



National Health and Nutrition Examination Survey (NHANES)

Oral Health Examiners Manual



2009-2010

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1. OVERVIEW TO THE ORAL HEALTH COMPONENT

1.1 Introduction

The 2009–2010 Oral Health Component of NHANES is sponsored by the following organizations:

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

This component was developed by the DOH and the NCHS. A portion of this component, the periodontal assessment and questionnaire, was developed in collaboration with the American Academy of Periodontology.

The purpose of this component is to assess the prevalence of oral conditions and diseases, such as edentulism, dental sealants, dental fluorosis, dental caries, and periodontal disease. A set of periodontal questions will be assessed to determine the extent to which these questions provide an accurate basis for estimating prevalence of clinically measured periodontitis in the U.S.

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) and the National Health Interview Surveys (NHIS), as well as special surveys such as the Hispanic Health and Nutrition Examination Survey and the children's and adult surveys conducted by the National Institute of Dental and Craniofacial Research.

Oral and dental diseases affect many in the United States. Dental caries and tooth loss remain significant problems affecting the Nation's oral health. Although average dental caries rates for school-aged children have declined, approximately one-fifth of children age 6-11 years and two-fifths of children age 12-15 years have experienced dental caries in permanent teeth. Additionally, nearly

90 percent of adults in the United States have experienced caries. Dental sealants, an effective caries prevention measure, have been underutilized in the United States, with about 30 percent of children aged 6-11 having them.

The 2009–2010 oral health component will meet a critical need to continue monitoring trends in oral health status. Unlike previous oral health exams conducted within NHANES, the 2009-10 oral health exams will be conducted by dental hygienists trained to administer the oral health screening assessments. The NHANES 2007-08 Basic Screening Exam for Oral Health (BSE) and Tooth Count will be continued. Additionally, an assessment for dental fluorosis will be performed on the upper six anterior permanent teeth. Finally, a full-mouth periodontal exam will be conducted, a first for any national health survey. This oral health exam will produce sufficient data to monitor six Healthy People 2010 oral health objectives (21.1 Dental caries experience; 21.2 Untreated dental decay; 21.3 No permanent tooth loss; 21.4 Complete tooth loss; 21.5 Periodontal disease; and 21.8 Dental sealants).

1.2 Data Collection

The Mobile Examination Center (MEC) contains an automated computer system referred to as ISIS, the Integrated Survey and Information System. The automated system is used as follows:

- Direct the flow of study participants (SPs) through the MEC, keeping track of which parts of the examinations have been completed;
- Record interview and examination data;
- Perform edits on collected data; and
- Enter quality control (QC) data for components.

The oral health examiner will have his or her observations (codes) directly entered into ISIS during the dental examination by MEC staff trained as dental recorders.

1.3 Operations Overview

This section summarizes the flow in the MEC and the responsibilities of the oral health team during the Pilot.

- The oral health exam is conducted by registered dental hygienists (RDHs).¹ Data are recorded by as separate dental recorder.
- The dental examiner (RDH) arrives at the MEC prior to the session start. He or she needs to arrive early enough to complete the following tasks prior to the start of the session:
 - Print and post the session schedule for the number of SPs and their ages;
 - Set up the oral health work area (details are provided later in this document);
 - Check all equipment;
 - Make sure that enough supplies are available for the session. A full session is quite busy and there will be no time to resupply; and
 - Complete the QC for setup in ISIS (refer to Quality Control procedures).
- At the start of the session, each SP checks in with the coordinator at the workstation, just inside the MEC entrance. The coordinator provides each SP with a bracelet with the SP's name, ID number, and corresponding bar code.
- The dental examiner notifies the coordinator that the room setup is complete and is ready to receive SPs.
- The dental recorder goes to the coordinator station to meet the SP and bring him or 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 dental examiner completes the oral health assessments while the recorder enters the data in the ISIS system.
- The SP is escorted to the reception area or to the next examination by the dental recorder.
- The dental examiner sets up the room for the next SP.

¹ Also referred to as a dental examiner.

- At the end of a session, the dental 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.

1.4 Conducting the Oral Health Exam

Data for this component will be collected using a visual-tactile examination. This component has several assessments. The specific assessment a SP receives is dependent on his or her age. Only SPs aged 3 years or older are eligible for one or more parts of the oral health component. The specific oral health screenings and question modules, with appropriate age ranges, are listed below:

- Safety Exclusion Questions (30 years and older);
- Tooth Count (3-19 and 30 years and older);
- Oral Health Basic Screening Exam (BSE) (3-19 years);
- Dental Fluorosis Assessment (6-19 years);
- Periodontal Exam (30 years and older); and
- Miscellaneous/Report of Findings (3-19 and 30 years and older).

The oral health exam will be conducted in the oral health examination room. The assessments will be performed with the SP in a recumbent position with the dental examiner seated behind the SP (positioning is typical of earlier oral health examinations in the MEC). The dental examiner will always use a new pair of examination gloves and hand washing should be performed before re-gloving. The oral health examination pack will contain the following dental hand instruments: #5 reflecting mirror and a Hu Friedy PCP-2 (2-4-6-8-10-12) Periodontal Probe. All instruments will be sterilized in a steam autoclave. CDC infection control guidelines for dental practice will be practiced (Appendix B).

The dental examiner will use the existing halogen dental light for illumination and will have access to compressed air and may use compressed air to clear the dental viewing area of residual food debris. If an assessment cannot be performed with the SP in the recumbent position, the examiner will

attempt to accurately complete the assessments with the SP in an alternative position. Assessments completed with the SP not in a recumbent position will be coded with the existing position tracking code. Details are described elsewhere in this manual.

1.5 Safety Exclusion Questions

SPs with certain medical conditions will not be permitted to participate in the periodontal examination. During the home interview, a module of oral health questions are administered to SPs by trained interviewers. When SPs are 30 years and older, they are asked two sets of oral health questions. The first group focuses on legibility for the periodontal exam, whereas the remaining group inquires about self-reported periodontal health status. The safety exclusion questions inquire into dentition status and health history, which could exclude an individual from receiving the periodontal exam.

Although the safety exclusion questions are asked during the household interview, they will be asked once more in the oral health room. The dental examiner will remind the SP that these questions were asked but will be asked again to verify the information. The dental examiner will briefly re-ask these questions and instruct the dental recorder to enter the information. If the SP answers “Yes” to any of the screening questions, they will be excluded from the oral health examination and the exam will end. If they answer “No” they will continue with the exam.

A set of shared exclusion questions might be asked in another component at the MEC or in the oral health exam. The two questions are:

Has a doctor ever told you that you have:

- Hemophilia? or
- A pacemaker or automatic defibrillator?

These two questions will not be asked here if the information is obtained elsewhere, such as in the other examination components. Answers obtained elsewhere will appear on the screen when it is initially displayed. Therefore, the examiner will 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 entries for those two items are “Yes,” “No,” and “Don’t Know.” Exhibit 1-1 provides a screen shot of the exclusion questions.

Exhibit 1-1. Safety exclusion questions

The screenshot shows a software window titled "Oral Health: Stand:410 Session:410912 11/17/2004 05:30 pm - 09:30 pm". The window contains a "Shared Exclusion and Edentulous Screen" with the following questions and responses:

Question	Response
Have you lost all of your upper and lower natural (permanent) teeth?	No
Has the doctor or dentist ever told you must ALWAYS take antibiotics (e.g. penicillin) before you get a dental check up or dental care?	No
Do you have an artificial heart valve?	No
Have you had heart disease since birth?	No
Have you had a bacterial infection of the heart, also called Bacterial Endocarditis?	No
Has a doctor ever told you that you have:	
Rheumatic fever?	No
Hemophilia?	No
Kidney disease requiring renal dialysis?	No
A pacemaker or automatic defibrillator?	No
A hip, bone or joint replacement?	No

At the bottom of the screen, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the bottom left shows "1 of 2".

1.6 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 when 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 a particular section of the examination. Section status screens are summary screens that appear at the end of each subcomponent section: dentition, periodontal, and recommendation for care. If the subcomponent is either partially complete or not done, the following reasons are programmed into the ISIS system and appear at the status screen:

- **SP refusal.** 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 only 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 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.
- **Safety exclusion.** If an SP is excluded from certain subcomponents because of a medical exclusion question, or the SP’s safety or medical condition is of concern to the examiner due to pain, fainting, seizure, bleeding, etc., it is recorded as a partially completed exam for safety exclusion.
- **Other reason.** A reason not programmed in the ISIS system requires a comment.

1.7 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 dental examiner gives the recorder. The Report of Findings will be handed to the SP when he or she leaves the MEC. It will indicate whether the SP should continue his or her usual dental care, see a dentist at his or 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 are discussed in depth in Chapter 8.

2. EQUIPMENT AND SUPPLIES

2.1 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 2-1.

2.2 Description of Equipment and Supplies

Exhibit 2-2 shows a list of necessary equipment and supplies and the anticipated quantities of each of these items. The specific manuals for each piece of equipment are located in the bottom drawer of the oral health room. They are 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.

2.2.1 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 2-1. Dental examination room

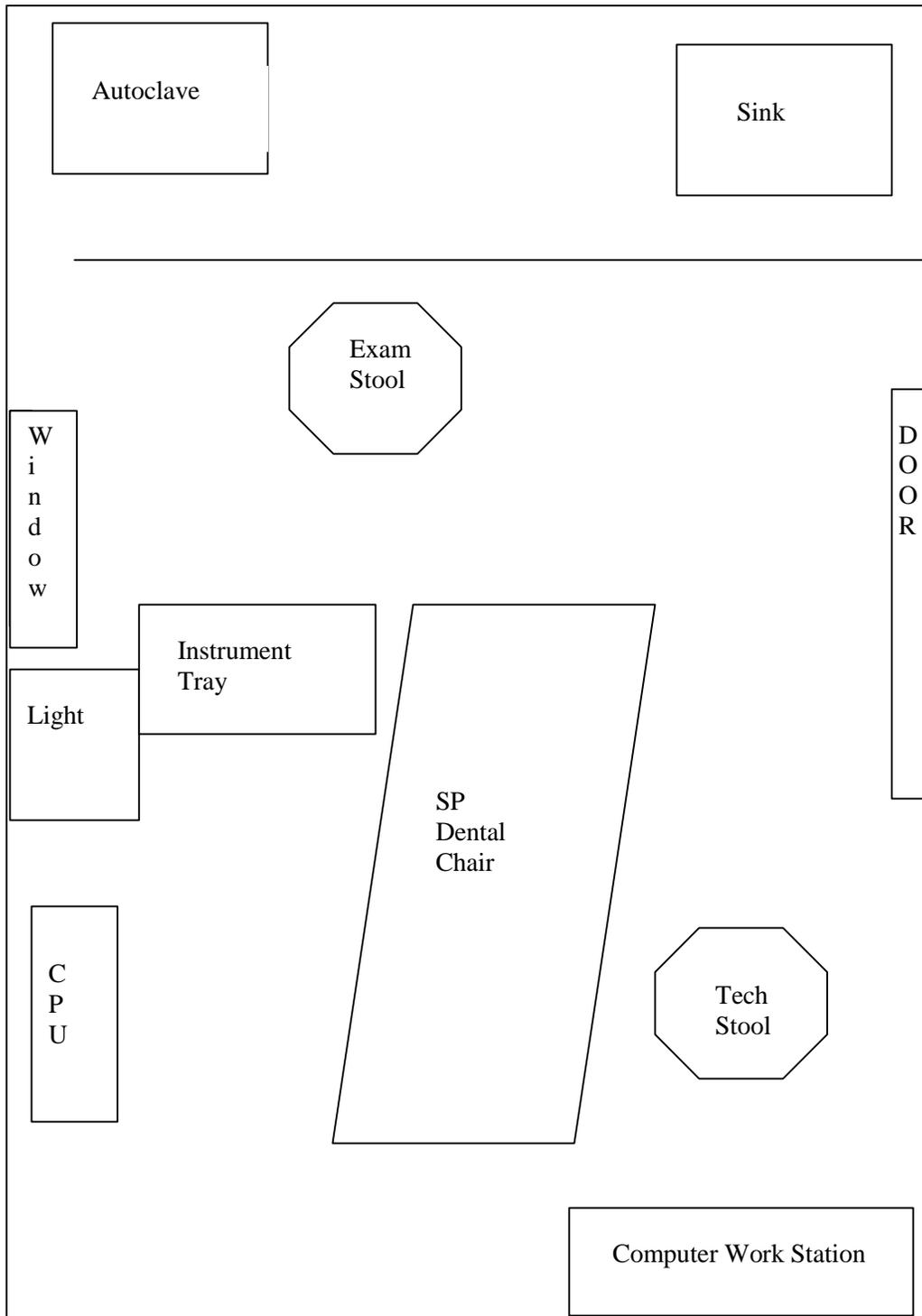


Exhibit 2-2. Equipment and supplies for dental component

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
Examination			
Dental Porta-Chair	1		
Backup 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		
Backup 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		
Backup light and replacement light bulb	1		
Replacement fuse for halogen light	2		
2x2 gauze, nonsterile (NuGauze)			2
Denture adhesive	1 tube		
Pillow (for elderly)	1		
Pillow covers	25		
Instrument setup 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		
Stickers (assorted cartoon for children)	4 rolls		
Instruments			
#23 Explorer	60		1
Hu Friedy PCP-2 periodontal probe	60		1 (SP 13+)
Mirrors (handles and heads)	60		1
Curettes	5		
Sterilization			
Ritter SpeedClave Steam Sterilizer	1		
SpeedClean Sterilizer Cleaner Solution		8 oz	
Attest incubator	1		
Attest (spore tests)		12 vials	
Peelvue sterilizing pouches			1
Sterigage indicator strips		12-18	
Door gasket (spare)	1		
Instrument brush with holder	1		

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

Supply	Per MEC	Per Stand (@ 6 weeks)	Per SP
Sterilization (continued)			
Utility gloves	1 pr		
Hot pad mitt	1		
Distilled water		3 gal	
Restore solution		1 bottle	
Infection Control			
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	
Nondental			
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. Write only 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 whether the next stand can get by without needing more. If not, put a 0.
- Lot numbers and expiration dates—all active lot numbers and expiration dates show up on the count sheets if they are applicable for that item. If you see a lot number and expiration date, you must enter 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.

2.2.1.1 Consumables vs. Nonconsumables

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

2.2.1.2 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 looks 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 to increase the warehouse inventory counts.

2.2.1.3 Tracking of Expired and Broken Inventory

The Delete Expired/Broken/Missing 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 your MEC manager as soon as possible when your supplies run low.

2.3 Equipment Procedures and Maintenance

The procedures for setup and maintenance of equipment at the beginning of a stand, daily, weekly, midstand, and at the end of a stand are described below. Then this chapter reviews specific procedures for use of equipment and supplies.

2.3.1 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 dental 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 setup 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 All-Purpose Cleaner and/or Soft Scrub. Use the washcloth, then throw it out. Counters, blinds, cabinets, walls, and windows 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 backup autoclave to make sure it is in working order.
- Stock cabinets with supplies per instructions in Chapter 10.
- 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.

