpieces and ultrasonic scalers. Appropriate work practices, including use of dental dams (172) and high-velocity air evacuation, should minimize dissemination of droplets, spatter, and aerosols (2).

Primary PPE used in oral health-care settings includes gloves, surgical masks, protective eyewear, face shields, and protective

clothing (e.g., gowns and jackets). All PPE should be removed before DHCP leave patient-care areas (13). Reusable PPE (e.g., clinician or patient protective eyewear and face shields) should be cleaned with soap and water, and when visibly soiled, disinfected between patients, according to the manufacturer's directions (2,13). Wearing gloves, surgical masks, protective eyewear, and protective clothing in specified circumstances to reduce the risk of exposures to bloodborne pathogens is mandated by OSHA (13). General work clothes (e.g., uniforms, scrubs, pants, and shirts) are neither intended to protect against a hazard nor considered PPE.

### Masks, Protective Eyewear, Face Shields

A surgical mask that covers both the nose and mouth and protective eyewear with solid side shields or a face shield should be worn by DHCP during procedures and patient-care activities likely to generate splashes or sprays of blood or body fluids. Protective eyewear for patients shields their eyes from spatter or debris generated during dental procedures. A surgical mask protects against microorganisms generated by the wearer, with >95% bacterial filtration efficiency, and also protects DHCP from large-particle droplet spatter that might contain bloodborne pathogens or other infectious microorganisms (173). The mask's outer surface can become contaminated with infectious droplets from spray of oral fluids or from touching the mask with contaminated fingers. Also, when a mask becomes wet from exhaled moist air, the resistance to airflow through the mask increases, causing more airflow to pass around edges of the mask. If the mask becomes wet, it should be changed between patients or even during patient treatment, when possible (2,174).

When airborne infection isolation precautions (expanded or transmission-based) are necessary (e.g., for TB patients), a National Institute for Occupational Safety and Health (NIOSH)-certified particulate-filter respirator (e.g., N95, N99, or N100) should be used (20). N95 refers to the ability to filter 1- $\mu$ m particles in the unloaded state with a filter efficiency of >95% (i.e., filter leakage <5%), given flow rates of  $\leq$ 50 L/min (i.e., approximate maximum airflow rate of HCP during breathing). Available data indicate infectious droplet nuclei measure 1–5  $\mu$ m; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particles in this range.

The majority of surgical masks are not NIOSH-certified as respirators, do not protect the user adequately from exposure to TB, and do not satisfy OSHA requirements for respiratory protection (174,175). However, certain surgical masks (i.e., surgical N95 respirator) do meet the requirements and are certified by NIOSH as respirators. The level of protection a respirator provides is determined by the efficiency of the filter

material for incoming air and how well the face piece fits or seals to the face (e.g., qualitatively or quantitatively tested in a reliable way to obtain a face-seal leakage of <10% and to fit the different facial sizes and characteristics of HCP).

When respirators are used while treating patients with diseases requiring airborne-transmission precautions (e.g., TB), they should be used in the context of a complete respiratory protection program (175). This program should include training and fit testing to ensure an adequate seal between the edges of the respirator and the wearer's face. Detailed information regarding respirator programs, including fit-test procedures are available at <http://www.cdc.gov/niosh/99-143.html> (174,176).

### Protective Clothing

Protective clothing and equipment (e.g., gowns, lab coats, gloves, masks, and protective eyewear or face shield) should be worn to prevent contamination of street clothing and to protect the skin of DHCP from exposures to blood and body substances (2,7,10,11,13,137). OSHA bloodborne pathogens standard requires sleeves to be long enough to protect the forearms when the gown is worn as PPE (i.e., when spatter and spray of blood, saliva, or OPIM to the forearms is anticipated) (13,14). DHCP should change protective clothing when it becomes visibly soiled and as soon as feasible if penetrated by blood or other potentially infectious fluids (2,13,14,137). All protective clothing should be removed before leaving the work area (13).

### Gloves and Gloving

DHCP wear gloves to prevent contamination of their hands when touching mucous membranes, blood, saliva, or OPIM, and also to reduce the likelihood that microorganisms present on the hands of DHCP will be transmitted to patients during surgical or other patient-care procedures (1,2,7,10). Medical gloves, both patient examination and surgeon's gloves, are manufactured as single-use disposable items that should be used for only one patient, then discarded. Gloves should be changed between patients and when torn or punctured.

Wearing gloves does not eliminate the need for handwashing. Hand hygiene should be performed immediately before donning gloves. Gloves can have small, unapparent defects or can be torn during use, and hands can become contaminated during glove removal (122,177–187). These circumstances increase the risk of operative wound contamination and exposure of the DHCP's hands to microorganisms from patients. In addition, bacteria can multiply rapidly in the moist environments underneath gloves, and thus, the hands should be dried thoroughly before donning gloves and washed again immediately after glove removal.



## Types of Gloves

Because gloves are task-specific, their selection should be based on the type of procedure to be performed (e.g., surgery or patient examination) (Table 3). Sterile surgeon's gloves must meet standards for sterility assurance established by FDA and are less likely than patient examination gloves to harbor pathogens that could contaminate an operative wound (188). Appropriate gloves in the correct size should be readily accessible (13).

## Glove Integrity

Limited studies of the penetrability of different glove materials under conditions of use have been conducted in the dental environment. Consistent with observations in clinical medicine, leakage rates vary by glove material (e.g., latex, vinyl, and nitrile), duration of use, and type of procedure performed (182,184,186,189–191), as well as by manufacturer (192–194). The frequency of perforations in surgeon's gloves used during outpatient oral surgical procedures has been determined to range from 6% to 16% (181,185,195,196).

Studies have demonstrated that HCP and DHCP are frequently unaware of minute tears in gloves that occur during use (186,190,191,197). These studies determined that gloves

developed defects in 30 minutes–3 hours, depending on type of glove and procedure. Investigators did not determine an optimal time for changing gloves during procedures.

During dental procedures, patient examination and surgeon's gloves commonly contact multiple types of chemicals and materials (e.g., disinfectants and antiseptics, composite resins, and bonding agents) that can compromise the integrity of latex as well as vinyl, nitrile, and other synthetic glove materials (198–206). In addition, latex gloves can interfere with the setting of vinyl polysiloxane impression materials (207–209), although the setting is apparently not adversely affected by synthetic vinyl gloves (207,208). Given the diverse selection of dental materials on the market, dental practitioners should consult glove manufacturers regarding the chemical compatibility of glove materials.

If the integrity of a glove is compromised (e.g., punctured), it should be changed as soon as possible (13,210,211). Washing latex gloves with plain soap, chlorhexidine, or alcohol can lead to the formation of glove micropunctures (177,212,213) and subsequent hand contamination (138). Because this condition, known as wicking, can allow penetration of liquids through undetected holes, washing gloves is not recommended. After a hand rub with alcohol, the hands should be thoroughly

**TABLE 3. Glove types and indications**

Glove	Indication	Comment	Commercially available glove materials*	
			Material	Attributes†
Patient examination gloves§	Patient care, examinations, other nonsurgical procedures involving contact with mucous membranes, and laboratory procedures	Medical device regulated by the Food and Drug Administration (FDA).	Natural-rubber latex (NRL)	1, 2
		Nonsterile and sterile single-use disposable. Use for one patient and discard appropriately.	Nitrile Nitrile and chloroprene (neoprene) blends Nitrile & NRL blends Butadiene methyl methacrylate Polyvinyl chloride (PVC, vinyl) Polyurethane Styrene-based copolymer	2, 3 2, 3 1, 2, 3 2, 3 4 4 4, 5
Surgeon's gloves§	Surgical procedures	Medical device regulated by the FDA.	NRL	1, 2
		Sterile and single-use disposable. Use for one patient and discard appropriately.	Nitrile Chloroprene (neoprene) NRL and nitrile or chloroprene blends Synthetic polyisoprene Styrene-based copolymer Polyurethane	2, 3 2, 3 2, 3 2 4, 5 4
Nonmedical gloves	Housekeeping procedures (e.g., cleaning and disinfection)	Not a medical device regulated by the FDA.	NRL and nitrile or chloroprene blends	2, 3
		Commonly referred to as utility, industrial, or general purpose gloves. Should be puncture- or chemical-resistant, depending on the task. Latex gloves do not provide adequate chemical protection.	Chloroprene (neoprene) Nitrile Butyl rubber Fluoroelastomer	2, 3 2, 3 2, 3 3, 4, 6
	Handling contaminated sharps or chemicals	Sanitize after use.	Polyethylene and ethylene vinyl alcohol copolymer	3, 4, 6
	Not for use during patient care			

\* Physical properties can vary by material, manufacturer, and protein and chemical composition.

† 1 contains allergenic NRL proteins.

2 vulcanized rubber, contains allergenic rubber processing chemicals.

3 likely to have enhanced chemical or puncture resistance.

4 nonvulcanized and does not contain rubber processing chemicals.

5 inappropriate for use with methacrylates.

6 resistant to most methacrylates.

§ Medical or dental gloves include patient-examination gloves and surgeon's (i.e., surgical) gloves and are medical devices regulated by the FDA. Only FDA-cleared medical or dental patient-examination gloves and surgical gloves can be used for patient care.

dried before gloving, because hands still wet with an alcohol-based hand hygiene product can increase the risk of glove perforation (192).

FDA regulates the medical glove industry, which includes gloves marketed as sterile surgeon's and sterile or nonsterile patient examination gloves. General-purpose utility gloves are also used in dental health-care settings but are not regulated by FDA because they are not promoted for medical use. More rigorous standards are applied to surgeon's than to examination gloves. FDA has identified acceptable quality levels (e.g., maximum defects allowed) for glove manufacturers (214), but even intact gloves eventually fail with exposure to mechanical (e.g., sharps, fingernails, or jewelry) and chemical (e.g., dimethylacrylates) hazards and over time. These variables can be controlled, ultimately optimizing glove performance, by 1) maintaining short fingernails, 2) minimizing or eliminating hand jewelry, and 3) using engineering and work-practice controls to avoid injuries with sharps.

### **Sterile Surgeon's Gloves and Double-Gloving During Oral Surgical Procedures**

Certain limited studies have determined no difference in postoperative infection rates after routine tooth extractions when surgeons wore either sterile or nonsterile gloves (215,216). However, wearing sterile surgeon's gloves during surgical procedures is supported by a strong theoretical rationale (2,7,137). Sterile gloves minimize transmission of microorganisms from the hands of surgical DHCP to patients and prevent contamination of the hands of surgical DHCP with the patient's blood and body fluids (137). In addition, sterile surgeon's gloves are more rigorously regulated by FDA and therefore might provide an increased level of protection for the provider if exposure to blood is likely.

Although the effectiveness of wearing two pairs of gloves in preventing disease transmission has not been demonstrated, the majority of studies among HCP and DHCP have demonstrated a lower frequency of inner glove perforation and visible blood on the surgeon's hands when double gloves are worn (181,185,195,196,198,217–219). In one study evaluating double gloves during oral surgical and dental hygiene procedures, the perforation of outer latex gloves was greater during longer procedures (i.e., >45 minutes), with the highest rate (10%) of perforation occurring during oral surgery procedures (196). Based on these studies, double gloving might provide additional protection from occupational blood contact (220). Double gloving does not appear to substantially reduce either manual dexterity or tactile sensitivity (221–223). Additional protection might also be provided by specialty products (e.g., orthopedic surgical gloves and glove liners) (224).

### **Contact Dermatitis and Latex Hypersensitivity**

Occupationally related contact dermatitis can develop from frequent and repeated use of hand hygiene products, exposure to chemicals, and glove use. Contact dermatitis is classified as either irritant or allergic. Irritant contact dermatitis is common, nonallergic, and develops as dry, itchy, irritated areas on the skin around the area of contact. By comparison, allergic contact dermatitis (type IV hypersensitivity) can result from exposure to accelerators and other chemicals used in the manufacture of rubber gloves (e.g., natural rubber latex, nitrile, and neoprene), as well as from other chemicals found in the dental practice setting (e.g., methacrylates and glutaraldehyde). Allergic contact dermatitis often manifests as a rash beginning hours after contact and, similar to irritant dermatitis, is usually confined to the area of contact.

Latex allergy (type I hypersensitivity to latex proteins) can be a more serious systemic allergic reaction, usually beginning within minutes of exposure but sometimes occurring hours later and producing varied symptoms. More common reactions include runny nose, sneezing, itchy eyes, scratchy throat, hives, and itchy burning skin sensations. More severe symptoms include asthma marked by difficult breathing, coughing spells, and wheezing; cardiovascular and gastrointestinal ailments; and in rare cases, anaphylaxis and death (32,225). The American Dental Association (ADA) began investigating the prevalence of type I latex hypersensitivity among DHCP at the ADA annual meeting in 1994. In 1994 and 1995, approximately 2,000 dentists, hygienists, and assistants volunteered for skin-prick testing. Data demonstrated that 6.2% of those tested were positive for type I latex hypersensitivity (226). Data from the subsequent 5 years of this ongoing cross-sectional study indicated a decline in prevalence from 8.5% to 4.3% (227). This downward trend is similar to that reported by other studies and might be related to use of latex gloves with lower allergen content (228–230).

Natural rubber latex proteins responsible for latex allergy are attached to glove powder. When powdered latex gloves are worn, more latex protein reaches the skin. In addition, when powdered latex gloves are donned or removed, latex protein/powder particles become aerosolized and can be inhaled, contacting mucous membranes (231). As a result, allergic patients and DHCP can experience cutaneous, respiratory, and conjunctival symptoms related to latex protein exposure. DHCP can become sensitized to latex protein with repeated exposure (232–236). Work areas where only powder-free, low-allergen latex gloves are used demonstrate low or undetectable amounts of latex allergy-causing proteins (237–239) and fewer symptoms among HCP related to natural rubber latex allergy.

Because of the role of glove powder in exposure to latex protein, NIOSH recommends that if latex gloves are chosen, HCP should be provided with reduced protein, powder-free gloves (32). Nonlatex (e.g., nitrile or vinyl) powder-free and low-protein gloves are also available (31,240). Although rare, potentially life-threatening anaphylactic reactions to latex can occur; dental practices should be appropriately equipped and have procedures in place to respond to such emergencies.

DHCP and dental patients with latex allergy should not have direct contact with latex-containing materials and should be in a latex-safe environment with all latex-containing products removed from their vicinity (31). Dental patients with histories of latex allergy can be at risk from dental products (e.g., prophylaxis cups, rubber dams, orthodontic elastics, and medication vials) (241). Any latex-containing devices that cannot be removed from the treatment environment should be adequately covered or isolated. Persons might also be allergic to chemicals used in the manufacture of natural rubber latex and synthetic rubber gloves as well as metals, plastics, or other materials used in dental care. Taking thorough health histories for both patients and DHCP, followed by avoidance of contact with potential allergens can minimize the possibility of adverse reactions. Certain common predisposing conditions for latex allergy include previous history of allergies, a history of spina bifida, urogenital anomalies, or allergies to avocados, kiwis, nuts, or bananas. The following precautions should be considered to ensure safe treatment for patients who have possible or documented latex allergy:

- Be aware that latent allergens in the ambient air can cause respiratory or anaphylactic symptoms among persons with latex hypersensitivity. Patients with latex allergy can be scheduled for the first appointment of the day to minimize their inadvertent exposure to airborne latex particles.
- Communicate with other DHCP regarding patients with latex allergy (e.g., by oral instructions, written protocols, and posted signage) to prevent them from bringing latex-containing materials into the treatment area.
- Frequently clean all working areas contaminated with latex powder or dust.

- Have emergency treatment kits with latex-free products available at all times.
- If latex-related complications occur during or after a procedure, manage the reaction and seek emergency assistance as indicated. Follow current medical emergency response recommendations for management of anaphylaxis (32).

## Sterilization and Disinfection of Patient-Care Items

Patient-care items (dental instruments, devices, and equipment) are categorized as critical, semicritical, or noncritical, depending on the potential risk for infection associated with their intended use (Table 4) (242). Critical items used to penetrate soft tissue or bone have the greatest risk of transmitting infection and should be sterilized by heat. Semicritical items touch mucous membranes or nonintact skin and have a lower risk of transmission; because the majority of semicritical items in dentistry are heat-tolerant, they also should be sterilized by using heat. If a semicritical item is heat-sensitive, it should, at a minimum, be processed with high-level disinfection (2).

Noncritical patient-care items pose the least risk of transmission of infection, contacting only intact skin, which can serve as an effective barrier to microorganisms. In the majority of cases, cleaning, or if visibly soiled, cleaning followed by disinfection with an EPA-registered hospital disinfectant is adequate. When the item is visibly contaminated with blood or OPIM, an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant) should be used (2,243,244). Cleaning or disinfection of certain noncritical patient-care items can be difficult or damage the surfaces; therefore, use of disposable barrier protection of these surfaces might be a preferred alternative.

FDA-cleared sterilant/high-level disinfectants and EPA-registered disinfectants must have clear label claims for intended use, and manufacturer instructions for use must be followed (245). A more complete description of the regulatory framework in the United States by which liquid chemical germicides are evaluated and regulated is included (Appendix A).

**TABLE 4. Infection-control categories of patient-care instruments**

Category	Definition	Dental instrument or item
Critical	Penetrates soft tissue, contacts bone, enters into or contacts the bloodstream or other normally sterile tissue.	Surgical instruments, periodontal scalers, scalpel blades, surgical dental burs
Semicritical	Contacts mucous membranes or nonintact skin; will not penetrate soft tissue, contact bone, enter into or contact the bloodstream or other normally sterile tissue.	Dental mouth mirror, amalgam condenser, reusable dental impression trays, dental handpieces*
Noncritical	Contacts intact skin.	Radiograph head/cone, blood pressure cuff, facebow, pulse oximeter

\* Although dental handpieces are considered a semicritical item, they should always be heat-sterilized between uses and not high-level disinfected (246). See Dental Handpieces and Other Devices Attached to Air or Waterlines for detailed information.

Three levels of disinfection, high, intermediate, and low, are used for patient-care devices that do not require sterility and two levels, intermediate and low, for environmental surfaces (242). The intended use of the patient-care item should determine the recommended level of disinfection. Dental practices should follow the product manufacturer's directions regarding concentrations and exposure time for disinfectant activity relative to the surface to be disinfected (245). A summary of sterilization and disinfection methods is included (Appendix C).

### **Transporting and Processing Contaminated Critical and Semicritical Patient-Care Items**

DHCP can be exposed to microorganisms on contaminated instruments and devices through percutaneous injury, contact with nonintact skin on the hands, or contact with mucous membranes of the eyes, nose, or mouth. Contaminated instruments should be handled carefully to prevent exposure to sharp instruments that can cause a percutaneous injury. Instruments should be placed in an appropriate container at the point of use to prevent percutaneous injuries during transport to the instrument processing area (13).

Instrument processing requires multiple steps to achieve sterilization or high-level disinfection. Sterilization is a complex process requiring specialized equipment, adequate space, qualified DHCP who are provided with ongoing training, and regular monitoring for quality assurance (247). Correct cleaning, packaging, sterilizer loading procedures, sterilization methods, or high-level disinfection methods should be followed to ensure that an instrument is adequately processed and safe for reuse on patients.

### **Instrument Processing Area**

DHCP should process all instruments in a designated central processing area to more easily control quality and ensure safety (248). The central processing area should be divided into sections for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Ideally, walls or partitions should separate the sections to control traffic flow and contain contaminants generated during processing. When physical separation of these sections cannot be achieved, adequate spatial separation might be satisfactory if the DHCP who process instruments are trained in work practices to prevent contamination of clean areas (248). Space should be adequate for the volume of work anticipated and the items to be stored (248).

### **Receiving, Cleaning, and Decontamination**

Reusable instruments, supplies, and equipment should be received, sorted, cleaned, and decontaminated in one section of the processing area. Cleaning should precede all disinfection

and sterilization processes; it should involve removal of debris as well as organic and inorganic contamination. Removal of debris and contamination is achieved either by scrubbing with a surfactant, detergent, and water, or by an automated process (e.g., ultrasonic cleaner or washer-disinfector) using chemical agents. If visible debris, whether inorganic or organic matter, is not removed, it will interfere with microbial inactivation and can compromise the disinfection or sterilization process (244,249–252). After cleaning, instruments should be rinsed with water to remove chemical or detergent residue. Splashing should be minimized during cleaning and rinsing (13). Before final disinfection or sterilization, instruments should be handled as though contaminated.

Considerations in selecting cleaning methods and equipment include 1) efficacy of the method, process, and equipment; 2) compatibility with items to be cleaned; and 3) occupational health and exposure risks. Use of automated cleaning equipment (e.g., ultrasonic cleaner or washer-disinfector) does not require presoaking or scrubbing of instruments and can increase productivity, improve cleaning effectiveness, and decrease worker exposure to blood and body fluids. Thus, using automated equipment can be safer and more efficient than manually cleaning contaminated instruments (253).

If manual cleaning is not performed immediately, placing instruments in a puncture-resistant container and soaking them with detergent, a disinfectant/detergent, or an enzymatic cleaner will prevent drying of patient material and make cleaning easier and less time-consuming. Use of a liquid chemical sterilant/high-level disinfectant (e.g., glutaraldehyde) as a holding solution is not recommended (244). Using work-practice controls (e.g., long-handled brush) to keep the scrubbing hand away from sharp instruments is recommended (14). To avoid injury from sharp instruments, DHCP should wear puncture-resistant, heavy-duty utility gloves when handling or manually cleaning contaminated instruments and devices (6). Employees should not reach into trays or containers holding sharp instruments that cannot be seen (e.g., sinks filled with soapy water in which sharp instruments have been placed). Work-practice controls should include use of a strainer-type basket to hold instruments and forceps to remove the items. Because splashing is likely to occur, a mask, protective eyewear or face shield, and gown or jacket should be worn (13).

### **Preparation and Packaging**

In another section of the processing area, cleaned instruments and other dental supplies should be inspected, assembled into sets or trays, and wrapped, packaged, or placed into container systems for sterilization. Hinged instruments should be processed open and unlocked. An internal chemical indicator should be placed in every package. In addition, an external



chemical indicator (e.g., chemical indicator tape) should be used when the internal indicator cannot be seen from outside the package. For unwrapped loads, at a minimum, an internal chemical indicator should be placed in the tray or cassette with items to be sterilized (254) (see Sterilization of Unwrapped Instruments). Dental practices should refer to the manufacturer's instructions regarding use and correct placement of chemical indicators (see Sterilization Monitoring). Critical and semicritical instruments that will be stored should be wrapped or placed in containers (e.g., cassettes or organizing trays) designed to maintain sterility during storage (2,247,255–257).

Packaging materials (e.g., wraps or container systems) allow penetration of the sterilization agent and maintain sterility of the processed item after sterilization. Materials for maintaining sterility of instruments during transport and storage include wrapped perforated instrument cassettes, peel pouches of plastic or paper, and sterilization wraps (i.e., woven and nonwoven). Packaging materials should be designed for the type of sterilization process being used (256–259).

## Sterilization

The sterilization section of the processing area should include the sterilizers and related supplies, with adequate space for loading, unloading, and cool down. The area can also include incubators for analyzing spore tests and enclosed storage for sterile items and disposable (single-use) items (260). Manufacturer and local building code specifications will determine placement and room ventilation requirements.

**Sterilization Procedures.** Heat-tolerant dental instruments usually are sterilized by 1) steam under pressure (autoclaving), 2) dry heat, or 3) unsaturated chemical vapor. All sterilization should be performed by using medical sterilization equipment cleared by FDA. The sterilization times, temperatures, and other operating parameters recommended by the manufacturer of the equipment used, as well as instructions for correct use of containers, wraps, and chemical or biological indicators, should always be followed (243,247).

Items to be sterilized should be arranged to permit free circulation of the sterilizing agent (e.g., steam, chemical vapor, or dry heat); manufacturer's instructions for loading the sterilizer should be followed (248,260). Instrument packs should be allowed to dry inside the sterilizer chamber before removing and handling. Packs should not be touched until they are cool and dry because hot packs act as wicks, absorbing moisture, and hence, bacteria from hands (247). The ability of equipment to attain physical parameters required to achieve sterilization should be monitored by mechanical, chemical, and biological indicators. Sterilizers vary in their types of indicators and their ability to provide readings on the mechani-

cal or physical parameters of the sterilization process (e.g., time, temperature, and pressure). Consult with the sterilizer manufacturer regarding selection and use of indicators.

**Steam Sterilization.** Among sterilization methods, steam sterilization, which is dependable and economical, is the most widely used for wrapped and unwrapped critical and semicritical items that are not sensitive to heat and moisture (260). Steam sterilization requires exposure of each item to direct steam contact at a required temperature and pressure for a specified time needed to kill microorganisms. Two basic types of steam sterilizers are the gravity displacement and the high-speed prevacuum sterilizer.

The majority of tabletop sterilizers used in a dental practice are gravity displacement sterilizers, although prevacuum sterilizers are becoming more widely available. In gravity displacement sterilizers, steam is admitted through steam lines, a steam generator, or self-generation of steam within the chamber. Unsaturated air is forced out of the chamber through a vent in the chamber wall. Trapping of air is a concern when using saturated steam under gravity displacement; errors in packaging items or overloading the sterilizer chamber can result in cool air pockets and items not being sterilized.

Prevacuum sterilizers are fitted with a pump to create a vacuum in the chamber and ensure air removal from the sterilizing chamber before the chamber is pressurized with steam. Relative to gravity displacement, this procedure allows faster and more positive steam penetration throughout the entire load. Prevacuum sterilizers should be tested periodically for adequate air removal, as recommended by the manufacturer. Air not removed from the chamber will interfere with steam contact. If a sterilizer fails the air removal test, it should not be used until inspected by sterilizer maintenance personnel and it passes the test (243,247). Manufacturer's instructions, with specific details regarding operation and user maintenance information, should be followed.

**Unsaturated Chemical-Vapor Sterilization.** Unsaturated chemical-vapor sterilization involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Unsaturated chemical vapor sterilization of carbon steel instruments (e.g., dental burs) causes less corrosion than steam sterilization because of the low level of water present during the cycle. Instruments should be dry before sterilizing. State and local authorities should be consulted for hazardous waste disposal requirements for the sterilizing solution.

**Dry-Heat Sterilization.** Dry heat is used to sterilize materials that might be damaged by moist heat (e.g., burs and certain orthodontic instruments). Although dry heat has the advantages of low operating cost and being noncorrosive, it is

a prolonged process and the high temperatures required are not suitable for certain patient-care items and devices (261).

Dry-heat sterilizers used in dentistry include static-air and forced-air types.

- The static-air type is commonly called an oven-type sterilizer. Heating coils in the bottom or sides of the unit cause hot air to rise inside the chamber through natural convection.
- The forced-air type is also known as a rapid heat-transfer sterilizer. Heated air is circulated throughout the chamber at a high velocity, permitting more rapid transfer of energy from the air to the instruments, thereby reducing the time needed for sterilization.

**Sterilization of Unwrapped Instruments.** An unwrapped cycle (sometimes called *flash sterilization*) is a method for sterilizing unwrapped patient-care items for immediate use. The time required for unwrapped sterilization cycles depends on the type of sterilizer and the type of item (i.e., porous or non-porous) to be sterilized (243). The unwrapped cycle in tabletop sterilizers is preprogrammed by the manufacturer to a specific time and temperature setting and can include a drying phase at the end to produce a dry instrument with much of the heat dissipated. If the drying phase requirements are unclear, the operation manual or manufacturer of the sterilizer should be consulted. If the unwrapped sterilization cycle in a steam sterilizer does not include a drying phase, or has only a minimal drying phase, items retrieved from the sterilizer will be hot and wet, making aseptic transport to the point of use more difficult. For dry-heat and chemical-vapor sterilizers, a drying phase is not required.

Unwrapped sterilization should be used only under certain conditions: 1) thorough cleaning and drying of instruments precedes the unwrapped sterilization cycle; 2) mechanical monitors are checked and chemical indicators used for each cycle; 3) care is taken to avoid thermal injury to DHCP or patients; and 4) items are transported aseptically to the point of use to maintain sterility (134,258,262). Because all implantable devices should be quarantined after sterilization until the results of biological monitoring are known, unwrapped or flash sterilization of implantable items is not recommended (134).

Critical instruments sterilized unwrapped should be transferred immediately by using aseptic technique, from the sterilizer to the actual point of use. Critical instruments should not be stored unwrapped (260). Semicritical instruments that are sterilized unwrapped on a tray or in a container system should be used immediately or within a short time. When sterile items are open to the air, they will eventually become contaminated. Storage, even temporary, of unwrapped semicritical instruments is discouraged because it permits exposure to dust, airborne organisms, and other unnecessary contamination before use on a patient (260). A carefully written protocol for minimiz-

ing the risk of contaminating unwrapped instruments should be prepared and followed (260).

**Other Sterilization Methods.** Heat-sensitive critical and semicritical instruments and devices can be sterilized by immersing them in liquid chemical germicides registered by FDA as sterilants. When using a liquid chemical germicide for sterilization, certain poststerilization procedures are essential. Items need to be 1) rinsed with sterile water after removal to remove toxic or irritating residues; 2) handled using sterile gloves and dried with sterile towels; and 3) delivered to the point of use in an aseptic manner. If stored before use, the instrument should not be considered sterile and should be sterilized again just before use. In addition, the sterilization process with liquid chemical sterilants cannot be verified with biological indicators (263).

