

National Health and Nutrition Examination Survey (NHANES)

Volatile Organic Compounds (VOC) and Perchlorate Study Procedures Manual





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1. PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS AND PERCHLORATE (VOC/PERCHLORATE) STUDY

1.1 Overview

The purpose of the VOC/Perchlorate study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs) and Perchlorates. Volatile organic compounds are emitted as gases from certain solids or liquids. VOCs include a variety of chemicals, some of which may have short- and long-term adverse health effects. Concentrations of many VOCs are consistently higher indoors (up to ten times higher) than outdoors. VOCs are emitted by a wide array of products numbering in the thousands. Examples include paints and lacquers, paint strippers, cleaning supplies, pesticides, building materials and furnishings, office equipment such as copiers and printers, correction fluids and carbonless copy paper, graphics and craft materials including glues and adhesives, permanent markers, and photographic solutions.

Perchlorate is an oxidizer used in rocket fuel, explosives, and road flares, and it also occurs naturally in the atmosphere. Since the 1950s, unused amounts of the chemical have been dumped into unlined pits throughout the United States, where it has seeped into water supplies. The chemical is highly mobile and soluble in water, aiding its dispersion through the environment.

Exposure to VOCs is tested from one 10-mL gray top tube for blood (vessel 54) and one 10-mL glass tube for tap water (vessel 105). Perchlorates are tested using the tap water from the same 10-mL glass tube. The one-half subsample requirements are aged 12+ with remainders 1, 2, 4, 5, 10, 11.

1.2 Household Interviewer and Field Office Process Description

Household interviewers collect a household water sample for every household that may have an SP aged 12 or older sampled into the MEC. The analysis laboratory staff aliquot the household water sample for VOC and perchlorate water testing. The household water sample test results are then linked back to the appropriate SPs that fall into the VOC/Perchlorate water subsample.

The household interviewer introduces SPs in households with potentially eligible SPs aged 12+ to the water collection component. The NHANES household interviewer collects one tap water sample from these households. The water sample is collected from the bathtub the SP uses or from any nonaerated spigot.

The interviewer application includes a reminder window that prompts the interviewer to collect the water sample. The interviewer case list screen includes a column to access the water collection module. Household interviewers collect and label the outside of the water collection kit with a preprinted bar code label, transport the samples to the field office, and store them in the refrigerator. The office manager uses the VOC - Household Water Collection (HHWC) System to receipt, reconcile the samples, and transfer the samples to the MEC manager. The MEC manager uses this same system to document the samples they receive and then transports these samples to the MEC lab. A summary Water Sample Report allows the office manager, MEC manager, MEC lab staff, and home office staff to view the collection status of every water collection sample.

1.3 MEC Process Description

When SPs come to the MEC for their exam, the phlebotomist collects one additional 10-mL tube of blood for VOC, and the MEC interviewer administers a VOC questionnaire. The label for the blood tube prints on the Dymo printer in the phlebotomy room. The phlebotomist transfers the blood tube (vessel 54) to the MEC laboratory. (The blood sample must be refrigerated within 15 minutes after completion of the venipuncture.) The tube displays on the blood processing screen for each eligible SP. The lab staff marks the tube as collected "Yes" or collected "No" and ships the sample weekly to the analysis laboratory.

The laboratory application includes the HHWC module that allows the lab staff to print labels, receipt the samples, and assign them to containers. They print and label the household water sample with a label containing the household ID and Astro ID. The technologists use the Water Sample Report located on the Intraweb under the Household Water Collection System to reconcile the samples. The technologists process, store, and ship the SP's VOC blood tube (vessel 54) and household water vial (vessel 105) once a week via next day courier in insulated containers with enough ice packs to maintain their refrigerated temperature.

2. SAMPLE WATER COLLECTION

2.1 Overview

The NHANES household interviewers will collect one sample of tap water sample from each household with at least one SP aged 12+. The water sample will be collected from a nonfiltered/nonaerated faucet in the respondent's home. For a random half-sample of these SPs, the tap water will be examined together with blood obtained from the SP during the MEC exam to assess the SP's exposure to numerous volatile organic compounds (VOCs) and perchlorates.

NHANES has been examining environmental chemical exposures for close to 30 years (1976 blood lead). Since 1999, NHANES has been studying about 150-200 environmental toxicants in blood, urine, and water samples of NHANES participants. Beginning in 2005, the number of environmental chemicals being studied doubled to approximately 450. These data, collected for NCHS in collaboration with the National Center for Environment Health (NCEH), are the cornerstone of the CDC publication, *The National Report on Human Exposure to Environmental Chemicals*.

VOCs are one of the major classes of environmental exposure chemicals being studied by NHANES. VOCs exist everywhere, however, chronic exposure to extremely high levels of certain VOCs can lead to cancer and neurocognitive dysfunction. NHANES VOC exposure assessment of blood will include examining selected chemicals that are on priority toxicant or critical contaminant lists (e.g., chemicals used in solvents, the plastic or rubber industry, in soil fumigants, etc.). VOC exposure assessment of blood and water will include examining chemicals formed by water disinfection and fuel oxygenate ethers.

In addition to VOC exposures, urine and water samples will be used to measure perchlorate, a chemical used primarily in the production of solid fuel propellants for rockets and missiles but also used to produce everyday items such as matches, fireworks, and automotive airbags. Industries using perchlorate have dumped this substance so that there are large areas of contamination in many parts of the U.S. Perchlorate is currently found in tap water samples from 4% of communities nationwide. Long-term exposure to high levels of perchlorate can inhibit the thyroid gland and possibly compromise fetal brain development.

The household interviewer introduces SPs in households with potentially eligible SPs aged 12+ to the water collection component. The interviewer application includes a reminder window that prompts the interviewer to collect the water sample.

The interviewer case list screen includes a column to access the water collection module. Household interviewers collect and label the outside of the water collection kit with a preprinted bar code label, transport the samples to the field office, and store them in the refrigerator.

This chapter describes the procedures to be used in the VOC water collection component conducted by the household interviewers.

2.2 Additional Background Information

NCHS has developed the following "talking points" to describe the VOC/perchlorate component.

Component: Volatile Organic Compounds (VOCs) and Perchlorate exposure

assessment

Who: Selected participants aged 12+ who are examined in the MEC

Samples: One water sample in households with at least one SP 12 years old or older

Phlebotomist draws one 10-ml blood tube

A questionnaire on the MEC

Results: No reporting as of now

In addition, use the following information to encourage SPs to participate.

- This component is part of an epidemiologic analysis of personal exposures to volatile organic compounds among a subset of participants in a statistically designed national survey.
- The NCEH is collaborating with NCHS on this component to collect environmental exposure data for a subset of the U.S. population, as part of a comprehensive nationally-based health study.

The primary aims of this component are:

- 1. To characterize the distribution of exposures to selected VOCs and perchlorate within the population;
- 2. To examine the relationship between exposures to VOCs/perchlorate, and socioeconomic, demographic, and other characteristics; and
- 3. To investigate possible associations between exposures to VOCs and some selected indicators of health status that are collected as part of the larger study.

The purpose of the VOC analysis will be to assess exposures to the group of VOCs being monitored, as well as exposures to particular VOCs, and to explore potential linkages between exposures and economic, behavioral, and other factors. A tap water sample is needed for the measurement of a subset of VOCs, which may be present in water. These include byproducts from disinfecting water (for example, chlorination) and oxygenates added to gasoline. The latter can sometimes contaminate ground water and end up in water supplies. An example is MTBE. Perchlorate will be measured from the same water sample.

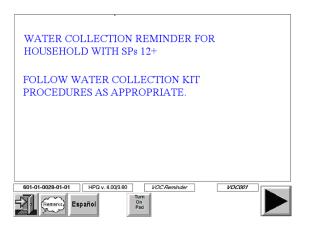
Associations of VOC and perchlorate exposures with potential health outcomes may not be possible to demonstrate because of the size of the sample. However, the opportunity exists to investigate health status markers among the data points collected as part of the larger study to determine any patterns, which are consistent with published studies of health outcomes.

2.3 Eligibility and Samples

Approximately 3,550 SPs per year will be eligible for the VOC/Perchlorate component. As noted earlier, the phlebotomist will draw one 10-ml blood tube and the household interview will collect one 10-ml tube of water from each household. VOCs and perchlorates will be tested from the same 10-ml tube of water. The lab staff will process the sample once the first SP from the household is MEC examined.

2.4 When to Collect the Water Sample

Generally, water collection should be conducted immediately following the first SP interview. Interviewers will be prompted by CAPI to collect the SP water sample at the end of the SP questionnaire.



Because water collection is so easy and short, we expect that few respondents will postpone or refuse this task. In the **rare** situations when water cannot be collected during the interview/appointment making visit, collect the sample if you need to complete another task in the household. We want to avoid making trips to a household or neighborhood simply to collect a water sample.

2.5 Supplies

At the start of each stand, the home office warehouse will ship water collection kits to the field office. Each kit contains everything an interviewer will need to complete the water collection for each SP. Each kit contains the following:

- 10-mL vial;
- Instructions (English and Spanish versions in all kits); and
- Small zip closable bag with a green identification label (name, date, time).

In addition, each interviewer will receive a set of 3 household ID labels for every household in his/her assignment. These labels are attached to the Household Folder.

Whenever you are in the field you should always have 10 water collection kits and the assignment specific labels. This will ensure that you are fully prepared for any situation encountered on a given day. Inventory your water collection supplies on a regular basis so that you always have 10 complete kits on hand. Remember to pick up additional kits from your supervisor when you are running low.

2.6 Water Sample Collection Process

1. To assist you in introducing this component to the SP, we have provided a sample introduction in your Hand Card set. It is available in English and Spanish.

"When you come to the examination center, some of the tests you will have look at chemicals that are in your body. We'd also like to check your home water for a few of these chemicals. For this I need to collect a sample of tap water. I need to get the water sample from a faucet that doesn't have a water filter or aerator. The best one is usually a bathroom sink. I need to let the cold water run for about 3 minutes and then fill this little bottle with water. I will take the water sample with me when I leave. Can you take me to the bathroom to collect this sample?"

- 2. Prior to collecting the water sample for the household, enter the required information on the green label (family name and sample collection date and time) on the water collection kit and place the correct Household ID label on the kit plastic bag (never the vial) as well. The latter label will have the stand, segment, and serial number appropriate to the case preprinted.
- 3. Collect the water sample for each household with an SP 12+, using the instructions in the water collection kit (Exhibit 2-1).

If the bathroom sink is not available, collect it from the following nonaerated/nonfiltered sources in this order—bathtub, kitchen sink, outside faucet minus hose, apartment building faucet.

Use your watch to time the running of cold water for 3 minutes.

If the SP prefers to collect the water him/herself, ask the SP to follow the instructions in the kit.

The liquid in the vial is a mixture of two nonhazardous chemicals. Both of the chemicals dechlorinate water. If you spill some of the liquid, wash your hands and/or wipe the spill.