2.3.2 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.
- Visually check the following pieces of equipment:
 - The light;
 - The air compressor and air tank valves; and
 - The sterilizer.
- Turn the air compressor on and close valve.
- Check airflow from air syringe.
- 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); and
 - Place Restore solution in Rubbermaid containers for used instruments. These should be on counter with lids on.

2.3.3 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 (needed only 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.
- If instruments were sterilized, complete the information required in the Integrated Survey and Information System (ISIS) utilities for this (instruments must be washed and bagged with 1 mirror, explorer, perio-probe, and 2 gauze squares prior to

- Clean room.
- Remove biohazardous waste to the storage facility in the MEC taking the following steps:
 1. Seal the biohazard bag with a twist tie.
 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 in the belly compartment.
 8. Remove the gloves and place them in the belly compartment.
 9. Lock the belly compartment.
- Exit the ISIS system.

2.3.4 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.
- Check supply levels in cabinets; restock if necessary.

2.3.5 Midstand

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

- Drain and clean sterilizer chamber with SpeedClean.
- Refill sterilizer chamber with distilled water.

2.3.6 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 and secure it 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 a drawer or box.
- 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.
- Secure the door to the oral health room in the open position.
- Pack supplies in the belly compartment in water resistant containers. Move any items that are breakable or not stored in water-resistant containers to the oral health room.
- The backup air compressor, dental chair, and the plastic containers with supplies should remain in the belly compartment.
- The backup light should be moved to the oral health room.

2.4 Equipment

2.4.1 Porta-Chair

The Porta-Chair is the chair in which the SP sits during the dental examination. Exhibit 2-3 shows the steps used in setting up the Porta-Chair.

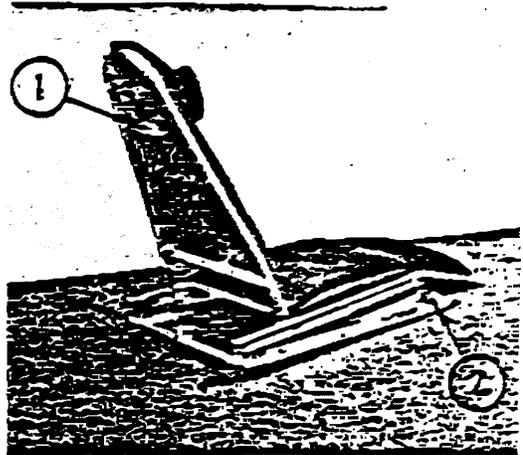
NOTE: The chair must be placed on its side when raising, collapsing, or adjusting the legs. Raising, collapsing, or adjusting the chair while it is upright could result in severe injury to the hands and wrists.

2.4.1.1 Setup

1. Remove the chair from the soft case. The other contents of the soft case can remain in the belly compartment.
2. 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 2-3. Illustration of Porta-Chair

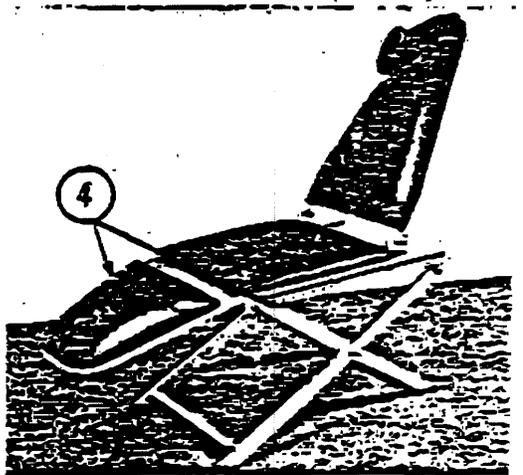
1 Connect adjustable back support with attached quick release pin.



2 Loosen height adjustment knobs.

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

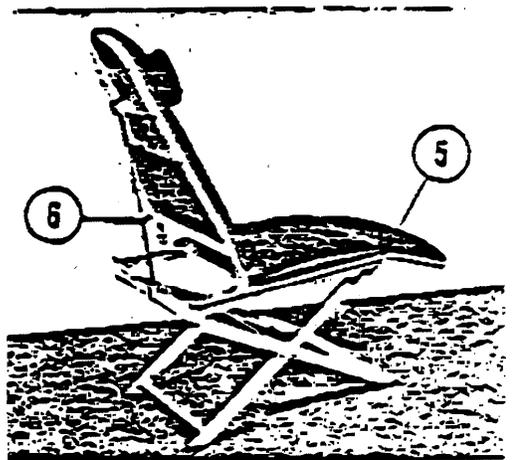
4 Raise toe board of chair with left hand while lifting chair leg with height adjustment knobs up into slots on chair frame.



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.



3. 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 that 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.
4. 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.

2.4.1.2 Breakdown

1. To detach the adjustable rod, remove the connecting T-pin from the upper portion rod that is attached to 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. Lay chair flat for storage.

2.4.1.3 Cleaning

A mild soap or foam-type upholstery cleaner (e.g., 409 All-Purpose Cleaner) 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.

2.4.2 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.

2.4.3 ProBrite Halogen Dental Light (Model HEINE HL 1200)

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

2.4.3.1 Setup

Remove the light from the plastic packing container and bubble wrap. Leave the bubble wrap in the container for teardown. Attach the light mounting to the pole above the stainless steel tray and then tighten the mounting screws.

2.4.3.2 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.

2.4.3.3 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.

2.4.3.4 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 nonabrasive soap solution.

2.4.3.5 Replacement of Light Bulb

To replace the light bulb, follow these steps:

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.

2.4.3.6 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.

2.4.3.7 Packup

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. Retighten 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.

2.4.4 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.

2.4.4.1 Setup

While travelling, the air compressor is secured to the back of the cabinet with U-hooks and a bungee cord. During setup, move the air compressor back into position. Make sure that it is sitting on a rug in the cabinet, that the door is padded, and that 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.

2.4.4.2 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.

2.4.4.3 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 it again.

2.4.4.4 Packing 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.

2.4.5 Air Syringe

2.4.5.1 Setup

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.

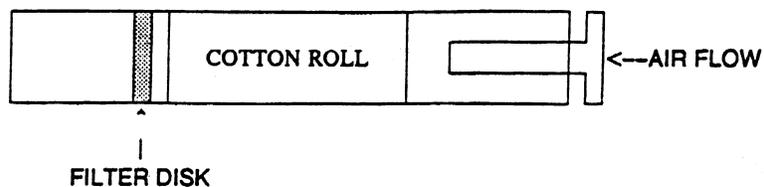
2.4.5.2 Changing the filter element (cotton roll)

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. Insert a clean cotton roll into the clear tube and position as shown in Exhibit 2-4.
7. Insert 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.

Exhibit 2-4. Air syringe



2.4.5.3 Packup

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.

2.4.6 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.

2.5 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 as follows:

- 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 are 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.

2.6 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 Public Health Service. The dentist is responsible for ensuring proper infection control practices in the dental examination room.

2.6.1 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, and syringe holder; light head and controls; and mounted instrument tray.
- The examiner must wear a face mask, 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 a 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 weekly.

2.6.2 After Each Examination

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

- Used instruments are 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 de-gloving.
- 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 into 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.

2.6.3 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 masking tape.
2. Wear gloves to transport the bag.

3. Biohazard bags will be taken to the MEC storage area following MEC standard protocol. Examiners will consult with the chief health technologist regarding current procedures for transporting biohazard bags off the MEC.

2.6.4 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.

2.6.4.1 Chemical Solutions

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

2.6.4.2 Disposable Barriers

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

2.6.4.3 Sterilization Supplies

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

- Distilled water
- Instrument brush
- Dishwashing detergent

2.6.4.4 Personal Protection

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

2.6.4.5 Containers

- Biohazardous waste container
- Biohazardous sharps containers

2.6.4.6 Hand Washing

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

The following list summarizes infection control supplies for use with equipment and biohazards 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.

2.6.5 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. If necessary, place lids on containers and agitate. Rinse instruments thoroughly to remove debris. Pat instruments dry with paper towels and place them in Peelvue pouches for sterilization.
- One instrument pack prepared for sterilization should consist of an explorer, mirror, perio probe, and 2x2 gauze.

2.6.6 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.

2.6.6.1 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 rinse them for sterilization.
- Instruments must be stored in the plastic container overnight if not prepared for sterilization in the SpeedClave. Extra care must be taken with the mirror heads.

2.6.6.2 SpeedClave Setup

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.

2.6.6.3 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.

2.6.6.4 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 counterclockwise. This will give a maximum temperature of 270° F.

2.6.6.5 Placing Instruments in SpeedClave

- Use self-seal paper bags for sterilizing the instruments. **Place one set of instruments and two pieces of gauze in each bag.** Place mirror heads and sharp points of instrument 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. Wear gloves 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 in a Peelvue pouch and place in the middle 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.

2.6.6.6 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 doors. 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.

2.6.6.7 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 within 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.

2.6.6.8 Maintenance

2.6.6.8.1 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.

2.6.6.8.2 Midstand

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.

2.6.6.8.3 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 30-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 30-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.

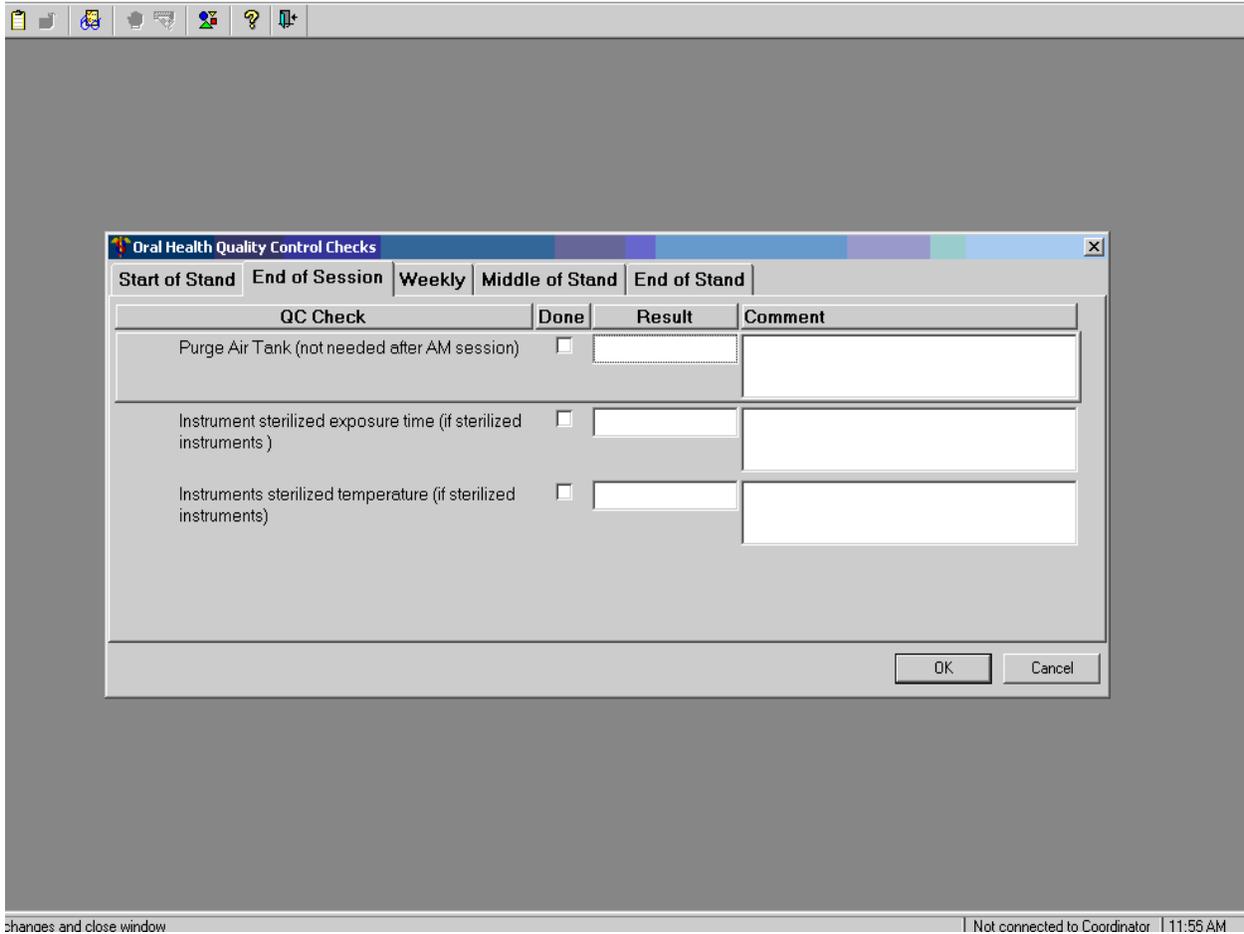
2.6.6.9 Repair

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

2.6.6.10 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 Quality Control (QC), see Exhibit 2-5. It should be filled out the day the instruments are sterilized.

Exhibit 2-5. End of Session QC screen



2.7 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. Use gloves and safety glasses at all times when handling these indicators. Complete the weekly test by using the following procedures:

2.7.1 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 in 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.

2.7.2 Interpretation

- Examine the biological indicator at the following intervals: 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.

2.7.3 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.

2.7.4 Reporting Results

Record results of the “test indicator” and the “positive control” incubations 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 Number:** 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.

Exhibits 2-6 and 2-7 show Weekly QC screen 1 and Weekly QC screen 2, respectively.

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 determine 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.