Because of these limitations and because liquid chemical sterilants can require approximately 12 hours of complete immersion, they are almost never used to sterilize instruments. Rather, these chemicals are more often used for high-level disinfection (249). Shorter immersion times (12–90 minutes) are used to achieve high-level disinfection of semicritical instruments or items. These powerful, sporicidal chemicals (e.g., glutaraldehyde, peracetic acid, and hydrogen peroxide) are highly toxic (244,264,265). Manufacturer instructions (e.g., regarding dilution, immersion time, and temperature) and safety precautions for using chemical sterilants/high-level disinfectants must be followed precisely (15,245). These chemicals should not be used for applications other than those indicated in their label instructions. Misapplications include use as an environmental surface disinfectant or instrument-holding solution.

When using appropriate precautions (e.g., closed containers to limit vapor release, chemically resistant gloves and aprons, goggles, and face shields), glutaraldehyde-based products can be used without tissue irritation or adverse health effects. However, dermatologic, eye irritation, respiratory effects, and skin sensitization have been reported (266–268). Because of their lack of chemical resistance to glutaraldehydes, medical gloves are not an effective barrier (200,269,270). Other factors might apply (e.g., room exhaust ventilation or 10 air exchanges/hour) to ensure DHCP safety (266,271). For all of these reasons, using heat-sensitive semicritical items that must be processed with liquid chemical germicides is discouraged; heat-tolerant or disposable alternatives are available for the majority of such items.

Low-temperature sterilization with ethylene oxide gas (ETO) has been used extensively in larger health-care facilities. Its primary advantage is the ability to sterilize heat- and moisture-sensitive patient-care items with reduced deleterious effects. However, extended sterilization times of 10–48 hours

and potential hazards to patients and DHCP requiring stringent health and safety requirements (272–274) make this method impractical for private-practice settings. Handpieces cannot be effectively sterilized with this method because of decreased penetration of ETO gas flow through a small lumen (250,275). Other types of low-temperature sterilization (e.g., hydrogen peroxide gas plasma) exist but are not yet practical for dental offices.

Bead sterilizers have been used in dentistry to sterilize small metallic instruments (e.g., endodontic files). FDA has determined that a risk of infection exists with these devices because of their potential failure to sterilize dental instruments and has required their commercial distribution cease unless the manufacturer files a premarket approval application. If a bead sterilizer is employed, DHCP assume the risk of employing a dental device FDA has deemed neither safe nor effective (276).

**Sterilization Monitoring.** Monitoring of sterilization procedures should include a combination of process parameters, including mechanical, chemical, and biological (247,248,277). These parameters evaluate both the sterilizing conditions and the procedure's effectiveness.

Mechanical techniques for monitoring sterilization include assessing cycle time, temperature, and pressure by observing the gauges or displays on the sterilizer and noting these parameters for each load (243,248). Some tabletop sterilizers have recording devices that print out these parameters. Correct readings do not ensure sterilization, but incorrect readings can be the first indication of a problem with the sterilization cycle.

Chemical indicators, internal and external, use sensitive chemicals to assess physical conditions (e.g., time and temperature) during the sterilization process. Although chemical indicators do not prove sterilization has been achieved, they allow detection of certain equipment malfunctions, and they can help identify procedural errors. External indicators applied to the outside of a package (e.g., chemical indicator tape or special markings) change color rapidly when a specific parameter is reached, and they verify that the package has been exposed to the sterilization process. Internal chemical indicators should be used inside each package to ensure the sterilizing agent has penetrated the packaging material and actually reached the instruments inside. A single-parameter internal chemical indicator provides information regarding only one sterilization parameter (e.g., time or temperature). Multiparameter internal chemical indicators are designed to react to  $\geq 2$  parameters (e.g., time and temperature; or time, temperature, and the presence of steam) and can provide a more reliable indication that sterilization conditions have been met (254). Multiparameter internal indicators are available only for steam sterilizers (i.e., autoclaves).

Because chemical indicator test results are received when the sterilization cycle is complete, they can provide an early indication of a problem and where in the process the problem might exist. If either mechanical indicators or internal or external chemical indicators indicate inadequate processing, items in the load should not be used until reprocessed (134).

Biological indicators (BIs) (i.e., spore tests) are the most accepted method for monitoring the sterilization process (278,279) because they assess it directly by killing known highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species), rather than merely testing the physical and chemical conditions necessary for sterilization (243). Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, an inactivated BI indicates other potential pathogens in the load have been killed (280).

Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic use (at least weekly) of BIs (2,9,134,243,278,279). Every load containing implantable devices should be monitored with such indicators (248), and the items quarantined until BI results are known. However, in an emergency, placing implantable items in quarantine until spore tests are known to be negative might be impossible.

Manufacturer's directions should determine the placement and location of BI in the sterilizer. A control BI, from the same lot as the test indicator and not processed through the sterilizer, should be incubated with the test BI; the control BI should yield positive results for bacterial growth.

In-office biological monitoring is available; mail-in sterilization monitoring services (e.g., from private companies or dental schools) can also be used to test both the BI and the control. Although some DHCP have expressed concern that delays caused by mailing specimens might cause false-negatives, studies have determined that mail delays have no substantial effect on final test results (281,282).

Procedures to follow in the event of a positive spore test have been developed (243,247). If the mechanical (e.g., time, temperature, and pressure) and chemical (i.e., internal or external) indicators demonstrate that the sterilizer is functioning correctly, a single positive spore test probably does not indicate sterilizer malfunction. Items other than implantable devices do not necessarily need to be recalled; however the spore test should be repeated immediately after correctly loading the sterilizer and using the same cycle that produced the failure. The sterilizer should be removed from service, and all records reviewed of chemical and mechanical monitoring since the last negative BI test. Also, sterilizer operating procedures should be reviewed, including packaging, loading, and spore testing, with all persons who work with the sterilizer to determine whether operator error could be responsible (9,243,247).

Overloading, failure to provide adequate package separation, and incorrect or excessive packaging material are all common reasons for a positive BI in the absence of mechanical failure of the sterilizer unit (260). A second monitored sterilizer in the office can be used, or a loaner from a sales or repair company obtained, to minimize office disruption while waiting for the repeat BI.

If the repeat test is negative and chemical and mechanical monitoring indicate adequate processing, the sterilizer can be put back into service. If the repeat BI test is positive, and packaging, loading, and operating procedures have been confirmed as performing correctly, the sterilizer should remain out of service until it has been inspected, repaired, and rechallenged with BI tests in three consecutive empty chamber sterilization cycles (9,243). When possible, items from suspect loads dating back to the last negative BI should be recalled, rewrapped, and resterilized (9,283).

A more conservative approach has been recommended (247) in which any positive spore test is assumed to represent sterilizer malfunction and requires that all materials processed in that sterilizer, dating from the sterilization cycle having the last negative biologic indicator to the next cycle indicating satisfactory biologic indicator results, should be considered nonsterile and retrieved, if possible, and reprocessed or held in quarantine until the results of the repeat BI are known. This approach is considered conservative because the margin of safety in steam sterilization is sufficient enough that infection risk, associated with items in a load indicating spore growth, is minimal, particularly if the item was properly cleaned and the temperature was achieved (e.g., as demonstrated by acceptable chemical indicator or temperature chart) (243). Published studies are not available that document disease transmission through a nonretrieved surgical instrument after a steam sterilization cycle with a positive biological indicator (243). This more conservative approach should always be used for sterilization methods other than steam (e.g., dry heat, unsaturated chemical vapor, ETO, or hydrogen peroxide gas plasma) (243).

Results of biological monitoring should be recorded and sterilization monitoring records (i.e., mechanical, chemical, and biological) retained long enough to comply with state and local regulations. Such records are a component of an overall dental infection-control program (see Program Evaluation).

### **Storage of Sterilized Items and Clean Dental Supplies**

The storage area should contain enclosed storage for sterile items and disposable (single-use) items (173). Storage practices for wrapped sterilized instruments can be either date- or event-related. Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness.

Although some health-care facilities continue to date every sterilized package and use shelf-life practices, other facilities have switched to event-related practices (243). This approach recognizes that the product should remain sterile indefinitely, unless an event causes it to become contaminated (e.g., torn or wet packaging) (284). Even for event-related packaging, minimally, the date of sterilization should be placed on the package, and if multiple sterilizers are used in the facility, the sterilizer used should be indicated on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure (247). If packaging is compromised, the instruments should be recleaned, packaged in new wrap, and sterilized again.

Clean supplies and instruments should be stored in closed or covered cabinets, if possible (285). Dental supplies and instruments should not be stored under sinks or in other locations where they might become wet.

### **Environmental Infection Control**

In the dental operator, environmental surfaces (i.e., a surface or equipment that does not contact patients directly) can become contaminated during patient care. Certain surfaces, especially ones touched frequently (e.g., light handles, unit switches, and drawer knobs) can serve as reservoirs of microbial contamination, although they have not been associated directly with transmission of infection to either DHCP or patients. Transfer of microorganisms from contaminated environmental surfaces to patients occurs primarily through DHCP hand contact (286,287). When these surfaces are touched, microbial agents can be transferred to instruments, other environmental surfaces, or to the nose, mouth, or eyes of workers or patients. Although hand hygiene is key to minimizing this transfer, barrier protection or cleaning and disinfecting of environmental surfaces also protects against health-care-associated infections.

Environmental surfaces can be divided into clinical contact surfaces and housekeeping surfaces (249). Because housekeeping surfaces (e.g., floors, walls, and sinks) have limited risk of disease transmission, they can be decontaminated with less rigorous methods than those used on dental patient-care items and clinical contact surfaces (244). Strategies for cleaning and disinfecting surfaces in patient-care areas should consider the 1) potential for direct patient contact; 2) degree and frequency of hand contact; and 3) potential contamination of the surface with body substances or environmental sources of microorganisms (e.g., soil, dust, or water).

Cleaning is the necessary first step of any disinfection process. Cleaning is a form of decontamination that renders the environmental surface safe by removing organic matter, salts,



and visible soils, all of which interfere with microbial inactivation. The physical action of scrubbing with detergents and surfactants and rinsing with water removes substantial numbers of microorganisms. If a surface is not cleaned first, the success of the disinfection process can be compromised. Removal of all visible blood and inorganic and organic matter can be as critical as the germicidal activity of the disinfecting agent (249). When a surface cannot be cleaned adequately, it should be protected with barriers (2).

### Clinical Contact Surfaces

Clinical contact surfaces can be directly contaminated from patient materials either by direct spray or spatter generated during dental procedures or by contact with DHCP's gloved hands. These surfaces can subsequently contaminate other instruments, devices, hands, or gloves. Examples of such surfaces include

- light handles,
- switches,
- dental radiograph equipment,
- dental chairside computers,
- reusable containers of dental materials,
- drawer handles,
- faucet handles,
- countertops,
- pens,
- telephones, and
- doorknobs.

Barrier protection of surfaces and equipment can prevent contamination of clinical contact surfaces, but is particularly effective for those that are difficult to clean. Barriers include clear plastic wrap, bags, sheets, tubing, and plastic-backed paper or other materials impervious to moisture (260,288). Because such coverings can become contaminated, they should be removed and discarded between patients, while DHCP are still gloved. After removing the barrier, examine the surface to make sure it did not become soiled inadvertently. The surface needs to be cleaned and disinfected only if contamination is evident. Otherwise, after removing gloves and performing hand hygiene, DHCP should place clean barriers on these surfaces before the next patient (1,2,288).

If barriers are not used, surfaces should be cleaned and disinfected between patients by using an EPA-registered hospital disinfectant with an HIV, HBV claim (i.e., low-level disinfectant) or a tuberculocidal claim (i.e., intermediate-level disinfectant). Intermediate-level disinfectant should be used when the surface is visibly contaminated with blood or OPIM (2,244). Also, general cleaning and disinfection are recommended for clinical contact surfaces, dental unit surfaces, and countertops at the end of daily work activities and are required

if surfaces have become contaminated since their last cleaning (13). To facilitate daily cleaning, treatment areas should be kept free of unnecessary equipment and supplies.

Manufacturers of dental devices and equipment should provide information regarding material compatibility with liquid chemical germicides, whether equipment can be safely immersed for cleaning, and how it should be decontaminated if servicing is required (289). Because of the risks associated with exposure to chemical disinfectants and contaminated surfaces, DHCP who perform environmental cleaning and disinfection should wear gloves and other PPE to prevent occupational exposure to infectious agents and hazardous chemicals. Chemical- and puncture-resistant utility gloves offer more protection than patient examination gloves when using hazardous chemicals.

### Housekeeping Surfaces

Evidence does not support that housekeeping surfaces (e.g., floors, walls, and sinks) pose a risk for disease transmission in dental health-care settings. Actual, physical removal of microorganisms and soil by wiping or scrubbing is probably as critical, if not more so, than any antimicrobial effect provided by the agent used (244,290). The majority of housekeeping surfaces need to be cleaned only with a detergent and water or an EPA-registered hospital disinfectant/detergent, depending on the nature of the surface and the type and degree of contamination. Schedules and methods vary according to the area (e.g., dental operatory, laboratory, bathrooms, or reception rooms), surface, and amount and type of contamination.

Floors should be cleaned regularly, and spills should be cleaned up promptly. An EPA-registered hospital disinfectant/detergent designed for general housekeeping purposes should be used in patient-care areas if uncertainty exists regarding the nature of the soil on the surface (e.g., blood or body fluid contamination versus routine dust or dirt). Unless contamination is reasonably anticipated or apparent, cleaning or disinfecting walls, window drapes, and other vertical surfaces is unnecessary. However, when housekeeping surfaces are visibly contaminated by blood or OPIM, prompt removal and surface disinfection is appropriate infection-control practice and required by OSHA (13).

Part of the cleaning strategy is to minimize contamination of cleaning solutions and cleaning tools (e.g., mop heads or cleaning cloths). Mops and cloths should be cleaned after use and allowed to dry before reuse, or single-use, disposable mop heads and cloths should be used to avoid spreading contamination. Cost, safety, product-surface compatibility, and acceptability by housekeepers can be key criteria for selecting a cleaning agent or an EPA-registered hospital disinfectant/

detergent. PPE used during cleaning and housekeeping procedures followed should be appropriate to the task.

In the cleaning process, another reservoir for microorganisms can be dilute solutions of detergents or disinfectants, especially if prepared in dirty containers, stored for long periods of time, or prepared incorrectly (244). Manufacturers' instructions for preparation and use should be followed. Making fresh cleaning solution each day, discarding any remaining solution, and allowing the container to dry will minimize bacterial contamination. Preferred cleaning methods produce minimal mists and aerosols or dispersion of dust in patient-care areas.

### **Cleaning and Disinfection Strategies for Blood Spills**

The majority of blood contamination events in dentistry result from spatter during dental procedures using rotary or ultrasonic instrumentation. Although no evidence supports that HBV, HCV, or HIV have been transmitted from a housekeeping surface, prompt removal and surface disinfection of an area contaminated by either blood or OPIM are appropriate infection-control practices and required by OSHA (13,291).

Strategies for decontaminating spills of blood and other body fluids differ by setting and volume of the spill (113,244). Blood spills on either clinical contact or housekeeping surfaces should be contained and managed as quickly as possible to reduce the risk of contact by patients and DHCP (244,292). The person assigned to clean the spill should wear gloves and other PPE as needed. Visible organic material should be removed with absorbent material (e.g., disposable paper towels discarded in a leak-proof, appropriately labeled container). Nonporous surfaces should be cleaned and then decontaminated with either an EPA-registered hospital disinfectant effective against HBV and HIV or an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate-level disinfectant). If sodium hypochlorite is chosen, an EPA-registered sodium hypochlorite product is preferred. However, if such products are unavailable, a 1:100 dilution of sodium hypochlorite (e.g., approximately ¼ cup of 5.25% household chlorine bleach to 1 gallon of water) is an inexpensive and effective disinfecting agent (113).

### **Carpeting and Cloth Furnishings**

Carpeting is more difficult to clean than nonporous hard-surface flooring, and it cannot be reliably disinfected, especially after spills of blood and body substances. Studies have documented the presence of diverse microbial populations, primarily bacteria and fungi, in carpeting (293–295). Cloth furnishings pose similar contamination risks in areas of direct patient care and places where contaminated materials are man-

aged (e.g., dental operatory, laboratory, or instrument processing areas). For these reasons, use of carpeted flooring and fabric-upholstered furnishings in these areas should be avoided.

### **Nonregulated and Regulated Medical Waste**

Studies have compared microbial load and diversity of microorganisms in residential waste with waste from multiple health-care settings. General waste from hospitals or other health-care facilities (e.g., dental practices or clinical/research laboratories) is no more infective than residential waste (296,297). The majority of soiled items in dental offices are general medical waste and thus can be disposed of with ordinary waste. Examples include used gloves, masks, gowns, lightly soiled gauze or cotton rolls, and environmental barriers (e.g., plastic sheets or bags) used to cover equipment during treatment (298).

Although any item that has had contact with blood, exudates, or secretions might be infective, treating all such waste as infective is neither necessary nor practical (244). Infectious waste that carries a substantial risk of causing infection during handling and disposal is regulated medical waste. A complete definition of regulated waste is included in OSHA's bloodborne pathogens standard (13).

Regulated medical waste is only a limited subset of waste: 9%–15% of total waste in hospitals and 1%–2% of total waste in dental offices (298,299). Regulated medical waste requires special storage, handling, neutralization, and disposal and is covered by federal, state, and local rules and regulations (6,297,300,301). Examples of regulated waste found in dental-practice settings are solid waste soaked or saturated with blood or saliva (e.g., gauze saturated with blood after surgery), extracted teeth, surgically removed hard and soft tissues, and contaminated sharp items (e.g., needles, scalpel blades, and wires) (13).

Regulated medical waste requires careful containment for treatment or disposal. A single leak-resistant biohazard bag is usually adequate for containment of nonsharp regulated medical waste, provided the bag is sturdy and the waste can be discarded without contaminating the bag's exterior. Exterior contamination or puncturing of the bag requires placement in a second biohazard bag. All bags should be securely closed for disposal. Puncture-resistant containers with a biohazard label, located at the point of use (i.e., sharps containers), are used as containment for scalpel blades, needles, syringes, and unused sterile sharps (13).

Dental health-care facilities should dispose of medical waste regularly to avoid accumulation. Any facility generating regulated medical waste should have a plan for its management that complies with federal, state, and local regulations to ensure health and environmental safety.

## Discharging Blood or Other Body Fluids to Sanitary Sewers or Septic Tanks

All containers with blood or saliva (e.g., suctioned fluids) can be inactivated in accordance with state-approved treatment technologies, or the contents can be carefully poured down a utility sink, drain, or toilet (6). Appropriate PPE (e.g., gloves, gown, mask, and protective eyewear) should be worn when performing this task (13). No evidence exists that bloodborne diseases have been transmitted from contact with raw or treated sewage. Multiple bloodborne pathogens, particularly viruses, are not stable in the environment for long periods (302), and the discharge of limited quantities of blood and other body fluids into the sanitary sewer is considered a safe method for disposing of these waste materials (6). State and local regulations vary and dictate whether blood or other body fluids require pretreatment or if they can be discharged into the sanitary sewer and in what volume.

## Dental Unit Waterlines, Biofilm, and Water Quality

Studies have demonstrated that dental unit waterlines (i.e., narrow-bore plastic tubing that carries water to the high-speed handpiece, air/water syringe, and ultrasonic scaler) can become colonized with microorganisms, including bacteria, fungi, and protozoa (303–309). Protected by a polysaccharide slime layer known as a glycocalyx, these microorganisms colonize and replicate on the interior surfaces of the waterline tubing and form a biofilm, which serves as a reservoir that can amplify the number of free-floating (i.e., planktonic) microorganisms in water used for dental treatment. Although oral flora (303,310,311) and human pathogens (e.g., *Pseudomonas aeruginosa* [303,305,312,313], *Legionella* species [303,306,313], and nontuberculous *Mycobacterium* species [303,304]), have been isolated from dental water systems, the majority of organisms recovered from dental waterlines are common heterotrophic water bacteria (305,314,315). These exhibit limited pathogenic potential for immunocompetent persons.

### Clinical Implications

Certain reports associate waterborne infections with dental water systems, and scientific evidence verifies the potential for transmission of waterborne infections and disease in hospital settings and in the community (306,312,316). Infection or colonization caused by *Pseudomonas* species or nontuberculous mycobacteria can occur among susceptible patients through direct contact with water (317–320) or after exposure to residual waterborne contamination of inadequately reprocessed medical instruments (321–323). Nontuberculous mycobacteria can also be transmitted to patients from tap water aero-

sols (324). Health-care-associated transmission of pathogenic agents (e.g., *Legionella* species) occurs primarily through inhalation of infectious aerosols generated from potable water sources or through use of tap water in respiratory therapy equipment (325–327). Disease outbreaks in the community have also been reported from diverse environmental aerosol-producing sources, including whirlpool spas (328), swimming pools (329), and a grocery store mist machine (330). Although the majority of these outbreaks are associated with species of *Legionella* and *Pseudomonas* (329), the fungus *Cladosporium* (331) has also been implicated.

Researchers have not demonstrated a measurable risk of adverse health effects among DHCP or patients from exposure to dental water. Certain studies determined DHCP had altered nasal flora (332) or substantially greater titers of *Legionella* antibodies in comparisons with control populations; however, no cases of legionellosis were identified among exposed DHCP (333,334). Contaminated dental water might have been the source for localized *Pseudomonas aeruginosa* infections in two immunocompromised patients (312). Although transient carriage of *P. aeruginosa* was observed in 78 healthy patients treated with contaminated dental treatment water, no illness was reported among the group. In this same study, a retrospective review of dental records also failed to identify infections (312).

Concentrations of bacterial endotoxin  $\leq 1,000$  endotoxin units/mL from gram-negative water bacteria have been detected in water from colonized dental units (335). No standards exist for an acceptable level of endotoxin in drinking water, but the maximum level permissible in United States Pharmacopeia (USP) sterile water for irrigation is only 0.25 endotoxin units/mL (336). Although the consequences of acute and chronic exposure to aerosolized endotoxin in dental health-care settings have not been investigated, endotoxin has been associated with exacerbation of asthma and onset of hypersensitivity pneumonitis in other occupational settings (329,337).

### Dental Unit Water Quality

Research has demonstrated that microbial counts can reach  $\leq 200,000$  colony-forming units (CFU)/mL within 5 days after installation of new dental unit waterlines (305), and levels of microbial contamination  $\leq 10^6$  CFU/mL of dental unit water have been documented (309,338). These counts can occur because dental unit waterline factors (e.g., system design, flow rates, and materials) promote both bacterial growth and development of biofilm.

Although no epidemiologic evidence indicates a public health problem, the presence of substantial numbers of pathogens in dental unit waterlines generates concern. Exposing patients or DHCP to water of uncertain microbiological quality, despite

the lack of documented adverse health effects, is inconsistent with accepted infection-control principles. Thus in 1995, ADA addressed the dental water concern by asking manufacturers to provide equipment with the ability to deliver treatment water with  $\leq 200$  CFU/mL of unfiltered output from waterlines (339). This threshold was based on the quality assurance standard established for dialysate fluid, to ensure that fluid delivery systems in hemodialysis units have not been colonized by indigenous waterborne organisms (340).

Standards also exist for safe drinking water quality as established by EPA, the American Public Health Association (APHA), and the American Water Works Association (AWWA); they have set limits for heterotrophic bacteria of  $\leq 500$  CFU/mL of drinking water (341,342). Thus, the number of bacteria in water used as a coolant/irrigant for nonsurgical dental procedures should be as low as reasonably achievable and, at a minimum,  $\leq 500$  CFU/mL, the regulatory standard for safe drinking water established by EPA and APHA/AWWA.

### Strategies To Improve Dental Unit Water Quality

In 1993, CDC recommended that dental waterlines be flushed at the beginning of the clinic day to reduce the microbial load (2). However, studies have demonstrated this practice does not affect biofilm in the waterlines or reliably improve the quality of water used during dental treatment (315,338,343). Because the recommended value of  $\leq 500$  CFU/mL cannot be achieved by using this method, other strategies should be employed. Dental unit water that remains untreated or unfiltered is unlikely to meet drinking water standards (303–309). Commercial devices and procedures designed to improve the quality of water used in dental treatment are available (316); methods demonstrated to be effective include self-contained water systems combined with chemical treatment, in-line microfilters, and combinations of these treatments. Simply using source water containing  $\leq 500$  CFU/mL of bacteria (e.g., tap, distilled, or sterile water) in a self-contained water system will not eliminate bacterial contamination in treatment water if biofilms in the water system are not controlled. Removal or inactivation of dental waterline biofilms requires use of chemical germicides.

Patient material (e.g., oral microorganisms, blood, and saliva) can enter the dental water system during patient treatment (311,344). Dental devices that are connected to the dental water system and that enter the patient's mouth (e.g., handpieces, ultrasonic scalers, or air/water syringes) should be operated to discharge water and air for a minimum of 20–30 seconds after each patient (2). This procedure is intended to physically flush out patient material that might have entered

the turbine, air, or waterlines. The majority of recently manufactured dental units are engineered to prevent retraction of oral fluids, but some older dental units are equipped with antiretraction valves that require periodic maintenance. Users should consult the owner's manual or contact the manufacturer to determine whether testing or maintenance of antiretraction valves or other devices is required. Even with antiretraction valves, flushing devices for a minimum of 20–30 seconds after each patient is recommended.

### Maintenance and Monitoring of Dental Unit Water

DHCP should be trained regarding water quality, biofilm formation, water treatment methods, and appropriate maintenance protocols for water delivery systems. Water treatment and monitoring products require strict adherence to maintenance protocols, and noncompliance with treatment regimens has been associated with persistence of microbial contamination in treated systems (345). Clinical monitoring of water quality can ensure that procedures are correctly performed and that devices are working in accordance with the manufacturer's previously validated protocol.

Dentists should consult with the manufacturer of their dental unit or water delivery system to determine the best method for maintaining acceptable water quality (i.e.,  $\leq 500$  CFU/mL) and the recommended frequency of monitoring. Monitoring of dental water quality can be performed by using commercial self-contained test kits or commercial water-testing laboratories. Because methods used to treat dental water systems target the entire biofilm, no rationale exists for routine testing for such specific organisms as *Legionella* or *Pseudomonas*, except when investigating a suspected waterborne disease outbreak (244).

### Delivery of Sterile Surgical Irrigation

Sterile solutions (e.g., sterile saline or sterile water) should be used as a coolant/irrigation in the performance of oral surgical procedures where a greater opportunity exists for entry of microorganisms, exogenous and endogenous, into the vascular system and other normally sterile areas that support the oral cavity (e.g., bone or subcutaneous tissue) and increased potential exists for localized or systemic infection (see Oral Surgical Procedures). Conventional dental units cannot reliably deliver sterile water even when equipped with independent water reservoirs because the water-bearing pathway cannot be reliably sterilized. Delivery devices (e.g., bulb syringe or sterile, single-use disposable products) should be used to deliver sterile water (2,121). Oral surgery and implant handpieces, as well as ultrasonic scalers, are commercially available that bypass the dental unit to deliver sterile water or other solutions by using single-use disposable or sterilizable tubing (316).



## Boil-Water Advisories

A boil-water advisory is a public health announcement that the public should boil tap water before drinking it. When issued, the public should assume the water is unsafe to drink. Advisories can be issued after 1) failure of or substantial interruption in water treatment processes that result in increased turbidity levels or particle counts and mechanical or equipment failure; 2) positive test results for pathogens (e.g., *Cryptosporidium*, *Giardia*, or *Shigella*) in water; 3) violations of the total coliform rule or the turbidity standard of the surface water treatment rule; 4) circumstances that compromise the distribution system (e.g., watermain break) coupled with an indication of a health hazard; or 5) a natural disaster (e.g., flood, hurricane, or earthquake) (346). In recent years, increased numbers of boil-water advisories have resulted from contamination of public drinking water systems with waterborne pathogens. Most notable was the outbreak of cryptosporidiosis in Milwaukee, Wisconsin, where the municipal water system was contaminated with the protozoan parasite *Cryptosporidium parvum*. An estimated 403,000 persons became ill (347,348).

During a boil-water advisory, water should not be delivered to patients through the dental unit, ultrasonic scaler, or other dental equipment that uses the public water system. This restriction does not apply if the water source is isolated from the municipal water system (e.g., a separate water reservoir or other water treatment device cleared for marketing by FDA). Patients should rinse with bottled or distilled water until the boil-water advisory has been cancelled. During these advisory periods, tap water should not be used to dilute germicides or for hand hygiene unless the water has been brought to a rolling boil for  $\geq 1$  minute and cooled before use (346,349–351). For hand hygiene, antimicrobial products that do not require water (e.g., alcohol-based hand rubs) can be used until the boil-water notice is cancelled. If hands are visibly contaminated, bottled water and soap should be used for handwashing; if bottled water is not immediately available, an antiseptic towelette should be used (13,122).