NOTE: It's critical that the water vial be filled to the top of the vial. Headspace introduces error into the water analysis and renders the samples non-analyzable. However, they should not be filled to overflowing.

- 4. Complete the "WATER COLLECTED" column on the front cover of the case Household Folder.
- 5. Complete the WATER module for the case in CAPI.
- 6. Give the water sample(s) to your supervisor during your next visit to the field office. He or she will store the samples in the field office refrigerator until they are picked up by the MEC manager. Pick up by the MEC manager will occur about once per week once he or she arrives at the stand.

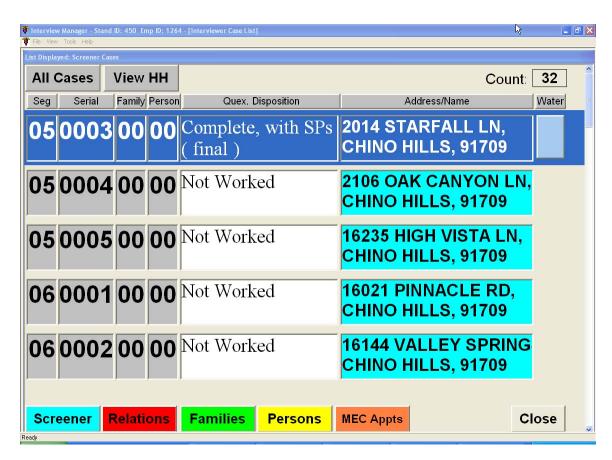
Exhibit 2-1. Water collection instructions

Water Collection Instructions

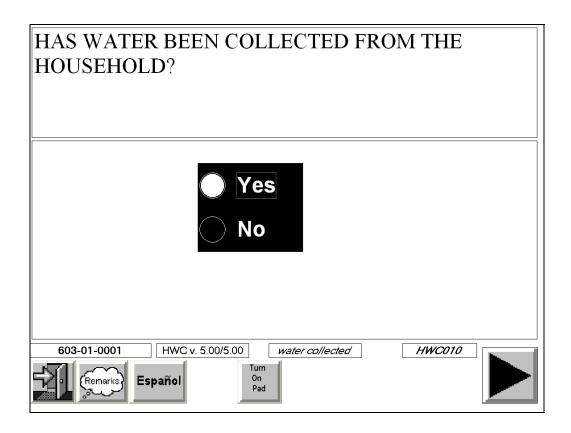
Instructions for collecting tap water sample:

- 1. Collect the water sample from a faucet that isn't filtered or aerated. The first choice is the bathroom sink, the second the bathtub. If for some reason you can't get water from one of these or if they are filtered or aerated, we suggest the kitchen sink (if no filter/aerator) or an outside faucet without a hose attached.
- 2. Turn on the cold water (all the way on).
- 3. Let the cold water run for 3 minutes (all the way on) and then decrease the flow to a trickle.
- 4. Take the black cap off the glass tube. (If the white liner in the cap falls out, put it back into the cap. The shiny side should be facing up.)
- 5. Carefully fill the glass tube with water until it is **completely full**.
- 6. Screw the black cap tightly and carefully onto the tube.
- 7. Turn the tube upside down to make sure it does not leak. (If the tube does leak, then remove the cap and try tightening the cap again.)
- 8. Put the water vial back into the plastic bag.

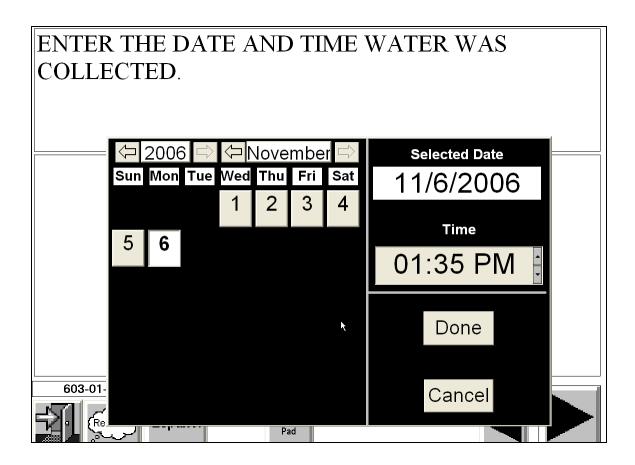
2.7 Recording the Results of the Water Collection Process in CAPI



After you complete the screener, a water collection module will appear under the column labeled "Water" next to the case. It will appear in the list of Screener, SP, Family and Appointment modules. It is shaded in blue.



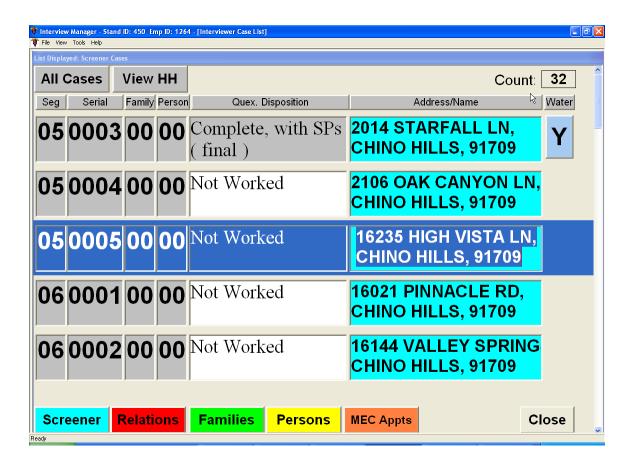
The collection screen opens after the Water module has been tapped. You will collect the water. Label the kit with green labels and HHID sticker and respond to the question.



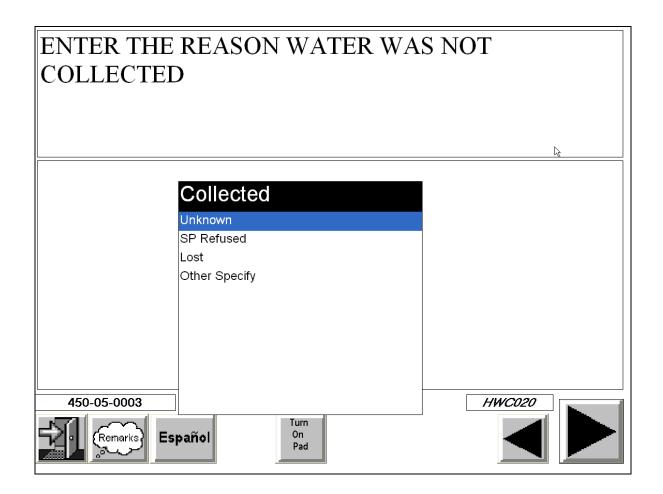
If "Yes" was selected, the collection date and time will display. It defaults to current date and time. Review this date and time for accuracy.

- To change the month tap on the arrow to the left of the month.
- To change the day tap on the date you want to select.
- To change the time (hours or minutes), first tap on the hour or the minutes on the screen and then on the up or down arrows.
- Note that you cannot change the date or time to something in the future (a date or time that has not occurred yet).

When you are finished, tap the DONE button. The date and the time you collected the water will be displayed.



A "Y" will be displayed in the column labeled "Water," next to the case module.

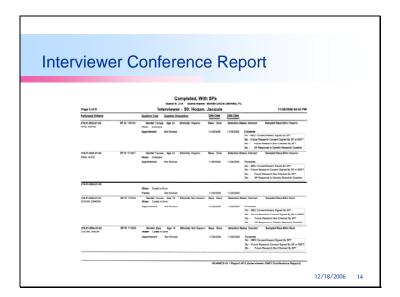


If water was not collected, you will be prompted to select the reason. Select a reason from the drop-down list. Your choices are: SP Refused, Lost, Other Specify.

After you record the status of the water collection process in CAPI, you should also record the status on the front of the Household Folder.

The easiest way to keep track of all of your collections is to look at your Conference Report. The water collection status of each SP will be displayed on the report as demonstrated in Exhibit 2-2.

Exhibit 2-2. Interviewer Conference Report



3. FIELD OFFICE PROCESSING

The office manager uses the Household Water Collection (HHWC) System to receipt and reconcile the samples. The MEC manager uses this same system to document the samples he or she receives and then transports these samples to the MEC laboratory.

3.1 Accessing the System

The VOC - Household Water Collection (HHWC) System is located on the Portal under the Sub-Systems header.

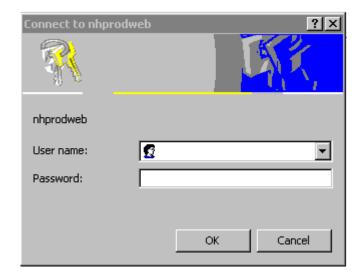
To access the Portal type, http://nhportals1/ss/default.aspx into the Address text box.

Select the Sub-Systems header to locate the VOC-HHWC link.



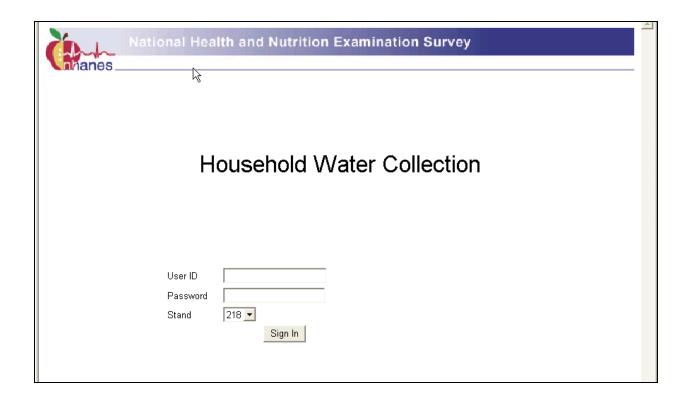
Select the VOC - Household Water Collection System link to access the system.

Log on to the system.



Enter nhanes\ and your **User name** (last name_first initial.) Enter the **Password** and then select the \overline{OK} button to progress to the application or select the \overline{Cancel} button to close the window.

The **Household Water Collection** login screen displays. Only field office staff assigned to the current stand can access the HHWC System while working at that stand.



Enter your **User ID** (last name_first initial) and **Password**. Select the <u>Sign-In</u> button or touch the [Enter] key. The system validates the user name and password and provides access based on their role. The **Stand** option is not visible when accessed by staff in the field office or MEC; it is only visible when accessed by home office staff.

Data entry options are based on the role of the person logging into the system:

- Field Office Staff can enter and edit the field office (FO) section of the system that includes the "Household Water Receipt" and the "Water Reconciliation" pages.
- **MEC Manager** can access the "Transfer samples" section of the system.
- Home Office Staff can view and edit only the "Water Reconciliation" page in the FO section.
- **Reports** can be viewed by all staff—field office, MEC, and home office.