Exhibit 2-6. Weekly QC screen 1

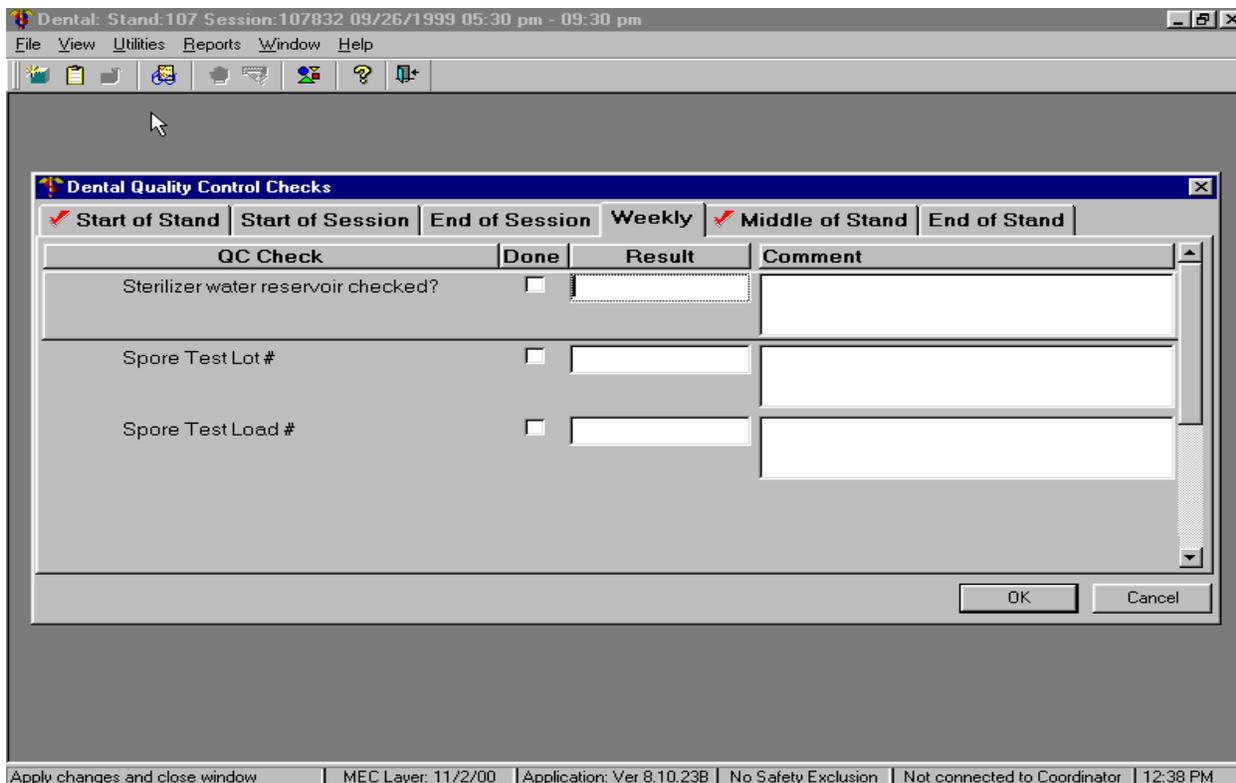
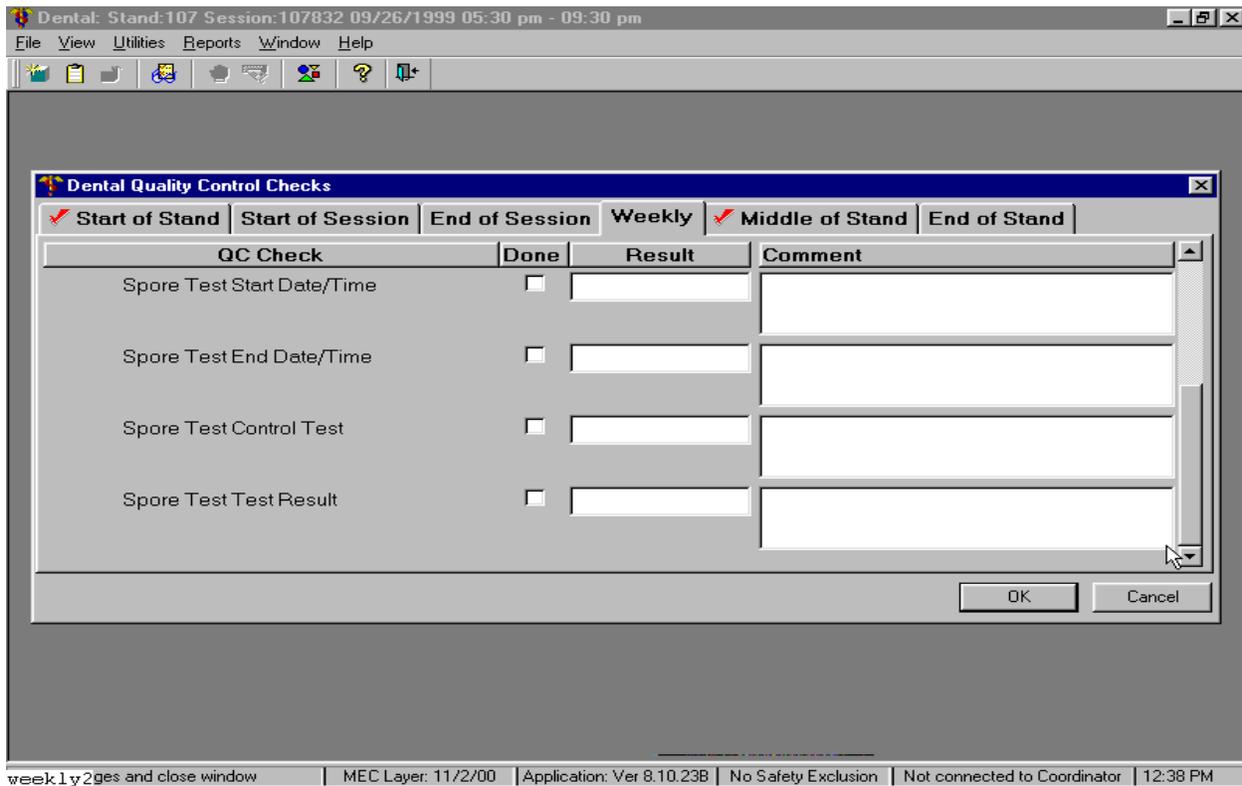


Exhibit 2-7. Weekly QC screen 2



2.8 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.

3. ORAL HEALTH EXAMINATION METHODS

The oral health exam consists of four assessment modules and a section for report of findings. The dental examiner conducts the oral health assessments and completes the report of findings. All examiner observations are directly entered by dental recorders.

3.1 Sequence of the Examination Subcomponents

Most study participants (SPs) aged 3 years and older are eligible for some part of the oral health component. The subcomponents are conducted in the following order:

- Tooth Count (3-19 and 30 years and older)
- Oral Health Basic Screening Exam (BSE) (3-19 years)
- Dental Fluorosis Assessment (6-19 years)
- Periodontal Exam (30 years and older)
- Miscellaneous/Report of Findings (3-19 and 30 years and older)

The assessment procedures and methods are discussed in the following sections of this manual. The assessment sequences follow the sequences shown on the Integrated Survey and Information System (ISIS) screen. Each assessment has its own sequence.

3.2 Pre-examination Procedures

Before conducting the oral health exam, the examiner will explain the component to the SP in his or her own words and will include the following facts:

- The dental exam that I am about to perform is for study purposes only and is not a substitute for a dental exam that you would normally receive by a dentist.
- I will be entering numbers and letters into the computer that have meaning only for this study.

- I will be looking at your teeth and may touch your mouth, teeth, gums, or dental appliances.
- The exam I will do today involves making 6 measurements around each tooth. I will use a periodontal probe to gently measure the health of your gums around each tooth.
- You may briefly experience possible gum tenderness, minor gum bleeding, and potential dislodging of an already loose dental filling or material following the dental examination.
- I would like to remind you that you can stop the exam at any time and you are free to ask questions at any time.
- I may be able to give you some very general information regarding what I saw at the end of this exam.

3.3 Answering Study Participant Questions

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

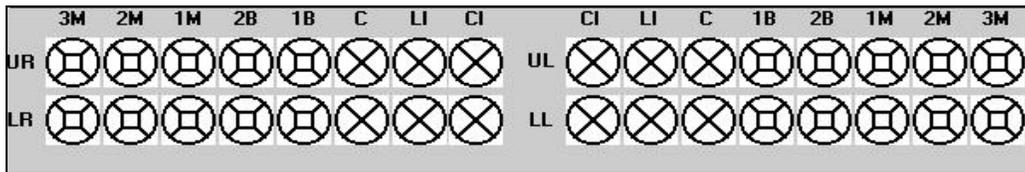
- **Treatment.** If the SP asks, assure him or her that the exam will not include treatment, x-rays, a drill, or anesthesia. The examiner will use only a dental mirror and periodontal probe to examine the mouth.
- **Existing dental work.** The exam will not interfere with any existing dental work such as fillings, bridges, or orthodontic braces. 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 U.S. Public Health Service, has established standard practices for dentists and staff to use to prevent the spread of diseases, viruses, and bacteria, and these procedures are strictly observed by the staff on this study. The precautions used in this study are the same as those maintained in dental offices.
- **Qualifications of the examiner.** I am a registered dental hygienist and I have been trained by a licensed dentist with expertise in conducting dental surveys.

3.4 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; see Exhibit 3-1.

Exhibit 3-1. Tooth Count



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 slash, green | = | Retained dental root |

- **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

3.5 General Data Entry Guidelines

This section summarizes key data entry guidelines. Summary instructions for oral health data entry codes are provided in Appendix A. Directions regarding allowable codes, acceptable ways to move through a screen, allowable shortcuts, and mandatory Quality Control (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 in the program are used as follows:

- TAB Use this key to move **forward** 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 **backwards** 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. |
| F11 | Use this key to clear data on a screen and restart the assessment. |
| F12 | Use this key to stop in the middle of an assessment and continue with the remainder of the exam. |

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.

3.6 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 that 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 look only at permanent teeth.
- 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.

3.7 Section Status Screens

After each component section (dentition, periodontal, and recommendation of 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.

3.8 Sample Section Start-Up Screen

Exhibit 3-2. Sample Section Start-Up Screen

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Periodontal Section Status Screen

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

Status

Complete
 Partial
 Not Done

Comments

Other text

5 of 5

End of Section Close Exam Finish

3.9 Examination Breakoffs

There are several types of examination breakoffs. 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.

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 are 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.

2. 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 are 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 you 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.

3. 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 enabled only 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. TOOTH COUNT

4.1 Background

Establishing the number of teeth in the dental arch is critical in assessing for functionality. The tooth count serves as a reference for all subsequent tooth-based assessments. An independent Tooth Count is conducted within the oral health exam component to establish eligible teeth for the Basic Screening Exam (BSE), dental fluorosis assessment, and the periodontal examination. With minor modifications, this tooth count assessment has been used in several surveys, including NHANES III, NHANES 1999-2004, and NHANES 2005-2008.

This Tooth Count assessment will produce oral health data to monitor three Healthy People 2010 oral health objectives (21.1 Dental Caries Experience; 21.2 Untreated Dental Decay; 21.8 Dental Sealants).

4.2 Examination Procedures

This assessment is very similar to the Tooth Count currently performed in NHANES. Participants aged 3-19 years and adults eligible for the periodontal exam (age 30 years and older) receive this assessment, which assesses the number of primary and permanent teeth. Unlike NHANES 1999-2004, information on surgical implants will not be obtained by the examiner.

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 root fragments 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 dental mirror as needed.

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 30 and older.**

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 = Dental implant
- 4 = Tooth not present
- 5 = Permanent dental root fragment

4.3 Guidelines for Scoring

To assist with the guidelines listed below, the codes used in the Tooth Count are listed below, again.

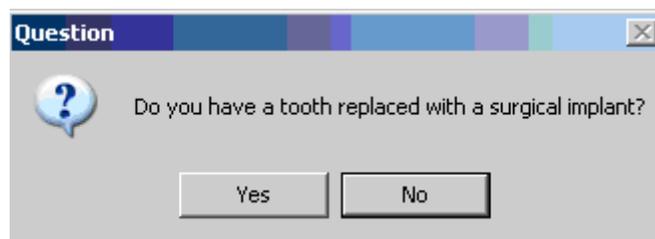
- 1 = Primary tooth (deciduous/baby tooth)
 - 2 = Permanent tooth (adult tooth)
 - 4 = Tooth not present (missing tooth)
 - 5 = Permanent dental root fragment (exposed root/tooth completely broken down to the gums)
1. A tooth is considered to be present if any part of its crown projects through the gum.
 2. If a permanent and a primary tooth are visible in the same tooth space, assign the permanent tooth to the tooth space.
 3. In instances of supernumerary teeth (i.e., “extra teeth”), you 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. You 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. You 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”).
7. If a SP has any type of denture(s), ask the SP to remove his or her denture(s) to assess for any retained dental roots under the denture. A call of “5” is appropriate for that tooth space if a retained root is present. If the SP has difficulty in removing the prosthesis, you may advise the SP to leave the denture in place.

4.4 Recording Procedures

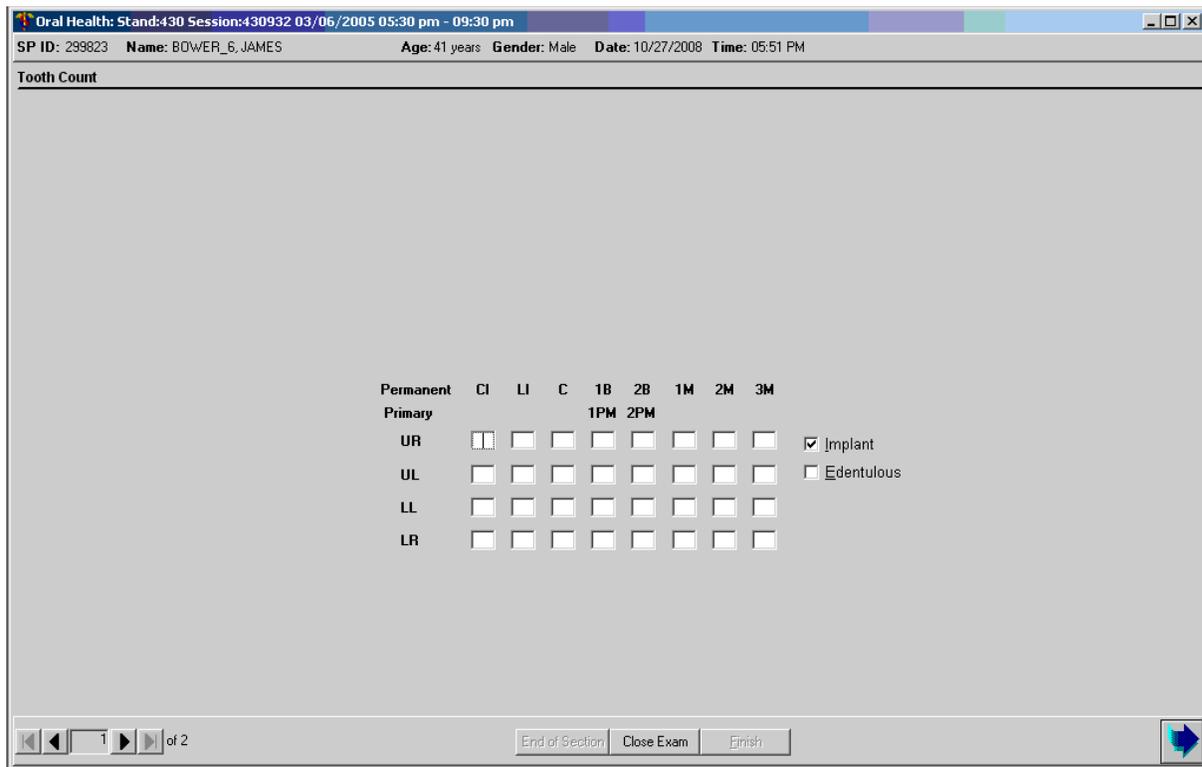
Surgical implants may be used to replace specific teeth or to support fixed or removable appliances. These may be difficult to detect without suitable radiographs. Questions must be asked of SPs to determine whether implants are present. ISIS will prompt to ask the following question: Do you have a tooth replaced with a surgical implant? (See Exhibit 4-1.)

Exhibit 4-1. Implant Question screen



When “Yes” is selected from the question box, the program will prefill the implant box on the Implant Box Checked screen (Exhibit 4-2). When “No” is selected from the question box, the program will not prefill the Implant box on the Tooth Count screen (Exhibit 4-3). The answer to this question must be called to the recorder.

Exhibit 4-2. Implant Box Checked screen



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 to indicate where in the mouth the surgical implants are. Then examine the whole mouth for implants.