When the advisory is cancelled, the local water utility should provide guidance for flushing of waterlines to reduce residual microbial contamination. All incoming waterlines from the public water system inside the dental office (e.g., faucets, waterlines, and dental equipment) should be flushed. No consensus exists regarding the optimal duration for flushing procedures after cancellation of the advisory; recommendations range from 1 to 5 minutes (244,346,351,352). The length of time needed can vary with the type and length of the plumbing system leading to the office. After the incoming public water system lines are flushed, dental unit waterlines should be disinfected according to the manufacturer's instructions (346).

## Special Considerations

### Dental Handpieces and Other Devices Attached to Air and Waterlines

Multiple semicritical dental devices that touch mucous membranes are attached to the air or waterlines of the dental unit. Among these devices are high- and low-speed handpieces, prophylaxis angles, ultrasonic and sonic scaling tips, air abrasion devices, and air and water syringe tips. Although no epidemiologic evidence implicates these instruments in disease transmission (353), studies of high-speed handpieces using dye expulsion have confirmed the potential for retracting oral fluids into internal compartments of the device (354–358). This determination indicates that retained patient material can be expelled intraorally during subsequent uses. Studies using laboratory models also indicate the possibility for retention of viral DNA and viable virus inside both high-speed handpieces and prophylaxis angles (356,357,359). The potential for contamination of the internal surfaces of other devices (e.g., low-speed handpieces and ultrasonic scalers), has not been studied, but restricted physical access limits their cleaning. Accordingly, any dental device connected to the dental air/water system that enters the patient's mouth should be run to discharge water, air, or a combination for a minimum of 20–30 seconds after each patient (2). This procedure is intended to help physically flush out patient material that might have entered the turbine and air and waterlines (2,356,357).

Heat methods can sterilize dental handpieces and other intraoral devices attached to air or waterlines (246,275,356,357,360). For processing any dental device that can be removed from the dental unit air or waterlines, neither surface disinfection nor immersion in chemical germicides is an acceptable method. Ethylene oxide gas cannot adequately sterilize internal components of handpieces (250,275). In clinical evaluations of high-speed handpieces, cleaning and lubrication were the most critical factors in determining performance and durability (361–363). Manufacturer's instructions for cleaning, lubrication, and sterilization should be followed closely to ensure both the effectiveness of the process and the longevity of handpieces.

Some components of dental instruments are permanently attached to dental unit waterlines and although they do not enter the patient's oral cavity, they are likely to become contaminated with oral fluids during treatment procedures. Such components (e.g., handles or dental unit attachments of saliva ejectors, high-speed air evacuators, and air/water syringes) should be covered with impervious barriers that are changed after each use. If the item becomes visibly contaminated during use, DHCP should clean and disinfect with an EPA-

registered hospital disinfectant (intermediate-level) before use on the next patient.

## Saliva Ejectors

Backflow from low-volume saliva ejectors occurs when the pressure in the patient's mouth is less than that in the evacuator. Studies have reported that backflow in low-volume suction lines can occur and microorganisms be present in the lines retracted into the patient's mouth when a seal around the saliva ejector is created (e.g., by a patient closing lips around the tip of the ejector, creating a partial vacuum) (364–366). This backflow can be a potential source of cross-contamination; occurrence is variable because the quality of the seal formed varies between patients. Furthermore, studies have demonstrated that gravity pulls fluid back toward the patient's mouth whenever a length of the suction tubing holding the tip is positioned above the patient's mouth, or during simultaneous use of other evacuation (high-volume) equipment (364–366). Although no adverse health effects associated with the saliva ejector have been reported, practitioners should be aware that in certain situations, backflow could occur when using a saliva ejector.

## Dental Radiology

When taking radiographs, the potential to cross-contaminate equipment and environmental surfaces with blood or saliva is high if aseptic technique is not practiced. Gloves should be worn when taking radiographs and handling contaminated film packets. Other PPE (e.g., mask, protective eyewear, and gowns) should be used if spattering of blood or other body fluids is likely (11,13,367). Heat-tolerant versions of intraoral radiograph accessories are available and these semicritical items (e.g., film-holding and positioning devices) should be heat-sterilized before patient use.

After exposure of the radiograph and before glove removal, the film should be dried with disposable gauze or a paper towel to remove blood or excess saliva and placed in a container (e.g., disposable cup) for transport to the developing area. Alternatively, if FDA-cleared film barrier pouches are used, the film packets should be carefully removed from the pouch to avoid contamination of the outside film packet and placed in the clean container for transport to the developing area.

Various methods have been recommended for aseptic transport of exposed films to the developing area, and for removing the outer film packet before exposing and developing the film. Other information regarding dental radiography infection control is available (260,367,368). However, care should be taken to avoid contamination of the developing equipment. Protective barriers should be used, or any surfaces that

become contaminated should be cleaned and disinfected with an EPA-registered hospital disinfectant of low- (i.e., HIV and HBV claim) to intermediate-level (i.e., tuberculocidal claim) activity. Radiography equipment (e.g., radiograph tubehead and control panel) should be protected with surface barriers that are changed after each patient. If barriers are not used, equipment that has come into contact with DHCP's gloved hands or contaminated film packets should be cleaned and then disinfected after each patient use.

Digital radiography sensors and other high-technology instruments (e.g., intraoral camera, electronic periodontal probe, occlusal analyzers, and lasers) come into contact with mucous membranes and are considered semicritical devices. They should be cleaned and ideally heat-sterilized or high-level disinfected between patients. However, these items vary by manufacturer or type of device in their ability to be sterilized or high-level disinfected. Semicritical items that cannot be reprocessed by heat sterilization or high-level disinfection should, at a minimum, be barrier protected by using an FDA-cleared barrier to reduce gross contamination during use. Use of a barrier does not always protect from contamination (369–374). One study determined that a brand of commercially available plastic barriers used to protect dental digital radiography sensors failed at a substantial rate (44%). This rate dropped to 6% when latex finger cots were used in conjunction with the plastic barrier (375). To minimize the potential for device-associated infections, after removing the barrier, the device should be cleaned and disinfected with an EPA-registered hospital disinfectant (intermediate-level) after each patient. Manufacturers should be consulted regarding appropriate barrier and disinfection/sterilization procedures for digital radiography sensors, other high-technology intraoral devices, and computer components.

## Aseptic Technique for Parenteral Medications

Safe handling of parenteral medications and fluid infusion systems is required to prevent health-care-associated infections among patients undergoing conscious sedation. Parenteral medications can be packaged in single-dose ampules, vials or prefilled syringes, usually without bacteriostatic/preservative agents, and intended for use on a single patient. Multidose vials, used for more than one patient, can have a preservative, but both types of containers of medication should be handled with aseptic techniques to prevent contamination.

Single-dose vials should be used for parenteral medications whenever possible (376,377). Single-dose vials might pose a risk for contamination if they are punctured repeatedly. The leftover contents of a single-dose vial should be discarded and

never combined with medications for use on another patient (376,377). Medication from a single-dose syringe should not be administered to multiple patients, even if the needle on the syringe is changed (378).

The overall risk for extrinsic contamination of multidose vials is probably minimal, although the consequences of contamination might result in life-threatening infection (379). If necessary to use a multidose vial, its access diaphragm should be cleansed with 70% alcohol before inserting a sterile device into the vial (380,381). A multidose vial should be discarded if sterility is compromised (380,381).

Medication vials, syringes, or supplies should not be carried in uniform or clothing pockets. If trays are used to deliver medications to individual patients, they should be cleaned between patients. To further reduce the chance of contamination, all medication vials should be restricted to a centralized medication preparation area separate from the treatment area (382).

All fluid infusion and administration sets (e.g., IV bags, tubing, and connections) are single-patient use because sterility cannot be guaranteed when an infusion or administration set is used on multiple patients. Aseptic technique should be used when preparing IV infusion and administration sets, and entry into or breaks in the tubing should be minimized (378).

### Single-Use or Disposable Devices

A single-use device, also called a disposable device, is designed to be used on one patient and then discarded, not reprocessed for use on another patient (e.g., cleaned, disinfected, or sterilized) (383). Single-use devices in dentistry are usually not heat-tolerant and cannot be reliably cleaned. Examples include syringe needles, prophylaxis cups and brushes, and plastic orthodontic brackets. Certain items (e.g., prophylaxis angles, saliva ejectors, high-volume evacuator tips, and air/water syringe tips) are commonly available in a disposable form and should be disposed of appropriately after each use. Single-use devices and items (e.g., cotton rolls, gauze, and irrigating syringes) for use during oral surgical procedures should be sterile at the time of use.

Because of the physical construction of certain devices (e.g., burs, endodontic files, and broaches) cleaning can be difficult. In addition, deterioration can occur on the cutting surfaces of some carbide/diamond burs and endodontic files during processing (384) and after repeated processing cycles, leading to potential breakage during patient treatment (385–388). These factors, coupled with the knowledge that burs and endodontic instruments exhibit signs of wear during normal use, might make it practical to consider them as single-use devices.

### Preprocedural Mouth Rinses

Antimicrobial mouth rinses used by patients before a dental procedure are intended to reduce the number of microorganisms the patient might release in the form of aerosols or spatter that subsequently can contaminate DHCP and equipment operatory surfaces. In addition, preprocedural rinsing can decrease the number of microorganisms introduced in the patient's bloodstream during invasive dental procedures (389,390).

No scientific evidence indicates that preprocedural mouth rinsing prevents clinical infections among DHCP or patients, but studies have demonstrated that a preprocedural rinse with an antimicrobial product (e.g., chlorhexidine gluconate, essential oils, or povidone-iodine) can reduce the level of oral microorganisms in aerosols and spatter generated during routine dental procedures with rotary instruments (e.g., dental handpieces or ultrasonic scalers) (391–399). Preprocedural mouth rinses can be most beneficial before a procedure that requires using a prophylaxis cup or ultrasonic scaler because rubber dams cannot be used to minimize aerosol and spatter generation and, unless the provider has an assistant, high-volume evacuation is not commonly used (173).

The science is unclear concerning the incidence and nature of bacteremias from oral procedures, the relationship of these bacteremias to disease, and the preventive benefit of antimicrobial rinses. In limited studies, no substantial benefit has been demonstrated for mouth rinsing in terms of reducing oral microorganisms in dental-induced bacteremias (400,401). However, the American Heart Association's recommendations regarding preventing bacterial endocarditis during dental procedures (402) provide limited support concerning preprocedural mouth rinsing with an antimicrobial as an adjunct for patients at risk for bacterial endocarditis. Insufficient data exist to recommend preprocedural mouth rinses to prevent clinical infections among patients or DHCP.

### Oral Surgical Procedures

The oral cavity is colonized with numerous microorganisms. Oral surgical procedures present an opportunity for entry of microorganisms (i.e., exogenous and endogenous) into the vascular system and other normally sterile areas of the oral cavity (e.g., bone or subcutaneous tissue); therefore, an increased potential exists for localized or systemic infection. Oral surgical procedures involve the incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or nonerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth,



and suturing if needed) (see Hand Hygiene, PPE, Single Use or Disposable Devices, and Dental Unit Water Quality).

## Handling of Biopsy Specimens

To protect persons handling and transporting biopsy specimens, each specimen must be placed in a sturdy, leakproof container with a secure lid for transportation (13). Care should be taken when collecting the specimen to avoid contaminating the outside of the container. If the outside of the container becomes visibly contaminated, it should be cleaned and disinfected or placed in an impervious bag (2,13). The container must be labeled with the biohazard symbol during storage, transport, shipment, and disposal (13,14).

## Handling of Extracted Teeth

### Disposal

Extracted teeth that are being discarded are subject to the containerization and labeling provisions outlined by OSHA's bloodborne pathogens standard (13). OSHA considers extracted teeth to be potentially infectious material that should be disposed in medical waste containers. Extracted teeth sent to a dental laboratory for shade or size comparisons should be cleaned, surface-disinfected with an EPA-registered hospital disinfectant with intermediate-level activity (i.e., tuberculocidal claim), and transported in a manner consistent with OSHA regulations. However, extracted teeth can be returned to patients on request, at which time provisions of the standard no longer apply (14). Extracted teeth containing dental amalgam should not be placed in a medical waste container that uses incineration for final disposal. Commercial metal-recycling companies also might accept extracted teeth with metal restorations, including amalgam. State and local regulations should be consulted regarding disposal of the amalgam.

### Educational Settings

Extracted teeth are occasionally collected for use in preclinical educational training. These teeth should be cleaned of visible blood and gross debris and maintained in a hydrated state in a well-constructed closed container during transport. The container should be labeled with the biohazard symbol (13,14). Because these teeth will be autoclaved before clinical exercises or study, use of the most economical storage solution (e.g., water or saline) might be practical. Liquid chemical germicides can also be used but do not reliably disinfect both external surface and interior pulp tissue (403,404).

Before being used in an educational setting, the teeth should be heat-sterilized to allow safe handling. Microbial growth can be eliminated by using an autoclave cycle for 40 minutes (405),

but because preclinical educational exercises simulate clinical experiences, students enrolled in dental programs should still follow standard precautions. Autoclaving teeth for preclinical laboratory exercises does not appear to alter their physical properties sufficiently to compromise the learning experience (405,406). However, whether autoclave sterilization of extracted teeth affects dentinal structure to the point that the chemical and microchemical relationship between dental materials and the dentin would be affected for research purposes on dental materials is unknown (406).

Use of teeth that do not contain amalgam is preferred in educational settings because they can be safely autoclaved (403,405). Extracted teeth containing amalgam restorations should not be heat-sterilized because of the potential health hazard from mercury vaporization and exposure. If extracted teeth containing amalgam restorations are to be used, immersion in 10% formalin solution for 2 weeks should be effective in disinfecting both the internal and external structures of the teeth (403). If using formalin, manufacturer MSDS should be reviewed for occupational safety and health concerns and to ensure compliance with OSHA regulations (15).

## Dental Laboratory

Dental prostheses, appliances, and items used in their fabrication (e.g., impressions, occlusal rims, and bite registrations) are potential sources for cross-contamination and should be handled in a manner that prevents exposure of DHCP, patients, or the office environment to infectious agents. Effective communication and coordination between the laboratory and dental practice will ensure that appropriate cleaning and disinfection procedures are performed in the dental office or laboratory, materials are not damaged or distorted because of disinfectant overexposure, and effective disinfection procedures are not unnecessarily duplicated (407,408).

When a laboratory case is sent off-site, DHCP should provide written information regarding the methods (e.g., type of disinfectant and exposure time) used to clean and disinfect the material (e.g., impression, stone model, or appliance) (2,407,409). Clinical materials that are not decontaminated are subject to OSHA and U.S. Department of Transportation regulations regarding transportation and shipping of infectious materials (13,410).

Appliances and prostheses delivered to the patient should be free of contamination. Communication between the laboratory and the dental practice is also key at this stage to determine which one is responsible for the final disinfection process. If the dental laboratory staff provides the disinfection, an EPA-registered hospital disinfectant (low to intermediate) should be used, written documentation of the disinfection method

provided, and the item placed in a tamper-evident container before returning it to the dental office. If such documentation is not provided, the dental office is responsible for final disinfection procedures.

Dental prostheses or impressions brought into the laboratory can be contaminated with bacteria, viruses, and fungi (411,412). Dental prostheses, impressions, orthodontic appliances, and other prosthodontic materials (e.g., occlusal rims, temporary prostheses, bite registrations, or extracted teeth) should be thoroughly cleaned (i.e., blood and bioburden removed), disinfected with an EPA-registered hospital disinfectant with a tuberculocidal claim, and thoroughly rinsed before being handled in the in-office laboratory or sent to an off-site laboratory (2,244,249,407). The best time to clean and disinfect impressions, prostheses, or appliances is as soon as possible after removal from the patient's mouth before drying of blood or other bioburden can occur. Specific guidance regarding cleaning and disinfecting techniques for various materials is available (260,413–416). DHCP are advised to consult with manufacturers regarding the stability of specific materials during disinfection.

In the laboratory, a separate receiving and disinfecting area should be established to reduce contamination in the production area. Bringing untreated items into the laboratory increases chances for cross infection (260). If no communication has been received regarding prior cleaning and disinfection of a material, the dental laboratory staff should perform cleaning and disinfection procedures before handling. If during manipulation of a material or appliance a previously undetected area of blood or bioburden becomes apparent, cleaning and disinfection procedures should be repeated. Transfer of oral microorganisms into and onto impressions has been documented (417–419). Movement of these organisms onto dental casts has also been demonstrated (420). Certain microbes have been demonstrated to remain viable within gypsum cast materials for  $\leq 7$  days (421). Incorrect handling of contaminated impressions, prostheses, or appliances, therefore, offers an opportunity for transmission of microorganisms (260). Whether in the office or laboratory, PPE should be worn until disinfection is completed (1,2,7,10,13).

If laboratory items (e.g., burs, polishing points, rag wheels, or laboratory knives) are used on contaminated or potentially contaminated appliances, prostheses, or other material, they should be heat-sterilized, disinfected between patients, or discarded (i.e., disposable items should be used) (260,407). Heat-tolerant items used in the mouth (e.g., metal impression tray or face bow fork) should be heat-sterilized before being used on another patient (2,407). Items that do not normally contact the patient, prosthetic device, or appliance but frequently become contaminated and cannot withstand heat-sterilization (e.g., articulators, case

pan, or lathes) should be cleaned and disinfected between patients and according to the manufacturer's instructions. Pressure pots and water baths are particularly susceptible to contamination with microorganisms and should be cleaned and disinfected between patients (422). In the majority of instances, these items can be cleaned and disinfected with an EPA-registered hospital disinfectant. Environmental surfaces should be barrier-protected or cleaned and disinfected in the same manner as in the dental treatment area.

Unless waste generated in the dental laboratory (e.g., disposable trays or impression materials) falls under the category of regulated medical waste, it can be discarded with general waste. Personnel should dispose of sharp items (e.g., burs, disposable blades, and orthodontic wires) in puncture-resistant containers.

### Laser/Electrosurgery Plumes or Surgical Smoke

During surgical procedures that use a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke byproduct. Laser plumes or surgical smoke represent another potential risk for DHCP (423–425). Lasers transfer electromagnetic energy into tissues, resulting in the release of a heated plume that includes particles, gases (e.g., hydrogen cyanide, benzene, and formaldehyde), tissue debris, viruses, and offensive odors. One concern is that aerosolized infectious material in the laser plume might reach the nasal mucosa of the laser operator and adjacent DHCP. Although certain viruses (e.g., varicella-zoster virus and herpes simplex virus) appear not to aerosolize efficiently (426,427), other viruses and various bacteria (e.g., human papilloma virus, HIV, coagulase-negative *Staphylococcus*, *Corynebacterium* species, and *Neisseria* species) have been detected in laser plumes (428–434). However, the presence of an infectious agent in a laser plume might not be sufficient to cause disease from airborne exposure, especially if the agent's normal mode of transmission is not airborne. No evidence indicates that HIV or HBV have been transmitted through aerosolization and inhalation (435). Although continuing studies are needed to evaluate the risk for DHCP of laser plumes and electrosurgery smoke, following NIOSH recommendations (425) and practices developed by the Association of periOperative Registered Nurses (AORN) might be practical (436). These practices include using 1) standard precautions (e.g., high-filtration surgical masks and possibly full face shields) (437); 2) central room suction units with in-line filters to collect particulate matter from minimal plumes; and 3) dedicated mechanical smoke exhaust systems with a high-efficiency filter to remove substantial amounts of laser plume particles. Local smoke evacuation systems have been recom-

mended by consensus organizations, and these systems can improve the quality of the operating field. Employers should be aware of this emerging problem and advise employees of the potential hazards of laser smoke (438). However, this concern remains unresolved in dental practice and no recommendation is provided here.

## **M. tuberculosis**

Patients infected with *M. tuberculosis* occasionally seek urgent dental treatment at outpatient dental settings. Understanding the pathogenesis of the development of TB will help DHCP determine how to manage such patients.

*M. tuberculosis* is a bacterium carried in airborne infective droplet nuclei that can be generated when persons with pulmonary or laryngeal TB sneeze, cough, speak, or sing (439). These small particles (1–5  $\mu\text{m}$ ) can stay suspended in the air for hours (440). Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, which then travel to the alveoli of the lungs. Usually within 2–12 weeks after initial infection with *M. tuberculosis*, immune response prevents further spread of the TB bacteria, although they can remain alive in the lungs for years, a condition termed latent TB infection. Persons with latent TB infection usually exhibit a reactive tuberculin skin test (TST), have no symptoms of active disease, and are not infectious. However, they can develop active disease later in life if they do not receive treatment for their latent infection.

Approximately 5% of persons who have been recently infected and not treated for latent TB infection will progress from infection to active disease during the first 1–2 years after infection; another 5% will develop active disease later in life. Thus, approximately 90% of U.S. persons with latent TB infection do not progress to active TB disease. Although both latent TB infection and active TB disease are described as TB, only the person with active disease is contagious and presents a risk of transmission. Symptoms of active TB disease include a productive cough, night sweats, fatigue, malaise, fever, and unexplained weight loss. Certain immunocompromising medical conditions (e.g., HIV) increase the risk that TB infection will progress to active disease at a faster rate (441).

Overall, the risk borne by DHCP for exposure to a patient with active TB disease is probably low (20,21). Only one report exists of TB transmission in a dental office (442), and TST conversions among DHCP are also low (443,444). However, in certain cases, DHCP or the community served by the dental facility might be at relatively high risk for exposure to TB.

Surgical masks do not prevent inhalation of *M. tuberculosis* droplet nuclei, and therefore, standard precautions are not sufficient to prevent transmission of this organism. Recommen-

dations for expanded precautions to prevent transmission of *M. tuberculosis* and other organisms that can be spread by airborne, droplet, or contact routes have been detailed in other guidelines (5,11,20).

TB transmission is controlled through a hierarchy of measures, including administrative controls, environmental controls, and personal respiratory protection. The main administrative goals of a TB infection-control program are early detection of a person with active TB disease and prompt isolation from susceptible persons to reduce the risk of transmission. Although DHCP are not responsible for diagnosis and treatment of TB, they should be trained to recognize signs and symptoms to help with prompt detection. Because potential for transmission of *M. tuberculosis* exists in outpatient settings, dental practices should develop a TB control program appropriate for their level of risk (20,21).

- A community risk assessment should be conducted periodically, and TB infection-control policies for each dental setting should be based on the risk assessment. The policies should include provisions for detection and referral of patients who might have undiagnosed active TB; management of patients with active TB who require urgent dental care; and DHCP education, counseling, and TST screening.
- DHCP who have contact with patients should have a baseline TST, preferably by using a two-step test at the beginning of employment. The facility's level of TB risk will determine the need for routine follow-up TST.
- While taking patients' initial medical histories and at periodic updates, dental DHCP should routinely ask all patients whether they have a history of TB disease or symptoms indicative of TB.
- Patients with a medical history or symptoms indicative of undiagnosed active TB should be referred promptly for medical evaluation to determine possible infectiousness. Such patients should not remain in the dental-care facility any longer than required to evaluate their dental condition and arrange a referral. While in the dental health-care facility, the patient should be isolated from other patients and DHCP, wear a surgical mask when not being evaluated, or be instructed to cover their mouth and nose when coughing or sneezing.
- Elective dental treatment should be deferred until a physician confirms that a patient does not have infectious TB, or if the patient is diagnosed with active TB disease, until confirmed the patient is no longer infectious.
- If urgent dental care is provided for a patient who has, or is suspected of having active TB disease, the care should be provided in a facility (e.g., hospital) that provides airborne infection isolation (i.e., using such engineering con-



trols as TB isolation rooms, negatively pressured relative to the corridors, with air either exhausted to the outside or HEPA-filtered if recirculation is necessary). Standard surgical face masks do not protect against TB transmission; DHCP should use respiratory protection (e.g., fit-tested, disposable N-95 respirators).

- Settings that do not require use of respiratory protection because they do not treat active TB patients and do not perform cough-inducing procedures on potential active TB patients do not need to develop a written respiratory protection program.
- Any DHCP with a persistent cough (i.e., lasting >3 weeks), especially in the presence of other signs or symptoms compatible with active TB (e.g., weight loss, night sweats, fatigue, bloody sputum, anorexia, or fever), should be evaluated promptly. The DHCP should not return to the workplace until a diagnosis of TB has been excluded or the DHCP is on therapy and a physician has determined that the DHCP is noninfectious.

## Creutzfeldt-Jakob Disease and Other Prion Diseases

Creutzfeldt-Jakob disease (CJD) belongs to a group of rapidly progressive, invariably fatal, degenerative neurological disorders, transmissible spongiform encephalopathies (TSEs) that affect both humans and animals and are thought to be caused by infection with an unusual pathogen called a prion. Prions are isoforms of a normal protein, capable of self-propagation although they lack nucleic acid. Prion diseases have an incubation period of years and are usually fatal within 1 year of diagnosis.

Among humans, TSEs include CJD, Gerstmann-Straussler-Scheinker syndrome, fatal familial insomnia, kuru, and variant CJD (vCJD). Occurring in sporadic, familial, and acquired (i.e., iatrogenic) forms, CJD has an annual incidence in the United States and other countries of approximately 1 case/million population (445–448). In approximately 85% of affected patients, CJD occurs as a sporadic disease with no recognizable pattern of transmission. A smaller proportion of patients (5%–15%) experience familial CJD because of inherited mutations of the prion protein gene (448).

vCJD is distinguishable clinically and neuropathologically from classic CJD, and strong epidemiologic and laboratory evidence indicates a causal relationship with bovine spongiform encephalopathy (BSE), a progressive neurological disorder of cattle commonly known as *mad cow disease* (449–451). vCJD, was reported first in the United Kingdom in 1996 (449) and subsequently in other European countries (452). Only one case of vCJD has been reported in the United States, in an

immigrant from the United Kingdom (453). Compared with CJD patients, those with vCJD are younger (28 years versus 68 years median age at death), and have a longer duration of illness (13 months versus 4.5 months). Also, vCJD patients characteristically exhibit sensory and psychiatric symptoms that are uncommon with CJD. Another difference includes the ease with which the presence of prions is consistently demonstrated in lymphoreticular tissues (e.g., tonsil) in vCJD patients by immunohistochemistry (454).

CJD and vCJD are transmissible diseases, but not through the air or casual contact. All known cases of iatrogenic CJD have resulted from exposure to infected central nervous tissue (e.g., brain and dura mater), pituitary, or eye tissue. Studies in experimental animals have determined that other tissues have low or no detectable infectivity (243,455,456). Limited experimental studies have demonstrated that scrapie (a TSE in sheep) can be transmitted to healthy hamsters and mice by exposing oral tissues to infectious homogenate (457,458). These animal models and experimental designs might not be directly applicable to human transmission and clinical dentistry, but they indicate a theoretical risk of transmitting prion diseases through perioral exposures.

According to published reports, iatrogenic transmission of CJD has occurred in humans under three circumstances: after use of contaminated electroencephalography depth electrodes and neurosurgical equipment (459); after use of extracted pituitary hormones (460,461); and after implant of contaminated corneal (462) and dura mater grafts (463,464) from humans. The equipment-related cases occurred before the routine implementation of sterilization procedures used in health-care facilities.

Case-control studies have found no evidence that dental procedures increase the risk of iatrogenic transmission of TSEs among humans. In these studies, CJD transmission was not associated with dental procedures (e.g., root canals or extractions), with convincing evidence of prion detection in human blood, saliva, or oral tissues, or with DHCP becoming occupationally infected with CJD (465–467). In 2000, prions were not found in the dental pulps of eight patients with neuropathologically confirmed sporadic CJD by using electrophoresis and a Western blot technique (468).

Prions exhibit unusual resistance to conventional chemical and physical decontamination procedures. Considering this resistance and the invariably fatal outcome of CJD, procedures for disinfecting and sterilizing instruments potentially contaminated with the CJD prion have been controversial for years. Scientific data indicate the risk, if any, of sporadic CJD transmission during dental and oral surgical procedures is low to nil. Until additional information exists regarding the transmissibility of CJD or vCJD, special precautions in addition to

standard precautions might be indicated when treating known CJD or vCJD patients; the following list of precautions is provided for consideration without recommendation (243,249,277,469):

- Use single-use disposable items and equipment whenever possible.
- Consider items difficult to clean (e.g., endodontic files, broaches, and carbide and diamond burs) as single-use disposables and discard after one use.
- To minimize drying of tissues and body fluids on a device, keep the instrument moist until cleaned and decontaminated.
- Clean instruments thoroughly and steam-autoclave at 134°C for 18 minutes. This is the least stringent of sterilization methods offered by the World Health Organization. The complete list (469) is available at <http://www.who.int/emc-documents/tse/whocdscsraph2003c.html>.
- Do not use flash sterilization for processing instruments or devices.

Potential infectivity of oral tissues in CJD or vCJD patients is an unresolved concern. CDC maintains an active surveillance program on CJD. Additional information and resources are available at <http://www.cdc.gov/ncidod/diseases/cjd/cjd.htm>.

## Program Evaluation

The goal of a dental infection-control program is to provide a safe working environment that will reduce the risk of health-

care-associated infections among patients and occupational exposures among DHCP. Medical errors are caused by faulty systems, processes, and conditions that lead persons to make mistakes or fail to prevent errors being made by others (470). Effective program evaluation is a systematic way to ensure procedures are useful, feasible, ethical, and accurate. Program evaluation is an essential organizational practice; however, such evaluation is not practiced consistently across program areas, nor is it sufficiently well-integrated into the day-to-day management of the majority of programs (471).