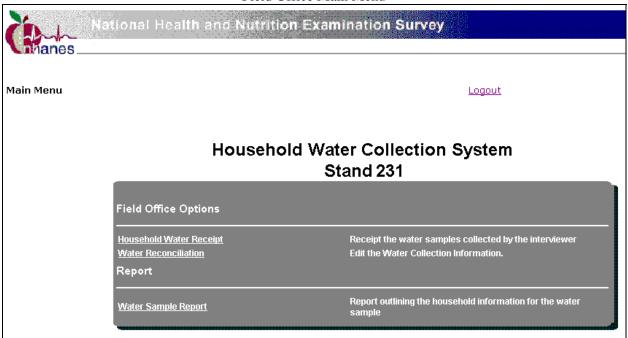
3.2 Main Menu Screen

The Household Water Collection System Main Menu screen displays after the system validates the name and password of the person who logged onto the system.

The menu shows the links that are relevant to staff according to their role. For example, the field office staff cannot see the "Transfer samples" page. The MEC manager cannot see the field office options. The home office staff can only see the Water Sample Report.

The stand at which the individual is working (Stand XXX) is displayed in the top center.

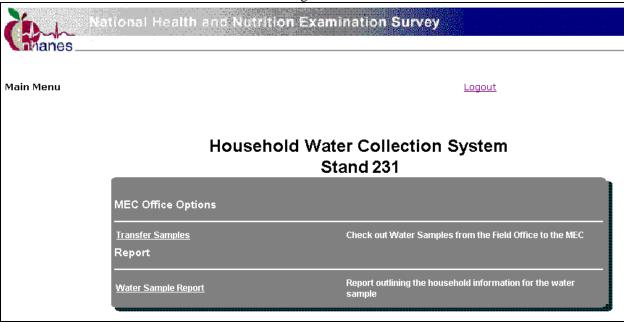
Field Office Main Menu



Use this screen to access:

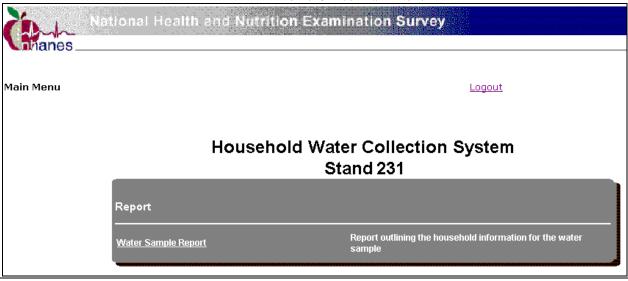
- **Field Office Options** available to field office staff.
 - <u>Household Water Receipt</u> Use at the field office to check in and edit the water samples collected by the interviewer.
 - <u>Water Reconciliation</u> Use at the field office to verify the data on the screen against the data on the outside of the bags.

MEC Manager Main Menu



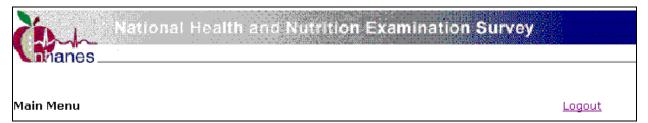
- **MEC Office Options** available to the MEC manager.
 - <u>Transfer Samples from Field Office to MEC Manager</u> Use to check out water samples from the field office to the MEC.

Home Office Main Menu



- **Reports** available to field office, MEC manager, and home office staff.
 - <u>Water Sample Report</u> A report of the HH water collection status that can be filtered and sorted according to user needs.

The top right corner of the HHWC screen includes a Logout link.



If the Logout Link is selected, a new page is presented that allows the user to log back onto the system.



To log back into the HHWC system, click on the link.

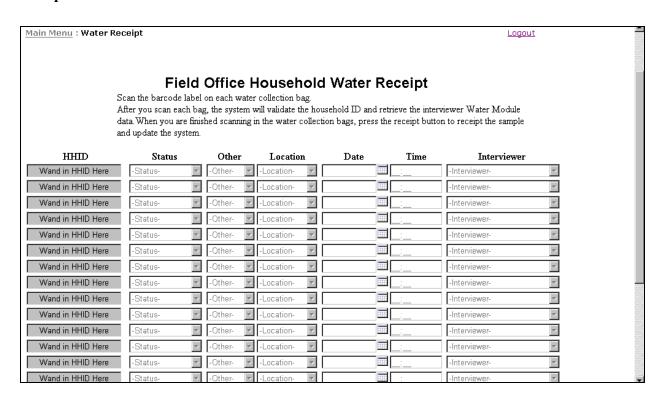
3.3 Field Office – Household Water Receipt

The office manager uses this link to receipt the interviewer's samples. (This assumes that the interviewer has already uploaded the data to the field office via the data transfer process.)

Field Office Options	
Household Water Receipt Water Reconciliation Report	Receipt the water samples collected by the interviewer Edit the Water Collection Information.
<u>Water Sample Report</u>	Report outlining the household information for the water sample

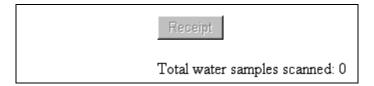
To access this module, click on the <u>Household Water Receipt</u> link.

The Field Office Household Water Receipt screen displays after the **Household Water Receipt** link is selected.



The top half of the screen includes a link to return to the <u>Main Menu: Water Receipt</u> <u>designation</u>, the <u>Logout</u> link, and instructions to receipt the samples.

The bottom half of the screen includes a Receipt button and Total water samples scanned counter.

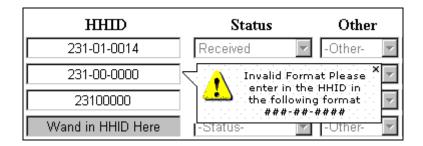


The screen includes 15 blank text boxes. Use the bar code gun to scan the bar code label on the outside of each household water collection bag. As the office manager scans a bar code label on the water collection bag, the system automatically enters the Household ID (concatenated with dashes between the stand ID, segment ID, and serial numbers) into a text box. Alternatively, manually type the Household ID into the text box using the keyboard.

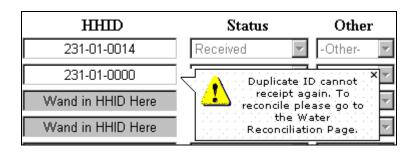


The system allows the office manager to scan multiple sample vessels without stopping. Visually compare the label on the bag to the data on the screen. The office manager should edit this information before clicking on the Receipt button.

If there is an error in the HH ID (Household ID), then the system immediately displays id Format." Please enter in the HHID in the following format ###-##-###" next to the text box.



Duplicated IDs cannot be scanned in; the system also checks the database to determine if the sample was already scanned during an earlier session. If a sample has been scanned more than once, then the system displays "Duplicate ID cannot receipt again. To reconcile please go to the Water Reconciliation Page" informational text box when the HHID is entered. The system will not proceed until the correction has been made.

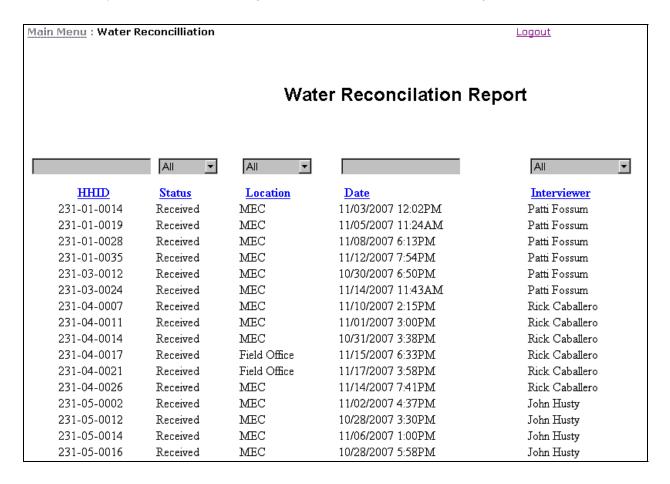


Continue scanning each sample until all samples have been scanned. When finished, select the Receipt button to receipt the samples into the system. The Receipt button cannot be activated until all of the relevant fields are correctly populated.

Click on the Main Menu link on the top half of the screen to go back to the Main Menu screen.

3.4 Field Office – Daily Water Reconciliation

After the office manager selects the Receipt button to save the data, the Water Reconciliation Report screen displays. This screen includes every sample that was just scanned. Use this screen to verify the data on the screen against the data on the outside of the bags.



This screen displays the **HHID** for each sample in addition to the sample **status** and sample **location**. The Household ID cannot be edited here. The samples display in the same order in which they were scanned. The **interviewer** name and **date** and time collected are the actual date and time the interviewer marked the sample as collected during the SP questionnaire process.

The HHWC system automatically sets the status as "Received" and location as "Field Office." To override the default, edit the data using procedures described in Section 3.4.1.

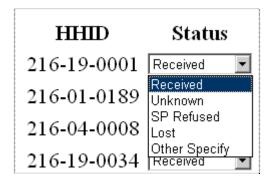
If a Household ID does not exist in the system because the interviewer has not completed the data transfer, the office manager staff can still scan the sample using the bar code label on the bag. The system will set the Sample location to "Field Office" and the Sample Status to "Received." The sample collected date, and interviewer ID can be entered by the office manager by referencing information available on the bag.

3.4.1 Editing a Sample

Edit the status, other, location, collection date and time, and interviewer name when receipting the samples.

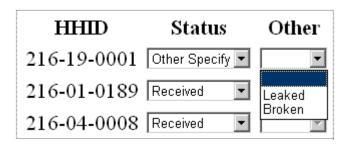


To edit the status of a sample, access the Field Office Household Water Receipt screen. Select the drop-down arrow to view the options.



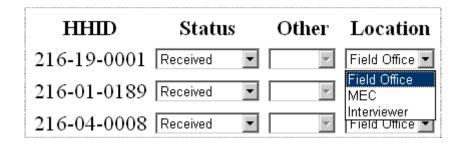
The choices are Received, Unknown, SP Refused, Lost, or Other Specify. Select the desired choice and right click.

If **Other Specify** is selected then the Other text box is enabled.



The choices are Leaked or Broken. Select the desired choice and right click.

To edit the **Location** of a sample, select the drop-down arrow to view the options.

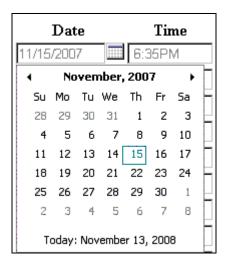


The Location choices are Field Office, MEC, and Interviewer.

To change the name of the interviewer, select the drop-down list, select the correct name, and click.



To change or insert the date, click in the calendar icon and a calendar displays.



To select a date, click on the desired number. Allow the screen to refresh. Type the time into the text box using the keyboard. The time entered must be in the HH:MMAM/PM format.

Use the **Main Menu** link on the top to get to the "Main Menu" page.