If the SP does not know whether he or she received a surgical implant, go over the fact that this is a procedure where the implant is surgically (emphasis on surgically) implanted into the bone. If he or she still does not know, then answer NO and 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 you determine that no implants are present, tell the recorder to uncheck the implant box on the Tooth Count screen.

Then assess the upper right quadrant first and call your observations to the dental recorder for data entry using the Tooth Count screen as a guide. Then assess the upper left quadrant, the lower left quadrant, and finally the lower right quadrant calling your observations to the dental recorder.

NOTE: It is extremely important that the correct calls be made by the examiner and entered correctly on this screen, as the outcome of this assessment determines how other assessments are performed and coded. For example, the BSE is implemented only on dentate SPs (i.e., have teeth).

Whenever a call in the Tooth Count precludes a later assessment, such as those posterior teeth not eligible for sealant assessment in the BSE, the program automatically shades the affected teeth 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, the Integrated Survey Information System (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 the rare event that an SP is edentulous:

1. There is a box on the screen labeled “Edentulous” which must be checked if the SP is edentulous. Simply recording all “4s” in the tooth spaces will not suffice for coding the SP as edentulous.
2. Natural teeth used as an overdenture abutment are coded as a “5.” Any retained root fragments under denture plates are coded “5” as well.

A retained root fragment is classified as any permanent residual tooth structure that is predominately composed of dental root structure with more than 90 percent of the coronal structure (tooth crown) destroyed by caries and that occupies a dental position within the dental arch. Because multirooted posterior teeth may present as multiple root tips, dental examiner will assign multiple root tips to the appropriate dental position in the arch and code accordingly. Exhibit 4-3 provides a sample of the ISIS data entry screen.

Exhibit 4-3. Tooth Count screen

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Tooth Count

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

1 of 2

End of Section Close Exam Finish

5. ORAL HEALTH BASIC SCREENING EXAM

5.1 Background

Previous oral health exams have required visual-tactile assessments of all tooth surfaces by trained and standardized dentists by applying the diagnostic criteria attributed to Radike in 1968. Data from these surveys have been used to produce a variety of caries status indicators and to monitor trends and progress toward achieving national health objectives. The Basic Screening Exam was introduced to NHANES in 2005 and, for the past 4 years, has been conducted by trained health technologists (MEC staff) in order to maintain a minimum level of ongoing oral health surveillance in NHANES.

This Oral Health Basic Screening Exam will produce oral health data to monitor two Healthy People 2010 oral health objectives (21.3 No permanent tooth loss; 21.4 Complete tooth loss).

5.2 Examination Procedures

The BSE is conducted on all SPs aged 3-19 years. The dental examiner performs the assessment with a disposable dental mirror.

The BSE is designed to ascertain:

1. Presence of at least one tooth with an untreated carious lesion
2. Presence of at least one tooth with a restoration
3. Presence of at least one tooth with at least one sealed pit-and-fissure surface

The assessment is a fast and simple process by which an examiner visually inspects the oral cavity to detect the presence or absence of specific oral conditions. The assessment procedure begins with the central incisor in the quadrant. Each tooth in that quadrant is assessed visually for the specific condition of interest. Inspection systematically proceeds towards the posterior until the 2nd molar has been inspected. Then the dental examiner proceeds to the upper left central incisor and proceeds with inspection towards the upper left 2nd molar. The lower left and lower right quadrants follow in sequence. This systematic inspection approach is identical to the sequence for the Tooth Count assessment.

A full intraoral assessment for one disease/condition is known as a cycle. However, after the condition is encountered, the ascertainment criterion is fulfilled, and there is no need to complete the cycle for the same condition; this process is called stop-after-first-encounter (SAFE).

The entire number of cycles needed to ascertain a group of diseases/conditions constitutes an intraoral screening. Therefore, in the BSE protocol, the examiner will need three cycles to ascertain the presence of untreated carious lesions, restorations, and pit-and-fissure sealants. If the SP is identified as edentulous, the BSE assessments are not performed.

The codes used for the BSE are listed below. Only one code per cycle is to be entered.

1 = Present

2 = Not present

9 = Could not assess

5.3 Scoring Guidelines

For Cycle #1 (at least one tooth with untreated decay)

Untreated decay is defined as a “cavity” in a tooth that appears as a darkened fracture (hole) with irregular breakdown of the enamel surface of the tooth. The area may appear soft-spongy in texture. The occlusal surfaces of teeth (chewing surfaces) are normally characterized with pits and fissures. If a pit or fissure is stained, but there is no apparent breakdown of the enamel structure, this is not a decayed tooth and the assessment should proceed until the cycle is completed.

As previously described, the cycle sequence begins with the upper right central incisor. The examiner follows the sequence until a “cavity” is observed. The dental examiner stops the assessment for this cycle and enters the code for untreated decay **present** or a “1.” If the examiner has completed the full assessment sequence (i.e., assessing the upper right, upper left, lower left, and lower right quadrants) without observing a “cavity,” the examiner calls a “2,” the code for untreated decay **not present**, to the dental recorder for data entry. If the examiner could not assess a SP’s mouth for untreated decay, a code of “9” is entered.

Guidelines:

1. Stain and pigmentation alone are not indicative of decay.
2. White spot lesions are not considered decay.
3. Dark, shiny, pitted areas of enamel are not decay.
4. Apparent tooth wear or erosion is not considered decay.

For Cycle #2 (at least one tooth with a dental restoration)

A dental restoration is defined as a “filling” in a tooth that could be silver amalgam, yellow or white gold, metal crown, or other restorative materials using tooth-colored porcelain, ceramic, or composite resins. Denture teeth (teeth on removable acrylic plates) are not considered for restorations.

A tooth is considered restored if a temporary filling is in place. By convention, all crowns placed on posterior teeth (molars and premolars/bicuspid) are considered placed as a result of caries. On anterior teeth (incisors and canines/cuspids), the dental examiner should determine the reason for crown placement. Crowns that are placed because of malformations, esthetics, or trauma/injuries are **not** considered restored due to dental caries.

As previously described, the cycle sequence begins with the upper right central incisor. The examiner follows the sequence until a “filling” is observed. The dental examiner stops the assessment for this cycle and directs the recorder to enter the code for dental restoration **present** or a “1.” If the examiner has completed the full assessment sequence (i.e., assessing the upper right, upper left, lower left, and lower right quadrants) without observing a “filling,” the examiner directs the recorder to enter the code for dental restoration **not present** or a “2.” If the dental examiner could not assess a SP’s mouth for dental restoration, a code of “9” is entered.

Guidelines:

1. Fractured or missing fillings are scored as if the restoration is intact.
2. If a majority of the filling is on the dental root and some of the same filling is on the dental coronal structure, the filling is considered to be a root restoration and is not assessed.

For Cycle #3 (at least one tooth with a dental sealant)

A dental sealant is defined as a “protective resin coating” painted on the chewing surfaces of molars and premolars. A dental sealant may be clear or opaque white in color. The borders of the sealant are often irregular, reflecting the flow of the material into and around the pits and fissures. If no posterior teeth are present as identified by Tooth Count, this assessment is not performed.

As previously described, the cycle sequence begins with the upper right central incisor. The examiner follows the sequence until a dental sealant is observed. The dental examiner stops the assessment for this cycle and calls the code for dental sealant **present** or a “1” to the recorder. If the examiner has completed the full assessment sequence (i.e., assessing the upper right, upper left, lower left, and lower right quadrants) without observing a dental sealant, he or she directs the recorder to enter the code for dental sealant **not present** or a “2.” If the examiner could not assess a SP’s mouth for dental sealant, a code of “9” is entered.

5.4 General Guidelines

1. Teeth with orthodontic braces/brackets/or bands are coded as eligible for the BSE assessment.
2. Malformed teeth are eligible for the BSE assessment.
3. Compressed air may be use advantageously to ascertain the presence of sealants by drying the occlusal (chewing surfaces) of the eligible teeth.
4. Only the coronal portion (i.e., the tooth crown) is eligible for the BSE assessment.

5. Decay or restorations present below the tooth crown (i.e., on the dental root structure) are not eligible for the assessment.
6. Third molars (wisdom teeth) are not assessed for BSE regardless of current position.

5.5 Guide for Referral and Followup

A code of “1” in the untreated decay assessment 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. The examiner may modify this level based upon professional judgment in the Recommendation of Care section detailed later in this manual. See exhibit 5-1.

Exhibit 5-1. Level 3 Recommendation for Care

Oral Health: Stand:430 Session:430931 03/06/2005 01:30 pm - 05:30 pm
 SP ID: 239108 Name: ESTRADA_4, PACD Age: 5 years Gender: Male Date: 10/03/2008 Time: 10:10 AM

Recommendation for Care and Referral Screen

Assessments

Recomm. for care for Basic Screening Exam:

Recomm. for care for Dental Fluorosis:

Recomm. for care for Periodontal:

Other Referral Comments

Referral Refuse

Overall recommendation for care

Other Conditions

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

2 of 3

6. DENTAL FLUOROSIS

6.1 Background

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 are 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.

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 oral health examination in this study, only the six maxillary anterior teeth are classified. The modified criteria and the corresponding scores described by Dean are provided in Exhibit 6-1.

6.2 Examination Procedures

The assessment is conducted on all study participants (SPs) aged 6-19 years and only the maxillary anterior teeth (cuspids and incisors) are evaluated. The examiner performs the assessment using a dental mirror. The index scores the entire tooth and is used for assessing fully erupted permanent teeth only. 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 dental mirror. **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 one-quarter of the tooth surface)
- 2 = Mild (opaque, paper white areas involving one-quarter to less than one-half of the tooth surface)
- 3 = Moderate (opaque paper white areas involving one-half 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. The exam proceeds tooth by tooth similar to the tooth count examination, beginning with the maxillary right central incisor and proceeding posteriorly to the upper right cuspid. Then the same sequence is repeated for the upper left side. The examiner should observe the enamel condition of the corresponding bilateral tooth. For example, if initially examining tooth #6, then #11 is 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 all six teeth are scored. See Exhibit 6-2 for the data entry screen.
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 uses a score of "5" for Dean's "0.5" score as noted in Exhibit 6-1. Codes for nonfluoride opacity ("8") and nonassessment ("9") have also been added.

Exhibit 6-1. 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.

Exhibit 6-2. Fluorosis Data Entry Screen

The screenshot shows a software window titled "Oral Health: Stand:430 Session:430941 03/07/2005 01:30 pm - 05:30 pm". Below the title bar, patient information is displayed: "SP ID: 347272 Name: MILLER_6, SHEILA Age: 18 years Gender: Female Date: 10/07/2008 Time: 01:21 PM". The main area is titled "Dental Fluorosis Assessment Screen" and contains a grid of tooth icons. The grid is organized by quadrant (UR, LR, UL, LL) and tooth type (3M, 2M, 1M, 2B, 1B, C, LI, CI). Each tooth icon is a circle with a cross inside, indicating a tooth that has been assessed. Below the grid, there are checkboxes for "Permanent" and "Primary" teeth, with columns for "CI", "LI", and "C". The "Permanent" section has checkboxes for "UR" and "UL". The "Primary" section has checkboxes for "UR" and "UL". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish", along with a blue arrow button. A status bar at the bottom left shows "3 of 4" and navigation arrows.

6.3 Scoring Guidelines

The scoring 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 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.

6.4 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.

6.5 Special Assessment 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 appears 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 that 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 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 3rd, 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.

6.6 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 6-3) are used.

Exhibit 6-3. 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.

6.7 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 3rd 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 appear 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 3rd 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).**

7. PERIODONTAL EXAMINATION

7.1 Background

Periodontitis is a prevalent form of gum disease and is a common chronic disease in the U.S. population. Severe periodontitis is a major cause of tooth loss that results in diminished oral function and quality of life in adults. A growing body of evidence now supports important associations between periodontitis and several systemic diseases or conditions, including coronary heart disease, cerebral vascular disease, and peripheral arterial disease; adverse pregnancy outcomes; glycemic control in diabetes; and pneumonia in older adults. The importance of periodontitis to public health was highlighted in the 2004 Surgeon General's Report on the health consequences of smoking, in which periodontitis was one of nine conditions reported to be caused by smoking that were not previously causally linked with smoking.

The importance of assessing periodontal health in the U.S. adult population is well recognized as an objective for Healthy People 2010 (Objective 21-5). Historically, clinical periodontal examination has been included in past national health surveys. In the past, random half-mouth periodontal examinations (rather than full-mouth examinations) limited to two quadrants probing two or three sites per tooth for gingival bleeding, pocket depth, and attachment level were conducted.

For the past 4 years, a workgroup convened by the Centers for Disease Control and Prevention in collaboration with the American Academy of Periodontology (CDC-AAP) has been working on alternative methods for monitoring periodontitis within the US population. The workgroup has generated numerous findings that have recently been published as a 2007 supplement to the *Journal of Periodontology*.

7.2 Examination Procedure

For NHANES 2009-2010, diagnostic criteria used in the NHANES 2003-2004 will be expanded to include a full-mouth periodontal exam. Measurements will be made of gingival recession and pocket depth. An algorithm is subsequently used to calculate loss of attachment. Adults age 30 years and

older will be eligible for the full-mouth periodontal examination. The examiner performs the assessment using a dental mirror and the HU-Friedy periodontal probe.

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. 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 (DF), mid-facial (BF), and mesio-facial interproximal (MF) sites. This is followed by measuring the distal-lingual (DL), mid-lingual (BL), and mesio-lingual (ML) sites. For each site, the distance from the free gingival margin (FGM) to the cemento-enamel junction (CEJ) is measured first, and then the distance from the FGM to the bottom of the pocket is measured. Where the gingival margin has receded and the CEJ is exposed, the distance from the CEJ to the gingival margin is assigned a negative value. The computer program calculates loss of attachment. The examiner takes two measurements per site for use in this calculation.

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 parallel to the long axis of the tooth. Each measurement is rounded to the lowest whole millimeter. The probe is inserted from the facial aspect to measure all three facial sites—the distal interproximal, the mid-facial, and the mesial interproximal. The probe is inserted from the lingual aspect to measure all three lingual sites—the distal interproximal, the mid-lingual, and the mesial interproximal.

For the interproximal sites, (ML), (DL), (MF), and (DF), 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. Similarly, the mid-lingual measurement of these teeth is made at the location of the mid-lingual furcation area.

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 periodontal assessment is conducted in the following order:

- The examiner identifies the most distal tooth that is eligible in the upper right quadrant (URQ) and proceeds tooth by tooth in a posterior to anterior direction. The examiner makes the distal FGM-CEJ measurement first, followed by the distal FGM-pocket depth measurement. The examiner proceeds to the mid-facial aspect of the tooth and makes the FGM-CEJ measurement followed by the FGM-pocket depth measurement. The examiner proceeds to the mesial site of the same tooth and measure accordingly. The examiner will then repeat for the lingual measurements.
- The examiner then proceeds to the next tooth toward the anterior and repeats the same measures for attachment loss. This process continues until measurements are made and recorded for all teeth in the quadrant.
- The examiner then repeats the measuring process for the upper left quadrant (ULQ).
- Once the ULQ is completed, the examiner proceeds to the lower left quadrant (LLQ) and repeats the measuring sequence; and then to the lower right quadrant (LRQ) and repeats the measuring sequence. This now completes the periodontal assessment.