A successful infection-control program depends on developing standard operating procedures, evaluating practices, routinely documenting adverse outcomes (e.g., occupational exposures to blood) and work-related illnesses in DHCP, and monitoring health-care-associated infections in patients. Strategies and tools to evaluate the infection-control program can include periodic observational assessments, checklists to document procedures, and routine review of occupational exposures to bloodborne pathogens. Evaluation offers an opportunity to improve the effectiveness of both the infection-control program and dental-practice protocols. If deficiencies or problems in the implementation of infection-control procedures are identified, further evaluation is needed to eliminate the problems. Examples of infection-control program evaluation activities are provided (Table 5).

**TABLE 5. Examples of methods for evaluating infection-control programs**

Program element	Evaluation activity
Appropriate immunization of dental health-care personnel (DHCP).	Conduct annual review of personnel records to ensure up-to-date immunizations.
Assessment of occupational exposures to infectious agents.	Report occupational exposures to infectious agents. Document the steps that occurred around the exposure and plan how such exposure can be prevented in the future.
Comprehensive postexposure management plan and medical follow-up program after occupational exposures to infectious agents.	Ensure the postexposure management plan is clear, complete, and available at all times to all DHCP. All staff should understand the plan, which should include toll-free phone numbers for access to additional information.
Adherence to hand hygiene before and after patient care.	Observe and document circumstances of appropriate or inappropriate handwashing. Review findings in a staff meeting.
Proper use of personal protective equipment to prevent occupational exposures to infectious agents.	Observe and document the use of barrier precautions and careful handling of sharps. Review findings in a staff meeting.
Routine and appropriate sterilization of instruments using a biologic monitoring system.	Monitor paper log of steam cycle and temperature strip with each sterilization load, and examine results of weekly biologic monitoring. Take appropriate action when failure of sterilization process is noted.
Evaluation and implementation of safer medical devices.	Conduct an annual review of the exposure control plan and consider new developments in safer medical devices.
Compliance of water in routine dental procedures with current drinking U.S. Environmental Protection Agency water standards (fewer than 500 CFU of heterotrophic water bacteria).	Monitor dental water quality as recommended by the equipment manufacturer, using commercial self-contained test kits, or commercial water-testing laboratories.
Proper handling and disposal of medical waste.	Observe the safe disposal of regulated and nonregulated medical waste and take preventive measures if hazardous situations occur.
Health-care-associated infections.	Assess the unscheduled return of patients after procedures and evaluate them for an infectious process. A trend might require formal evaluation.



## Infection-Control Research Considerations

Although the number of published studies concerning dental infection control has increased in recent years, questions regarding infection-control practices and their effectiveness remain unanswered. Multiple concerns were identified by the working group for this report, as well as by others during the

public comment period (Box). This list is not exhaustive and does not represent a CDC research agenda, but rather is an effort to identify certain concerns, stimulate discussion, and provide direction for determining future action by clinical, basic science, and epidemiologic investigators, as well as health and professional organizations, clinicians, and policy makers.

### BOX. Dental infection-control research considerations

#### Education and promotion

- Design strategies to communicate, to the public and providers, the risk of disease transmission in dentistry.
- Promote use of protocols for recommended postexposure management and follow-up.
- Educate and train dental health-care personnel (DHCP) to screen and evaluate safer dental devices by using tested design and performance criteria.

#### Laboratory-based research

- Develop animal models to determine the risk of transmitting organisms through inhalation of contaminated aerosols (e.g., influenza) produced from rotary dental instruments.
- Conduct studies to determine the effectiveness of gloves (i.e., material compatibility and duration of use).
- Develop devices with passive safety features to prevent percutaneous injuries.
- Study the effect of alcohol-based hand-hygiene products on retention of latex proteins and other dental allergens (e.g., methylmethacrylate, glutaraldehyde, thiurams) on the hands of DHCP after latex glove use.
- Investigate the applicability of other types of sterilization procedures (e.g., hydrogen peroxide gas plasma) in dentistry.
- Encourage manufacturers to determine optimal methods and frequency for testing dental-unit waterlines and maintaining dental-unit water-quality standards.
- Determine the potential for internal contamination of low-speed handpieces, including the motor, and other devices connected to dental air and water supplies, as well as more efficient ways to clean, lubricate, and sterilize handpieces and other devices attached to air or waterlines.
- Investigate the infectivity of oral tissues in Creutzfeldt-Jakob disease (CJD) or variant CJD patients.
- Determine the most effective methods to disinfect dental impression materials.
- Investigate the viability of pathogenic organisms on dental materials (e.g., impression materials, acrylic resin, or gypsum materials) and dental laboratory equipment.
- Determine the most effective methods for sterilization or disinfection of digital radiology equipment.
- Evaluate the effects of repetitive reprocessing cycles on burs and endodontic files.
- Investigate the potential infectivity of vapors generated from the various lasers used for oral procedures.

#### Clinical and population-based epidemiologic research and development

- Continue to characterize the epidemiology of blood contacts, particularly percutaneous injuries, and the effectiveness of prevention measures.
- Further assess the effectiveness of double gloving in preventing blood contact during routine and surgical dental procedures.
- Continue to assess the stress placed on gloves during dental procedures and the potential for developing defects during different procedures.
- Develop methods for evaluating the effectiveness and cost-effectiveness of infection-control interventions.
- Determine how infection-control guidelines affect the knowledge, attitudes, and practices of DHCP.

## Recommendations

Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability. Rankings are based on the system used by CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) to categorize recommendations:

**Category IA.** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

**Category IB.** Strongly recommended for implementation and supported by experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

**Category IC.** Required for implementation as mandated by federal or state regulation or standard. When IC is used, a second rating can be included to provide the basis of existing scientific data, theoretical rationale, and applicability. Because of state differences, the reader should not assume that the absence of a IC implies the absence of state regulations.

**Category II.** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

**Unresolved issue.** No recommendation. Insufficient evidence or no consensus regarding efficacy exists.

### I. Personnel Health Elements of an Infection-Control Program

#### A. General Recommendations

1. Develop a written health program for DHCP that includes policies, procedures, and guidelines for education and training; immunizations; exposure prevention and postexposure management; medical conditions, work-related illness, and associated work restrictions; contact dermatitis and latex hypersensitivity; and maintenance of records, data management, and confidentiality (IB) (5,16–18,22).
2. Establish referral arrangements with qualified health-care professionals to ensure prompt and appropriate provision of preventive services, occupationally related medical services, and postexposure management with medical follow-up (IB, IC) (5,13,19,22).

#### B. Education and Training

1. Provide DHCP 1) on initial employment, 2) when new tasks or procedures affect the employee's occupational exposure, and 3) at a minimum, annually, with education and training regarding occupational exposure to potentially infectious agents and infection-control procedures/protocols appropriate for and spe-

cific to their assigned duties (IB, IC) (5,11,13,14,16,19,22).

2. Provide educational information appropriate in content and vocabulary to the educational level, literacy, and language of DHCP (IB, IC) (5,13).

#### C. Immunization Programs

1. Develop a written comprehensive policy regarding immunizing DHCP, including a list of all required and recommended immunizations (IB) (5,17,18).
2. Refer DHCP to a prearranged qualified health-care professional or to their own health-care professional to receive all appropriate immunizations based on the latest recommendations as well as their medical history and risk for occupational exposure (IB) (5,17).

#### D. Exposure Prevention and Postexposure Management

1. Develop a comprehensive postexposure management and medical follow-up program (IB, IC) (5,13,14,19).
  - a. Include policies and procedures for prompt reporting, evaluation, counseling, treatment, and medical follow-up of occupational exposures.
  - b. Establish mechanisms for referral to a qualified health-care professional for medical evaluation and follow-up.
  - c. Conduct a baseline TST, preferably by using a two-step test, for all DHCP who might have contact with persons with suspected or confirmed infectious TB, regardless of the risk classification of the setting (IB) (20).

#### E. Medical Conditions, Work-Related Illness, and Work Restrictions

1. Develop and have readily available to all DHCP comprehensive written policies regarding work restriction and exclusion that include a statement of authority defining who can implement such policies (IB) (5,22).
2. Develop policies for work restriction and exclusion that encourage DHCP to seek appropriate preventive and curative care and report their illnesses, medical conditions, or treatments that can render them more susceptible to opportunistic infection or exposures; do not penalize DHCP with loss of wages, benefits, or job status (IB) (5,22).

3. Develop policies and procedures for evaluation, diagnosis, and management of DHCP with suspected or known occupational contact dermatitis (IB) (32).
4. Seek definitive diagnosis by a qualified health-care professional for any DHCP with suspected latex allergy to carefully determine its specific etiology and appropriate treatment as well as work restrictions and accommodations (IB) (32).

#### **F. Records Maintenance, Data Management, and Confidentiality**

1. Establish and maintain confidential medical records (e.g., immunization records and documentation of tests received as a result of occupational exposure) for all DHCP (IB, IC) (5,13).
2. Ensure that the practice complies with all applicable federal, state, and local laws regarding medical recordkeeping and confidentiality (IC) (13,34).

## **II. Preventing Transmission of Bloodborne Pathogens**

### **A. HBV Vaccination**

1. Offer the HBV vaccination series to all DHCP with potential occupational exposure to blood or other potentially infectious material (IA, IC) (2,13,14,19).
2. Always follow U.S. Public Health Service/CDC recommendations for hepatitis B vaccination, serologic testing, follow-up, and booster dosing (IA, IC) (13,14,19).
3. Test DHCP for anti-HBs 1–2 months after completion of the 3-dose vaccination series (IA, IC) (14,19).
4. DHCP should complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAg-positive if no antibody response occurs to the primary vaccine series (IA, IC) (14,19).
5. Retest for anti-HBs at the completion of the second vaccine series. If no response to the second 3-dose series occurs, nonresponders should be tested for HBsAg (IC) (14,19).
6. Counsel nonresponders to vaccination who are HBsAg-negative regarding their susceptibility to HBV infection and precautions to take (IA, IC) (14,19).
7. Provide employees appropriate education regarding the risks of HBV transmission and the availability of the vaccine. Employees who decline

the vaccination should sign a declination form to be kept on file with the employer (IC) (13).

### **B. Preventing Exposures to Blood and OPIM**

1. General recommendations
  - a. Use standard precautions (OSHA's blood-borne pathogen standard retains the term universal precautions) for all patient encounters (IA, IC) (11,13,19,53).
  - b. Consider sharp items (e.g., needles, scalers, burs, lab knives, and wires) that are contaminated with patient blood and saliva as potentially infective and establish engineering controls and work practices to prevent injuries (IB, IC) (6,13,113).
  - c. Implement a written, comprehensive program designed to minimize and manage DHCP exposures to blood and body fluids (IB, IC). (13,14,19,97).
2. Engineering and work-practice controls
  - a. Identify, evaluate, and select devices with engineered safety features at least annually and as they become available on the market (e.g., safer anesthetic syringes, blunt suture needle, retractable scalpel, or needleless IV systems) (IC) (13,97,110–112).
  - b. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers located as close as feasible to the area in which the items are used (IA, IC) (2,7,13,19,113,115).
  - c. Do not recap used needles by using both hands or any other technique that involves directing the point of a needle toward any part of the body. Do not bend, break, or remove needles before disposal (IA, IC) (2,7,8,13,97,113).
  - d. Use either a one-handed scoop technique or a mechanical device designed for holding the needle cap when recapping needles (e.g., between multiple injections and before removing from a nondisposable aspirating syringe) (IA, IC) (2,7,8,13,14,113).
3. Postexposure management and prophylaxis
  - a. Follow CDC recommendations after percutaneous, mucous membrane, or nonintact skin exposure to blood or other potentially infectious material (IA, IC) (13,14,19).

### III. Hand Hygiene

#### A. General Considerations

1. Perform hand hygiene with either a nonantimicrobial or antimicrobial soap and water when hands are visibly dirty or contaminated with blood or other potentially infectious material. If hands are not visibly soiled, an alcohol-based hand rub can also be used. Follow the manufacturer's instructions (IA) (123).
2. Indications for hand hygiene include
  - a. when hands are visibly soiled (IA, IC);
  - b. after barehanded touching of inanimate objects likely to be contaminated by blood, saliva, or respiratory secretions (IA, IC);
  - c. before and after treating each patient (IB);
  - d. before donning gloves (IB); and
  - e. immediately after removing gloves (IB, IC) (7–9,11,13,113,120–123,125,126,138).
3. For oral surgical procedures, perform surgical hand antisepsis before donning sterile surgeon's gloves. Follow the manufacturer's instructions by using either an antimicrobial soap and water, or soap and water followed by drying hands and application of an alcohol-based surgical hand-scrub product with persistent activity (IB) (121–123,127–133,144,145).
4. Store liquid hand-care products in either disposable closed containers or closed containers that can be washed and dried before refilling. Do not add soap or lotion to (i.e., top off) a partially empty dispenser (IA) (9,120,122,149,150).

#### B. Special Considerations for Hand Hygiene and Glove Use

1. Use hand lotions to prevent skin dryness associated with handwashing (IA) (153,154).
2. Consider the compatibility of lotion and antiseptic products and the effect of petroleum or other oil emollients on the integrity of gloves during product selection and glove use (IB) (2,14,122,155).
3. Keep fingernails short with smooth, filed edges to allow thorough cleaning and prevent glove tears (II) (122,123,156).
4. Do not wear artificial fingernails or extenders when having direct contact with patients at high risk (e.g., those in intensive care units or operating rooms) (IA) (123,157–160).
5. Use of artificial fingernails is usually not recommended (II) (157–160).

6. Do not wear hand or nail jewelry if it makes donning gloves more difficult or compromises the fit and integrity of the glove (II) (123,142,143).

### IV. PPE

#### A. Masks, Protective Eyewear, and Face Shields

1. Wear a surgical mask and eye protection with solid side shields or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures likely to generate splashing or spattering of blood or other body fluids (IB, IC) (1,2,7,8,11,13,137).
2. Change masks between patients or during patient treatment if the mask becomes wet (IB) (2).
3. Clean with soap and water, or if visibly soiled, clean and disinfect reusable facial protective equipment (e.g., clinician and patient protective eyewear or face shields) between patients (II) (2).

#### B. Protective Clothing

1. Wear protective clothing (e.g., reusable or disposable gown, laboratory coat, or uniform) that covers personal clothing and skin (e.g., forearms) likely to be soiled with blood, saliva, or OPIM (IB, IC) (7,8,11,13,137).
2. Change protective clothing if visibly soiled (134); change immediately or as soon as feasible if penetrated by blood or other potentially infectious fluids (IB, IC) (13).
3. Remove barrier protection, including gloves, mask, eyewear, and gown before departing work area (e.g., dental patient care, instrument processing, or laboratory areas) (IC) (13).

#### C. Gloves

1. Wear medical gloves when a potential exists for contacting blood, saliva, OPIM, or mucous membranes (IB, IC) (1,2,7,8,13).
2. Wear a new pair of medical gloves for each patient, remove them promptly after use, and wash hands immediately to avoid transfer of microorganisms to other patients or environments (IB) (1,7,8,123).
3. Remove gloves that are torn, cut, or punctured as soon as feasible and wash hands before regloving (IB, IC) (13,210,211).
4. Do not wash surgeon's or patient examination gloves before use or wash, disinfect, or sterilize gloves for reuse (IB, IC) (13,138,177,212,213).

5. Ensure that appropriate gloves in the correct size are readily accessible (IC) (13).
6. Use appropriate gloves (e.g., puncture- and chemical-resistant utility gloves) when cleaning instruments and performing housekeeping tasks involving contact with blood or OPIM (IB, IC) (7,13,15).
7. Consult with glove manufacturers regarding the chemical compatibility of glove material and dental materials used (II).

#### **D. Sterile Surgeon's Gloves and Double Gloving During Oral Surgical Procedures**

1. Wear sterile surgeon's gloves when performing oral surgical procedures (IB) (2,8,137).
2. No recommendation is offered regarding the effectiveness of wearing two pairs of gloves to prevent disease transmission during oral surgical procedures. The majority of studies among HCP and DHCP have demonstrated a lower frequency of inner glove perforation and visible blood on the surgeon's hands when double gloves are worn; however, the effectiveness of wearing two pairs of gloves in preventing disease transmission has not been demonstrated (Unresolved issue).

#### **V. Contact Dermatitis and Latex Hypersensitivity**

##### **A. General Recommendations**

1. Educate DHCP regarding the signs, symptoms, and diagnoses of skin reactions associated with frequent hand hygiene and glove use (IB) (5,31,32).
2. Screen all patients for latex allergy (e.g., take health history and refer for medical consultation when latex allergy is suspected) (IB) (32).
3. Ensure a latex-safe environment for patients and DHCP with latex allergy (IB) (32).
4. Have emergency treatment kits with latex-free products available at all times (II) (32).

#### **VI. Sterilization and Disinfection of Patient-Care Items**

##### **A. General Recommendations**

1. Use only FDA-cleared medical devices for sterilization and follow the manufacturer's instructions for correct use (IB) (248).
2. Clean and heat-sterilize critical dental instruments before each use (IA) (2,137,243,244,246,249,407).
3. Clean and heat-sterilize semicritical items before each use (IB) (2,249,260,407).
4. Allow packages to dry in the sterilizer before they are handled to avoid contamination (IB) (247).

5. Use of heat-stable semicritical alternatives is encouraged (IB) (2).
6. Reprocess heat-sensitive critical and semi-critical instruments by using FDA-cleared sterilant/high-level disinfectants or an FDA-cleared low-temperature sterilization method (e.g., ethylene oxide). Follow manufacturer's instructions for use of chemical sterilants/high-level disinfectants (IB) (243).
7. Single-use disposable instruments are acceptable alternatives if they are used only once and disposed of correctly (IB, IC) (243,383).
8. Do not use liquid chemical sterilants/high-level disinfectants for environmental surface disinfection or as holding solutions (IB, IC) (243,245).
9. Ensure that noncritical patient-care items are barrier-protected or cleaned, or if visibly soiled, cleaned and disinfected after each use with an EPA-registered hospital disinfectant. If visibly contaminated with blood, use an EPA-registered hospital disinfectant with a tuberculocidal claim (i.e., intermediate level) (IB) (2,243,244).
10. Inform DHCP of all OSHA guidelines for exposure to chemical agents used for disinfection and sterilization. Using this report, identify areas and tasks that have potential for exposure (IC) (15).

##### **B. Instrument Processing Area**

1. Designate a central processing area. Divide the instrument processing area, physically or, at a minimum, spatially, into distinct areas for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Do not store instruments in an area where contaminated instruments are held or cleaned (II) (173,247,248).
2. Train DHCP to employ work practices that prevent contamination of clean areas (II).

##### **C. Receiving, Cleaning, and Decontamination Work Area**

1. Minimize handling of loose contaminated instruments during transport to the instrument processing area. Use work-practice controls (e.g., carry instruments in a covered container) to minimize exposure potential (II). Clean all visible blood and other contamination from dental instruments and devices before sterilization or disinfection procedures (IA) (243,249–252).
2. Use automated cleaning equipment (e.g., ultrasonic cleaner or washer-disinfector) to remove



debris to improve cleaning effectiveness and decrease worker exposure to blood (IB) (2,253).

3. Use work-practice controls that minimize contact with sharp instruments if manual cleaning is necessary (e.g., long-handled brush) (IC) (14).
4. Wear puncture- and chemical-resistant/heavy-duty utility gloves for instrument cleaning and decontamination procedures (IB) (7).
5. Wear appropriate PPE (e.g., mask, protective eyewear, and gown) when splashing or spraying is anticipated during cleaning (IC) (13).

#### D. Preparation and Packaging

1. Use an internal chemical indicator in each package. If the internal indicator cannot be seen from outside the package, also use an external indicator (II) (243,254,257).
2. Use a container system or wrapping compatible with the type of sterilization process used and that has received FDA clearance (IB) (243,247,256).
3. Before sterilization of critical and semicritical instruments, inspect instruments for cleanliness, then wrap or place them in containers designed to maintain sterility during storage (e.g., cassettes and organizing trays) (IA) (2,247,255,256).

#### E. Sterilization of Unwrapped Instruments

1. Clean and dry instruments before the unwrapped sterilization cycle (IB) (248).
2. Use mechanical and chemical indicators for each unwrapped sterilization cycle (i.e., place an internal chemical indicator among the instruments or items to be sterilized) (IB) (243,258).
3. Allow unwrapped instruments to dry and cool in the sterilizer before they are handled to avoid contamination and thermal injury (II) (260).
4. Semicritical instruments that will be used immediately or within a short time can be sterilized unwrapped on a tray or in a container system, provided that the instruments are handled aseptically during removal from the sterilizer and transport to the point of use (II).
5. Critical instruments intended for immediate reuse can be sterilized unwrapped if the instruments are maintained sterile during removal from the sterilizer and transport to the point of use (e.g., transported in a sterile covered container) (IB) (258).
6. Do not sterilize implantable devices unwrapped (IB) (243,247).

7. Do not store critical instruments unwrapped (IB) (248).

#### F. Sterilization Monitoring

1. Use mechanical, chemical, and biological monitors according to the manufacturer's instructions to ensure the effectiveness of the sterilization process (IB) (248,278,279).
2. Monitor each load with mechanical (e.g., time, temperature, and pressure) and chemical indicators (II) (243,248).
3. Place a chemical indicator on the inside of each package. If the internal indicator is not visible from the outside, also place an exterior chemical indicator on the package (II) (243,254,257).
4. Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant (IB) (243).
5. Do not use instrument packs if mechanical or chemical indicators indicate inadequate processing (IB) (243,247,248).
6. Monitor sterilizers at least weekly by using a biological indicator with a matching control (i.e., biological indicator and control from same lot number) (IB) (2,9,243,247,278,279).
7. Use a biological indicator for every sterilizer load that contains an implantable device. Verify results before using the implantable device, whenever possible (IB) (243,248).
8. The following are recommended in the case of a positive spore test:
  - a. Remove the sterilizer from service and review sterilization procedures (e.g., work practices and use of mechanical and chemical indicators) to determine whether operator error could be responsible (II) (8).
  - b. Retest the sterilizer by using biological, mechanical, and chemical indicators after correcting any identified procedural problems (II).
  - c. If the repeat spore test is negative, and mechanical and chemical indicators are within normal limits, put the sterilizer back in service (II) (9,243).
9. The following are recommended if the repeat spore test is positive:
  - a. Do not use the sterilizer until it has been inspected or repaired or the exact reason for the positive test has been determined (II) (9,243).

- b. Recall, to the extent possible, and reprocess all items processed since the last negative spore test (II) (9,243,283).
  - c. Before placing the sterilizer back in service, rechallenge the sterilizer with biological indicator tests in three consecutive empty chamber sterilization cycles after the cause of the sterilizer failure has been determined and corrected (II) (9,243,283).
10. Maintain sterilization records (i.e., mechanical, chemical, and biological) in compliance with state and local regulations (IB) (243).

#### G. Storage Area for Sterilized Items and Clean Dental Supplies

1. Implement practices on the basis of date- or event-related shelf-life for storage of wrapped, sterilized instruments and devices (IB) (243, 284).
2. Even for event-related packaging, at a minimum, place the date of sterilization, and if multiple sterilizers are used in the facility, the sterilizer used, on the outside of the packaging material to facilitate the retrieval of processed items in the event of a sterilization failure (IB) (243,247).
3. Examine wrapped packages of sterilized instruments before opening them to ensure the barrier wrap has not been compromised during storage (II) (243,284).
4. Reclean, repack, and resterilize any instrument package that has been compromised (II).
5. Store sterile items and dental supplies in covered or closed cabinets, if possible (II) (285).

### VII. Environmental Infection Control

#### A. General Recommendations

1. Follow the manufacturers' instructions for correct use of cleaning and EPA-registered hospital disinfecting products (IB, IC) (243–245).
2. Do not use liquid chemical sterilants/high-level disinfectants for disinfection of environmental surfaces (clinical contact or housekeeping) (IB, IC) (243–245).
3. Use PPE, as appropriate, when cleaning and disinfecting environmental surfaces. Such equipment might include gloves (e.g., puncture- and chemical-resistant utility), protective clothing (e.g., gown, jacket, or lab coat), and protective eyewear/face shield, and mask (IC) (13,15).

#### B. Clinical Contact Surfaces

1. Use surface barriers to protect clinical contact surfaces, particularly those that are difficult to

clean (e.g., switches on dental chairs) and change surface barriers between patients (II) (1,2,260, 288).

2. Clean and disinfect clinical contact surfaces that are not barrier-protected, by using an EPA-registered hospital disinfectant with a low- (i.e., HIV and HBV label claims) to intermediate-level (i.e., tuberculocidal claim) activity after each patient. Use an intermediate-level disinfectant if visibly contaminated with blood (IB) (2,243,244).

#### C. Housekeeping Surfaces

1. Clean housekeeping surfaces (e.g., floors, walls, and sinks) with a detergent and water or an EPA-registered hospital disinfectant/detergent on a routine basis, depending on the nature of the surface and type and degree of contamination, and as appropriate, based on the location in the facility, and when visibly soiled (IB) (243,244).
2. Clean mops and cloths after use and allow to dry before reuse; or use single-use, disposable mop heads or cloths (II) (243,244).
3. Prepare fresh cleaning or EPA-registered disinfecting solutions daily and as instructed by the manufacturer. (II) (243,244).
4. Clean walls, blinds, and window curtains in patient-care areas when they are visibly dusty or soiled (II) (9,244).

#### D. Spills of Blood and Body Substances

1. Clean spills of blood or OPIM and decontaminate surface with an EPA-registered hospital disinfectant with low- (i.e., HBV and HIV label claims) to intermediate-level (i.e., tuberculocidal claim) activity, depending on size of spill and surface porosity (IB, IC) (13,113).

#### E. Carpet and Cloth Furnishings

1. Avoid using carpeting and cloth-upholstered furnishings in dental operatories, laboratories, and instrument processing areas (II) (9,293–295).

#### F. Regulated Medical Waste

1. General Recommendations
  - a. Develop a medical waste management program. Disposal of regulated medical waste must follow federal, state, and local regulations (IC) (13,301).
  - b. Ensure that DHCP who handle and dispose of regulated medical waste are trained in appropriate handling and disposal methods

- and informed of the possible health and safety hazards (IC) (13).
2. Management of Regulated Medical Waste in Dental Health-Care Facilities
    - a. Use a color-coded or labeled container that prevents leakage (e.g., biohazard bag) to contain nonsharp regulated medical waste (IC) (13).
    - b. Place sharp items (e.g., needles, scalpel blades, orthodontic bands, broken metal instruments, and burs) in an appropriate sharps container (e.g., puncture resistant, color-coded, and leakproof). Close container immediately before removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping (IC) (2,8,13,113,115).
    - c. Pour blood, suctioned fluids or other liquid waste carefully into a drain connected to a sanitary sewer system, if local sewage discharge requirements are met and the state has declared this an acceptable method of disposal. Wear appropriate PPE while performing this task (IC) (7,9,13).

### VIII. Dental Unit Waterlines, Biofilm, and Water Quality

#### A. General Recommendations

1. Use water that meets EPA regulatory standards for drinking water (i.e.,  $\leq 500$  CFU/mL of heterotrophic water bacteria) for routine dental treatment output water (IB, IC) (341,342).
2. Consult with the dental unit manufacturer for appropriate methods and equipment to maintain the recommended quality of dental water (II) (339).
3. Follow recommendations for monitoring water quality provided by the manufacturer of the unit or waterline treatment product (II).
4. Discharge water and air for a minimum of 20–30 seconds after each patient, from any device connected to the dental water system that enters the patient's mouth (e.g., handpieces, ultrasonic scalers, and air/water syringes) (II) (2,311,344).
5. Consult with the dental unit manufacturer on the need for periodic maintenance of antiretraction mechanisms (IB) (2,311).

#### B. Boil-Water Advisories

1. The following apply while a boil-water advisory is in effect:
  - a. Do not deliver water from the public water system to the patient through the dental

- operative unit, ultrasonic scaler, or other dental equipment that uses the public water system (IB, IC) (341,342,346,349,350).
  - b. Do not use water from the public water system for dental treatment, patient rinsing, or handwashing (IB, IC) (341,342,346,349,350).
  - c. For handwashing, use antimicrobial-containing products that do not require water for use (e.g., alcohol-based hand rubs). If hands are visibly contaminated, use bottled water, if available, and soap for handwashing or an antiseptic towelette (IB, IC) (13,122).
2. The following apply when the boil-water advisory is cancelled:
    - a. Follow guidance given by the local water utility regarding adequate flushing of waterlines. If no guidance is provided, flush dental waterlines and faucets for 1–5 minutes before using for patient care (IC) (244,346,351,352).
    - b. Disinfect dental waterlines as recommended by the dental unit manufacturer (II).

### IX. Special Considerations

#### A. Dental Handpieces and Other Devices Attached to Air and Waterlines

1. Clean and heat-sterilize handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units between patients (IB, IC) (2,246,275,356,357,360,407).
2. Follow the manufacturer's instructions for cleaning, lubrication, and sterilization of handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units (IB) (361–363).
3. Do not surface-disinfect, use liquid chemical sterilants, or ethylene oxide on handpieces and other intraoral instruments that can be removed from the air and waterlines of dental units (IC) (2,246,250,275).
4. Do not advise patients to close their lips tightly around the tip of the saliva ejector to evacuate oral fluids (II) (364–366).