3.4.2 Overriding Reconciled Samples

If a Household ID already exists in the system with status as "Water sample not collected or refused," and if the office manager scans in the collected sample vessel, then the system overrides the previous status and sets the status to "Received." The sample date collected and the Interviewer ID are blanked out for the office manager to fill in later or it is inserted if the interviewer does a new data transfer.

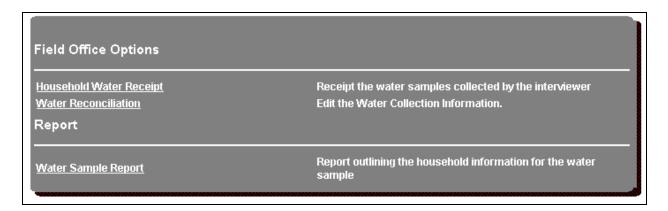
If the Household ID already exists in the system as "Collected but the water in the sample vessel has leaked/broke" or if the label on the sample vessel was destroyed, then the office manager should set the status to "Lost" or "Unknown" and instruct the interviewer to re-collect the sample. The sample date collected and the Interviewer ID are blanked out for the office manager to fill in later or it is inserted based on a new data transfer.

If a Household ID does not exist in the system, or if the interviewer has not completed the data transfer, the FO staff can still scan the sample vessels. The Household ID will be captured from the

sample vessel label, the location will be set to "FO" and status to "Received," and the sample date collected and interviewer ID can be typed in by the office manager.

3.5 Field Office – Water Reconciliation

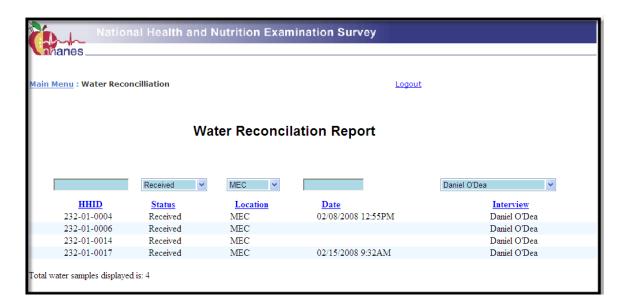
The office manager uses the $\underline{\text{Water Reconciliation}}$ link to filter the sample list by Status, Location, and Interviewer.



To access this module, click on the **Water Reconciliation** link.

The Water Reconciliation screen displays after the link is selected.

Use the filters to locate specific records by selecting the values from the drop-down list below the column heading. Click on the **Edit** link on a particular record to edit that record.

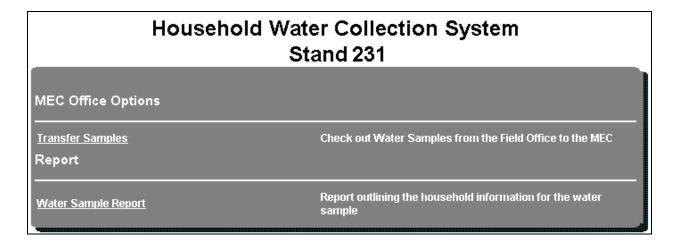


Use the <u>Status</u>, <u>Location</u>, or <u>Interviewer</u> drop-down arrows to view the filter choices. Allow the screen to update. Use the underlined links to sort the list.

3.6 Transfer Samples from Field Office to MEC Manager

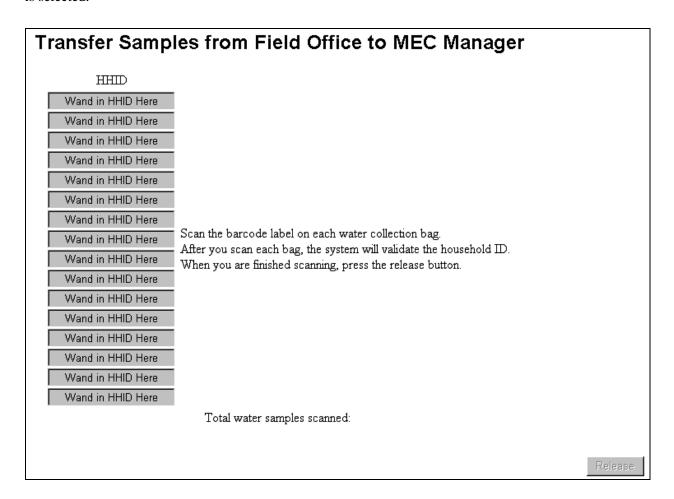
After the office manager has finished scanning and reconciling the water samples, they are stored in the refrigerator until the MEC manager retrieves them. The MEC manager collects all water samples from the office manager at least weekly. The MEC manager uses this same HHWC system to document the samples he or she receives and then transports these samples to the MEC lab.

The MEC manager uses the <u>Transfer Samples</u> link to create a list of reconciled samples that are ready for transport to the MEC.



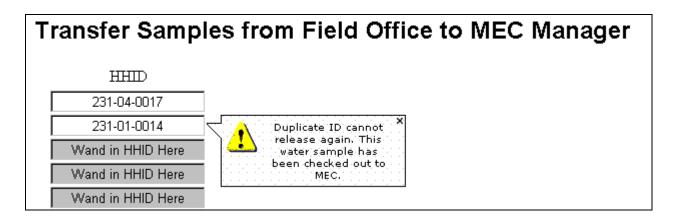
To access this module, click on the $\underline{\textbf{Transfer Samples}}$ link.

The Transfer Samples from the Field Office to MEC Manager screen displays after the link is selected.



This screen contains a column of blank fields. The number of blank fields displayed is based on the number of vials currently scanned in at the field office plus ten extra lines to scan in additional sample vials. Scan the bar code label on the outside of each household water collection bag to reconcile these against those receipted by the field office staff. When finished, click on the Release button, located on the bottom of the screen.

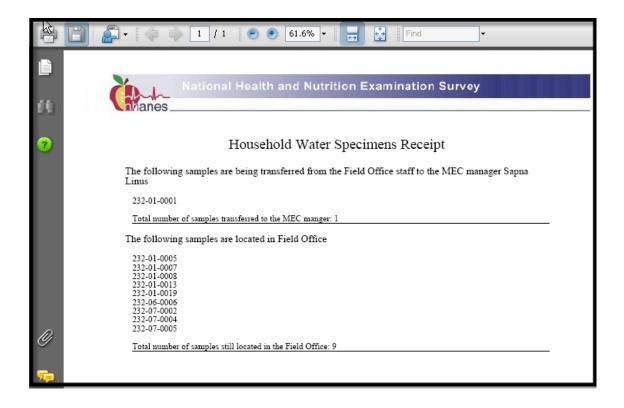
As each bar code is scanned, the system automatically enters the number (Household ID – concatenated with dashes between the stand ID, segment ID, and serial numbers) into the text fields.



Scan in multiple samples without stopping. When finished, click on the Release button, located on the bottom of the screen.

The "Release" button on the "Transfer Page" is not activated until the HH IDs are entered in the correct format. The system will not release a sample to the MEC if it has not already been receipted into the system by the field office or if the sample has already been released to the MEC.

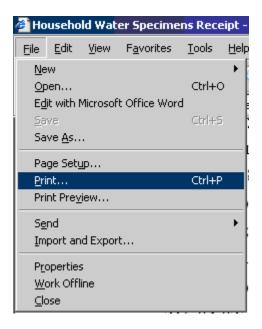
The system reconciles the sample received at the MEC with the ones received at the FO and creates and displays a Household Water Specimens Receipt report. A pdf report is generated after the sample has been "Released" to the MEC. The Users can save or print this pdf for future reference.



This report includes a list of samples that are being transferred from the office manager to the MEC manager by name.

The bottom of the report includes a list of samples still located in the field office and any samples collected by the interviewers but not receipted by the office manager.

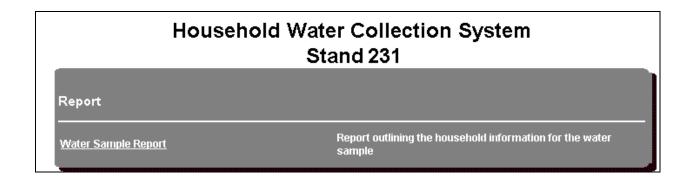
To print this report select **File**, then **Print** from the top tool bar.



Logout when finished.

3.7 Water Sample Report

A summary Water Sample Report allows the office manager, MEC manager, MEC lab staff, and home office staff to view the collection status of every sample.



To access this module, click on the **Water Sample Report** link.

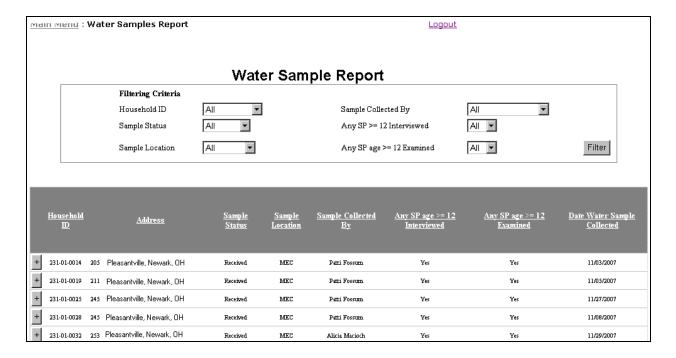
3.7.1 Water Sample Report Details

The Water Sample Report displays. Use any of the six filtering criteria to modify the data displayed in the report. By default, the report will initially display all the records.

Use the filters to select by:

- 1. Household ID: List of all processed samples.
- 2. Sample Status: Missing, Received.
- 3. Sample Location: FO, Interviewer, MEC.
- 4. Sample Collected By: List of all assigned interviews.
- 5. Any SP age >= 12 Interviewed: "Yes," "No."
- 6. Any SP age >= 12 Examined: "Yes," "No."

After selecting the desired filter options, click on the Filter button to view the modified report. It is also possible to sort by clicking on the column name.



The report contains a list of records based on the filtering criteria and initially displays by Household ID. Selecting the "+" sign next to the Household ID reveals the entire list of SPs in that household. The filtering criteria will not apply to this list of SPs in the household and it will show all the SPs even if their age is less than 12.

To print the report, select "File" and "Print" from the top menu.

4. LABORATORY PROCESSING

4.1 Overview

Exposure to VOCs is tested from one 10-mL gray top tube for blood (vessel 54) and one 10-mL glass tube for tap water (vessel 105.) Perchlorates are tested using the tap water from the same 10-mL glass tube. The one-half subsample requirements are households with at least one SP aged 12+. Subsample remainders are set at 1, 2, 4, 5, 10, and 11.

The phlebotomist collects and labels the VOC blood tube, vessel 54. Process the blood tube using the blood processing screen. Store the blood tubes in a 5-inch box with a 5 x 5 foam insert. Ship weekly in the same shipper as the water vials.

The MEC manager transports water samples from the field office to the MEC on a weekly basis. Process the water samples (vessel 105) using the Household Water Collection module. Scan each Household ID bar code using the bar code gun, label specimens, and store the sample in a 5×5 three-inch box with a foam insert. Ship weekly in the same shipper as the blood vials. At the end of each stand reconcile the samples using the web-based Water Sample Report.