7.3 Guidelines for Scoring

1. When calculus at the probing sites obscures the CEJ, the location for the CEJ is estimated. If calculus accumulation is very heavy and interferes with proper probe placement, the examiner may use the “Y” code. .

2. When the margin of a restoration is below the CEJ, the position of the CEJ is estimated using adjacent landmarks and dental anatomy.
3. 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.
4. Mobile teeth should be examined with care. The CEJ should be estimated if possible.
5. Orthodontically banded teeth, splinted teeth, and hemisected teeth are considered on an individual basis and should be examined if possible.
6. 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. Code “Y” should be used for the periodontal 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.

7.4 Recording Procedures

Findings for the periodontal assessment are recorded on the Periodontal Assessment screens. Each screen view is reserved for one quadrant. The examiner “calls out” the assessment codes to a dental recorder for direct data entry. See Exhibit 7-1 for the data entry screen.

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 “Y” for Cannot be Assessed.

Exhibit 7-1. Periodontal Data Entry Screen- Upper Right Quadrant

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Upper Right Quadrant Periodontal Exam Screen

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

Loss of Attachment - UR

2M facial	1M facial	2B facial	1B facial
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

C facial	LI facial	CI facial
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

2M lingual	1M lingual	2B lingual	1B lingual
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

C lingual	LI lingual	CI lingual
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

1 of 5 End of Section Close Exam Finish

Exhibit 7-2. Periodontal Data Entry Screen- Upper Left Quadrant

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Upper Left Quadrant Periodontal Exam Screen

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

Loss of Attachment - UL

2M facial	1M facial	2B facial	1B facial
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

C facial	LI facial	CI facial
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

2M lingual	1M lingual	2B lingual	1B lingual
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

C lingual	LI lingual	CI lingual
Dis Mid Mesio	Dis Mid Mesio	Dis Mid Mesio
<input type="text"/>	<input type="text"/>	<input type="text"/>

2 of 5 End of Section Close Exam Finish

Exhibit 7-3. Periodontal Data Entry Screen- Lower Left Quadrant

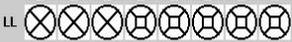
Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Lower Left Quadrant Periodontal Exam Screen

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

UR  UL 

LR  LL 

Loss of Attachment - LL

2M facial Dis Mid Mesio	1M facial Dis Mid Mesio	2B facial Dis Mid Mesio	1B facial Dis Mid Mesio
C facial Dis Mid Mesio	LI facial Dis Mid Mesio	CI facial Dis Mid Mesio	
2M lingual Dis Mid Mesio	1M lingual Dis Mid Mesio	2B lingual Dis Mid Mesio	1B lingual Dis Mid Mesio
C lingual Dis Mid Mesio	LI lingual Dis Mid Mesio	CI lingual Dis Mid Mesio	

3 of 5 End of Section Close Exam Finish

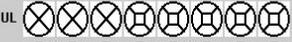
Exhibit 7-4. Periodontal Data Entry Screen- Lower Right Quadrant

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Lower Right Quadrant Periodontal Exam Screen

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

UR  UL 

LR  LL 

Loss of Attachment - LR

2M facial Dis Mid Mesio	1M facial Dis Mid Mesio	2B facial Dis Mid Mesio	1B facial Dis Mid Mesio
C facial Dis Mid Mesio	LI facial Dis Mid Mesio	CI facial Dis Mid Mesio	
2M lingual Dis Mid Mesio	1M lingual Dis Mid Mesio	2B lingual Dis Mid Mesio	1B lingual Dis Mid Mesio
C lingual Dis Mid Mesio	LI lingual Dis Mid Mesio	CI lingual Dis Mid Mesio	

4 of 5 End of Section Close Exam Finish

7.5 Guide to Referral and Followup

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

- More than two sites have a sulcus depth $>4\text{mm}$; or
- More than two sites have a depth from FGM to CEJ $\leq -4\text{mm}$; or
- More than one 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 level 1 or 2 for care, based on the examiner's professional judgment, and generate a referral letter for the SP.

8. RECOMMENDATION FOR CARE, REFERRALS, AND MISCELLANEOUS

8.1 Background

As stated earlier, each study participant (SP) will receive some general results about the dental examination he or 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 to 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 wheelchair-bound and may 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.

8.2 SP Exam Position Tracking Code

Before the Recommendation for Care screen appears, an inquiry box will appear in the Integrated Survey Information System (ISIS) asking if the SP was in a recumbent (lying down) position for all eligible assessments of the oral health exam (including oral-facial pain through loss of attachment measures.) The examiner will dictate a “Y” to the recorder if a “yes” is applicable. If not, the examiner will dictate “N” 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.

Exhibit 8-1. Position Tracking screen

The screenshot shows a software window titled "Oral Health: Stand:410 Session:410021 08/20/2004 01:30 pm - 05:30 pm". The window contains a header with patient information: "SP ID: 557808 Name: MARCOSI, STAN Age: 6 years Gender: Male Date: 10/17/2008 Time: 03:05 PM". Below the header is the "SP Position Screen" section. The main area of the screen displays the question: "Was the SP in a recumbent (laying down) position for all eligible assessments of the oral health exam?" followed by a dropdown menu currently set to "Yes". At the bottom of the window, there are navigation controls including a "1 of 3" indicator, "End of Section", "Close Exam", and "Finish" buttons, along with a blue arrow icon.

8.2.1 Scoring Code

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

Y = Yes

N = No

9 = Cannot assess

8.2.2 Guidelines for Scoring

If a child was held by a parent or guardian during the exam, the child will be coded as "N." 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 "Y." If, during any part of 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 "N."

8.3 Recommendation for Care and Referrals

The computer system generates a list of specific recommendations for followup care based on subcomponent evaluation. There are four levels of referrals for care 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 or her earliest convenience
- Level 4 – SP should continue with his or 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 or her clinical judgment. Additional guidance is provided in Exhibit 8-2.

An examination recommendation for care level must be assigned to each 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 or 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 or she will override the system's referral.

Exhibit 8-2. 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 2-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 exists that should be addressed before 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.

8.3.1 Recommendation for Care Recording Procedure

The Recommendation for Care section comprises 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.

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. See Exhibit 8-3. 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.

Exhibit 8-3. Recommendation for Care screen

Oral Health: Stand:430 Session:430940 03/07/2005 08:30 am - 12:30 pm

SP ID: 314779 Name: HARRIS_7, MARIA Age: 31 years Gender: Female Date: 10/02/2008 Time: 03:52 PM

Recommendation for Care and Referral Screen

Assessments

Recomm. for care for Basic Screening Exam: 4

Recomm. for care for Dental Fluorids: 4

Recomm. for care for Periodontal: 4

Other Referral Comments

Referral Refuse

Generate Referral Letter

Overall recommendation for care

Other Conditions

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

2 of 3

End of Section Close Exam Finish

The “Assessments” section is 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. If 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 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 or 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 the 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 used only 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 for care level and recording conditions for the SP Referral Letter with regard to professional and ethical considerations are provided in the section below.

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 or she feels may need to be documented. The system then proceeds directly to the Recommendation for Care 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 Section 8.4.

8.4 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. The examiner will also 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 which the letter should be sent, the Clinic Pickup feature on the upper right 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 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 himself or 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 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. Use this function only when the examiner needs to review a hard copy of this letter with the SP. **Do not provide the SP with a copy of this letter.** He or she will receive a copy of the letter along with other related documents when he or she leaves the MEC.

- **Preview.** This button is used to view the letter on the computer screen. You can scroll through the letter to verify that all items have been inserted properly: Dentist name and address, the SP name, and the conditions entered on the Recommendation-for-Care screen. Any necessary changes 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 return 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.

8.5 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.

9. DATA QUALITY CONTROL

9.1 Description

The oral health team and support staff is responsible for protecting the accuracy and precision of the data collected. Staff are to protect the survey from errors that may compromise the representativeness of the sample and from errors in measurement of the conditions being studied. Activities that may diminish the analytical value of the oral health data collected should be minimized.

Staff will be exposed to and instructed in procedures for the oral health component prior to participating in oral health data collection in the MEC. The NHANES Reference Examiner will provide training.

Time for component administration will be collected and compartmentalized into the following modules:

- Dentition (Tooth Count, BSE, and Dental Fluorosis); and
- Periodontal Examination.

An overall component exam time will also be computed.

9.2 Training

Training for the oral health component consists of an Initial Training Session and a Field Training Session. The Initial Training Session (ITS) will consist of lecture, model review, practice simulations and standardization sessions, including an initial calibration session. The ITS will be conducted in the Washington, DC metropolitan area over a 5-day period. All dental examiners must complete the ITS in its entirety. Other health professionals may be trained at the discretion of the NHANES reference examiner and management staff, and one backup examiner will be trained.

An examiner’s Field Training Session (FTS) will commence following a successful ITS training session. The FTS will consist of practice simulations, standardization and calibration sessions on a MEC under current NHANES operational parameters over a 3-day period.

9.3 Evaluation and Gold Standard Examinations

The NCHS OH Project Officer and /or Reference Examiner will conduct periodic site visits during the operationalization of the oral health component to observe staff and operational procedures. Pre-op interrater reliability statistics will be calculated using data collected during the calibration session. Followup calibration sessions will be periodically conducted by the Reference Examiner to assess for post-op interrater reliability. These “gold-standard” sessions will be performed over the course of the 2-year data collection cycle.

Additional resources made available to examiners to promote consistency in data collection include access to an electronic NHANES dental health application within the ISIS operating system (Appendix D).

In order to identify gold-standard examinations, the following variables will be collected for those exams including tooth count, Basic Screening Exam (BSE), dental fluorosis, and periodontal:

OHAGS	Examiner response to GSE?: Yes / No
OHAGSCON	SP consent to GSE?: Yes / No
OHAGSEXM	Gold Standard Examiner ID
OHABSREC	Gold Standard Recorder ID

9.4 Unusual Field Occurrence (UFO)

Document any unusual occurrence that occurs during the operation of a stand by using the Unusual Field Occurrence utility. All MEC staff, including the MEC managers, use the UFO Utility to document any unusual occurrences that occur during an examination session. This includes equipment issues, SP issues, and protocol issues, trailer issues, supply or inventory issues, etc. This module has been incorporated into the Utility menu bar option of the oral health application.

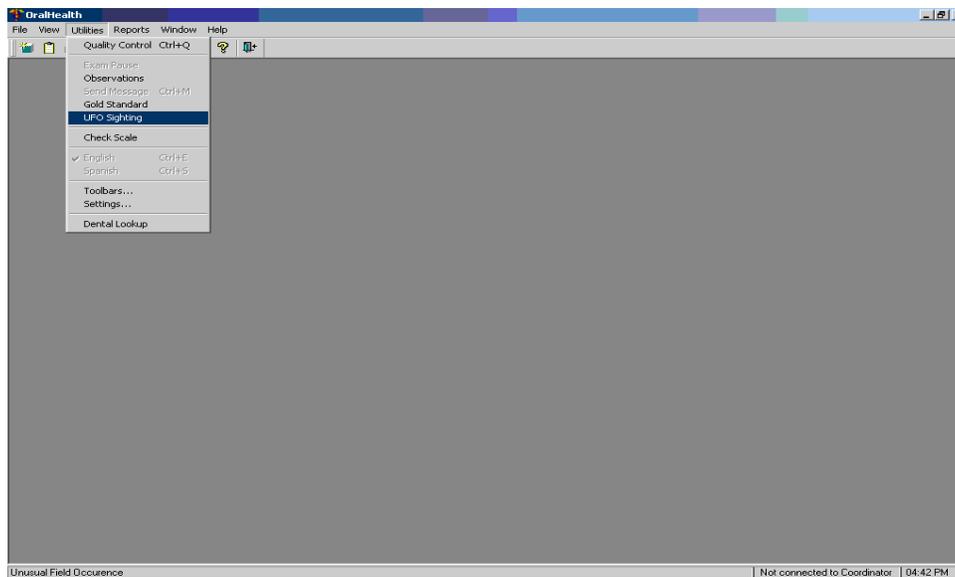
The advantages of the UFO module are as follows:

- Allows for better tracking, review, and followup of MEC occurrences and unusual occurrences;
- Provides for a better tie to tech QC and data QC by allowing the ability to search on all unusual occurrences by Tech, by SP_ID (very helpful when reviewing component data occurrences); and
- Provides the ability to track types of occurrences by a particular MEC or MEC workstation (for example if there are several Dr. Watson messages occurring on the MEC 1 anthropometry workstation).

9.4.1 UFO Utility

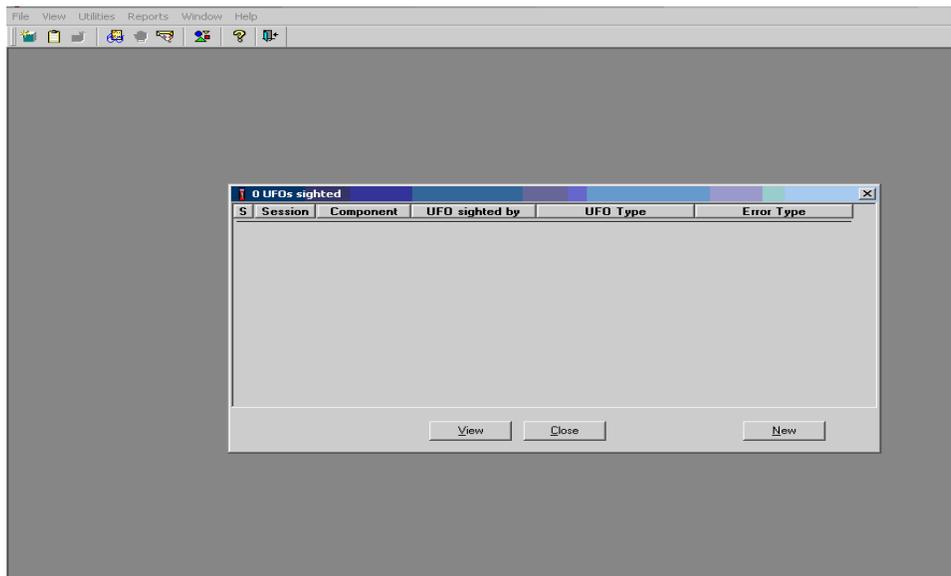
To access the “UFO Sighting” module, use the mouse to direct the mouse arrow to ‘Utilities’ in the menu bar, left click, drag the arrow to “UFO Sighting,” and left click.

Exhibit 9-1. UFO screen



The “UFOs Sighted” screen includes six column headers and three buttons. This screen is blank if no occurrences have been recorded for the selected session.

Exhibit 9-2. UFO Sighted screen



The six column headers are:

- **S** – Status (created, reviewed, finalized);
- **Session** – The session number in which the UFO occurred;
- **Component** – Default;
- **UFO sighted by** – Default;
- **UFO Type** – Pick list; and
- **Error Type** – The pick list if occurrence is an ISIS application issue.