#### B. Dental Radiology

1. Wear gloves when exposing radiographs and handling contaminated film packets. Use other PPE (e.g., protective eyewear, mask, and gown) as appropriate if spattering of blood or other body fluids is likely (IA, IC) (11,13).



2. Use heat-tolerant or disposable intraoral devices whenever possible (e.g., film-holding and positioning devices). Clean and heat-sterilize heat-tolerant devices between patients. At a minimum, high-level disinfect semicritical heat-sensitive devices, according to manufacturer's instructions (IB) (243).
3. Transport and handle exposed radiographs in an aseptic manner to prevent contamination of developing equipment (II).
4. The following apply for digital radiography sensors:
  - a. Use FDA-cleared barriers (IB) (243).
  - b. Clean and heat-sterilize, or high-level disinfect, between patients, barrier-protected semicritical items. If the item cannot tolerate these procedures then, at a minimum, protect with an FDA-cleared barrier and clean and disinfect with an EPA-registered hospital disinfectant with intermediate-level (i.e., tuberculocidal claim) activity, between patients. Consult with the manufacturer for methods of disinfection and sterilization of digital radiology sensors and for protection of associated computer hardware (IB) (243).

#### C. Aseptic Technique for Parenteral Medications

1. Do not administer medication from a syringe to multiple patients, even if the needle on the syringe is changed (IA) (378).
2. Use single-dose vials for parenteral medications when possible (II) (376,377).
3. Do not combine the leftover contents of single-use vials for later use (IA) (376,377).
4. The following apply if multidose vials are used:
  - a. Cleanse the access diaphragm with 70% alcohol before inserting a device into the vial (IA) (380,381).
  - b. Use a sterile device to access a multiple-dose vial and avoid touching the access diaphragm. Both the needle and syringe used to access the multidose vial should be sterile. Do not reuse a syringe even if the needle is changed (IA) (380,381).
  - c. Keep multidose vials away from the immediate patient treatment area to prevent inadvertent contamination by spray or spatter (II).
  - d. Discard the multidose vial if sterility is compromised (IA) (380,381).

5. Use fluid infusion and administration sets (i.e., IV bags, tubings and connections) for one patient only and dispose of appropriately (IB) (378).

#### D. Single-Use (Disposable) Devices

1. Use single-use devices for one patient only and dispose of them appropriately (IC) (383).

#### E. Preprocedural Mouth Rinses

1. No recommendation is offered regarding use of preprocedural antimicrobial mouth rinses to prevent clinical infections among DHCP or patients. Although studies have demonstrated that a preprocedural antimicrobial rinse (e.g., chlorhexidine gluconate, essential oils, or povidone-iodine) can reduce the level of oral microorganisms in aerosols and spatter generated during routine dental procedures and can decrease the number of microorganisms introduced in the patient's bloodstream during invasive dental procedures (391–399), the scientific evidence is inconclusive that using these rinses prevents clinical infections among DHCP or patients (see discussion, Preprocedural Mouth Rinses) (Unresolved issue).

#### F. Oral Surgical Procedures

1. The following apply when performing oral surgical procedures:
  - a. Perform surgical hand antisepsis by using an antimicrobial product (e.g., antimicrobial soap and water, or soap and water followed by alcohol-based hand scrub with persistent activity) before donning sterile surgeon's gloves (IB) (127–132,137).
  - b. Use sterile surgeon's gloves (IB) (2,7,121,123,137).
  - c. Use sterile saline or sterile water as a coolant/irrigant when performing oral surgical procedures. Use devices specifically designed for delivering sterile irrigating fluids (e.g., bulb syringe, single-use disposable products, and sterilizable tubing) (IB) (2,121).

#### G. Handling of Biopsy Specimens

1. During transport, place biopsy specimens in a sturdy, leakproof container labeled with the biohazard symbol (IC) (2,13,14).
2. If a biopsy specimen container is visibly contaminated, clean and disinfect the outside of a

container or place it in an impervious bag labeled with the biohazard symbol, (IC) (2,13).

#### H. Handling of Extracted Teeth

1. Dispose of extracted teeth as regulated medical waste unless returned to the patient (IC) (13,14).
2. Do not dispose of extracted teeth containing amalgam in regulated medical waste intended for incineration (II).
3. Clean and place extracted teeth in a leakproof container, labeled with a biohazard symbol, and maintain hydration for transport to educational institutions or a dental laboratory (IC) (13,14).
4. Heat-sterilize teeth that do not contain amalgam before they are used for educational purposes (IB) (403,405,406).

#### I. Dental Laboratory

1. Use PPE when handling items received in the laboratory until they have been decontaminated (IA, IC) (2,7,11,13,113).
2. Before they are handled in the laboratory, clean, disinfect, and rinse all dental prostheses and prosthodontic materials (e.g., impressions, bite registrations, occlusal rims, and extracted teeth) by using an EPA-registered hospital disinfectant having at least an intermediate-level (i.e., tuberculocidal claim) activity (IB) (2,249,252,407).
3. Consult with manufacturers regarding the stability of specific materials (e.g., impression materials) relative to disinfection procedures (II).
4. Include specific information regarding disinfection techniques used (e.g., solution used and duration), when laboratory cases are sent off-site and on their return (II) (2,407,409).
5. Clean and heat-sterilize heat-tolerant items used in the mouth (e.g., metal impression trays and face-bow forks) (IB) (2,407).
6. Follow manufacturers' instructions for cleaning and sterilizing or disinfecting items that become contaminated but do not normally contact the patient (e.g., burs, polishing points, rag wheels, articulators, case pans, and lathes). If manufacturer instructions are unavailable, clean and heat-sterilize heat-tolerant items or clean and disinfect with an EPA-registered hospital disinfectant with low- (HIV, HBV effectiveness claim) to intermediate-level (tuberculocidal claim) activity, depending on the degree of contamination (II).

#### J. Laser/Electrosurgery Plumes/Surgical Smoke

1. No recommendation is offered regarding practices to reduce DHCP exposure to laser plumes/surgical smoke when using lasers in dental practice. Practices to reduce HCP exposure to laser plumes/surgical smoke have been suggested, including use of a) standard precautions (e.g., high-filtration surgical masks and possibly full face shields) (437); b) central room suction units with in-line filters to collect particulate matter from minimal plumes; and c) dedicated mechanical smoke exhaust systems with a high-efficiency filter to remove substantial amounts of laser-plume particles. The effect of the exposure (e.g., disease transmission or adverse respiratory effects) on DHCP from dental applications of lasers has not been adequately evaluated (see previous discussion, Laser/Electrosurgery Plumes or Surgical Smoke) (Unresolved issue).

#### K. *Mycobacterium tuberculosis*

1. General Recommendations
  - a. Educate all DHCP regarding the recognition of signs, symptoms, and transmission of TB (IB) (20,21).
  - b. Conduct a baseline TST, preferably by using a two-step test, for all DHCP who might have contact with persons with suspected or confirmed active TB, regardless of the risk classification of the setting (IB) (20).
  - c. Assess each patient for a history of TB as well as symptoms indicative of TB and document on the medical history form (IB) (20,21).
  - d. Follow CDC recommendations for 1) developing, maintaining, and implementing a written TB infection-control plan; 2) managing a patient with suspected or active TB; 3) completing a community risk-assessment to guide employee TSTs and follow-up; and 4) managing DHCP with TB disease (IB) (2,21).
2. The following apply for patients known or suspected to have active TB:
  - a. Evaluate the patient away from other patients and DHCP. When not being evaluated, the patient should wear a surgical mask or be instructed to cover mouth and nose when coughing or sneezing (IB) (20,21).
  - b. Defer elective dental treatment until the patient is noninfectious (IB) (20,21).

- c. Refer patients requiring urgent dental treatment to a previously identified facility with TB engineering controls and a respiratory protection program (IB) (20,21).

#### L. Creutzfeldt-Jakob Disease (CJD) and Other Prion Diseases

1. No recommendation is offered regarding use of special precautions in addition to standard precautions when treating known CJD or vCJD patients. Potential infectivity of oral tissues in CJD or vCJD patients is an unresolved issue. Scientific data indicate the risk, if any, of sporadic CJD transmission during dental and oral surgical procedures is low to nil. Until additional information exists regarding the transmissibility of CJD or vCJD during dental procedures, special precautions in addition to standard precautions might be indicated when treating known CJD or vCJD patients; a list of such precautions is provided for consideration without recommendation (see Creutzfeldt-Jakob Disease and Other Prion Diseases) (Unresolved issue).

#### M. Program Evaluation

1. Establish routine evaluation of the infection-control program, including evaluation of performance indicators, at an established frequency (II) (470-471).

## Infection-Control Internet Resources

### Advisory Committee on Immunization Practices

<http://www.cdc.gov/nip/ACIP/default.htm>

### American Dental Association

<http://www.ada.org>

### American Institute of Architects Academy of Architecture for Health

<http://www.aahaia.org>

### American Society of Heating, Refrigeration, Air-conditioning Engineers

<http://www.ashrae.org>

### Association for Professionals in Infection Control and Epidemiology, Inc.

<http://www.apic.org/resc/guidlist.cfm>

### CDC, Division of Healthcare Quality Promotion

<http://www.cdc.gov/ncidod/hip>

### CDC, Division of Oral Health, Infection Control

<http://www.cdc.gov/OralHealth/infectioncontrol/index.htm>

### CDC, *Morbidity and Mortality Weekly Report*

<http://www.cdc.gov/mmwr>

### CDC, NIOSH

<http://www.cdc.gov/niosh/homepage.html>

### CDC Recommends, Prevention Guidelines System

<http://www.phppo.cdc.gov/cdcRecommends/AdvSearchV.asp>

### EPA, Antimicrobial Chemicals

<http://www.epa.gov/oppad001/chemregindex.htm>

### FDA

<http://www.fda.gov>

### Immunization Action Coalition

<http://www.immunize.org/acip>

### Infectious Diseases Society of America

<http://www.idsociety.org/PG/toc.htm>

### OSHA, Dentistry, Bloodborne Pathogens

<http://www.osha.gov/SLTC/dentistry/index.html>

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

### Organization for Safety and Asepsis Procedures

<http://www.osap.org>

### Society for Healthcare Epidemiology of America, Inc., Position Papers

<http://www.shea-online.org/PositionPapers.html>

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## Appendix A

### Regulatory Framework for Disinfectants and Sterilants

When using the guidance provided in this report regarding use of liquid chemical disinfectants and sterilants, dental health-care personnel (DHCP) should be aware of federal laws and regulations that govern the sale, distribution, and use of these products. In particular, DHCPs should know what requirements pertain to them when such products are used. Finally, DHCP should understand the relative roles of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and CDC.

The choice of specific cleaning or disinfecting agents is largely a matter of judgment, guided by product label claims and instructions and government regulations. A single liquid chemical germicide might not satisfy all disinfection requirements in a given dental practice or facility. Realistic use of liquid chemical germicides depends on consideration of multiple factors, including the degree of microbial killing required; the nature and composition of the surface, item, or device to be treated; and the cost, safety, and ease of use of the available agents. Selecting one appropriate product with a higher degree of potency to cover all situations might be more convenient.

In the United States, liquid chemical germicides (disinfectants) are regulated by EPA and FDA (*A-1-A-3*). In health-care settings, EPA regulates disinfectants that are used on environmental surfaces (housekeeping and clinical contact surfaces), and FDA regulates liquid chemical sterilants/high-level disinfectants (e.g., glutaraldehyde, hydrogen peroxide, and peracetic acid) used on critical and semicritical patient-care devices. Disinfectants intended for use on clinical contact surfaces (e.g., light handles, radiographic-ray heads, or drawer knobs) or housekeeping surfaces (e.g., floors, walls, or sinks) are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended in 1996 (*A-4*). Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution. To obtain a registration, a manufacturer must submit specific data regarding the safety and the effectiveness of each product.

EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product

may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly. The following statement appears on all EPA-registered product labels under the Directions for Use heading: "It is a violation of federal law to use this product inconsistent with its labeling." This means that DHCP must follow the safety precautions and use directions on the labeling of each registered product. Not following the specified dilution, contact time, method of application, or any other condition of use is considered misuse of the product.

FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug, and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices (e.g., dental unit waterline or flexible endoscope). A liquid chemical germicide marketed for use on a specific device is considered, for regulatory purposes, a medical device itself when used to disinfect that specific medical device. Also, this FDA regulatory authority over a particular instrument or device dictates that the manufacturer is obligated to provide the user with adequate instructions for the safe and effective use of that device. These instructions must include methods to clean and disinfect or sterilize the item if it is to be marketed as a reusable medical device.

OSHA develops workplace standards to help ensure safe and healthful working conditions in places of employment. OSHA is authorized under Pub. L. 95-251, and as amended, to enforce these workplace standards. In 1991, OSHA published Occupational Exposure to Bloodborne Pathogens; final rule [29 CFR Part 1910.1030] (*A-5*). This standard is designed to help prevent occupational exposures to blood or other potentially infectious substances. Under this standard, OSHA has interpreted that, to decontaminate contaminated work surfaces, either an EPA-registered hospital tuberculocidal disinfectant or an EPA-registered hospital disinfectant labeled as effective against human immunodeficiency virus (HIV) and hepatitis B virus (HBV) is appropriate. Hospital disinfectants with such HIV and HBV claims can be used, provided surfaces are not contaminated with agents or concentration of agents for which higher level (i.e., intermediate-level) disinfection is recommended. In addition, as with all disinfectants, effectiveness is governed by strict adherence to the label instructions for intended use of the product.

CDC is not a regulatory agency and does not test, evaluate, or otherwise recommend specific brand-name products of chemical germicides. This report is intended to provide overall guidance for providers to select general classifications of products based on certain infection-control principles. In this report, CDC provides guidance to practitioners regarding appropriate application of EPA- and FDA-registered liquid chemical disinfectants and sterilants in dental health-care settings.

CDC recommends disinfecting environmental surfaces or sterilizing or disinfecting medical equipment, and DHCP should use products approved by EPA and FDA unless no such products are available for use against certain microorganisms or sites. However, if no registered or approved products are available for a specific pathogen or use situation, DHCP are advised to follow the specific guidance regarding unregistered or unapproved (e.g., off-label) uses for various chemical germicides. For example, no antimicrobial products are registered for use specifically against certain emerging pathogens (e.g., Norwalk virus), potential terrorism agents (e.g., variola major or *Yersinia pestis*), or Creutzfeldt-Jakob disease agents.

One point of clarification is the difference in how EPA and FDA classify disinfectants. FDA adopted the same basic terminology and classification scheme as CDC to categorize medical devices (i.e., critical, semicritical, and noncritical) and to define antimicrobial potency for processing surfaces (i.e., sterilization, and high-, intermediate- and low-level disinfection) (A-6). EPA registers environmental surface disinfectants based on the manufacturer's microbiological activity claims when registering its disinfectant. This difference has led to confusion on the part of users because the EPA does not use the terms intermediate- and low-level disinfectants as used in CDC guidelines.

CDC designates any EPA-registered hospital disinfectant without a tuberculocidal claim as a low-level disinfectant and any EPA-registered hospital disinfectant with a tuberculocidal claim as an intermediate-level disinfectant. To understand this comparison, one needs to know how EPA registers disinfectants. First, to be labeled as an EPA hospital disinfectant, the product must pass Association of Official Analytical Chemists (AOAC) effectiveness tests against three target organisms: *Salmonella choleraesuis* for effectiveness against gram-negative bacteria; *Staphylococcus aureus* for effectiveness against gram-positive bacteria; and *Pseudomonas aeruginosa* for effectiveness

against a primarily nosocomial pathogen. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the test microorganisms are permitted, but not required, provided that the test microorganisms are likely to be present in or on the recommended use areas and surfaces. Therefore, manufacturers might also test specifically against organisms of known concern in health-care practices (e.g., HIV, HBV, hepatitis C virus [HCV], and herpes) although it is considered likely that any product satisfying AOAC tests for hospital disinfectant designation will also be effective against these relatively fragile organisms when the product is used as directed by the manufacturer.

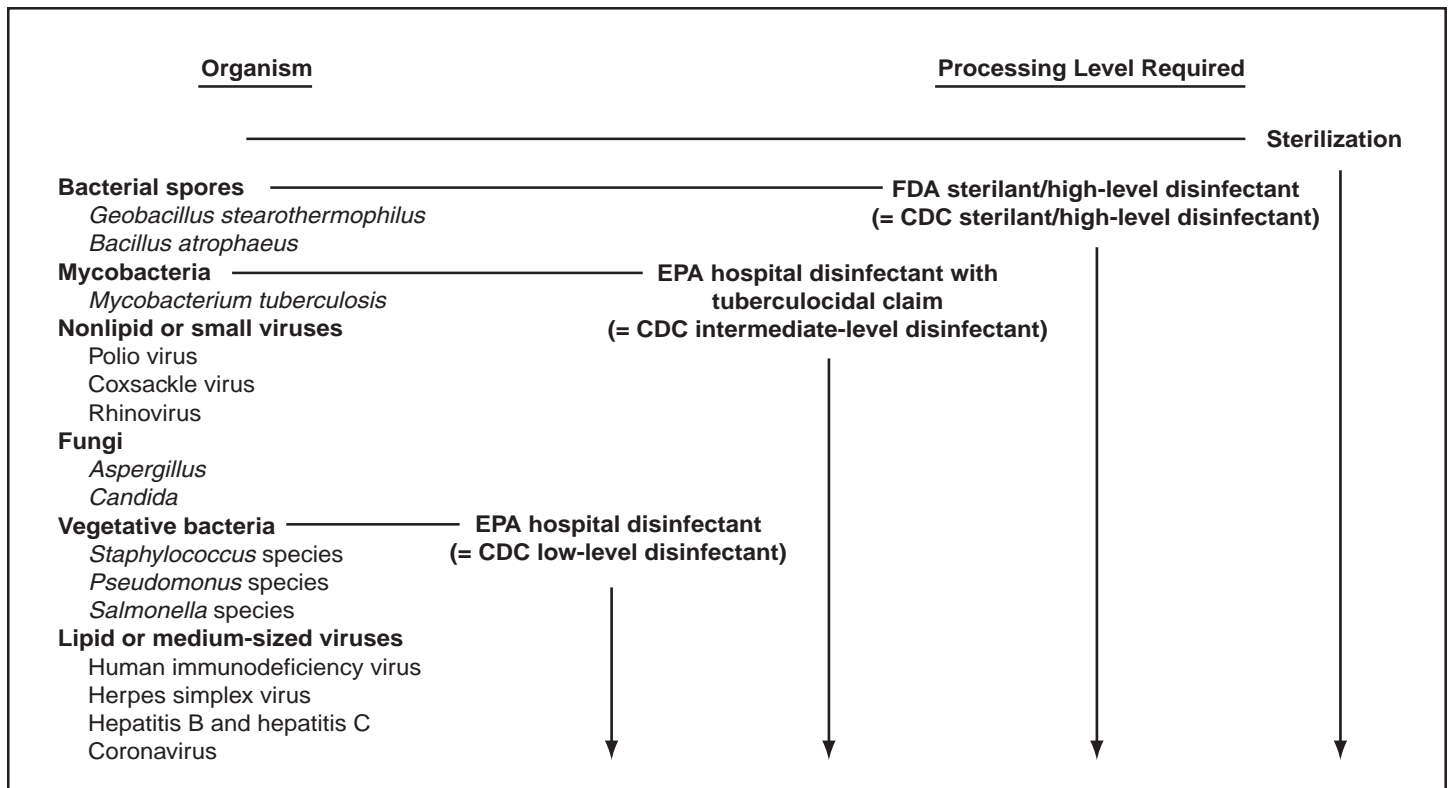
Potency against *Mycobacterium tuberculosis* has been recognized as a substantial benchmark. However, the tuberculocidal claim is used only as a benchmark to measure germicidal potency. Tuberculosis is not transmitted via environmental surfaces but rather by the airborne route. Accordingly, use of such products on environmental surfaces plays no role in preventing the spread of tuberculosis. However, because mycobacteria have among the highest intrinsic levels of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label is considered capable of inactivating a broad spectrum of pathogens, including such less-resistant organisms as bloodborne pathogens (e.g., HBV, HCV, and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection.

EPA also lists disinfectant products according to their labeled use against these organisms of interest as follows:

- **List B.** Tuberculocide products effective against *Mycobacterium* species.
- **List C.** Products effective against human HIV-1 virus.
- **List D.** Products effective against human HIV-1 virus and HBV.
- **List E.** Products effective against *Mycobacterium* species, human HIV-1 virus, and HBV.
- **List F.** Products effective against HCV.

Microorganisms vary in their resistance to disinfection and sterilization, enabling CDC's designation of disinfectants as high-, intermediate-, and low-level, when compared with EPA's designated organism spectrum (Figure). However, exceptions to this general guide exist, and manufacturer's label claims and instructions should always be followed.

FIGURE. Decreasing order of resistance of microorganisms to germicidal chemicals



**Source:** Adapted from Bond WW, Ott BJ, Franke K, McCracken JE. Effective use of liquid chemical germicides on medical devices; instrument design problems. In: Block SS, ed. Disinfection, sterilization and preservation. 4<sup>th</sup> ed. Philadelphia, PA: Lea & Gebiger, 1991:1100.

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- A-1. Food and Drug Administration (FDA) and US Environmental Protection Agency (EPA). Memorandum of understanding between the FDA and EPA: notice regarding matters of mutual responsibility—regulation of liquid chemical germicides intended for use on medical devices. Rockville, MD: US Department of Health and Human Services, Public Health Service, Food and Drug Administration, US Environmental Protection Agency, 1993.
- A-2. Food and Drug Administration (FDA). Interim measures for registration of antimicrobial products/liquid chemical germicides with medical device use claims under the memorandum of understanding between EPA and FDA. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, 1994.
- A-3. Food and Drug Administration. Guidance for industry and FDA reviewers: content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, 2000. Available at <http://www.fda.gov/cdrh/ode/397.pdf>.
- A-4. US Environmental Protection Agency. 40 CFR Parts 152, 156, and 158. Exemption of certain pesticide substances from federal insecticide, fungicide, and rodenticide act requirements. Amended 1996. Federal Register 1996;61:8876–9.
- A-5. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; needlesticks and other sharps injuries; final rule. Federal Register 2001;66:5317–25. As amended from and includes 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; final rule. Federal Register 1991;56:64174–82. Available at <http://www.osha.gov/SLTC/dentistry/index.html>.
- A-6. Spaulding EH. Role of chemical disinfection in preventing nosocomial infections. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Brachman PS, Eickhoff TC, eds. Chicago, IL: American Hospital Association, 1971:247–54.

## Appendix B

### Immunizations Strongly Recommended for Health-Care Personnel (HCP)

Vaccine	Dose schedule	Indications	Major precautions and contraindications	Special considerations
Hepatitis B recombinant vaccine*	Three-dose schedule administered intramuscularly (IM) in the deltoid; 0, 1, 6 - second dose administered 1 month after first dose; third dose administered 4 months after second. Booster doses are not necessary for persons who have developed adequate antibodies to hepatitis B surface antigen (anti-HBs).	Health-care personnel (HCP) at risk for exposure to blood and body fluids.	History of anaphylactic reaction to common baker's yeast. Pregnancy is not a contraindication.	No therapeutic or adverse effects on hepatitis B virus (HBV)-infected persons; cost-effectiveness of prevaccination screening for susceptibility to HBV depends on costs of vaccination and antibody testing and prevalence of immunity in the group of potential vaccinees; health-care personnel who have ongoing contact with patients or blood should be tested 1–2 months after completing the vaccination series to determine serologic response. If vaccination does not induce adequate anti-HBs (>10 mIU/mL), a second vaccine series should be administered.
Influenza vaccine (inactivated) <sup>¶</sup>	Annual single-dose vaccination IM with current vaccine.	HCP who have contact with patients at high risk or who work in chronic-care facilities; HCP aged ≥50 years or who have high-risk medical conditions.	History of anaphylactic hypersensitivity to eggs or to other components of the vaccine.	Recommended for women who will be in the second or third trimesters of pregnancy during the influenza season and women in any stage of pregnancy who have chronic medical conditions that are associated with an increased risk of influenza. <sup>§</sup>
Measles live-virus vaccine	One dose administered subcutaneously (SC); second dose ≥4 weeks later.	HCP who were born during or after 1957 without documentation of 1) receipt of 2 doses of live vaccine on or after their first birthday, 2) physician-diagnosed measles, or 3) laboratory evidence of immunity. Vaccine should also be considered for all HCP who have no proof of immunity, including those born before 1957.	Pregnancy; immunocompromised <sup>†</sup> state (including human immunodeficiency virus [HIV]-infected persons with severe immunosuppression); history of anaphylactic reactions after gelatin ingestion or receipt of neomycin; or recent receipt of antibody-containing blood products.	Measles, mumps, rubella (MMR) is the recommended vaccine, if recipients are also likely to be susceptible to rubella or mumps; persons vaccinated during 1963–1967 with 1) measles killed-virus vaccine alone, 2) killed-virus vaccine followed by live-virus vaccine, or 3) a vaccine of unknown type, should be revaccinated with two doses of live-virus measles vaccine.
Mumps live-virus vaccine	One dose SC; no booster.	HCP believed susceptible can be vaccinated; adults born before 1957 can be considered immune.	Pregnancy; immunocompromised <sup>†</sup> state; history of anaphylactic reaction after gelatin ingestion or receipt of neomycin.	MMR is the recommended vaccine.
Rubella live-virus vaccine	One dose SC; no booster.	HCP, both male and female, who lack documentation of receipt of live vaccine on or after their first birthday, or lack of laboratory evidence of immunity can be vaccinated. Adults born before 1957 can be considered immune, except women of childbearing age.	Pregnancy; immunocompromised <sup>†</sup> state; history of anaphylactic reaction after receipt of neomycin.	Women pregnant when vaccinated or who become pregnant within 4 weeks of vaccination should be counseled regarding theoretic risks to the fetus; however, the risk of rubella vaccine-associated malformations among these women is negligible. MMR is the recommended vaccine.
Varicella-zoster live-virus vaccine	Two 0.5 mL doses SC 4–8 weeks apart if aged ≥13 years.	HCP without reliable history of varicella or laboratory evidence of varicella immunity.	Pregnancy; immunocompromised <sup>†</sup> state; history of anaphylactic reaction after receipt of neomycin or gelatin; recent receipt of antibody-containing blood products; salicylate use should be avoided for 6 weeks after vaccination.	Because 71%–93% of U.S.-born persons without a history of varicella are immune, serologic testing before vaccination might be cost-effective.

**Sources:** Adapted from Bolyard EA, Hospital Infection Control Practices Advisory Committee. Guidelines for infection control in health care personnel, 1998. *Am J Infect Control* 1998;26:289–354.

CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997;46(No. RR-18).

CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2003;52:1-34.

CDC. Using live, attenuated influenza vaccine for prevention and control of influenza: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2003;52(No. RR-13).

\* A federal standard issued in December 1991 under the Occupational Safety and Health Act mandates that hepatitis B vaccine be made available at the employer's expense to all HCP occupationally exposed to blood or other potentially infectious materials. The Occupational Safety and Health Administration requires that employers make available hepatitis B vaccinations, evaluations, and follow-up procedures in accordance with current CDC recommendations.

<sup>†</sup> Persons immunocompromised because of immune deficiencies, HIV infection, leukemia, lymphoma, generalized malignancy; or persons receiving immunosuppressive therapy with corticosteroids, alkylating drugs, antimetabolites; or persons receiving radiation.

<sup>§</sup> Vaccination of pregnant women after the first trimester might be preferred to avoid coincidental association with spontaneous abortions, which are most common during the first trimester. However, no adverse fetal effects have been associated with influenza vaccination.

<sup>¶</sup> A live attenuated influenza vaccine (LAIV) is FDA-approved for healthy persons aged 5–49 years. Because of the possibility of transmission of vaccine viruses from recipients of LAIV to other persons and in the absence of data on the risk of illness and among immunocompromised persons infected with LAIV viruses, the inactivated influenza vaccine is preferred for HCP who have close contact with immunocompromised persons.