4.2 Supplies

The VOC blood and HH water collection supplies are listed in Exhibit 4-1.

Exhibit 4-1. Equipment and supplies – VOC blood and HH water collection

10-mL gray top Vacutainer ® blood tube	Water collection kit (Field office par level 325)
(phlebotomy par level 200)	10-mL vial
	Instructions
	Small zip closable bag
5-inch box with 5 x 5 foam grid	Refrigerant gel pack
3-inch box with 5 x 5 foam grid	Cardboard shipper
9 x 12 plastic bag	Absorbent pad
Packing tape	

The VOC/Perchlorate water vial is a 10-mL Wheaton glass vial that contains 125 μ L quench buffer. Quench buffer is water with 1 M phosphate buffer and 0.1 M sodium thiosulfate.

At the start of each stand, the warehouse staff prepares and ships 325 water collection kits for the field office. The warehouse staff places the collection instruction document and one 10-mL glass water collection vessel into a zip closable bag. The field office staff stores their collection kits in the field office. Do not discard any remaining water vials at the end of each stand; ship them back to the warehouse.

Blood Tube Preparation

CDC prescreens the gray-top tubes used for the VOC protocol for this study. The following is the procedure for preparing the 10-mL gray Vacutainer® VOC blood collection tubes and a statement of their purpose. Dr. David Ashley at the CDC provided this procedure.

Procedure for preparing the 10-mL gray Vacutainer® tubes:

- Because of the volatile organic compounds present in commercial Vacutainers® with rubber stoppers, it is necessary to decontaminate the tubes before blood collection. CDC laboratory personnel carry out this decontamination procedure. The vacuum is released and the glass tube with anticoagulant and the stopper are placed in a vacuum oven. These materials are then decontaminated under vacuum at 70°C for 2 weeks. The Vacutainers® are reassembled and tested for lack of contamination. A vacuum is reapplied to each Vacutainer® and they are sterilized in a Gamma-ray sterilizer to kill any microbiological organisms that may have entered the tubes.
- This procedure is necessary to acquiring a volatile organic compound measurement that is a true measure of an individual's internal dose level of VOCs.

Since the date on the Vacutainer® is a guarantee that the vacuum is reliable, this date has no reference to the current materials sent from CDC to NCHS. The laboratory at CDC will ensure that the Vacutainers® sent to the NHANES staff have been prepared on a date within the timeframe necessary for their use. Notify the technical supervisor if the tubes begin to lose their vacuum, but continue to use the tubes until replacements arrive.

4.3 MEC Exam

VOC data collection consists of the following: one 10-mL blood tube, a tap water sample, and answering the questions on the VOC questionnaire.

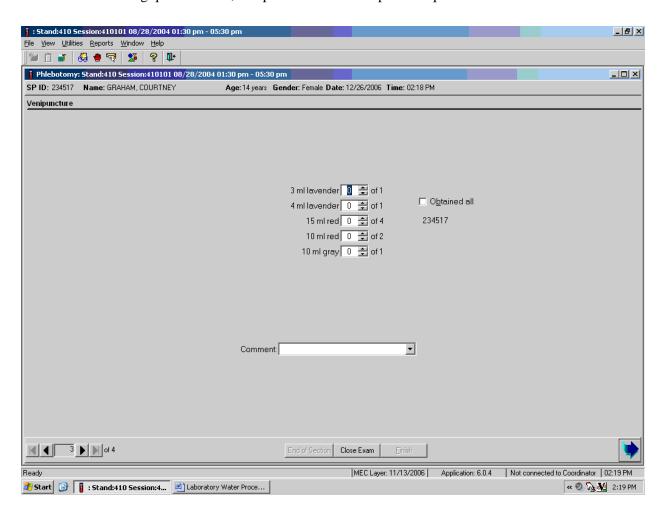
The coordinator assigns the SP to the phlebotomy room. In phlebotomy, the phlebotomist logs the SP into the application, and performs venipuncture to collect the protocol-dictated tubes, which includes the 10-mL gray top VOC blood tube. Labels automatically print for the blood tube.

The MEC manager transports the household water samples from the field office to the MEC on a weekly basis. The laboratory staff processes the blood and water samples, stores them in the MEC refrigerator, and ships them weekly to the Air Toxicant Branch of the CDC.

The MEC interviewers administer a short questionnaire.

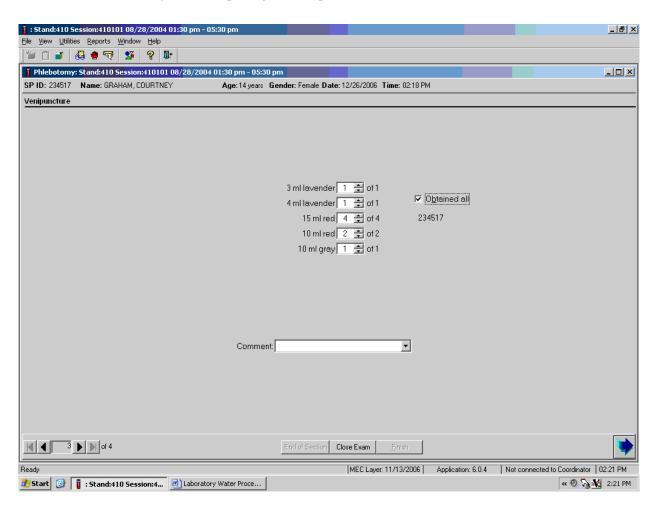
4.3.1 Draw the VOC Blood Tube in Phlebotomy

Access the Phlebotomy application. Log onto the application, open the Phlebotomy examination, log the SP into the component, verify the information, conduct the phlebotomy interview, administer the fasting questionnaire, and proceed to the Venipuncture protocol screen.



The window displays the appropriate venipuncture protocol for VOC SPs. Draw one 10-mL gray top tube as part of the venipuncture protocol using procedures described in Chapter 4 of the *Laboratory Procedures Manual*. Thoroughly mix the 10-mL gray top tube immediately after drawing the tube and place the tube on the specimen rocker until the tubes are labeled and passed through to the window to the laboratory.

Immediately after completing the venipuncture, enter the results of the blood draw.



Label the blood tubes by placing the bar code label on the tube. Pass the blood through the window to the laboratory. Review the venipuncture status.

4.3.2 MEC Interview VOC Questionnaire

The MEC interviewers administer the CAPI VTQ section of the MEC interview examination. These specifications and directions are documented in the MEC Interviewers Procedures Manual.

The CAPI VTQ collects data about the SP's home, activities, amount of time spent in various locations, and exposure to different chemicals over the past 72 hours. All VOC subsampled SPs are eligible for the VOC questionnaire.

4.4 VOC Blood and Water Processing

The MEC manager transports the household tap water samples from the field office to the MEC at least weekly. Samples should be sorted numerically by the Household ID and stored in the MEC laboratory refrigerator. Samples will exist for every household with an SP aged 12+ who was interviewed. They cannot be processed until someone from the household is MEC examined. Process these samples daily and ship them weekly. Use the web-based Water Sample Report to reconcile the samples. Notify the field office staff of any discrepancy.

Exhibit 4-2 illustrates the VOC blood and water processing and storage protocol.

Exhibit 4-2. VOC blood and water processing and storage protocol

			Sample	•	
Vessel No.	Assay	Age in years	size mL	Collection type	Container
54	VOC Blood	12+	10	10-mL	5 x 5
				gray top	5-inch box
					with foam
					insert
105	HH Water	12+	10	10-mL glass	5 x 5
					5-inch box
					with foam
					insert

4.4.1 Processing VOC Blood Tube (Vessel 54) in the Laboratory

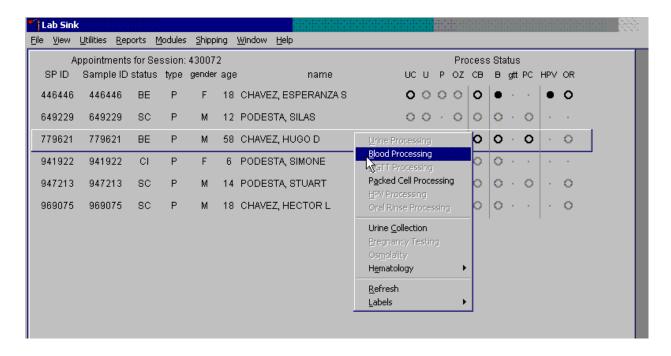
The VOC blood tube is labeled in phlebotomy; no further labeling is necessary. The tube is passed through to the lab immediately after collection. Ensure that the contents are thoroughly mixed; process the vial using the Blood Processing module and refrigerate the vial within 15 minutes after the blood draw.

4.4.1.1 Record the Results of Blood Processing

After filling or processing the whole blood, plasma, serum, packed cells, and/or the EDTA or gray top tubes for each SP, use the Blood Processing module to enter the blood processing results.

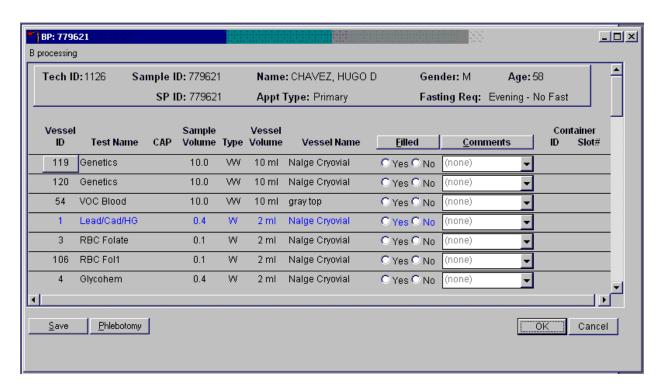
Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.

Select the correct SP and access the Blood Processing module.



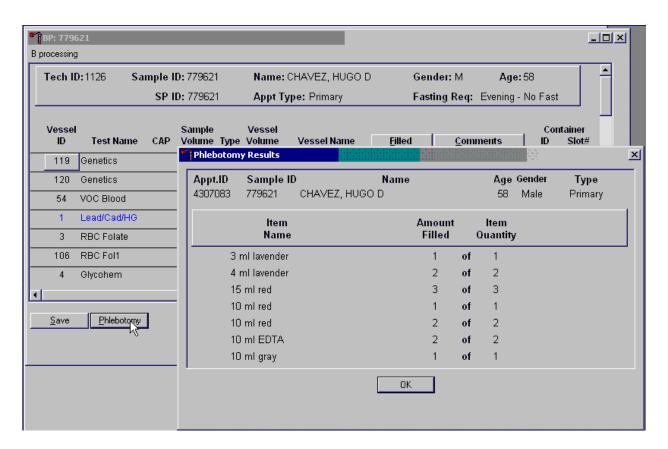
If labels have not been printed in advance, a Blood Processing message text box displays. To access the blood processing module, highlight the SP, right click, drag the mouse arrow to {Blood Processing}, and left click or type [Alt] [B/b].