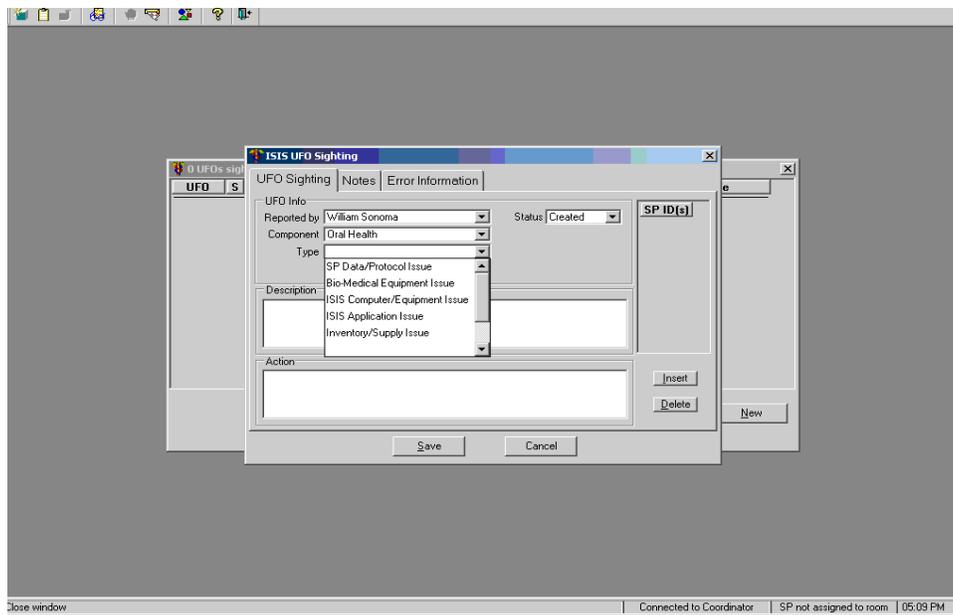
The three buttons are:

- **View** – Displays existing occurrences for this session and component;
- **Close** – Closes the window; and
- **New** – Allows the user to add an occurrence.

To create a UFO, Use the “UFO Sighting” tab to access and enter the information. The UFO Sighting screen contains the drop-down lists: Reported by, Component, and Type. The UFO Sighting screen defaults the “Reported by” and “Component” text boxes to the user who logged onto the application and the application in use. Issue types are defined as follows:

- SP Data/Protocol Issue;
- Bio-Medical Equipment Issue;
- ISIS Computer/Equipment Issue;
- ISIS Application Issue;
- Inventory/Supply Issue;
- MEC Trailer Issue; and
- Other.

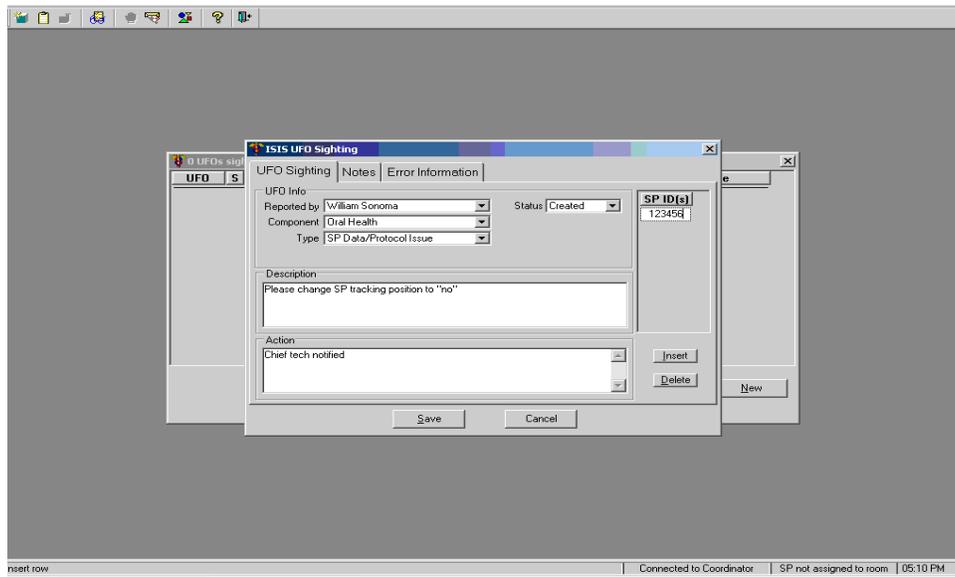
Exhibit 9-3. Type of UFO screen



Use the scroll bar to view all the various types. To select an issue “Type,” use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the choices, and drag the mouse arrow to the correct choice and left click.

Enter a description of the occurrence in the “Description” text box. Provide enough information and background to allow the reviewer to understand the details of the occurrence. Record the issue for the UFO and type the “Action” taken. Assign a “Status” to the new occurrence. The choices are: “Created,” “Reviewed,” and “Finalized.” The “Status” of an occurrence will default to “Created” for all new occurrences. Enter the SP ID(s) into the “SP ID(s)” text box. Review the information on the screen for accuracy. To save the information to the database, use the mouse to direct the mouse arrow to the “Save” button.

Exhibit 9-4. UFO Saved screen



10. QUALITY CONTROL FOR ORAL HEALTH OPERATIONS

10.1 Background

This section reviews the tasks required of the dental examiner during a stand. Some of these tasks require documentation in the Quality Control (QC) program in the Integrated Survey Information System (ISIS). 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 QC checks in ISIS is also the responsibility of the dental examiner. If the QC checks are not completed in the ISIS system, a pop-up error message will appear prior to each examination. QC checks will be completed at the following intervals:

- Start of stand;
- Start of session;
- End of session;
- Weekly;
- Mid-stand; and
- End of stand.

10.2 ISIS QC System

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 10-1, will appear on the screen.

Exhibit. 10-1. Dental Quality Control checks

QC Check	Done	Result	Comment
Visual light check?	<input type="checkbox"/>		
Compressor visual check?	<input type="checkbox"/>		
Close air tank valves?	<input type="checkbox"/>		
Sterilizer exterior cleaned?	<input type="checkbox"/>		

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 (ND), 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.

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

- The first column lists the QC check.
- The second column is the Done column and 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 clicks 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.

10.3 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 to locate equipment and supplies when he or she arrives at a different MEC.

10.3.1 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, backup equipment, and extra supplies in the belly compartment. Place the supplies needed during the stand towards the front of the compartment. When possible, store the extra supplies in the waterproof case provided.

10.3.2 Cleaning and Disinfecting

- Clean cabinet shelves and doors, drawers, countertops, 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 laboratory.

10.3.3 Setup

Set up the dental equipment using the specifications provided in Chapter 2; Section 2.3 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 countertop as follows:
 - Place the Sharps container above the sink.
 - Place miscellaneous non-SP supplies, such as pens, pencils, tape, and scissors in bins on the shelf located above the counter.
- The drawers should be organized as follows:
 - **Drawer 1:** Sterilized instrument sets.
 - **Drawer 2:** Syringe and holder covers, disposable air tips, and extra baggies.
 - **Drawer 4:** Manuals, paperwork, and miscellaneous non-SP supplies.
- The cabinets should be organized as follows:
 - **Upper left cabinet:** Tissues and the spore test kit are located on the top shelf; 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 shelf 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 top shelf; all contaminated supplies, such as the used instrument containers, are located on the lower 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.

The start of stand QC data will be entered in ISIS. Exhibit 10-2 shows the setup QC checks.

Exhibit. 10-2. Setup QC 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

10.4 Within-Stand Tasks

10.4.1 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 QC as listed in Exhibit 10-3.
- Prepare fresh holding solutions and label with the date made and the date it expires.
- Clean and disinfect the dental area as needed.
- Place the adhesive coverings on the light head, the lid of the storage container, and the light controls.
- Place plastic coverings on the instrument tray, the chair, the air syringe, and the air syringe holder. Place a new disposable air tip on the air syringe.

Exhibit 10-3. Start of session QC 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
Air tank valves closed	<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

10.4.2 Between SPs

- Place the used instruments and mirrors in the containers with the appropriately diluted Restore holding solution.
- Discard all used disposable items in the biohazardous waste container.
- Dispose of air tips in Sharps container.
- Remove and replace all disposable barriers, including the headrest covers on the pillow, if used.
- Wipe instrument tray, countertop, light head, air tip, chair head, etc., with disinfectant.

10.4.3 End of Session

- Complete all tasks necessary for the end of session QC as listed in Exhibit 10-4.
- 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.
- Double 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. 10-4. End of session QC checks

QC check	Done	Result	Comment
Purge Air tank (not needed after a.m. 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

10.4.4 Weekly Tasks

- Complete all tasks necessary for the weekly QC as listed in Exhibit 10-5.
- Clean the inside of the SpeedClave with mild soap and distilled water and rinse with distilled water. Drain the water from the reservoir and refill with fresh distilled water.
- Clean the areas not maintained on a daily basis (e.g., countertop under the autoclave, computer, screen, walls, shelves), as needed.
- Stock supplies, as needed.

Exhibit. 10-5. Weekly QC 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

10.4.5 Mid-Stand Procedures

- Complete all tasks necessary for the mid-stand QC as listed in Exhibit 10-6.

Exhibit 10-6. Mid-stand QC 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

10.4.6 End of Stand Pickup Procedures

- Review end of stand QC prior to pickup.
- Open ISIS system prior to the coordinator shutting down. Enter information as it is completed.

- Complete all tasks necessary for the end of stand QC as listed in Exhibit 10-7.
- Flush the SpeedClave with SpeedClean solution as described in Chapter 2.
- 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 2.
- Close ISIS QC session.

Exhibit. 10-7. End of stand QC 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
Instruments replaced	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Light bulb replaced	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Fuses changed	<input type="checkbox"/>	No required entry	Date replaced or ND if not replaced
Syringe cotton roll changed (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

10.5 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.

11. MEDICAL EXCLUSION QUESTIONS

SPs with certain medical conditions will not be permitted to participate in the periodontal examination. During the home interview, a module of oral health questions are administered to SPs by trained interviewers. When SPs are 30 years and older, they are asked two sets of oral health questions. The first group focuses on legibility for the periodontal exam, whereas the remaining group inquires about self-reported periodontal health status. The “screening” questions inquire into dentition status and health history, which could exclude an individual from receiving the periodontal exam.

Although the screening questions are asked during the household interview, they will be asked once more in the oral health room. The dental examiner will remind the SP that these questions were asked but will be asked again to verify the information. The dental examiner will briefly re-ask these questions and instruct the dental recorder to enter the information. If the SP answers “Yes” to any of the screening questions, they will be excluded from the oral health examination and the exam will end. If they answer “No” they will continue with the exam.

A set of shared exclusion questions might be asked in another component at the MEC or in the oral health exam. The two questions are:

Has a doctor ever told you that you have:

- Hemophilia? or
- A pacemaker or automatic defibrillator?

These two questions will not be asked here if the information is obtained elsewhere, such as in the other examination components. Answers obtained elsewhere will appear on the screen when it is **initially** displayed. Therefore, the examiner will 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 entries for those two items are “Yes,” “No,” and “Don’t Know.” Exhibit 11-1 provides a screen shot of the exclusion questions.

Exhibit 11-1. Shared exclusion questions

Oral Health: Stand:430 Session:430931 03/06/2005 01:30 pm - 05:30 pm

SP ID: 237886 Name: HARRIS_6, MARIA Age: 31 years Gender: Female Date: 10/16/2008 Time: 03:13 PM

Shared Exclusion and Edentulous Screen

Have you lost all of your upper and lower natural (permanent) teeth?

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

Do you have an artificial heart valve?

Have you had heart disease since birth?

Have you had a bacterial infection of the heart, also called Bacterial Endocarditis?

Has a doctor ever told you that you have:

Rheumatic fever?

Hemophilia?

Kidney disease requiring renal dialysis?

A pacemaker or automatic defibrillator?

A hip bone or joint replacement?

1 of 2

End of Section Close Exam Finish

Appendix A
Summary Dental Exam Reference Sheet

SUMMARY DENTAL EXAM REFERENCE SHEET

1. TOOTH COUNT (3-19 and 30+)

- 1 = Primary Tooth
- 2 = Permanent Tooth
- 3 = Implant
- 4 = Not present
- 5 = Permanent Root Tip

2. BASIC SCREENING EXAM (3-19)

- 1 = Present
- 2 = Not Present
- 9 = Cannot Be Assessed

3. FLUOROSIS (6-19)

- 0 = Normal (No Fluorosis)
- 1 = Very Mild (Less than $\frac{1}{4}$)
- 2 = Mild ($\frac{1}{4}$ to $\frac{1}{2}$)
- 3 = Moderate (More than $\frac{1}{2}$)
- 4 = Severe
- 5 = Questionable
- 8 = Non-fluoride Opacity
- 9 = Cannot Be Assessed

4. PERIODONTAL EXAM (30+)

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

5. RECOMMENDATION FOR DENTAL CARE (3-19 and 30+)

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 B

Guidelines for Infection Control in Dental Health-Care Settings

Please see the MMWR publication, Guidelines for Infection Control in Dental Health-Care Settings – 2003 at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm>

Appendix C
Backup Equipment

APPENDIX C. 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.

■ Setup

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 cowling 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.

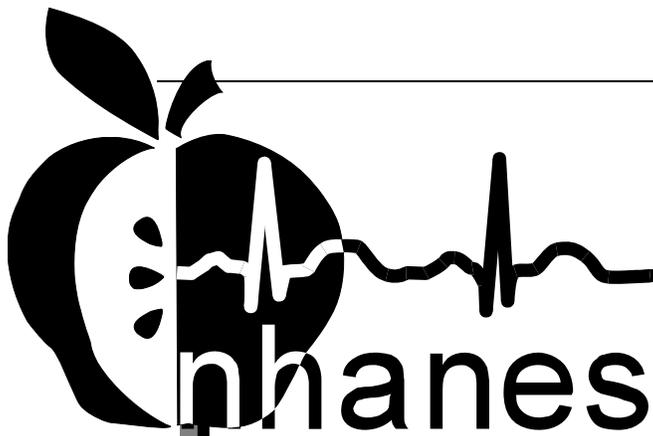
If no moisture is reaching the valve and it still closes, the difficulty may be that the spring has been bent in a convex condition or the legs of the spring may have been bent too flat. Should this condition occur, the spring must be replaced. Refer servicing to qualified personnel.

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 D
MEC Subsystem Overview



MEC Subsystem Overview



National Health and Nutrition Examination Survey

August 10, 2009

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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.