## Appendix C

### Methods for Sterilizing and Disinfecting Patient-Care Items and Environmental Surfaces\*

Process	Result	Method	Examples	Health-care application	
				Type of patient-care item	Environmental surfaces
Sterilization	Destroys all microorganisms, including bacterial spores.	Heat-automated High temperature	Steam, dry heat, unsaturated chemical vapor	Heat-tolerant critical and semicritical	Not applicable
		Low temperature	Ethylene oxide gas, plasma sterilization	Heat-sensitive critical and semicritical	
		Liquid immersion†	<b>Chemical sterilants.</b> Glutaraldehyde, glutaraldehydes with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, peracetic acid	Heat-sensitive critical and semicritical	
High-level disinfection	Destroys all microorganisms, but not necessarily high numbers of bacterial spores.	Heat-automated	Washer-disinfectant	Heat-sensitive semicritical	Not applicable
		Liquid immersion†	<b>Chemical sterilants/high-level disinfectants.</b> Glutaraldehyde, glutaraldehyde with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, ortho-phthalaldehyde		
Intermediate-level disinfection	Destroys vegetative bacteria and the majority of fungi and viruses. Inactivates <i>Mycobacterium bovis</i> .§ Not necessarily capable of killing bacterial spores.	Liquid contact	U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant with label claim of tuberculocidal activity (e.g., chlorine-containing products, quaternary ammonium compounds with alcohol, phenolics, iodophors, EPA-registered chlorine-based product¶)	Noncritical with visible blood	Clinical contact surfaces; blood spills on housekeeping surfaces
Low-level disinfection	Destroys the majority of vegetative bacteria, certain fungi, and viruses. Does not inactivate <i>Mycobacterium bovis</i> .§	Liquid contact	EPA-registered hospital disinfectant with no label claim regarding tuberculocidal activity.** The Occupational Safety and Health Administration also requires label claims of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) potency for clinical contact surfaces (e.g., quaternary ammonium compounds, some phenolics, some iodophors)	Noncritical without visible blood	Clinical contact surfaces; housekeeping surfaces

\* EPA and the Food and Drug Administration (FDA) regulate chemical germicides used in health-care settings. FDA regulates chemical sterilants used on critical and semicritical medical devices, and the EPA regulates gaseous sterilants and liquid chemical disinfectants used on noncritical surfaces. FDA also regulates medical devices, including sterilizers. More information is available at 1) <http://www.epa.gov/oppad001/chemregindex.htm>, 2) <http://www.fda.gov/cdrh/index.html>, and 3) <http://www.fda.gov/cdrh/ode/germlab.html>.

† Contact time is the single critical variable distinguishing the sterilization process from high-level disinfection with FDA-cleared liquid chemical sterilants. FDA defines a high-level disinfectant as a sterilant used under the same contact conditions as sterilization except for a shorter immersion time (C-1).

§ The tuberculocidal claim is used as a benchmark to measure germicidal potency. Tuberculosis (TB) is transmitted via the airborne route rather than by environmental surfaces and, accordingly, use of such products on environmental surfaces plays no role in preventing the spread of TB. Because mycobacteria have among the highest intrinsic levels of resistance among vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label (i.e., an intermediate-level disinfectant) is considered capable of inactivating a broad spectrum of pathogens, including much less resistant organisms, including bloodborne pathogens (e.g., HBV, hepatitis C virus [HCV], and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection.

¶ Chlorine-based products that are EPA-registered as intermediate-level disinfectants are available commercially. In the absence of an EPA-registered chlorine-based product, a fresh solution of sodium hypochlorite (e.g., household bleach) is an inexpensive and effective intermediate-level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately ¼ cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination. Appropriate personal protective equipment (e.g., gloves and goggles) should be worn when preparing hypochlorite solutions (C-2, C-3). Caution should be exercised, because chlorine solutions are corrosive to metals, especially aluminum.

\*\* Germicides labeled as "hospital disinfectant" without a tuberculocidal claim pass potency tests for activity against three representative microorganisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis*.

#### References

C-1. Food and Drug Administration. Guidance for industry and FDA reviewers: content and format of premarket notification [510(k)] submissions for liquid chemical sterilants/high level disinfectants. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, 2000. Available at <http://www.fda.gov/cdrh/ode/397.pdf>.

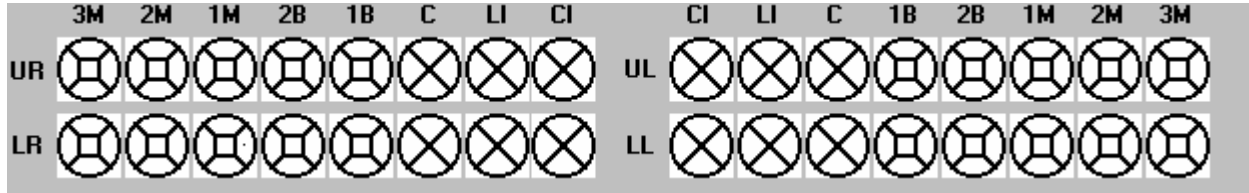
C-2. US Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. Occupational exposure to bloodborne

pathogens; needlesticks and other sharps injuries; final rule. Federal Register 2001;66:5317–25. As amended from and includes 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens; final rule. Federal Register 1991;56:64174–82. Available at <http://www.osha.gov/SLTC/dentistry/index.html>.

C-3. CDC. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52(No. RR-10).

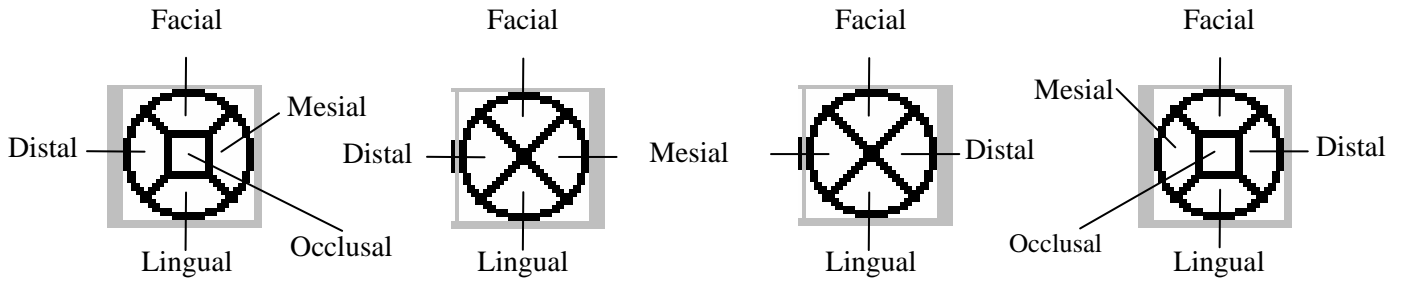
Appendix C  
Diagnostic Mouth Diagram

# Diagnostic Mouth Diagram



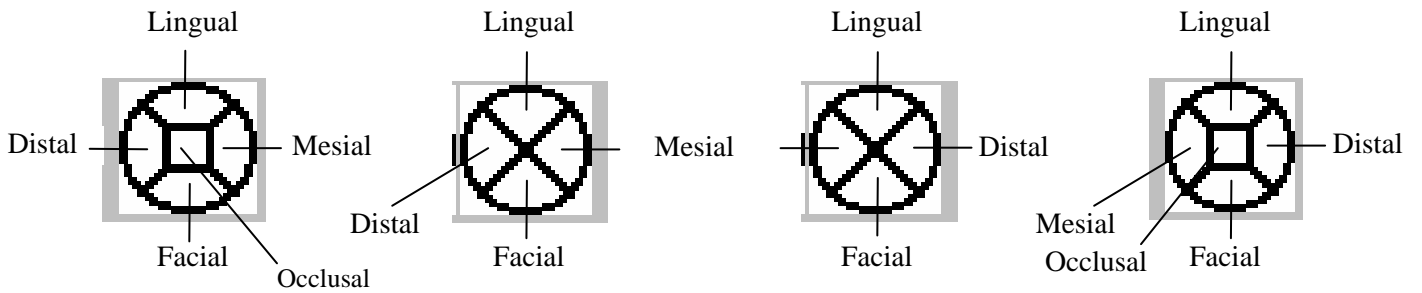
## UPPER RIGHT

## UPPER LEFT



## LOWER RIGHT

## LOWER LEFT



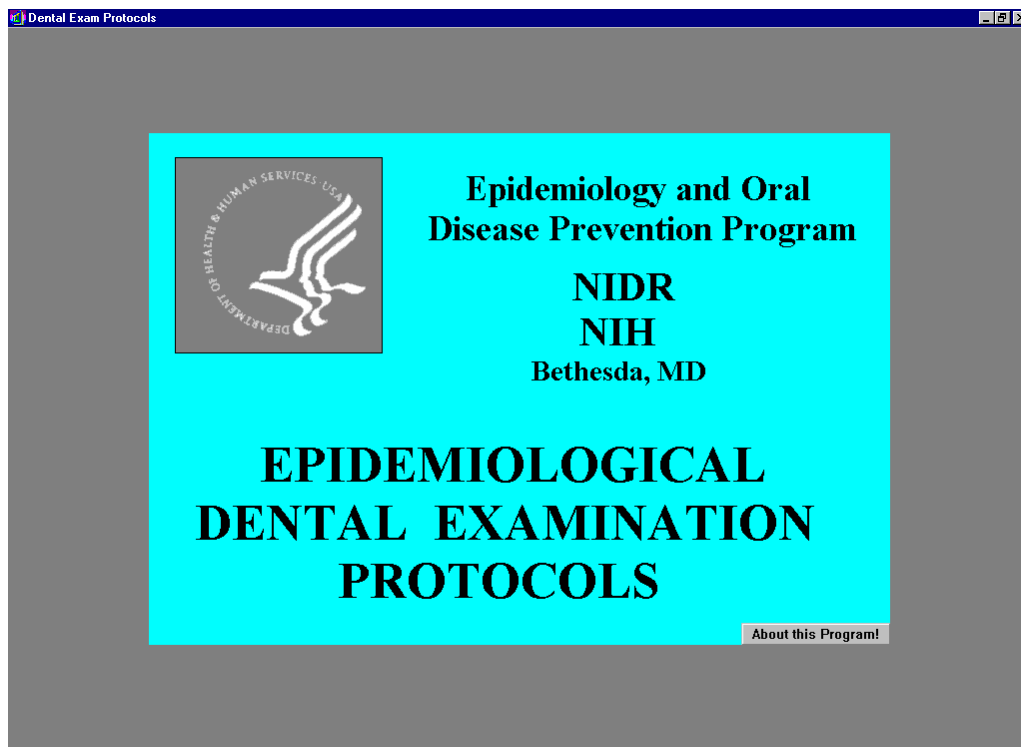
Appendix D  
Dental Help Feature



## Appendix D. Dental Help Feature

The Dental Help Feature is designed to provide the examiner with an on-line reference document for the examination and recording procedures specific for this study as well as color slides of oral conditions that may be used to assist the examiner in making appropriate assessment calls. This section of the manual provides basic instructions on using the system. Detailed instructions are found within the program itself.

**Accessing the Program:** The Dental Help Feature can be accessed by using the mouse to double click on the NHANES Protocols folder located on the main menu screen and then double clicking on the “HANES IV Protocols” icon within the folder. If the Dental Examination program is running, it should be minimized by clicking on the minimize box (-) in the upper right corner of the screen.



**Movement within the Program:** Navigation through the system is done with the mouse only. No key strokes have been defined for this program. An arrow is used as the cursor in this program.

Navigational buttons appear on the bottom of the screen and are clearly labeled to direct the user through the system. In addition, buttons are used on the menu option screens to direct the user to different segments of the program.

**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)**  
*NCHS*  
*CDC*

**ORAL HEALTH COMPONENTS**

About Epidemiological Exams  
 Quality Control Issues  
 Guide to ISIS  
 Safety Issues  
 Slides and Video Clips

Preliminaries					
Dental Q.	16+	Root Caries	18+	Tooth Wear	13+
Denture Q.	25+	Sealants	2-34	Functional Occ.	25+
Tooth Count	2+	Dent. Fluorosis	6-49	Periodontal	13+
Coronal Caries	2+	Trauma	6-29	Exit Procedures	

Home exit

**Assessment Screens:** There is a separate menu option for each assessment (see sample above). The first screen displayed for each assessment is an outline of the key discussion points of that assessment. Several features may appear on the screens as follows:

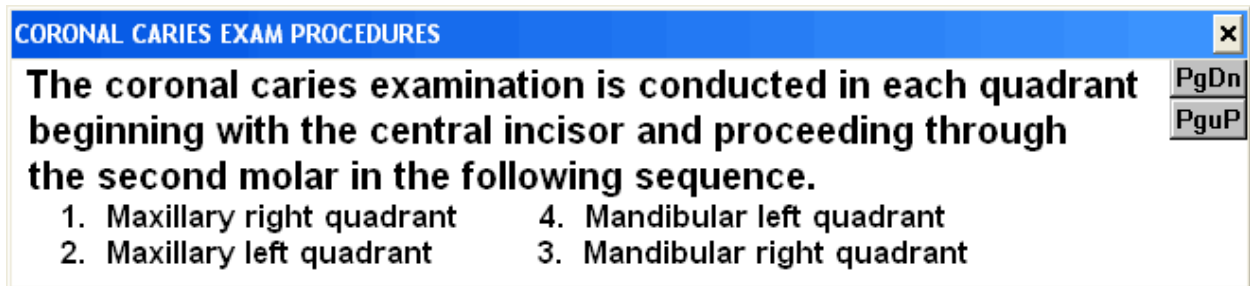
- Blue phrases: Additional information on these topics is available by accessing the associated dialog box as discussed below.
- “ISIS” button: Clicking on this button displays a copy of the ISIS screen used to record data for the assessment. Clicking on the “recording procedures” button on the ISIS screen will pull up specific information on the allowable codes for the assessment. Note there is no data entry allowed on these ISIS screens.
- “Slide” button: Clicking on this button allows the user to view slides related to this assessment. Note: there is a significant pause in the system while the program accesses the slides.

**CORONAL  
CARIES ASSESSMENT**

- 1. Examination Procedures**
- 2. Diagnostic Guidelines**
  - a. Decayed surfaces**
  - b. Missing teeth**
  - c. Filled surfaces**
- 3. DMFS Coding System** ISIS SCREEN
- 4. Conventions and Guidelines** Slides

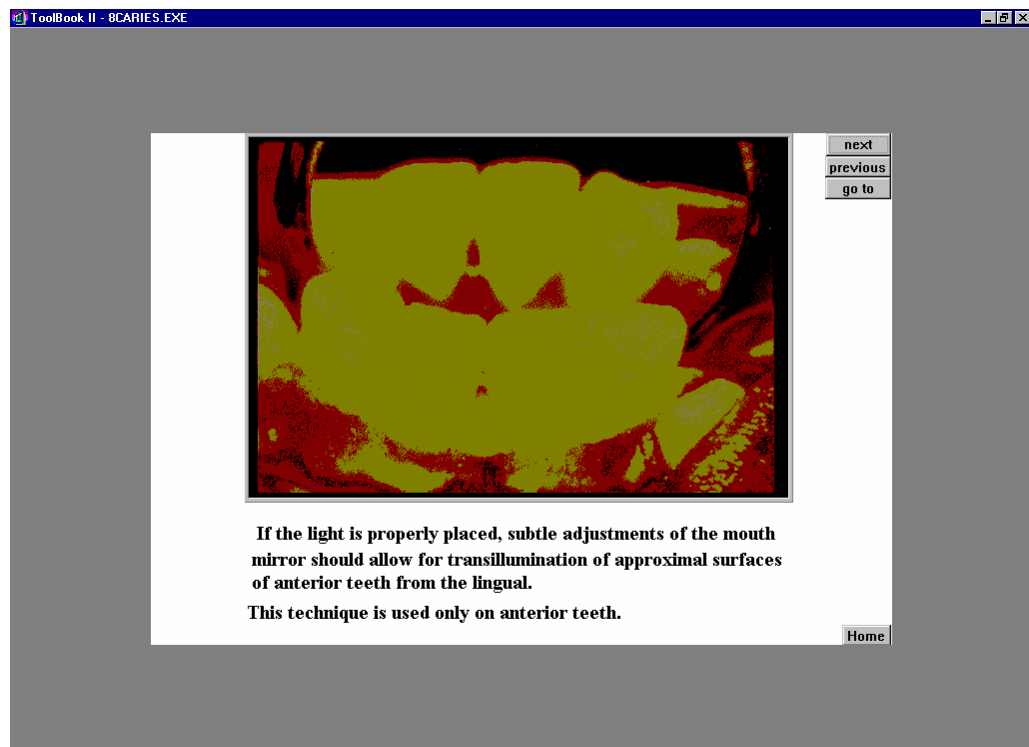
HANES IV Protocols

**Dialog Boxes:** Additional information on certain topics can be pulled up by clicking on phrases written in blue. (Note: the arrow will change to a pointing finger on these phrases.) Dialog boxes are displayed in the top portion of the screen. Use the mouse to click on the <PgDn> button to proceed to the next box in the series and the <PgUp> button to proceed to the previous box in the series. Clicking on the <PgDn> button on the last box in the series closes the dialog box. Clicking on the <PgUp> button on the first screen in the series does not cause a change to the box.



**Oral Health Slides:** The oral health slides are accessed when the user clicks on the “slide” buttons displayed on the various assessment screens. A significant pause occurs while the program accesses the slides. In the upper right corner of each slide are navigation buttons to aid the user in moving from slide to slide as follows:

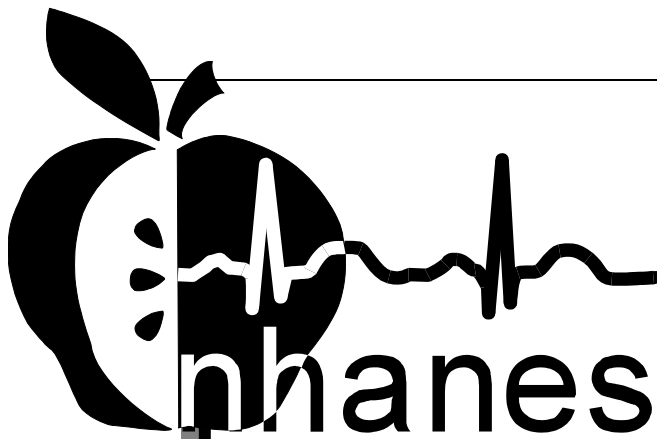
- Next: Moves the user to the next slide in the series.
- Previous: Moves the user to the previous slide in the series.
- Go to: Sends the user to the menu screen for that slide series so that the user may choose to go to any slide in that series without cycling through all of the previous slides.



Appendix E  
MEC Subsystem Overview

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## **MEC Subsystem Overview**



**National Health and Nutrition Examination Survey**

**August 24, 2005**








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# MEC Network & Coordinator Overview

## Network Overview

The illustration below depicts how the MEC subsystems are connected to the FO and HO to supply the SP data necessary to conduct the multitude of examinations. The Field Office manages the Interview Teams that conduct the footwork of identifying and gathering detailed data on prospective SPs and transmits the information to the FO and HO for processing. This information is stored in databases and retrieved by the MEC subsystems in preparation for examinations. The results of FO surveys and MEC examinations are collected, analyzed, and prepared for dissemination for public, research, and examination participants in various forms.

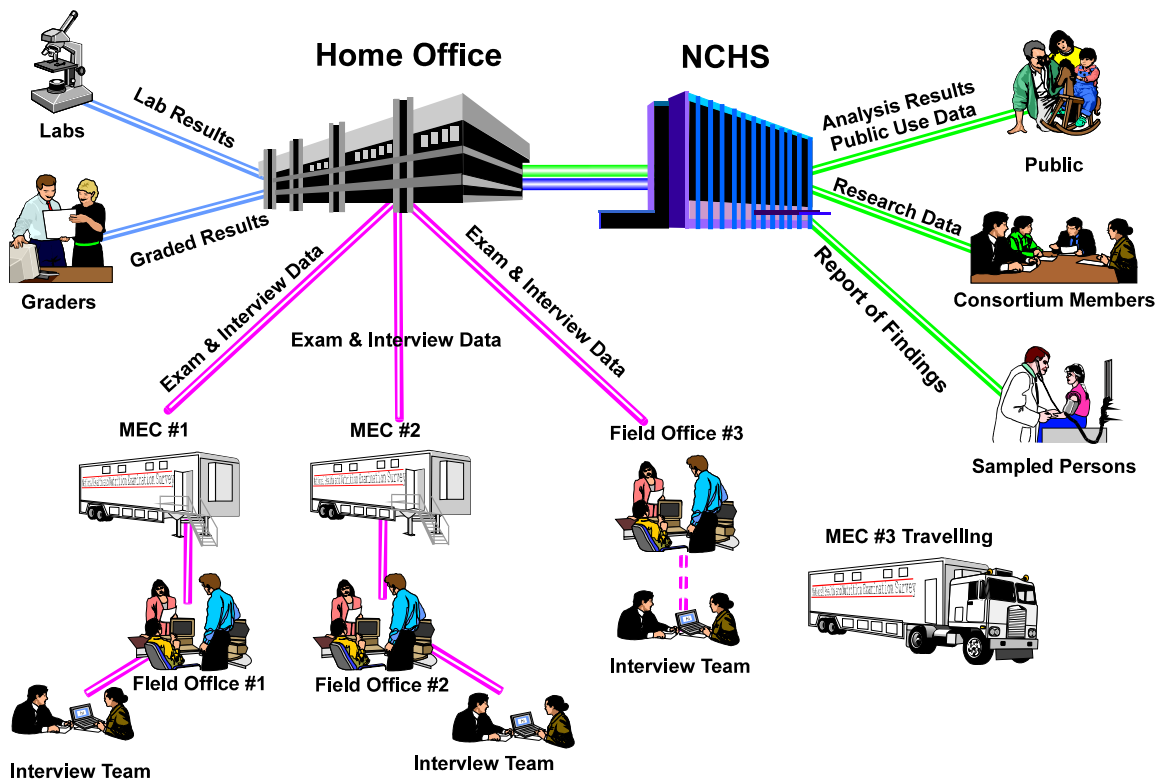


Figure 1: NHANES Network Connectivity

Each ISIS workstation is integral component of a sophisticated network that links the MEC workstations together with utility and database servers, and the Home Office. Continual status communications between the

workstations and the Coordinator station enable orchestration of activities and personnel flow.

A simplified Intranet schematic is illustrated below:

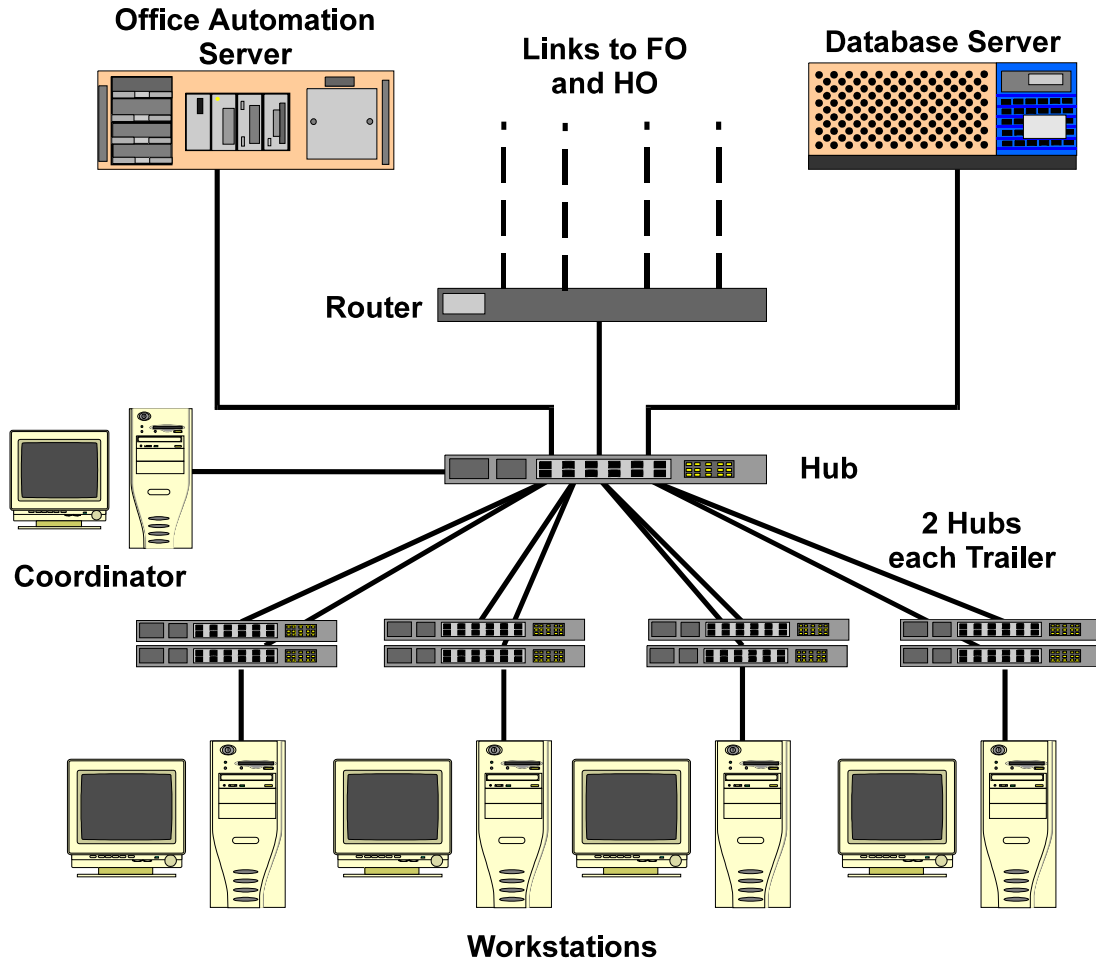


Figure 2: Network Connectivity Scheme

Each workstation connects to both the office automation server (NT Server) and the database server (Sybase) through a series of hubs. These hubs connect the servers and workstations (operating on Windows NT) within the MEC trailers to form part of the ISIS system. The MEC network communicates with both the Field Office (FO) and Home Office (HO) using primary and backup data links. The data links synchronize operational activities and transfer examination and other data as scheduled.

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## MEC Coordinator

The MEC Coordinator subsystem is designed to efficiently orchestrate the flow of Sample Persons (SPs) throughout the MEC examination process. Continual interaction between each workstation and the Coordinator enables smooth passing of SPs from one workstation to another. Each component examination program automatically transmits the status of the examination to the Coordinator to assist in synchronizing the next component assignment. Exams cannot be performed without specific assignment of a technician and an SP.

The MEC Coordinator subsystem receives appointments scheduled by the Field Office's Appointment Management subsystem. The Coordinator subsystem determines the appropriate examination program, called a 'profile', based on gender and age at the time of the Household Interview.

During the conduct of the session operations, the Coordinator subsystem provides a graphical representation of the location of SPs in the MEC, the status of exam components, the availability of examiners, and the availability of exam stations.

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## The Coordinator Screen Configuration

The Coordinator station is the nerve center for the MEC. All functions of the Coordinator are executed with the graphical interface designed to assign, monitor, and manage all activities within the MEC. The Coordinator screen, illustrated below, is organized into three major panes and a menu bar:



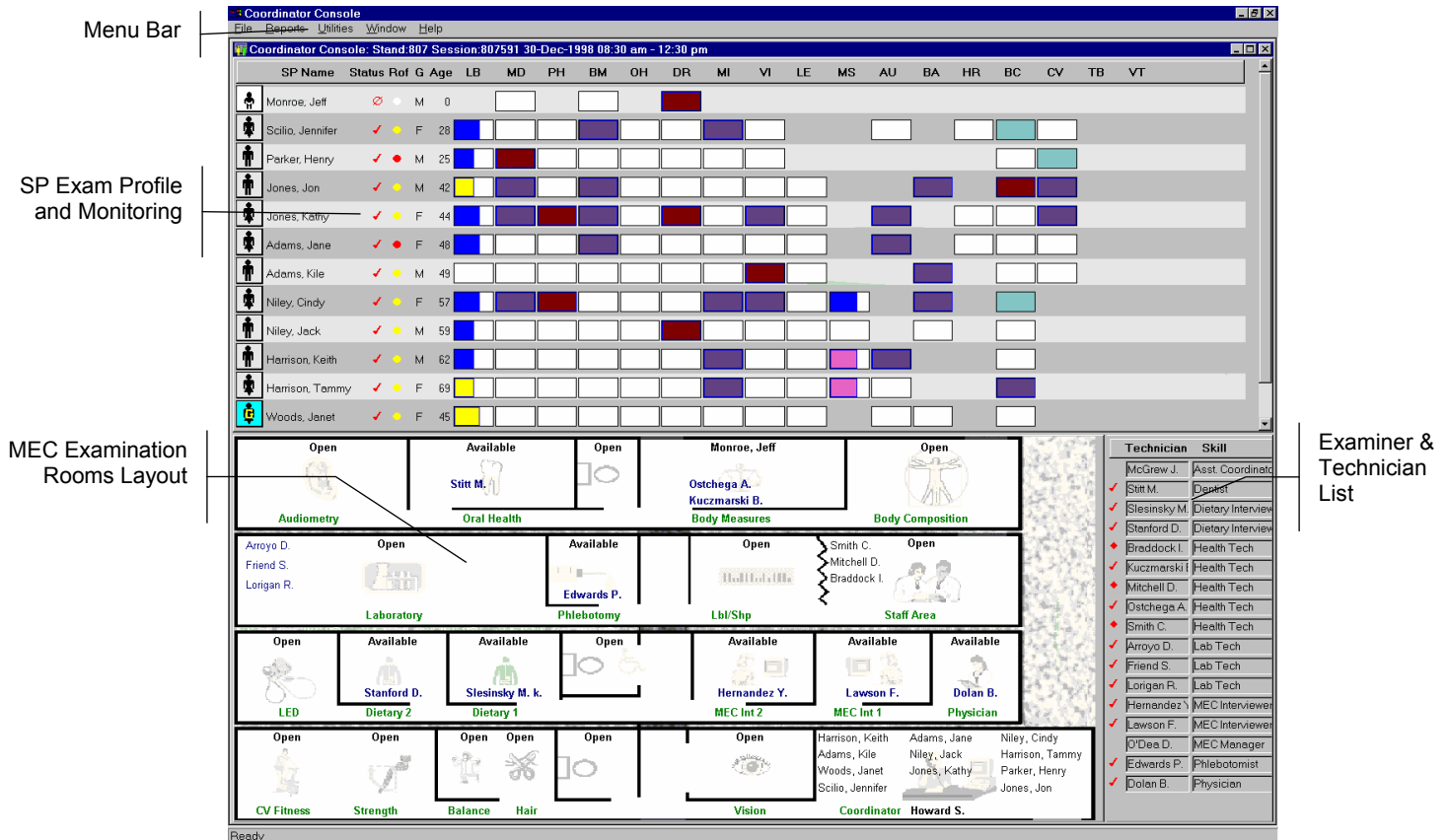


Figure 3: The Coordinator Screen

The Menu Bar provides access to options detailed in the following section.