The SP's blood processing screen displays.



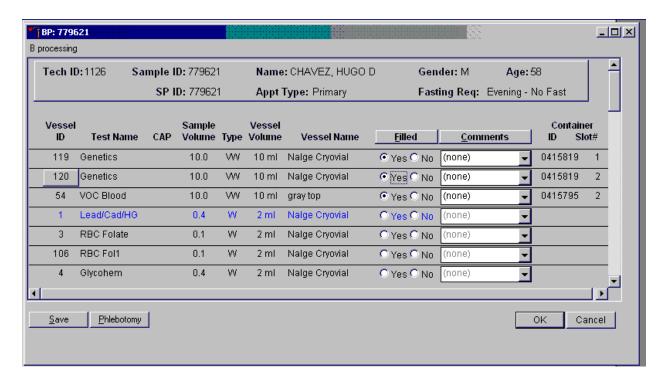
The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, Columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum), Vessel Volume, Vessel Name, Filled radio buttons, Comments text box, and a Container ID/Slot# column. Vessels that require sterile 2-mL cryovials are displayed in red.

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the bar code label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



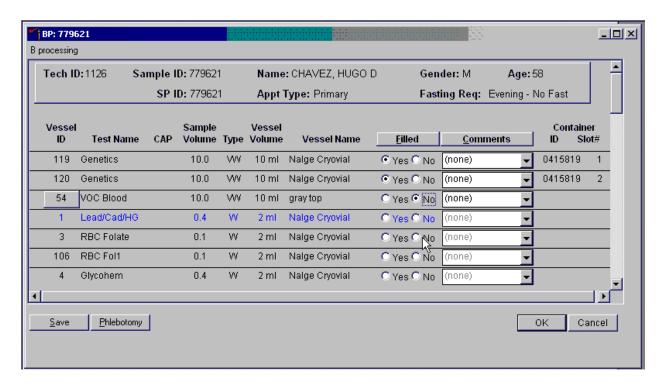
To review the phlebotomy results, use the mouse to direct the mouse arrow to the Phlebotomy button on the blood processing screen and left click or type [Shift] [P/p.] The phlebotomy protocol and the number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the OK button and left click.

Record blood processing results for each SP. Individually mark each vessel as Filled "Yes."



To mark the VW (whole blood tubes, vessels 119/120 and 54) as collected or Filled "Yes," use the mouse to direct the mouse arrow to the center of the "Yes" radio button and left click. As each vessel is marked as Filled "Yes," it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled "No."

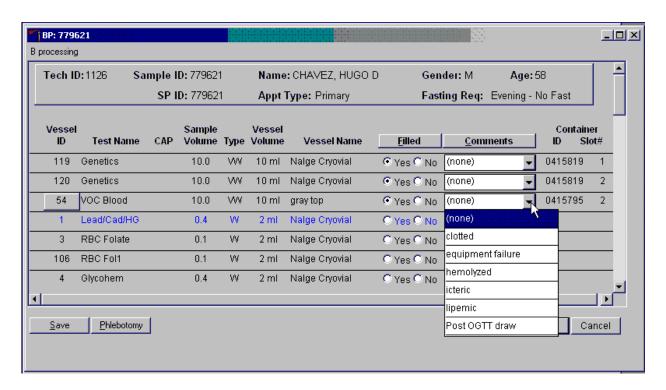


To mark an individual blood vessel as not collected or Filled "No," use the mouse to direct the mouse arrow to the center of the "No" radio button and left click. Vessels marked as "No" require a comment.

Quality comment codes are available to describe the quality of the specimen.

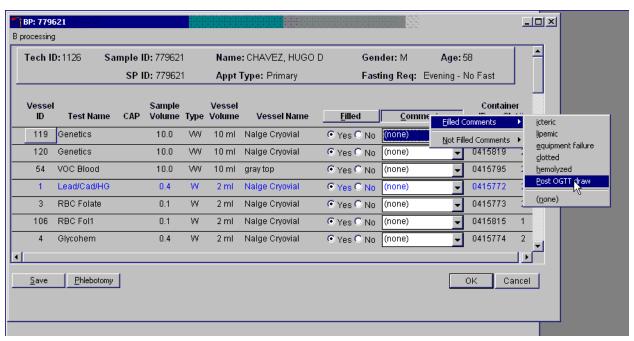
Comment for filled vessels	Use when:				
Clotted	The whole blood sample contains a fibrin formation. This is due to				
	inadequate mixing or inadequate clotting.				
Equipment failure	Pipettes are malfunctioning.				
Hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the				
	abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture				
	(in vivo hemolysis) or during the analytic procedure (in vitro hemolysis). If				
	in vivo, hemolysis will give plasma a red color. Use when describing visible				
	hemolysis, which occurs when the concentration of hemoglobin exceeds				
	200 mg/L.				
Icteric	There is visible orange color to the serum or plasma. Icteric refers to orange				
	color imparted to a sample because of the presence of bilirubin. Bilirubin				
	present in serum results in visible "jaundice" color when the concentration				
	of bilirubin is above 430 umol/L.				
Lipemic	There is turbid appearance to the serum or plasma. Lipemia refers to the				
	presence of lipid particles (usually very low-density lipoprotein) in a				
	sample, which gives the sample a turbid appearance. Plasma appears visibly				
	lactescent or lipemic when the concentration of triglycerides exceeds 4.6				
	mmol/L.				
Post OGTT draw	During the OGTT blood draw (2 hours after the initial venipuncture and				
	after the SP has consumed the Trutol), the phlebotomist will draw any tubes				
	that were missed during the first venipuncture. If any vessel is filled from				
	one of the tubes drawn during the OGTT blood draw, then add this				
	comment.				

Attach a comment to an individual filled vessel.



To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, i, l, p).

Use the following procedure when all filled vessels require the same comment.



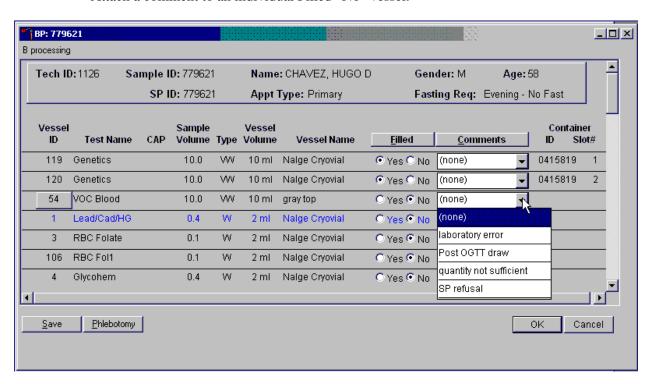
To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the Comments button on the top of the radio buttons, left click, drag the arrow to {Filled Comments}, drag the mouse arrow to the correct choice, and left click. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h, p).

All vessels marked as Filled "No" require a comment or explanation.

Enter comment codes to describe the reasons why a vessel is marked as Filled "No," or why the protocol is incomplete.

Comment for not filled vessels	Use when:
Laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist
	error.
Quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP does not provide consent, and consequently, is excluded from
	HIV.

Attach a comment to an individual Filled "No" vessel.



To attach a Filled "No" comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

_ 🗆 × BP: 779621 B processing Sample ID: 779621 Name: CHAVEZ, HUGO D Tech ID: 1126 Gender: M Age: 58 SP ID: 779621 Fasting Req: Evening - No Fast Appt Type: Primary Sample ID **Test Name** CAP Volume Type Volume Vessel Name <u>Filled</u> <u>C</u>omm **Eilled Comments** 119 Genetics 10.0 WW 10 ml Nalge Cryovial Yes ○ No (none) 120 Genetics 10.0 W 10 ml Nalge Cryovial Yes ○ No 0415819 SP refusa guantity not sufficient VOC Blood 10.0 W 10 ml gray top C Yes © No (none) Lead/Cad/HG 0.4 W 2 ml Nalge Cryovial C Yes @ No C Yes © No RBC Folate Nalge Cryovial 0.1 W 2 ml (none) RBC Fol1 0.1 W Nalge Cryovial 106 2 ml C Yes © No (none) C Yes © No Glycohem 0.4 W 2 ml Nalge Cryovial (none) Phlebotomy <u>S</u>ave OK Cancel

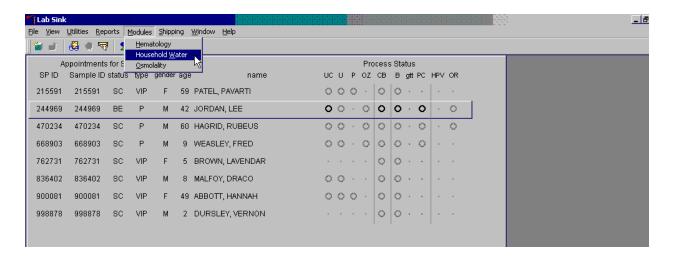
Use the following procedure when all Filled "No" vessels require the same comment.

To collectively attach the same comment to all Filled "No" vessels, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Not Filled All}, drag the mouse arrow to the desired choice, and left click. Alternatively, to collectively attach the same comment to all vessels marked as Filled "No" type [Shift] [L/I], [N/n], and the first letter of the desired choice (l=laboratory error, s= SP refusal, q=quantity not sufficient).

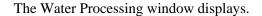
4.4.1.2 Process HH Water Samples

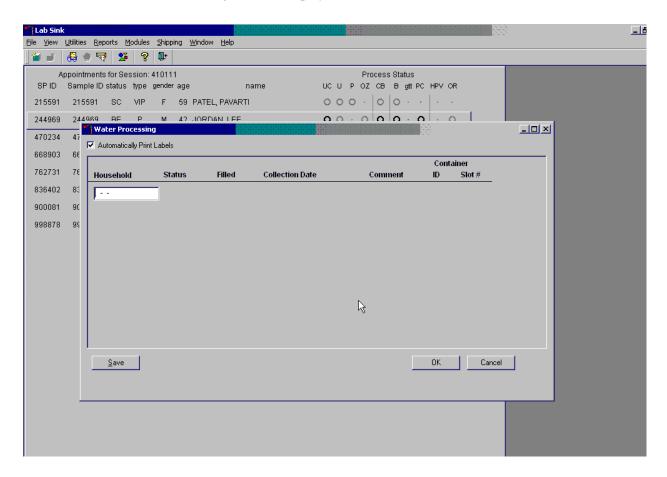
The household interviewers label the outside of the VOC/perchlorate water kit with a paper label containing the Household ID. They write the collection date and time on the green label that is located on the outside of the water collection kit. This date and time are also captured and stored in the database when the interviewer marks the sample as collected.

Access the Household Water module.