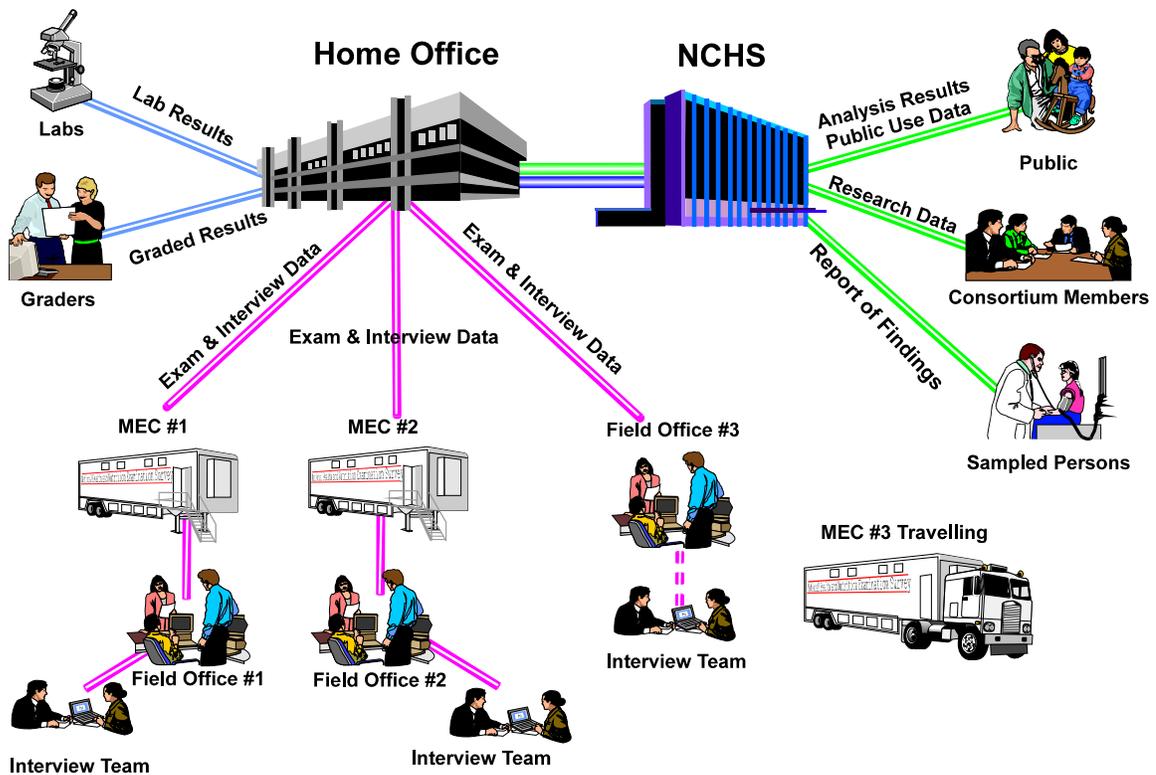


Figure 1: NHANES Network Connectivity

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:

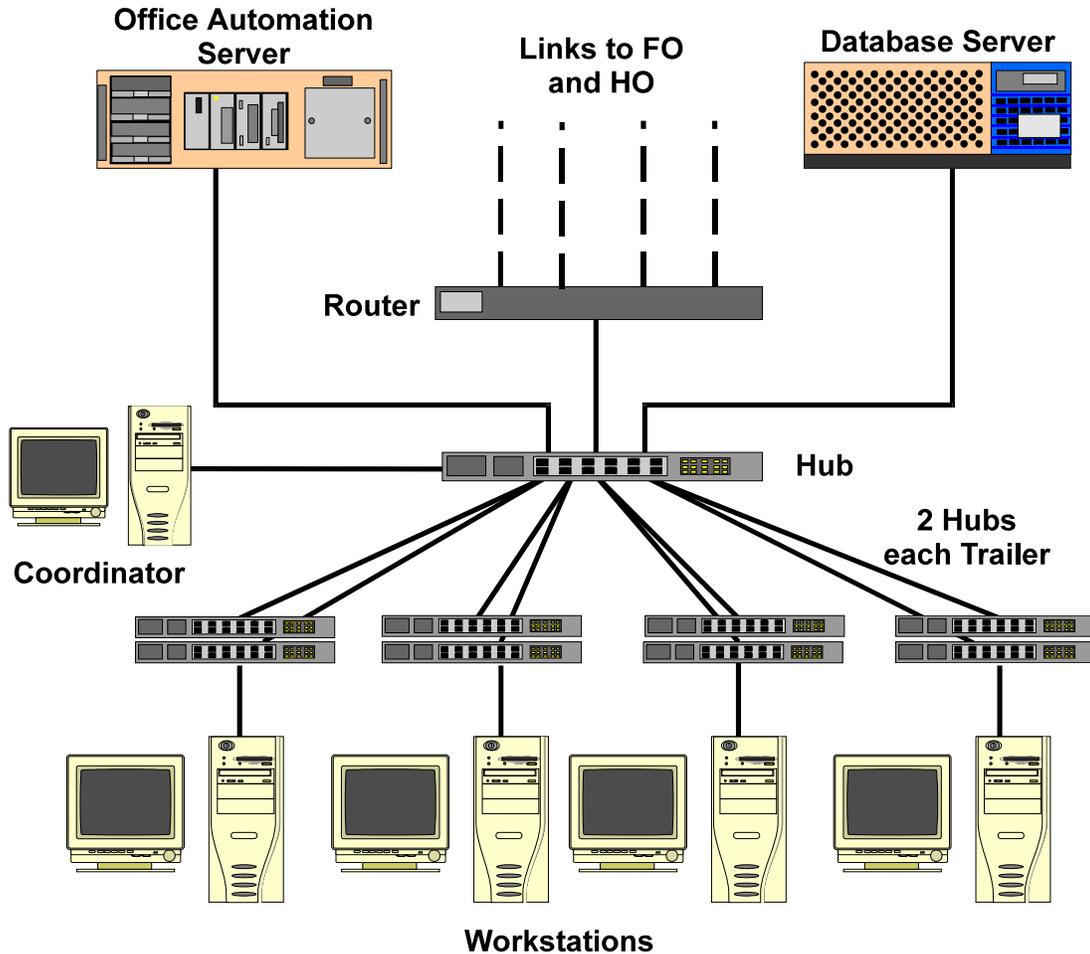


Figure 2: Network Connectivity Scheme

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.

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.

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:

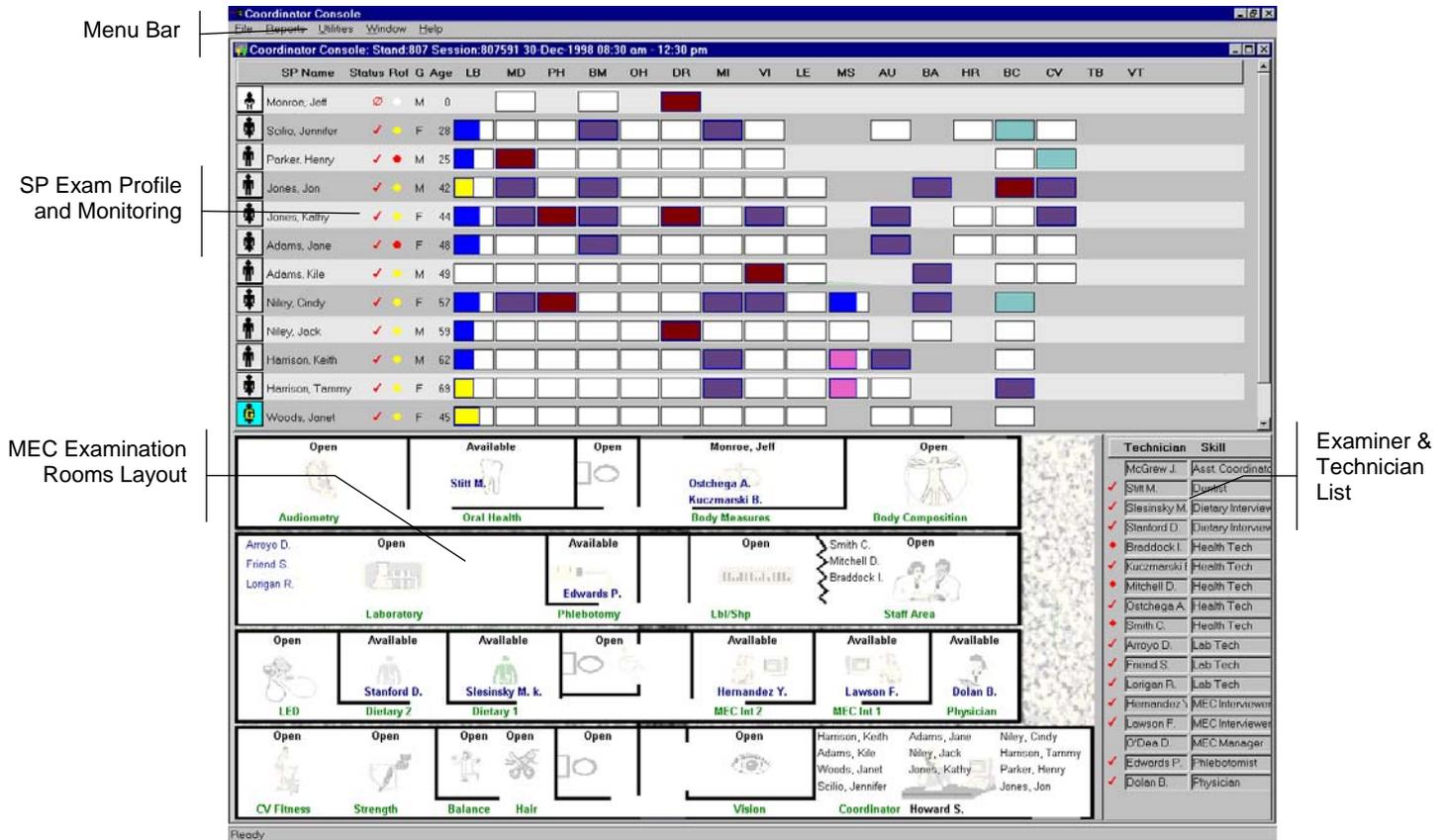


Figure 3: The Coordinator Screen

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.

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

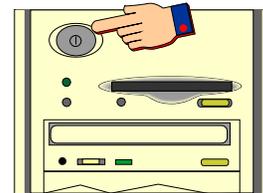
Workstation Startup

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.

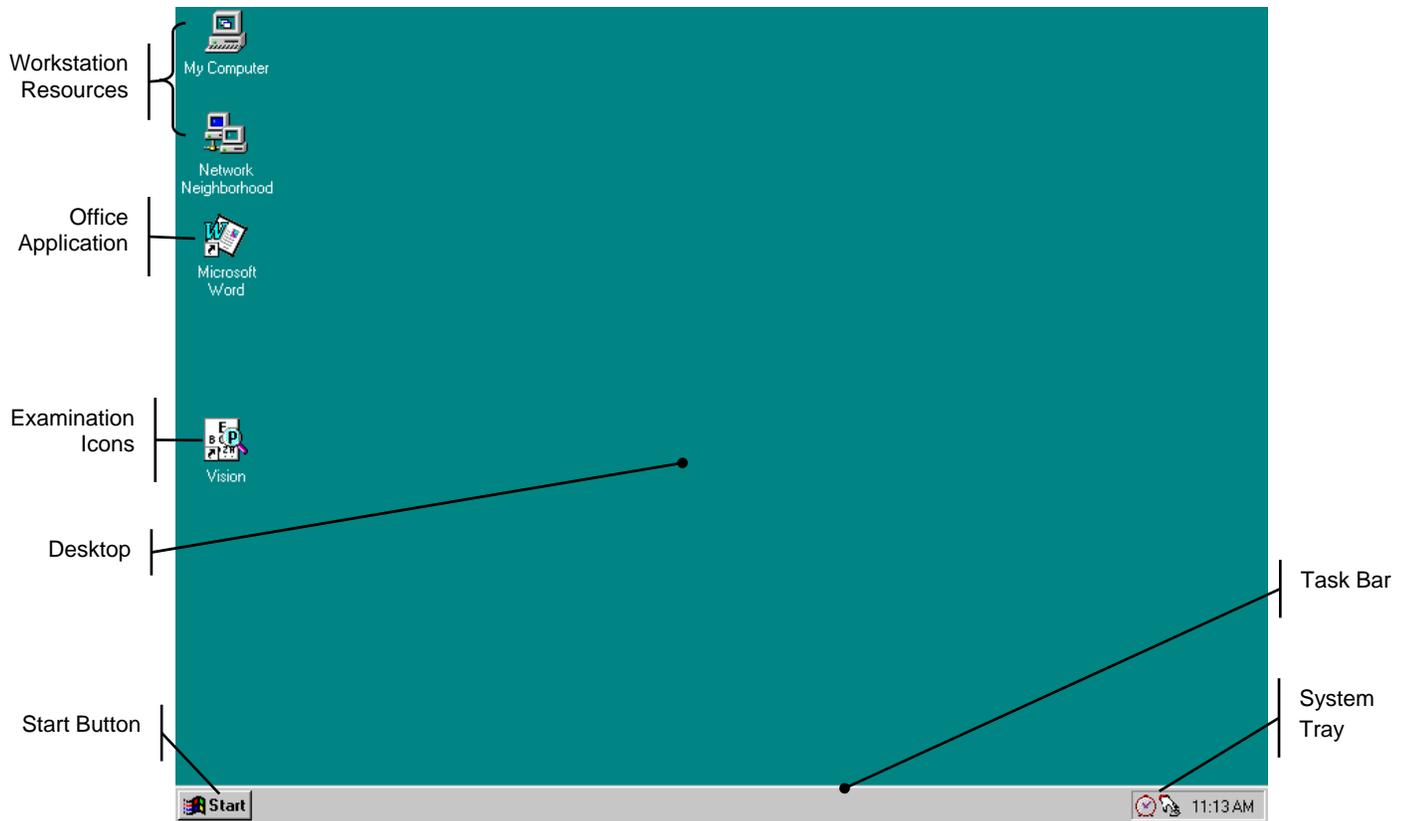


Figure 4: MEC Workstation Desktop

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.

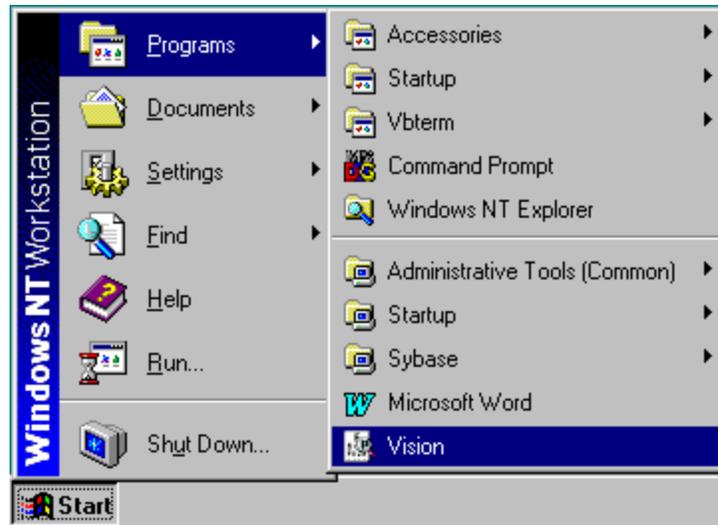


Figure 5: Start Button Menus

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.