The SP Exam Profile and Monitoring pane displays each SP exam profile, current status, and examination progress. (The actual screen shows all 10 scheduled SPs). The Examination Profile pane is designed to assist the Coordinator to rapidly assess the availability of examination components against the required examination profiles for each SP, and to manage the movement of SPs and staff.

The MEC Examination Rooms Layout visually portrays the floor plan of the MEC, availability of each examination room, assigned examiner and technician, the location of SPs, and examination status for each room.

The Examiner and Technician List shows available examiners and technicians along with their status.

## Assigning an SP to an Exam

After check-in and after completion of individual examinations, the MEC Coordinator assigns the SP to new components. Assignments are based on

a list of the SP's remaining required exams, available examiners, and available exam components.

Examiners are notified by a system-generated message when an SP is assigned to their component. When the examination is complete, the Coordinator system advises the examiner of the SP's next component for the SP.

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## **System Blocking and Exclusions**

Specified examinations are “blocked” or excluded for SP assignment or continuation of an examination due to medical, SP non-consent, or safety considerations. Some examinations become “unblocked” when medical conditions are verified, such as a negative pregnancy test result from the lab.

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# MEC Workstation

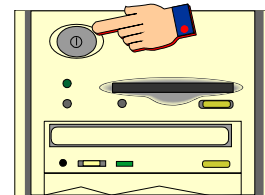
## Workstation Startup

The workstation startup procedures are rarely necessary since the workstations will remain powered and running the Windows NT operating systems for the stand duration. However, at times the workstation must be completely shutdown and restarted to resolve connectivity and other operating issues.

In the event that you must startup a workstation, follow these simple procedures:

### **To Startup the Workstation:**

- Locate and press the power button as shown on the right;
- Then turn on the monitor.



### **To Turn On the Monitor:**

- Locate and press the power button as shown.
- A small green light located near the power button will light if the monitor's power line is connected.



## The MEC Desktop

After workstation startup, the MEC desktop appears. The desktop is specially tailored to support the specific MEC examination or station. An illustration of the desktop and components are shown below.

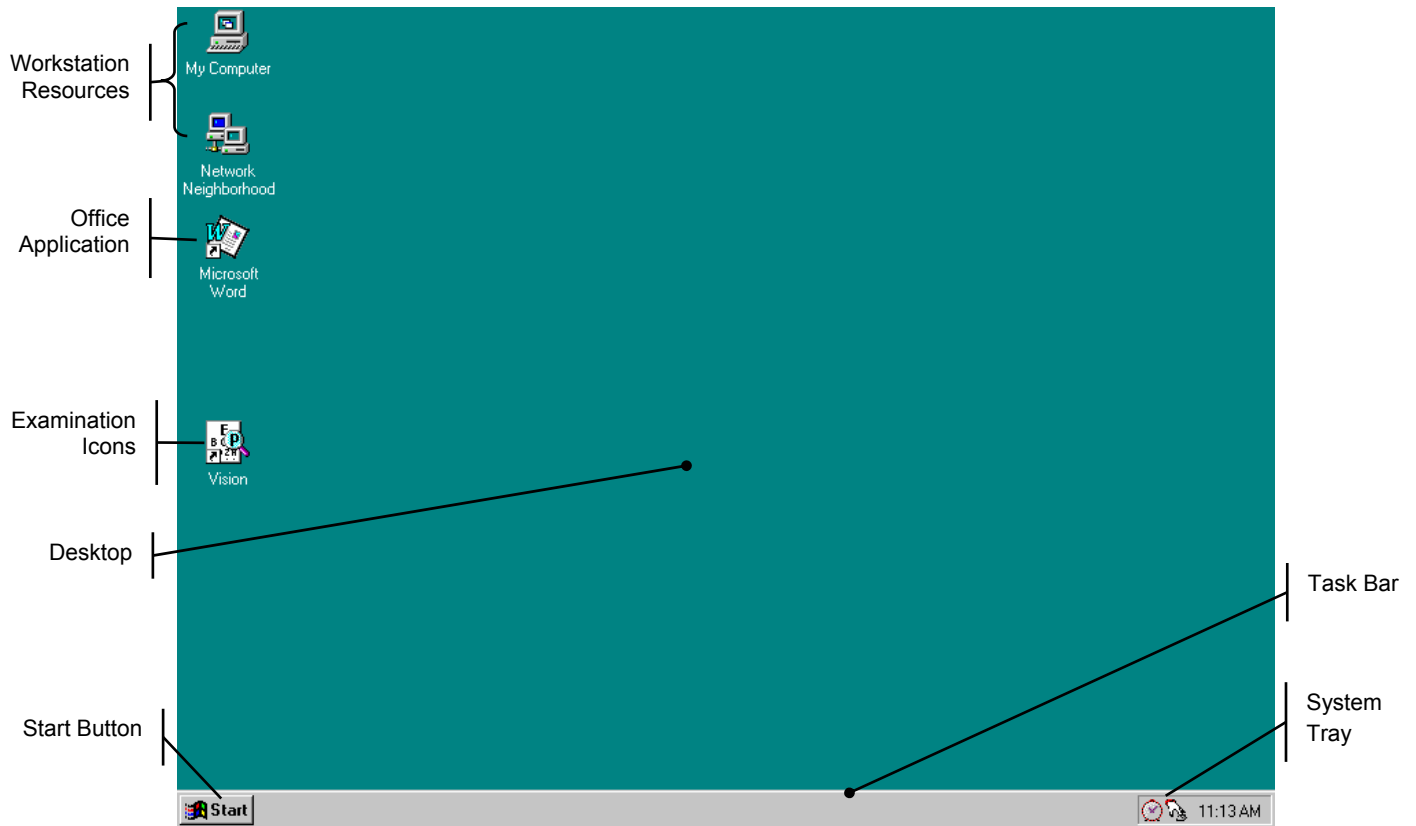


Figure 4: MEC Workstation Desktop

The desktop is similar to a real desktop, except perhaps a little neater. The desktop holds “shortcuts” to frequently used programs, such as the examination programs. Shortcuts are icons that represent a file or program located within the computer or network. The shortcuts provide a rapid means to open the program or file it represents. When an application opens, it displays on the desktop, as well as most other system activities.

Descriptions of the items that appear on all examination workstations are below.



The **Start** button, when clicked, displays a menu containing everything you need to begin using Windows. The menu options include:

**Shut Down** – Shut down menu options.

**Help** – Starts Windows NT Help.

**Documents** – Displays a list of previously opened documents.

**Programs** – Displays a list of programs you can start.

The Start button menu expands as programs are added to the system. The graphic below illustrates how the MEC desktop menu expands.

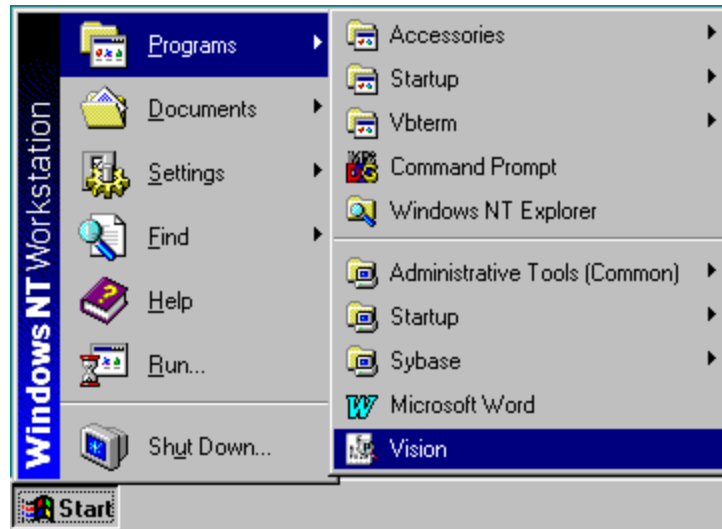


Figure 5: Start Button Menus

Note the highlighted selections. The menu expands when a small black arrow is shown on the menu's right margin. The main Start menu, the menu with the Windows NT banner on the first menu's left margin, is set by the development team. You may be asking yourself "Where is all the *fun* stuff?" The Explorer and many other Windows functions are disabled to discourage any modifications to the desktop, Start menus, and files. Inadvertent moving or deletions of files could and would cause havoc.



**My Computer** icon views and manages your files. Double-clicking the icon will open a window view of your computer and connected resources.



**Network Neighborhood** provides a view of all available resources on the network.



**Examination Program** icons (with shortcuts indicators) reside on the desktop to easily start an examination. Each examination has its own tailored icon. Double-click on the icon to open the examination program.

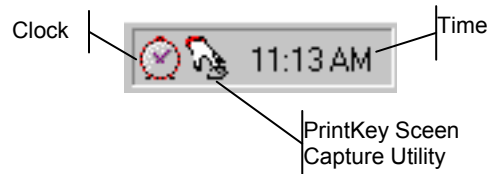


The **Taskbar**, located at the bottom of the Desktop, displays the Start button on the left side and the System Tray on the right side of the bar. By default, the system tray displays the current time and shows special system icons for programs that run in the background. The Physician button, shown to the right of the Start button, indicates the Physician examination

component is currently running. Programs running but **minimized** are also shown as a button on the Taskbar.

## The System Tray Icons

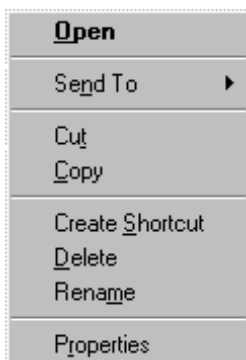
The **System Tray** holds icons that represent the programs for displaying time and a screen capture utility.



The PrintKey screen capture utility operates automatically in the background. This feature enables you to capture items for documentation and database or program error messages. See *Appendix A, Using PrintKey*, for directions on how this feature can help you.

## Right Mouse Button Menus

The right mouse button provides a short menu of common actions when clicked on a desktop icon, the desktop itself, or System Tray icons. The Task Bar menu is disabled.



The right mouse menu for the **Desktop Icons** appears as shown below:

**Open** will open the program or file with associated application.

**Send To** provides an option to send the selected program or file to either the A:\ drive (floppy) or Mail.

**Cut** removes the icon from the desktop and places it on the system clipboard.

**Copy** places the contents of the clipboard to the desktop.

**Create Shortcut** makes another Shortcut on the desktop.

**Delete** permanently removes the selected item.

**Rename** highlights the item's name for editing.

**Properties** displays information on the application the icon represents and shows the path and working area of the actual application.

The right mouse menu for the **Desktop** appears when right-clicked anywhere on the desktop, as shown below:



**Arrange Icons** provide options to display the icons.

**Line Up Icons** automatically rearranges your desktop in a manner you will not like.

**Paste** will place the contents of the clipboard onto the desktop.

**Paste Shortcut** places a shortcut of the item in the clipboard on the desktop.

**Undo Copy** will clear the clipboard of the last copied item.

**New** provides a menu of items from which you can create, such as a new folder or document.

**Properties** display the Display Properties window to view and change several properties, such as window appearance, background, and colors. Some, if not all properties, will be disabled to ensure consistent appearance of all MEC workstations.

If the **System Tray** menu appears as shown on the left, you have clicked in the wrong area of the Task Bar.



**Restore** brings the program to the last used or default window size on the desktop.

**Minimize** will reduce the program to an icon on the Task Bar. The Tray Utility program will reduce the connectivity applications back into the System Tray.

**Maximize** opens the program in a window that fills the screen.

**Close** will terminate the program.

Note: In the event you activate this menu from the System Tray, press the **ESC** key to escape the menu. *DO NOT select Close!* You will lose the background applications.

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## End of Day Procedures

The current procedure is to leave your workstation operational when departing the MEC. Examinations are closed and the programs in the system tray left running.

There will be times when the system malfunctions, such as failure to respond to keyboard or mouse commands or “hangs”, you may be directed to shut down or restart the workstation.

### **To Shut Down or Restart the Workstation:**

- Click on the **Start** button on the Taskbar.
- Select **Shutdown** from the Start Menu.

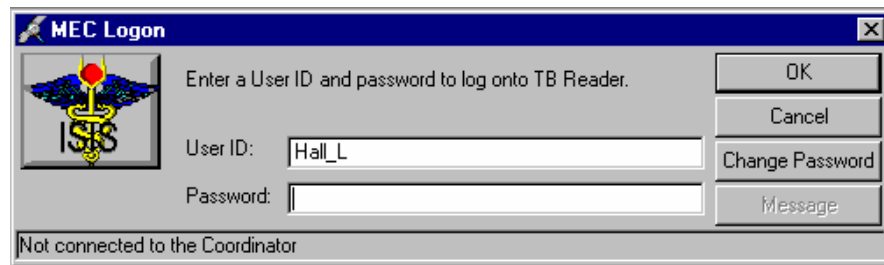


- The dialog box, shown below, appears.
- To shut down the system completely, select *Shut down the computer*.
- Wait for the message indicating that it is safe to turn off the computer.
- To restart the system without shutting down, select *Restart the computer*.
- The system will restart automatically.

## MEC Exam Application's Common Features

MEC applications are custom built for each specific component but share a common design. This commonality provides all component applications the same “look and feel” which minimizes reorienting technicians that rotate from component to component. These features and characteristics are described below.

### Examiner Logon



There are currently several types of examiner logon procedures. The logon procedure for an examination component is determined by whether the examiner is *static* or *rotates* through other components throughout a session. Static examiners include components such as Physician, Phlebotomy, Dietary, and MEC Interviewers that remain logged on throughout the session. Health technicians, such as Vision and CV Fitness, are not assigned to rooms but rotate through several examination components. These technicians are required to logon and logoff for each examination. Other examinations, such as Dental and Body Measurements, have slightly different requirements and are addressed in their specific User's Manual. The two basic approaches to logon are outlined below.

#### **Static Examiner Logon:**

- The logon screen, shown above, appears after the Coordinator assigns the examiner to the component and the assigned examiner starts the examination program.
- The **User ID** (Last Name\_First Initial) will automatically appear and cannot be changed.
- Type in the **Password** and press **OK**
- Examiner logoff is automatic at the end of the session.

### **Rotating Examiner Logon:**

- The logon screen appears when the Coordinator assigns an SP to an exam component.
- If the component involves both an examiner and a recorder, the examiner logon screens appear first, followed by the recorder logon screen.
- The **User IDs** will automatically appear and cannot be changed. Both exam technicians must logon.
- Type in the **Password**.
- Press **OK**.
- Logoff is automatic upon completion of the SP examination.

**NOTE:** Your password is your safeguard. All examination actions within the MEC are traced with the logon User ID and Password. Unauthorized entry and malicious actions to the ISIS system are prevented by a simple act of not ever, for any reason, give your password to another. You could jeopardize much more than study data.

After entering your password and prior to pressing **OK**, you can **change your password** by clicking on the **Change Password** button. The Change Password dialog box appears.

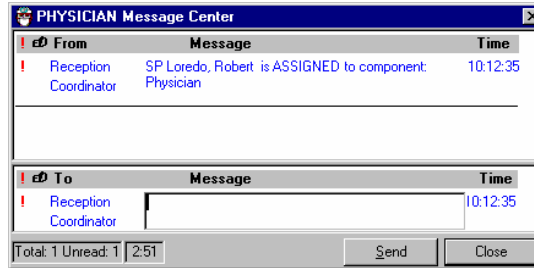
Enter your current password for access verification, followed by your new password. Confirm your new password and press **OK**.



Figure 6: Change Password Dialog Box

## SP Logon

The MEC Coordinator checks-in each SP upon arrival and assigns the SP to an initial examination component. The action of assigning the SP to a component automatically triggers a message from the Coordinator to alert the technician that an SP is assigned.



When the examiner selects *File / Open* to begin the exam, the SP logon screen appears.

- Acquire the SP ID through the wand device or manually enter the ID imprinted on the SP bracelet.
- Verify that the SP information is correct.
- Click **OK** to proceed with the examination.
- The **Message** button opens a dialog box for sending a message to the Coordinator.
- **Cancel** stops the logon process.

## Examination Screen Overview

The first examination screen appears after an SP is logged in or an existing record is opened. This example screen, shown on the next page and compressed for space, displays the basic visual appearance and design used throughout all MEC components.

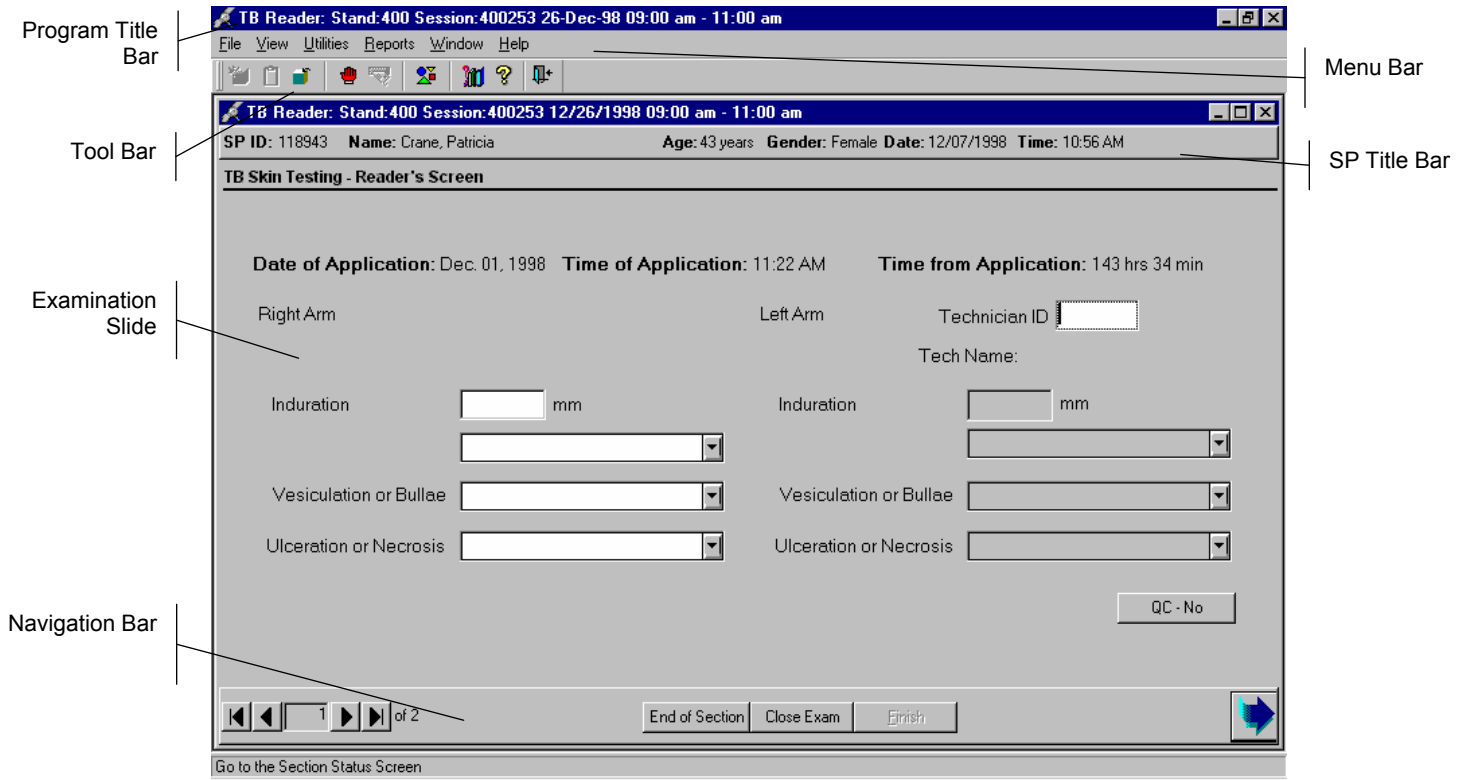


Figure 7: Sample Examination Screen

**Program Title Bar** shows the component program title, stand, session, and date time information.

**Menu Bar** displays the commands, functions, options, and information available during an examination.

**Tool Bars** hold buttons that execute common commands and other actions available in the menu bar. Buttons that are dimmed are not available.

**SP Title Bar** displays SP information during the course of the examination.

**Examination Slide** captures the measurements and other information.

**Navigation Bar** is used to move forward or back in the examination and displays the examination's relative location.

**Microhelp and Status Bar** displays the status of the computer, completion percentage message to the coordinator, and other information triggered by events.

## Menu Bar Options

Each MEC application has tailored menu options to support the specific examination. The menu options below list all available options. The options marked with an asterisk appear on all MEC examination programs. Options are grayed (inverted) or not present when they are not available for your subsystem.

Note the underlined letters in both the Menu and Menu Option. These underlined letters, used in conjunction with the **Alt** key, provide keyboard access to the menu selection without using the mouse. For example, pressing **Alt+F+O** will open a file. The **Ctrl+keystroke**, such as **Ctrl+O**, will also open a file.

Asterisks (\*) denotes menu options common to all MEC examination components.

<b>File*</b>	
<u>O</u> pen * <i>Ctrl+O</i>	Opens a new, Partial, or Not Done SP exam; must be assigned by Coordinator if not in standalone mode
<u>R</u> eview	Opens any existing SP examination in read-only mode; Coordinator assignment not required; no status updates sent to the coordinator system in Review mode
<u>C</u> lose *	Closes the current examination
<u>P</u> rint * <i>Ctrl+P</i>	Prints the current examination screen or report. Note the Ctrl+P shortcut keys.
<u>D</u> elete *	Deletes current exam and any associated references. Used primarily to delete an examination that clearly is in error, such as the wrong SP. Only enabled if it is a new exam and the status is not done or partial.
<u>E</u> xit *	Exits the application.

<b>View *</b>	
<u>F</u> irst *	Returns examination screen to first slide
<u>N</u> ext *	Advances to next examination slide.
<u>P</u> rior *	Displays previous slide IN THE SKIP PATTERN
<u>L</u> ast *	Advances to last slide.

<b>Utilities *</b>	
<u>Q</u> uality Control <i>Ctrl+Q</i>	Opens the quality control dialog box to initiate quality control procedures.
Exam <u>P</u> ause *	Used in case of an emergency in the MEC, such as an ill SP. Pauses the exam temporarily to stop the

	exam timer (in NH_Exam); sends “Exam paused” message to Coordinator.
<u>S</u> end <u>M</u> essage * <i>Ctrl+M</i>	Opens a dialog box to send messages to the coordinator.
<u>O</u> bservation*	Submits an observation to the Physician for possible referral.
<u>I</u> C Exclude	Posts an exclusion record for those SPs who do not want HIV, STD, Genetic Testing , or Future Research performed; available only for Coordinator, Physician, & Phlebotomy.
<u>S</u> ettings *	Allows user to view or modify subsystem settings, including the Coordinator connection. <i>Modifying setting requires approval by the data manager.</i>
<u>T</u> oolbars*	Configures placement of toolbars.
<u>E</u> nglish <i>Ctrl+E</i>	Toggle option to set exam language to English.
<u>S</u> panish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.

**Reports\***

<u>S</u> ession <u>P</u> review*	Lists all SPs in current session
<u>R</u> oom Log* <i>Ctrl+R</i>	Lists the SPs who have completed the component, including appt/exam and component status

**Window\***

<u>C</u> ascade *	Displays multiple windows overlapped and slightly offset as to show the title bar of each open window.
<u>T</u> ile <u>H</u> orizontal*	Displays open windows on top of each other and sized to fit all in the main program window.
<u>T</u> ile <u>V</u> ertical *	Displays open windows next to each and sized to fit in the main program window.
<u>L</u> ayer *	Displays open windows stacked over each other.
<u>M</u> inimize All <u>W</u> indows *	Reduces all windows to a button in the lower portion of the main program window.

**Help\***

<u>H</u> elp Topics * <i>F1</i>	Displays ISIS system help contents.
<u>N</u> HANES <u>P</u> rocedures *	Displays component procedures manual. (not in Pilot).

OMB Statement.	Displays the OMB Confidentiality Statement.
<u>A</u> bout *	Displays the About dialog box.

## Tool Bars

Tools Bar buttons display when the program first opens to provide an easy way to access menu commands. Buttons are dimmed to signify that the action is temporarily unavailable; such as a dimmed **Print** button when no examination is open.



The Tool Bars, labeled FrameBar and FrameBar2, are customizable through the *System | Customize Tool Bars...* menu option or the Arrange Toolbars button. The Tool Bars buttons are:



Opens a New Sample Person Examination.



Opens an Existing Sample Person Examination.



Prints the Current SP Examination.



Arranges toolbar buttons.



Modifies system configuration and settings.



Sends message to coordinator.



Quits the Exam Application.



Performs Quality Control Procedures.



Pauses the current SP examination.



Logs an Emergency for the Current SP.





Enters a Referral for the Current SP.



Displays NHANES Procedures.



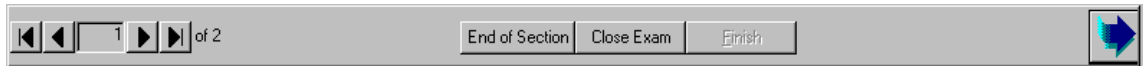
Displays program Help.

## SP Title Bar

SP ID: 118943 Name: Crane, Patricia Age: 43 years Gender: Female Date: 12/07/1998 Time: 10:56 AM

The Title Bar appears with the first examination slide after the SP is logged on. The Title Bar remains visible throughout the examination process. The example above illustrates the actual information displayed, but is not as compressed along the bar.

## Exam Slide Navigation



The slide navigation bar provides a means to move forward and back through an examination. The features of this bar are:



View **first** slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.



View **previous** slide in examination sequence. Disabled (dimmed) if current slide is first in examination sequence.



View **next** slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View **last** slide in examination sequence. Disabled (dimmed) if current slide is last slide in examination sequence.



View **next** slide in examination sequence. An easy to click button.

Note the slide counter between the previous and next slide buttons. This counter aids in determining your current location in the slideshow sequence.

**End of Section** button advances the examination slide to the status slide for the current section or the end of the examination for single section examinations.

**Close** button interrupts the examination and displays the Status screen for an appropriate status code and comment.

**Finish** button is disabled (dimmed) until the examination is complete. Partial and Not Done examinations require a status code and comment to activate the Finish button. The action completes the current examination.

## Quality Control

Several examinations incorporate medical equipment that requires periodic maintenance and inspection. These components have detailed procedures on conducting their specific inspection checks. Each subsystem notifies the examiner that QC inspections have not been performed when the examination program is started.

An example Quality Control window is shown below.

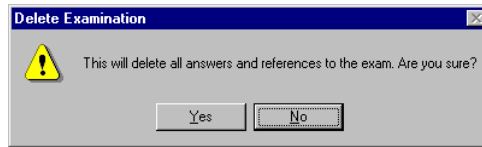
QC Check	Done	Result	Comment
Check stethoscope diaphragm for cracks	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input type="checkbox"/>		
Check for spilled mercury in the manometer case	<input type="checkbox"/>		

Figure 8: Quality Control Screen Sample

Included in the QC Checks are mandatory checks that must be completed prior to starting the examination program. The types of QC Checks are listed:

1. Start of Stand.
2. Start of Session.
3. Daily.
4. Weekly.
5. Middle of Stand.
6. End of Stand.

## Warning and Error Messages



Throughout the course of an examination, warning and error messages may appear when you attempt to perform an action the program can not execute or requires your confirmation to continue the action. The message normally appears with statements explaining the error condition.

Complying with the error message statement will normally remedy the error. When required to confirm an action, such as deleting records, be sure the action is necessary because in most cases the action is irreversible. Most “Oh #@%&” comments result from responding “Yes” when “No” was appropriate.

Data entry fields may have limitations on the acceptable range of values. The limitations imposed on these values are called **Hard** and **Soft Edits**.

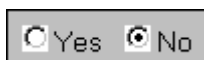
**Hard edits** impose a strict limitation on values entered in a data field. A data value entered outside of the hard edit range is not accepted and a program warning displays. For example, if a vision hard edit limitation is 20/500, an entry of 20/520 will not be accepted.



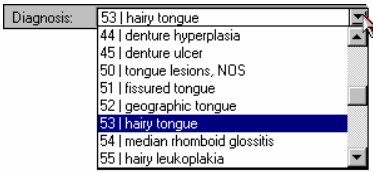
**Soft edits** are flexible limitations on values but prompts you for confirmation if a value exceeds the limit. For example, if a vision soft edit limitation is 20/400, an entry of 20/435 will prompt a confirmation dialog box.