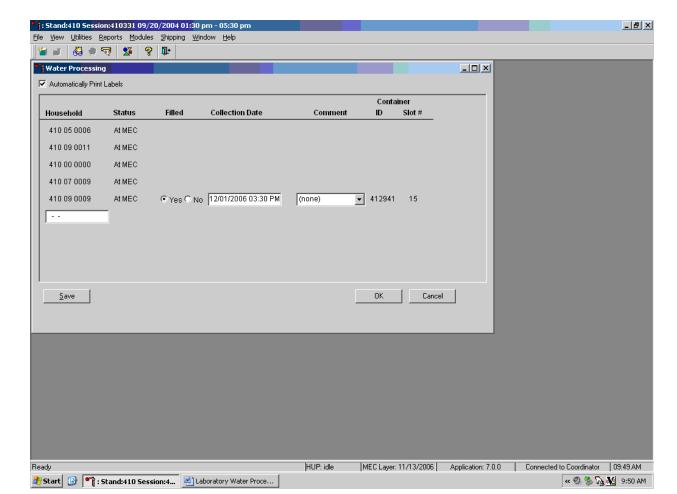


To access the {Household Water} module, use the mouse to direct the mouse arrow to {Household Water} and right click. Alternatively, to access the {Household Water} module, use the keyboard keys to type [Alt] [M/m], select the down arrow key to select {Household Water}, and then select [Enter.]





The Water Processing window includes an Automatically Print Labels check box, a blank Household text box, columns for Status, Filled, Collection Date, Comments, Container ID and Container Slot, and Save, OK, and Cancel buttons. The Automatically Print Labels check box will default to checked; do not change.



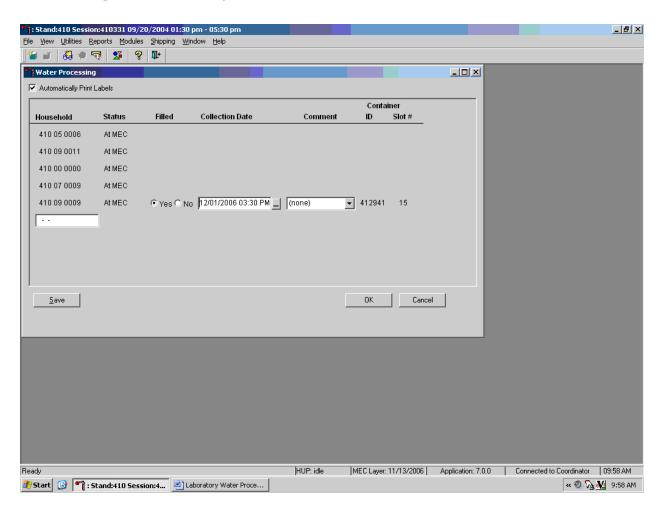
Use the bar code gun to scan the Household ID bar code on the front of every water sample.

As each bar code is read, the status or current location of the sample is displayed.

- At MEC = sample is at the MEC but no one from the household has been examined.
- At FO = sample has been receipted at the field office but it has not been transferred to the MEC.

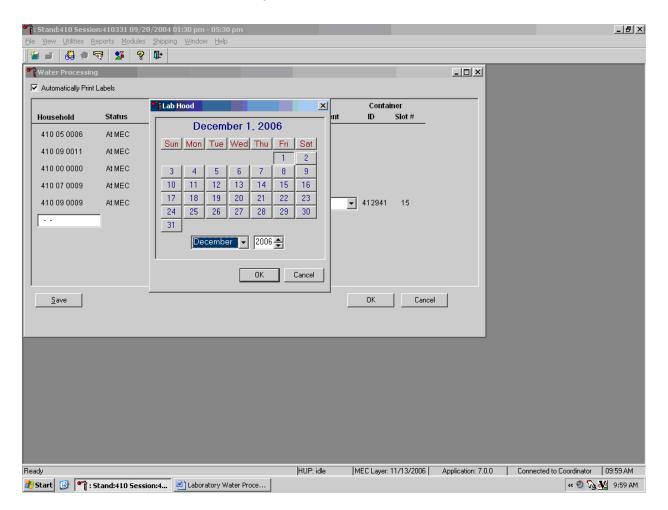
If the sample is at the MEC and someone from the household has checked in, then the "Filled" radio button will be filled in, the collection date and time will be displayed, the comment box will default to blank, and the Container ID and Slot number will be assigned and displayed. A label will automatically print on the Dymo printer. This label contains a Household ID bar code, an Astro ID bar code, and the words "HH Water" on the top.

Verify the collection date and time in the system with the date and time written on the outside of the plastic collection bag.



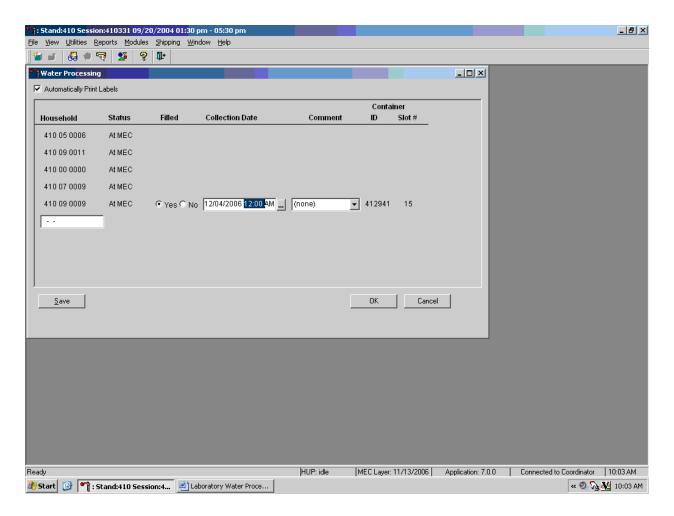
To change the collection date and/or time, place the cursor in the Collection Date and Time text box. An ellipse icon will display.

Access the calendar to change the date.



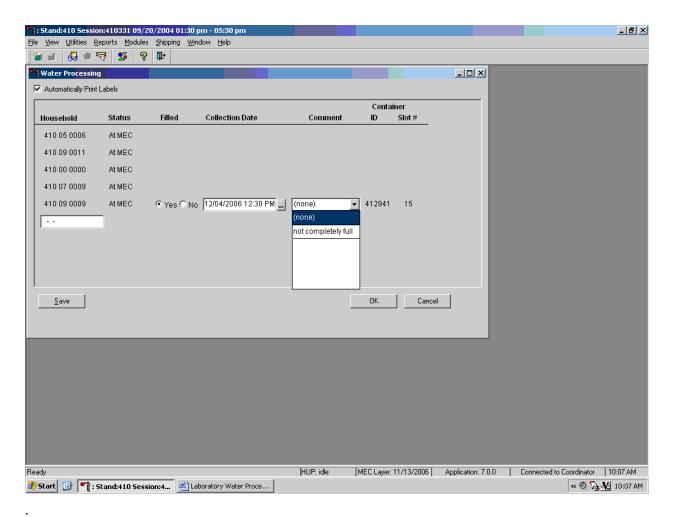
Type in the date using the keyboard's numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, use the mouse to direct the mouse arrow to the ellipse icon and left click. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the updown controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Correct the time.

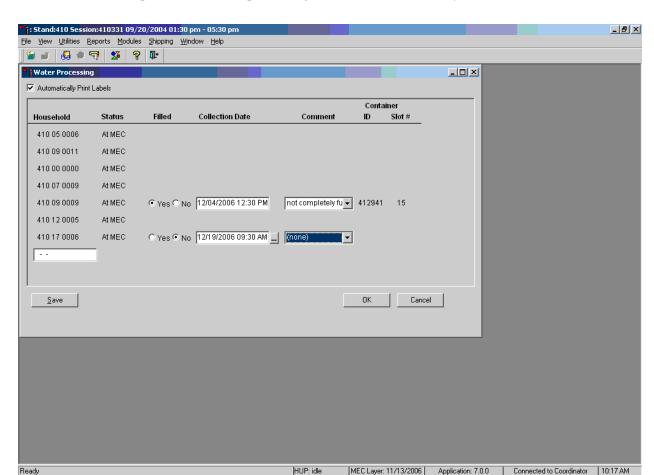


To correct the time, use the mouse to direct the mouse arrow to the time (HH:MM) and double click to highlight. Use the numeric keyboard keys to type the correct hours and minutes. To correct the AM/PM setting, use the mouse to direct the mouse arrow to AM or PM and double click to highlight. Use the keyboard keys to type "A" or "P."

Add a "not completely full" comment to any sample that does not have water filled to the top of the vial.



To select a comment for a Filled "Yes" sample, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the Comment text box and left click. Drag the mouse arrow to "not completely full" and left click.

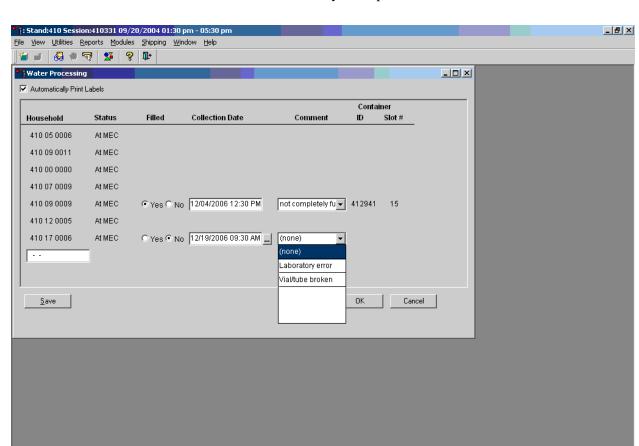


All samples that meet the processing criteria are automatically marked as Filled "Yes."

To change the Filled "Yes" to Filled "No," use the mouse to direct the mouse arrow to the "No" radio button and right click. Enter Filled "No" for a sample that has been collected, delivered to the MEC, an SP from the household has been checked in, but the vial has broken or there has been a laboratory error.

« Ø 🏡 🚹 10:17 AM

Start 3 Stand:410 Session:4... Laboratory Water Proce...



Add a comment to indicate the reason why a sample is marked as Filled "No."

To select a comment for a Filled "No" sample, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the Comment text box and left click. Drag the mouse arrow to "Laboratory Error" or "Vial/tube broken" and left click.