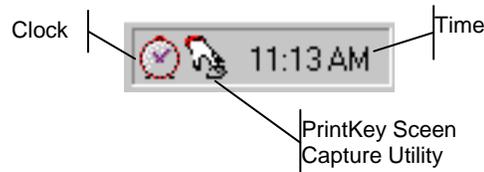


The **Taskbar**, located at the bottom of the Desktop, displays the Start button on the left side and the System Tray on the right side of the bar. By default, the system tray displays the current time and shows special system icons for programs that run in the background. The Physician button, shown 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

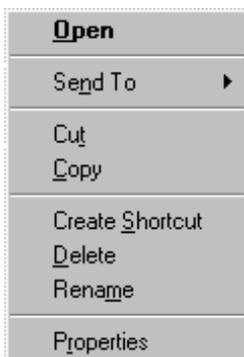
The **System Tray** holds icons that represent the programs for displaying time and a screen capture utility.



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.

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:

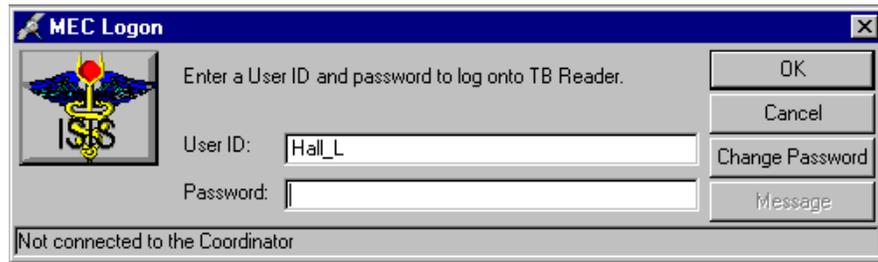
- Click on the **Start** button on the Taskbar.
- Select **Shutdown** from the Start Menu.

- 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.

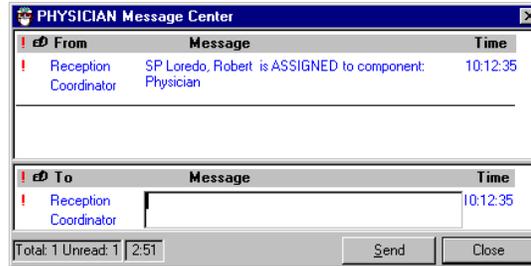
Enter your current password for access verification, followed by your new password. Confirm your new password and press **OK**.



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.

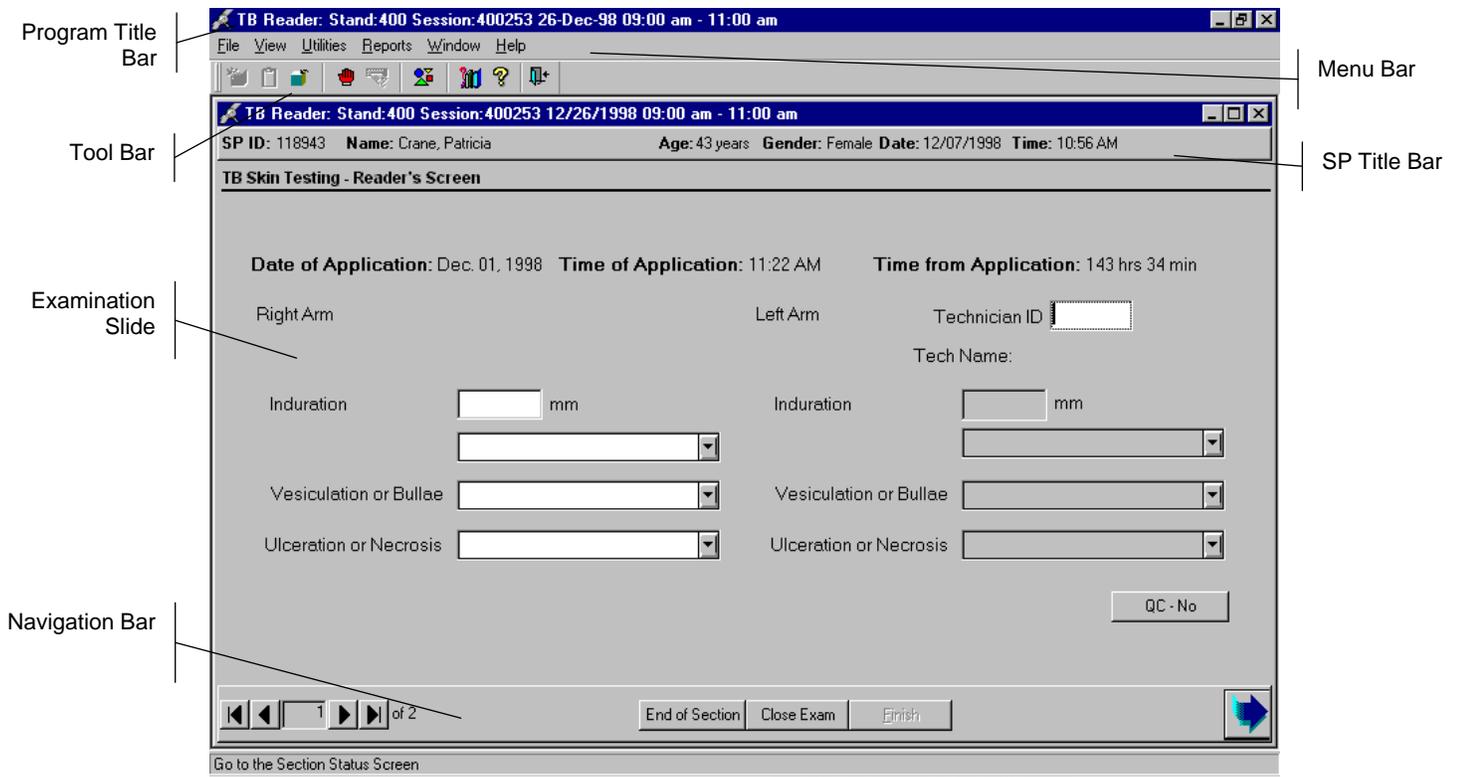


Figure 7: Sample Examination Screen

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.

File*	
<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.
View *	
<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.
Utilities *	
<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.

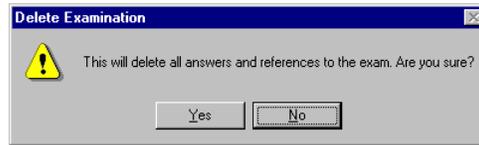
QC Check	Done	Result	Comment
Check stethoscope diaphragm for cracks	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input type="checkbox"/>		
Check for 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.



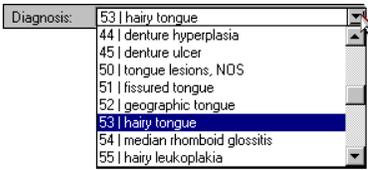
Soft edits are flexible limitations on values but prompts you for confirmation if a value exceeds the limit. For example, if a vision soft edit limitation is 20/400, an entry of 20/435 will prompt a confirmation dialog box.

Buttons and Boxes and Lists

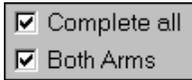
The examination slides use a variety of methods to capture acquired data. The methods include the following data control devices.



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.



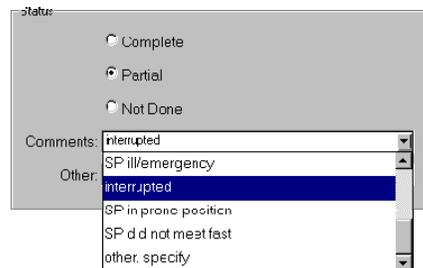
The *ellipsis button* indicates additional action is available, such as browsing for records or additional information.



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.

The screenshot shows a window titled "TB Reader" with a close button (X). The window displays the following information:

- SP ID: 118943 SP Name: Crane, Patricia
- Exam Status: partial
- Comments: A drop-down menu with a blue background and a downward arrow.
- Other text: A text input field.

At the bottom of the window, there is a blue message box that reads: "This will close the exam, saving all results and the exam status. Do you wish to close the exam?" Below this message are two buttons: "OK" and "Cancel".

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,

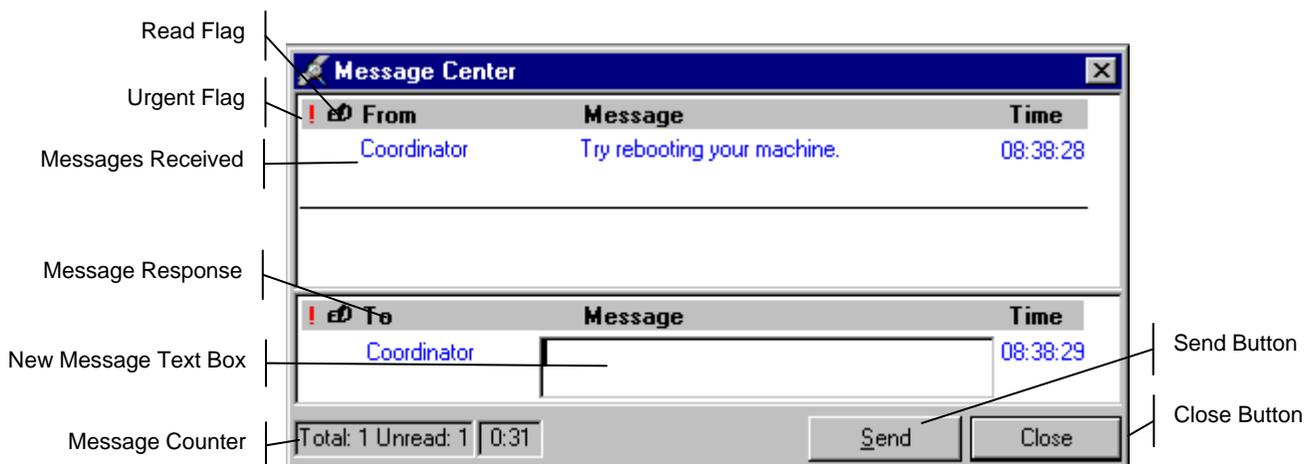
- Press *Ctrl+M* keystroke combination.

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

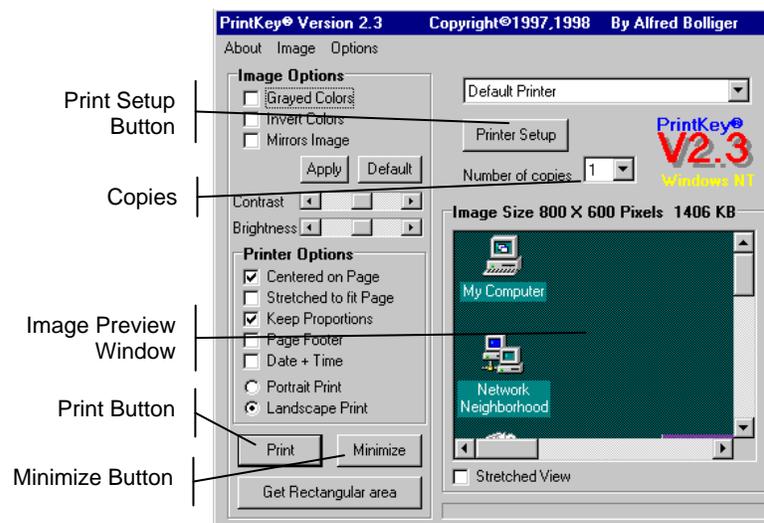
The PrintKey screen capture utility allows you to capture whole or partial screen images for immediate printing or saving to a file. Use this feature to capture any error messages that appear on the screen. Capturing the error message as it appears will enable the data manager to quickly determine the 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:

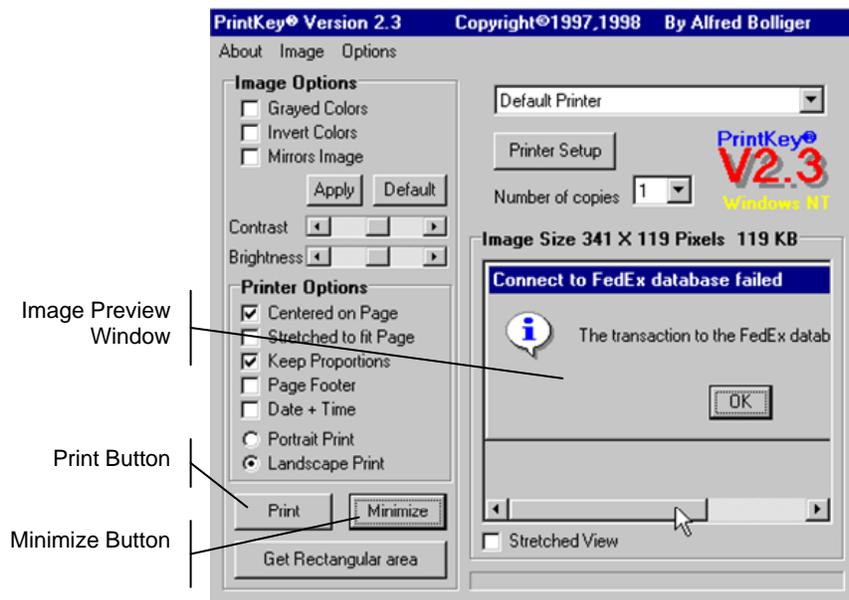


- Now you can print the image or save the image to a file.

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:



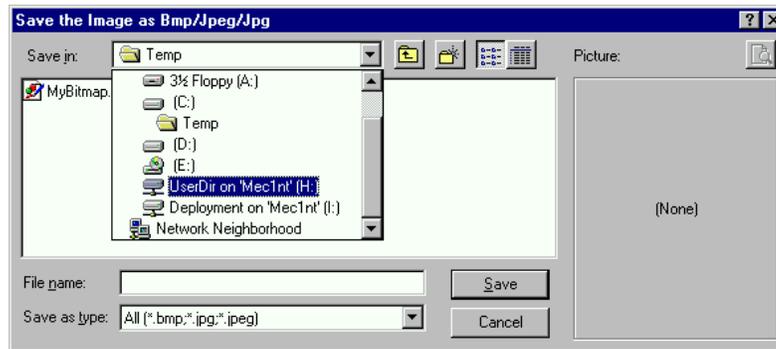
- Now you can print the image or save the image to a file.

Saving Images to a File

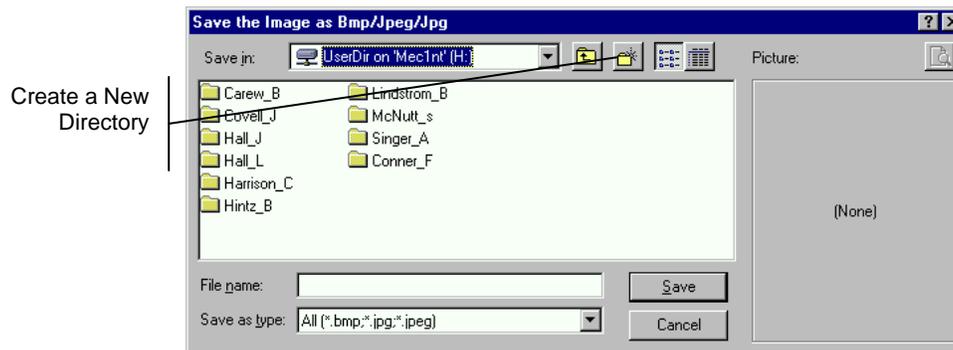
Images captured using any technique discussed below can be saved to a file for later use. This is how you do it:

- 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.