## Buttons and Boxes and Lists

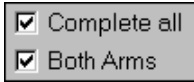
The examination slides use a variety of methods to capture acquired data. The methods include the following data control devices.



The *radio buttons* require a single response out of the responses displayed. The responses are mutually exclusive, but may have more than two displayed responses. To select a response, simply click on the appropriate button. The selected button will appear with a black dot in the center of the circle.



The *drop list*, or *drop-down list*, provides a rapid means of selecting a desired response from a fixed set of possible responses. The drop-down list window may initially appear blank, as shown in the top example above. To drop down the list of possible responses, click on the down arrow button. A scroll bar may appear on the windows right side to enable you to scroll down the list. Click to select the desired response. Your selection will appear in the upper list window.



The *check boxes* enable selection to all responses that apply. The responses are not mutually exclusive. To select a response, simply click on the appropriate box. The selected box will appear with a black check in the center of the box. Click on a selected box to deselect.



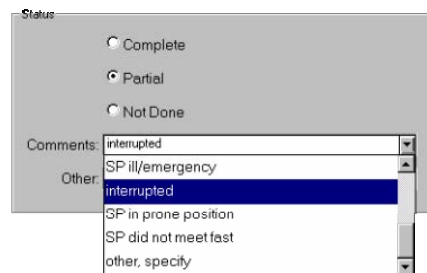
The *ellipsis button* indicates additional action is available, such as browsing for records or additional information.



The *spin box* accepts a limited set of discrete responses. The “spin” name is derived from the up-down arrow buttons that can be used to “spin” the set of responses up or down. To select a response, simply click on the appropriate up or down arrow button to increment the responses. You may also type the response value in the spin window, if known.

## Section or Component Status

The Section or Component Status screen displays the relative completion of the examination – **Complete**, **Partial**, or **Not Complete**. This is the last exam slide at the end of a section or a component if there are multiple sections. The status automatically displays and is not editable. Interruptions, emergencies, refusals, and other events that prematurely stop the examination will trigger this screen for appropriate incomplete comment codes. **Comments are not recorded for Complete examinations.**



### **Comment codes:**

Component status codes indicate the degree of component examination completion. The three standard codes are:

**Complete:** All sections of the component were completed or attempted.

**Partial:** At least one section of the component was not completed or attempted.

**Not Done:** No part of the component was done or attempted.

**Comment codes** are used to explain Partial complete or Not Done status codes. The Comment Codes defined below are common to all exams. There are other specific components and sections comment codes which are not defined here.

**Safety Exclusion:** The examinee was excluded from the component for safety reasons as defined by the protocol for the component.

**SP Refusal:** This is an SP initiated response due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the Coordinator can code the exam. If the SP refuses after starting the exam, the examiner will code the refusal.

**No Time:** The SP comes on time and stays for the entire session, there is adequate staff in the MEC but at the end of the session there is no time to do the examination.

**Physical Limitations:** SP is unable to have the test due to physical problems. For example, the SP is unable to lie flat for the total body composition scan.

**Communication Problems:** SP is unable to understand and follow the instructions for the component due to language, cognitive impairment or other problem, and is unable to complete the test.

**Equipment Failure:** The component equipment malfunctioned and the test could not be performed on the SP.

**SP Ill/Emergency:** The SP became ill or an emergency occurred and the test was not performed on the SP.

**Interrupted:** An exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.

**Other, specify:** If the above reason for a Status Code of Partial or Not Done is not explained by one of the above Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

Examinations closed prior to completion are automatically assigned a **Partial** status and the examiner is prompted for an appropriate comment.

Select the comment from the **Comments** drop-down list and press **OK**.

## The Messaging Subsystem

The Messaging subsystem is the communication nerve center that continually informs the Coordinator on the status of each component examination progress, assigned examiner(s), components available for SPs, and other management information.

Communication between the Coordinator and examination components is readily available through the **Utilities** menu or the Send Message button on the toolbar.



### **To Send a Message to the Coordinator:**

- Click on the **Send Message** button on the toolbar.

Or,

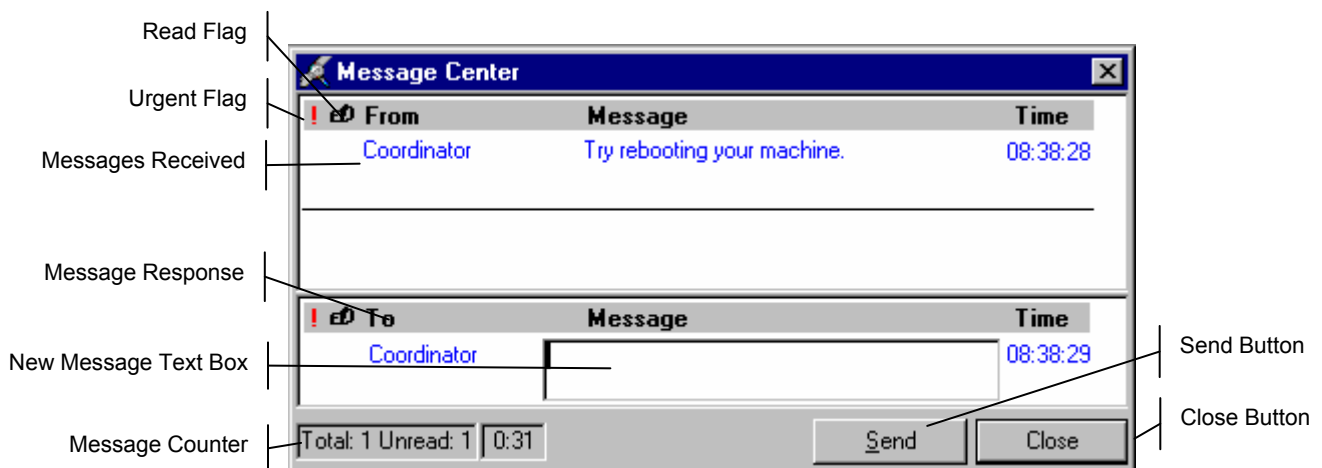
- Press *Ctrl+M* keystroke combination.

Or,

- Select **Send Message** from the Utilities menu.
- The Message Center transmittal box appears.

Messages sent to the Coordinator appear in the Message Center window on the Coordinator screen. Messages received from the Coordinator will remain visible on your screen for approximately 30 seconds.

Messages that have been flagged as “Read” (click the Read Flag column next to the read message) will be removed from the Messages Received pane during the system update, usually every 30 seconds.



- Received messages appear in the upper pane.
- Message responses are constructed in the lower pane.

- To respond to a message, select the message in the upper pane by clicking the “**Read**” flag.
- The Coordinator automatically appears in the “**To**” message response pane.
- Type your message in the **Message** text box.
- Click the **Send** button to send the message.
- Clicking the send button without including a text message automatically sends an “**Ok**”.
- Click the **Close** button to close the Message Center

## Sample Reports

The Reports menu options include the Session Preview, Room Log, and Results reports. Most reports display on screen and all reports can be printed.

### To Print a Report

Default printers are designated for each workstation and cannot be changed with the examination program.

#### **To Print a Report or Window:**

- Open the report.
- Select *File | Print* from the menu bar.

The report or print capable window is automatically sent to the default printer.

### Session Preview Report

This report can be viewed one day in advance. The report shows SPs scheduled for the scheduled sessions with special considerations and comments to notify the team in advance.

Session Preview Report							04/30/98 11:02
Stand: 551							
Session: 551574		04/25/98	08:30 - 12:30				
SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comment	
791318		Tim Broughton	7 years	M			
734079		Zack Broughton	17 years	M			
602170		Kerry Broughton	35 years	F			
508340		Allen Broughton	46 years	M			
735805		Lydia Broughton	21 years	F			

Figure 9: Session Preview Report



## Room Log

The Room Log displays SPs that have completed the component and other comments.

Physician Room Log							04/30/98 11:02
Stand: 551		Session: 551574 04/25/98 08:30 - 12:30				Total: 10 SPs	
Sp Id:	SP Name:	Gender:	Age:	Appt Status:	Comp. Status:	Comp. Comment:	
1	169910 Harris Broughton	M	35	Scheduled		Special Considerations:	
2	239464 Sarah Broughton	F	4	Scheduled		Special Considerations:	
3	479721 Sue Broughton	F	56	Scheduled		Special Considerations:	

Figure 10: Room Log

## Results Report

The Result Report displays a detailed listing of the examination results. Each component application is tailored to the examination. However all reports reflect the itemized results in tabular form in a style consistent with the sample below.

Physician Result Report							04/30/98 11:04
Stand: 551		Session: 551574 04/25/98 08:30 - 12:30					
Sp Id:	508340	SP Name:	Allen Broughton	Person Gender:	M	Age At Interview Yrs:	46
Appt Id:	5510669	Appt Status:	SC	Exam Status:	P	Exam Comment: SP refusal	
Section Id:	Section Name:	Section Status:	Section Comment Code:	Section Comment Other:			
1	Blood Pressure	C					
2	Fitness	N		SP refusal			
Ph Item Id:	Ph Item Text:	Ph Item Type:	Ph Result Num:	Ph Result String:			
BPQ010	Have you had any of the following in the past 30 minutes? (check each	1	1				
BPQ010A	food	1	2				
BPQ010B	alcohol	1	2				

Figure 11: Result Report

## Appendix A: Using PrintKey

### PRINTKEY OVERVIEW

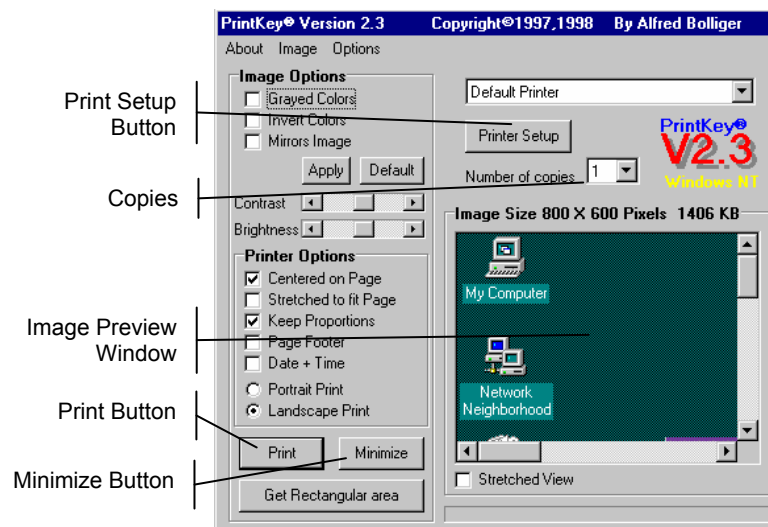
The PrintKey screen capture utility allows you to capture whole or partial screen images for immediate printing or saving to a file. Use this feature to capture any error messages that appear on the screen. Capturing the error message as it appears will enable the data manager to quickly determine the appropriate actions needed to correct the error.

PrintKey automatically loads whenever you logon a MEC workstation. It's icon appears in the system tray in the lower right corner of the screen next to the clock (looks like a little hand pushing a button). *Full Screen* and *Window Only* are two available options to capture various parts of a screen image. Full Screen captures the entire monitor screen, and Window Only captures the currently active window only, such as an error message window.

### Full Screen Capture

Full screen captures are used when the entire monitor image is needed. Each image will require approximately 1.5 Megabytes of space, which is more than what 1 floppy disk can hold.

- Press the **Print Scrn** key, a screen shot of the full screen is taken and the PrintKey utility window pops up:

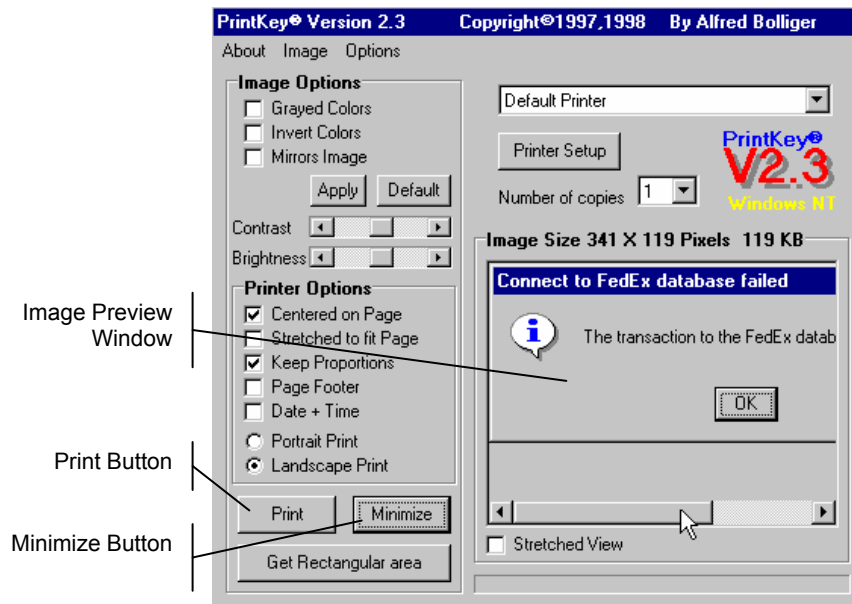


- Now you can print the image or save the image to a file.

## Window Only Capture

Window only captures are used when only the current window image is needed. The window can be an error message, dialog box, or a window within an application. Image sizes will vary depending on the area the window covers on the monitor. If you want to capture information in a program without the distraction of toolbars and other graphics, this method works best.

- Press and hold the **Alt** key, then press the **Print Scrn** key. The capture of the open window is taken and the PrintKey utility window pops up:



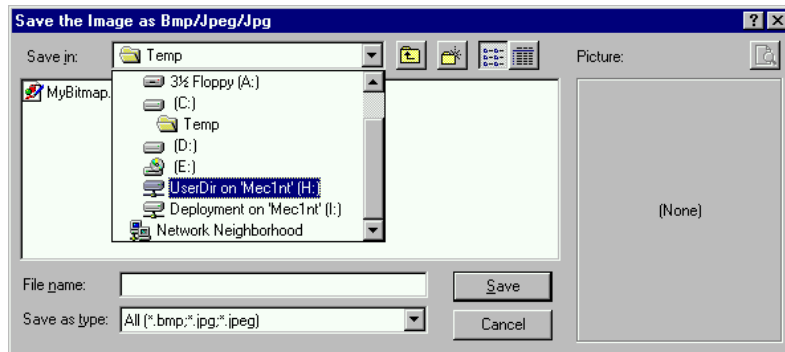
- Now you can print the image or save the image to a file.

## Saving Images to a File

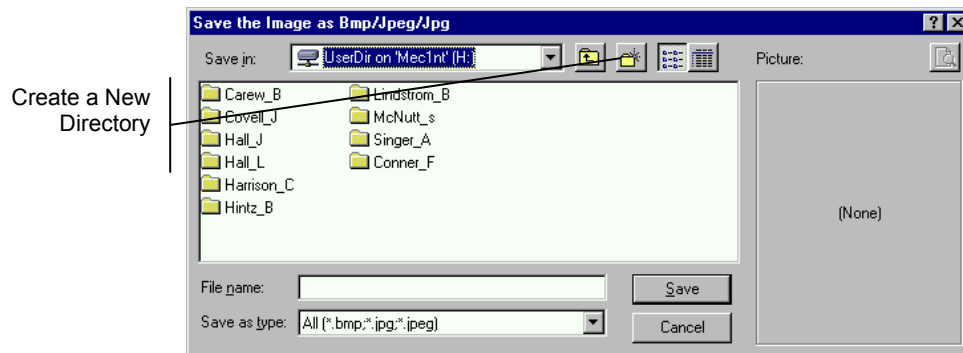
Images captured using any technique discussed below can be saved to a file for later use. This is how you do it:

- Click **Image** on the menu bar.
- Select **Save...** or press **Ctrl+S** keys.

- The Save dialog box appears.



- In the **Save in** drop-down list, select the destination directory/folder.
- The selected directory/folder, shown below, opens and displays individual subdirectories to store your files.



- Double-click to select your subdirectory if available, or make a new directory is you do not see one with your name.
- Name your image in the **File name** field.
- Select **BMP** from the **Save as type** drop down list.
- Click **Save**.
- Click **Minimize** on the PrintKey window.

## Printing a Screen Capture

### To print the image

- Click on **Print** in the lower left corner to print to the default printer.
- The capture will print at your designated printer.
- Click **Minimize** to hide the PrintKey window.

## Appendix F

### Dental Reference Sheets

- Summary Dental Reference Sheet
- Summary Dental Question Reference Sheet
- Medical Exclusion Questionnaire

## APPENDIX F. SUMMARY DENTAL REFERENCE SHEET

1. MEDICAL EXCLUSION QUESTIONNAIRE (13+)

2. DENTAL CONDITION QUESTIONS (16+)

3. DENTURE QUESTIONS (25+)

4. TOOTH COUNT (2+)

- 1 = Primary Tooth
- 2 = Permanent Tooth
- 3 = Implant
- 4 = Not present
- 5 = Permanent Root Tip

5. DMF: CORONAL (2+)

<u>Perm</u>	<u>Tooth Calls</u>	<u>Primary</u>
<b>S</b>	Sound	<b>D</b>
<b>Z</b>	Decayed or Filled	<b>K</b>
<b>U</b>	Unerupted	
<b>E</b>	Missing (Diseased)	
<b>M</b>	Missing (Non-Diseased)	
<b>R</b>	Missing (Diseased)/ Fixed Restoration	
<b>X</b>	Missing (Non- Diseased)/ Fixed Restoration	
<b>P</b>	Missing (Diseased)/ Removable Restoration	
<b>Q</b>	Missing (Non-Diseased)/ Removable Restoration	
<b>T</b>	Root Tip/Replaced	
<b>J</b>	Root Tip/Not Replaced	
<b>Y</b>	Tooth Not Assessed	

<u>Decay</u>	<u>Surface Calls</u>	<u>Restorations</u>
<b>0</b>	Lingual	<b>5</b>
<b>1</b>	Occlusal	<b>6</b>
<b>2</b>	Facial (Buccal)	<b>7</b>
<b>3</b>	Mesial	<b>8</b>
<b>4</b>	Distal	<b>9</b>
	Crown	<b>C</b>

6. DMF: ROOT (18+)

- Caries
- 1 = Root Caries
  - 2 = No Root Caries
  - 9 = Cannot Be Assessed

- Restorations
- 1 = Restoration(s)
  - 2 = No Restorations
  - 9 = Cannot Be Assessed

7. SEALANTS (2-34)

- 0 = Not Present
- 1 = Occlusal; Permanent
- 2 = Facial; Permanent Mandibular
- 3 = Lingual; Permanent Maxillary
- 4 = Occlusal; Primary
- 9 = Cannot Be Assessed

8. FLUOROSIS (6-49)

- 0 = Normal (No Fluorosis)
- 1 = Very Mild (Less than ¼)
- 2 = Mild (¼ to ½)
- 3 = Moderate (More than ½)
- 4 = Severe
- 5 = Questionable
- 8 = Non-fluoride Opacity
- 9 = Cannot Be Assessed

9. TRAUMATIC INJURIES (6-29)

- 0 = No Evidence
- 1 = Unrestored Fracture; Enamel
- 2 = Unrestored Fracture; Dentine
- 3 = Untreated Pulpal Damage
- 4 = Restored Fracture
- 5 = Lingual Restoration/RCT
- 6 = Missing Due to Trauma
- 9 = Cannot Be Assessed

10. TOOTH WEAR SCORES (13+)

<u>Score</u>	<u>Surface</u>	<u>Criteria</u>
<b>0</b>	All	Sound / No Wear
<b>1</b>	All	Enamel loss w/ exposed dentin.
<b>2</b>	B, L	Exposed dentin > 1/3 surface area.
	O, I	Exposed dentin buccal-lingual => 2mm at the widest point.
		No exposed secondary dentin or pulp.
<b>3</b>	B, L	Complete loss of enamel on a surface or pulp exposure
		Or exposure of secondary dentin where the pulp used to be.
	O, I	Pulp exposure or exposure of secondary dentin.
<b>8</b>	All	Fractured tooth.
<b>9</b>	All	Cannot assess.

{B = Buccal; L = Lingual; I = Incisal; O = Occlusal}

**APPENDIX F. SUMMARY DENTAL REFERENCE SHEET (continued)**

**11. FUNCTIONAL OCCLUSAL CONTACTS (25+)**

Maximal Incisal Opening

**0 – 65** = 0 – 65+ mm  
**99** = Cannot be assessed

Posterior Functional Occlusal Contact Zones

**0** = No posterior functional contact  
**1** = Contact between two natural teeth or fixed prosthesis  
**2** = Contact between natural tooth or fixed prosthesis and a removable prosthesis  
**3** = Contact between two denture teeth  
**9** = Cannot assess

Anterior Functional Occlusal Contact\*

**0** = No anterior functional contact  
**1** = Contact between two natural teeth or fixed prosthesis  
**2** = Contact between natural tooth or fixed prosthesis and a removable prosthesis  
**3** = Contact between two denture teeth  
**9** = Cannot assess

\*Choose best contact relationship involving any one mandibular incisor

**12. LOSS OF ATTACHMENT (13+)**

FGM to CEJ

**-9 to 9** = Measurement in mm  
**+A** = + 10 mm  
**+B** = + 11 mm  
**+C** = + 12 mm  
**Y** = Cannot Be Assessed

FGM to Sulcus Depth

**0 to 9** = Measurement in mm  
**A** = 10 mm  
**B** = 11 mm  
**C** = 12 mm  
**Y** = Cannot Be Assessed

**13. BLEEDING FROM PROBING (13+)**

**1** = Bleeding from probing detected  
**2** = No evidence of bleeding  
**9** = Cannot be assessed

**14. RECOMMENDATION FOR DENTAL CARE (2+)**

Position Tracking Code

**Y** = Yes  
**N** = No  
**C** = Cannot Assess

Overall Recommendation

**LEVEL 1** = See dentist immediately  
**LEVEL 2** = See dentist within 2 weeks  
**LEVEL 3** = See dentist at earliest convenience  
**LEVEL 4** = Continue with regular-routine dental care

Other Conditions

- A.** Decayed teeth
- B.** Gum problem/disease
- C.** Oral hygiene
- D.** Clinical impression of soft tissue condition
- E.** Denture/partial denture/ plates
- F.** No significant findings
- G.** Other finding

APPENDIX F. SUMMARY DENTAL QUESTION REFERENCE SHEET

SUMMARY DENTAL QUESTION REFERENCE SHEET

DENTAL CONDITION QUESTIONS

<b>Now I have some questions about your teeth.....</b>	Q2. What specific problems do you have with your teeth?
Q1. How would you describe the condition of your teeth? Would you say...	1 = Toothache 2 = Sensitivity 3 = Cavities / Caries 4 = Broken / Missing Fillings or Restorations 5 = Broken / Fractured Teeth 6 = Staining / Discoloration of Teeth 7 = Crooked Teeth / Need Braces 8 = Teeth Needing Extractions 9 = Missing Teeth 10 = Denture Problems 11 = Periodontal Related Problems 12 = Unsatisfactory Prior Dental Experience 13 = None / No Specific Problem 14 = Other 15 = Refused 16 = Don't Know
Excellent, Very Good, Good, Fair, or Poor? REFUSED DON'T KNOW	
{If response is "good", "fair", or "poor" to Q1, go to Q2; if not skip to tooth count}	

DENTURE QUESTIONS

<b><i>I am now going to ask you some questions about full and/or partial removable denture (i.e. plate or false teeth) use. A full denture is a replacement for either all of your upper or lower teeth. A partial denture replaces only some of your upper or lower teeth. Both a partial or full denture (plate) can be removed from the mouth or placed in the mouth by yourself.</i></b>	Q1. Do you have an <u>upper</u> removable partial or full denture?
	Q2. Do you usually wear it during the day?
	Q3. Do you have a <u>lower</u> removable partial or full denture?
	Q4. Do you usually wear it during the day?
	Y = Yes N = No R = Refused D = Don't Know

©



**APPENDIX F. MEDICAL EXCLUSION QUESTIONNAIRE**

**NHANES Oral Health Component  
Medical Exclusion Questionnaire**

1. Has the doctor or dentist ever told you that you must ALWAYS take antibiotics (e.g., penicillin) before you get a dental check-up or care?

Before we begin, I'd like to read you a list of health conditions that some people have. As I read off each condition, please tell me whether or not a doctor has ever told you that you have the condition.

2. Has a doctor ever told you that you have a heart problem?

Was the heart problem due to:

3. Congenital heart murmurs;
4. A heart valve problem;
5. Congenital heart disease; or
6. Bacterial endocarditis?

Has a doctor ever told you that you have:

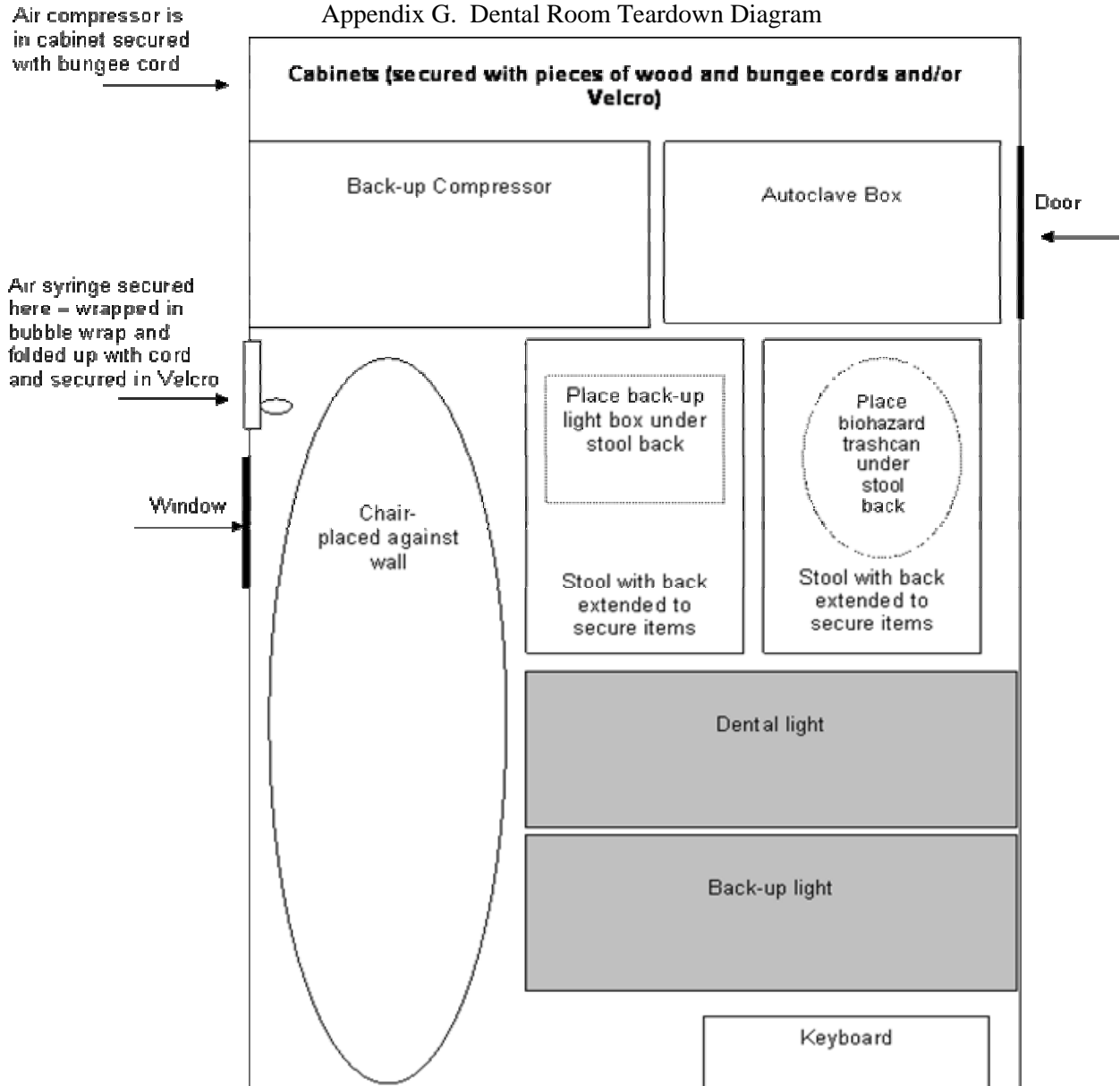
7. Rheumatic fever; or
8. Kidney disease requiring renal dialysis?

Do you have:

9. Hemophilia;
10. A pacemaker or automatic defibrillator;
11. Other artificial material in your heart, veins, or arteries; or
12. A hip, bone, or joint replacement?

Appendix G  
Dental Room Teardown Diagram

Appendix G. Dental Room Teardown Diagram



Take clock and mask down. Wrap in bubble wrap and place in bottom drawer. Leave the cheat sheets on the wall. Clean and disinfect the biohazard trashcan. Do not store anything in the biohazard trashcan. The back-up chair should be the only item left in the belly compartment. The back-up air compressor needs to be brought up from the belly. Items can be stored in the cabinets for travel. Move supplies from the top shelves down to the lower shelves. Pack securely on bottom shelf with heavier items on the bottom.