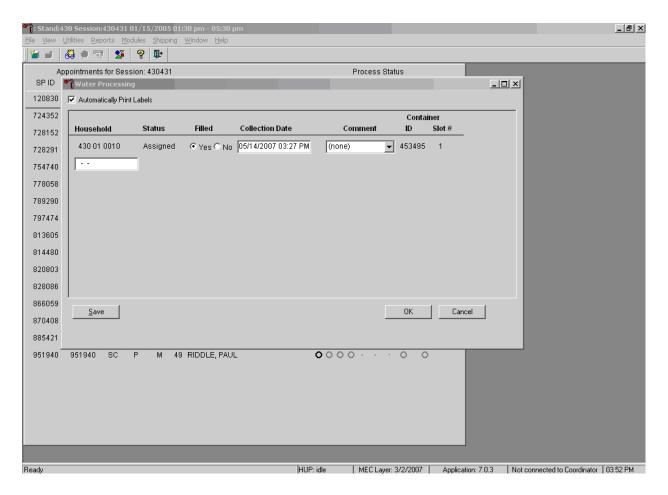
MEC Layer: 11/13/2006 | Application: 7.0.0 | Connected to Coordinator | 10:13 AM

« **② №** 10:13 AM

HUP: idle

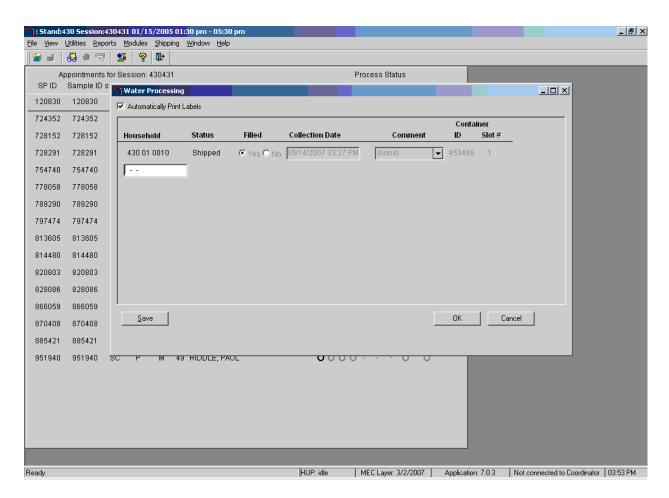
Start 3 Stand:410 Session:4... Laboratory Water Proce...

Water samples cannot be processed more than once.



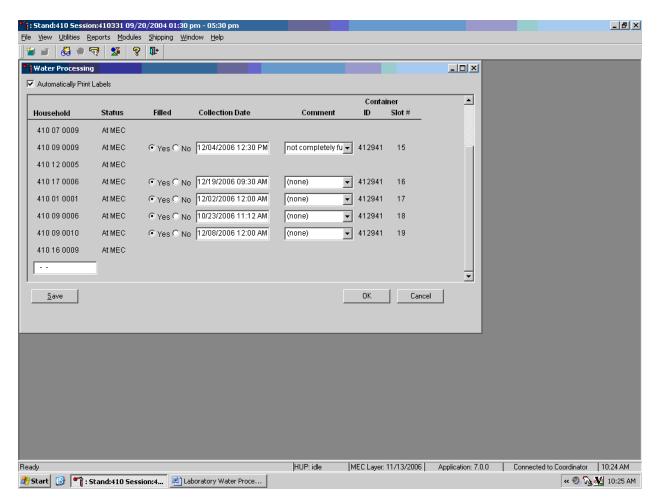
All samples that meet the processing criteria are automatically marked as Filled "Yes."

If a bar code is accidentally scanned more than once during the processing session, the Status field will display "Assigned." If the sample has not been shipped, the record will be editable. If the sample has been shipped the record status will display "Shipped." The record will appear greyed out and cannot be modified.



To continue, scan another water vial or select the Cancel or OK button.

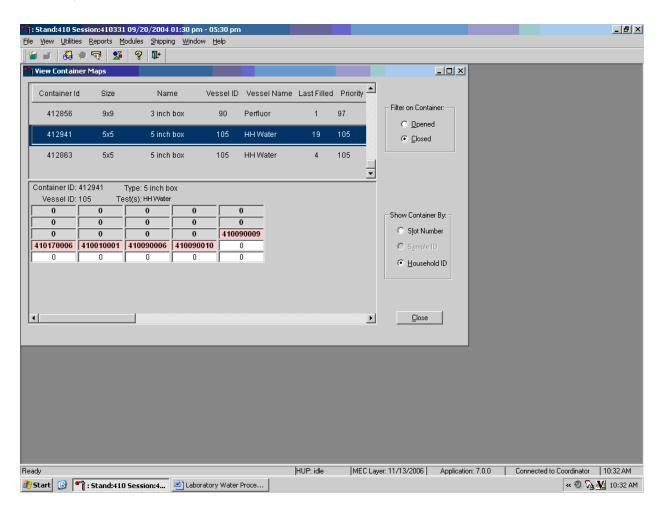
Continue to process all samples stored in the refrigerator.



Store each vessel in the correct slot in the correct container. To record these actions or to save these data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the Cancel button and left click.

4.4.2 Container Box Maps

Use the {Container Box Map} and {Close Containers} screens in the laboratory application to verify the contents of the vessel 54 and 105 containers before shipping the specimens to the contract laboratory.



The screens use a box map diagram. The vessel 105 map lists the sample ID of each sample in each container slot. The household water container (vessel 54) map displays the Household ID instead of the sample ID.

4.5 Shipping VOC Blood and HH Water Specimens

The integrity of laboratory specimens, including the blood and household water vessels, is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contact laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient refrigerant packs, and sending specimens FedEx priority overnight.

Store the VOC blood and HH water samples according to the protocol. Exhibit 4.3 Container Protocol, illustrates the specifications for the storage of the VOC blood and HH water samples.

Exhibit 4-3. Container protocol

Vessel					
ID	Test ID/Name	Sample type	Vessel type	Vessel storage	Storage unit
54	VOC Blood	WB	10-mL	5 x 5	Refrigerator #2
			gray top	5-inch box	
				(foam insert)	
105	HH Water	Water	10-mL	5 x 5	Refrigerator #2
			glass vial	5-inch box	
				(foam insert)	

Ship VOC blood and household water vessels to the designated contract laboratory (Exhibit 4-4) in a double-sided Styrofoam shipper or hard-sided cooler using wet refrigerant packs. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 4-5, the VOC blood/HH water shipping protocol, illustrates the specifications for the shipment of biological specimens to the contract laboratory.

Exhibit 4-4. Contract laboratory addresses

Laboratory/destination			Contact person(s)
specimen shipment address	Vessels/assays	Conditions	telephone number
CDC/NCEH Air Toxicant Branch	54/VOC Blood	Refrigerated	Dr. Ben Blount
4770 Buford Highway	105/HH Water		770-488-7962
Building 103, Loading Dock			
Atlanta, GA 30341			

Exhibit 4-5. VOC blood and HH water shipping protocol

				Shipping
Location	Vessels	Conditions	Vessel storage	frequency
CDC/NCEH Air Toxicant Branch	54/VOC Blood	Refrigerated	5 x 5	Weekly
			5-inch box with	
			foam insert	
CDC/NCEH Air Toxicant Branch	105/HH Water	Refrigerated	5 x 5	Weekly
			5-inch box with	
			foam insert	

The shipping technologist is primarily responsible for packing and shipping the specimens to all laboratories on a designated day. As necessary, other medical technologists, the phlebotomist, and the medical technologist assist in performing each of the steps listed below to complete the shipping procedures.

Shipping procedures:

- On the day before or the morning of a designated shipping day, create and print shipper labels (air bills) using FedEx Ship Manager.
- On the morning of a shipping day, close all containers, assign containers to a shipper, print the paper shipping manifest for each shipper, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return air bills, and assorted "warning" labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of refrigerant packs as appropriate.
- Pack the containers for vessels 54 and 105 in the shipper in the following order:
 - Cold packs at -20°C
 - Padding
 - Container for vessel 105 (HH Water)
 - Container for vessel 54 (VOC Blood tube)
 - Padding
- Place the appropriate paper manifest and the FedEx return air bill in a 9 x 12 plastic bag and place the plastic bag on the Styrofoam lid of shipper and place the lid on the shipper.
- Label each shipper with the appropriate FedEx label and warning labels.

When the contract laboratory personnel receive the shippers and/or hard-sided coolers, they unpack the specimens and return the shippers, coolers, and refrigerant packs to the NHANES warehouse.

Follow the instructions in Chapter 9 of the *Laboratory Procedures Manual*, Section 9.8, to create one air bill for CDC/NCEH Air Toxicant Branch. Follow instructions in Section 9.9 to close containers for vessels 54 and 105. Follow instructions in Section 9.10 to assign the air bills to the shippers. Vessels 54 and 105 are assigned to the same shipper.

Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed in Chapter 9, Section 9.11, to prepare the paper manifest and to send the electronic file.

4.5.1 Pack Medium Shipping Container for Refrigerated Shipment

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the container associated with vessel 54 into a pressure vessel (STP-740) and seal.
- Place the container associated with vessel 105 (HH Water) in a 9 x 12 plastic bag.
- Place at least two large frozen refrigerant packs in the bottom of a shipper. (Place enough cold packs to cover the bottom of the shipper; lay them flat, not on their edges.)
- Cover the cold packs with a blue insulation pad.
- Place the container associated with vessel 105 (HH Water) on top of the insulating material. The water samples are not as temperature sensitive as the blood samples.
- Place the sealed pressure vessel containing the blood samples (vessel 54) on top of the container associated with vessel 105.
- Add another layer of insulated material.
- Pack the sides with crumbled newsprint.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted air bill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted air bill on top of the Styrofoam lid.

- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

4.5.2 Label Shippers

For all destinations, include a preprinted FedEx return air bill containing the warehouse address.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- 1. A "Keep Frozen" label and a FedEx Class 9 Miscellaneous Dangerous Goods label on shippers containing dry ice.
- 2. A "Refrigerate" label on shippers containing refrigerant packs.
- 3. A UN 3373: "BIOLOGICAL SUBSTANCE, CATEGORY" B label on all shippers.
- 4. An "Overpack" label on all shippers
- 5. Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
- 6. Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- 7. Add one additional strip of tape across the FedEx pouch.

4.6 The MEC Environment

Maintaining a stable interior environment is critical to many laboratory analytes and processes. Environmental contamination of specimens can result if specimens are exposed to outdoor air and/or contaminants. For this reason, the windows in the MEC should generally be kept closed. This is especially important when actively processing specimens in the laboratory. Confine smoking outside the MEC to areas where there are no air intake vents and there is no possibility of second-hand smoke

entering the interior of the MEC. Adjust thermostats to maintain a comfortable MEC environment; opening and closing windows to adjust the temperature inside the MEC is not an alternative.

Exceptions to this policy are allowed under certain circumstances. Windows and/or bay doors can be opened when:

- An SP is uncomfortable and requires brief exposure to fresh air.
- The blood processing technologist is not processing specimens and the laboratory has dry ice inside the MEC.
- The MEC is not in session and the medical technologist is shipping specimens with dry ice.
- The blood processing technologist is not processing specimens, and opening the laboratory bay door is required to provide access to the FedEx courier.
- The blood processing technologist is not processing specimens, and opening the laboratory bay door is required to dispose of biohazardous trash.
- Performing setup and teardown activities. (This is done before any laboratory processing has occurred at the beginning of a stand and after all laboratory processing is complete at the end of a stand.)