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National Health  
and Nutrition  
Examination Survey

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LABORATORY  
PROCEDURES  
MANUAL



April 2001

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Appendix A  
Protocol for Volatile Organic Compounds (VOC) Study

**APPENDIX A**  
**PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS (VOC) STUDY**

**A.1 Overview**

The purpose of the VOC study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs). Approximately 1,000 primary SPs ages 20-59 years are randomly selected to participate in this study. This selection occurs when the SP ID is generated at the time the MEC appointment is made. In addition, all second exam SPs ages 20-59 are included as a convenient sample. The VOC study is conducted during the first 3 years of NHANES.

The phlebotomist recruits the primary SP for the VOC study during their first MEC exam after performing routine venipuncture. If the recruitment is successful, the phlebotomist gives the primary SP a personal exposure monitor (air-monitoring badge), and directions for wearing the exposure badge, records the SP's ID number, badge lot number and expiration date, gives instructions and a water sample vessel to the SP, and schedules a return visit for 46-76 hours later. The MEC phlebotomist must encourage all SPs to return to the first available MEC session at the 46-hour lower time limit. The MEC phlebotomist gives the SP a reminder card that lists the SP's return location, date, and time.

If there are MEC appointments available 46-76 hours after the initial recruitment, the primary SP is given a MEC return visit appointment. The SP returns to the MEC where the phlebotomist collects two additional tubes of blood, and the MEC interviewers collect the badge and water and administer the questionnaire. When the second exam SP returns to the MEC they have two additional tubes of blood drawn and the MEC interviewers administer a questionnaire. Payment of \$30 is made at the completion of the second MEC visit for primary SPs.

If there are no MEC appointments available 46-76 hours after the initial recruitment, the primary SP is given a VOC home exam (HO) appointment. The home examiner draws the two VOC blood tubes as part of the exam as long as the exam is conducted in the SP's home. The home examiner goes to the primary SP's home and collects two tubes of blood, the badge and water, and administers the questionnaire. The home examiner transports the specimens back to the MEC and processes them using the laboratory application. Primary SPs who do not refuse the blood receive a \$30 payment. If the SP refuses to have their blood collected, they are paid \$15.00.

The field office manager manages the home examiner's schedule. The office manager uses the Appointment Schedule for VOC Appointments with Time Constraints report (#71) to identify VOC SPs. The field office staff makes the reminder calls for MEC appointed SPs and confirms the



appointment date and time. They enter the appointment time in the Appointment Management System (AMS) and add any comments or other pertinent information. If the SP does not return to the MEC (no show) for their scheduled MEC appointment, the field office attempts to contact the SP to reschedule the SP into another MEC session or to schedule the exam as a VOC home exam.

The home examiner contacts all SPs scheduled into HO sessions and schedules their own VOC appointments using the VOC Appointments with Time Constraints report (#71) and the SP's Needing VOC Appt reports. The field office assumes this responsibility when the home examiners are off for 3 days. The home examiner uses the Calendar for Home Appointments in the AMS to review appointments and set the filter to "All." They use the comments entered by the phlebotomist to guide their conversation with the SP and use the VOC Reconciliation report daily to review the exam status and appointment status for all SPs. The home examiner also codes the final exam status for SPs who do not show up for either their MEC or HO appointment. The home examiner obtains cash from the office manager and locks the cash in a lock box in a dedicated filing cabinet in the field office. They take enough cash for each day's exams (plus \$60.00 extra) and store this money in a locked bag. The home examiner reconciles their cash at the field office at the first opportunity after completing the VOC home exams. The home examiner uses field office space and equipment to make reminder calls, print VOC reports, dock their laptop, secure their cash, and set up home VOC appointments. The MEC also contains a docking station. A Westat certified Spanish-speaking interpreter must accompany the home examiner if the home examiner is not certified bilingual.

The coordinator application identifies primary SPs who are returning to the MEC 46-76 hours later for the VOC return visit and assigns this SP to both the phlebotomy room and the MEC interview room. The two aspects of this component can be done in any order—there are no priorities for the blood or questionnaire. In phlebotomy, the phlebotomist logs the primary SP into the application, and performs venipuncture to collect the two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer collects the exposure monitor and water sample, and administers a short questionnaire. Labels for the badge and water samples print on the Intermec printer in the phlebotomy room. The coordinator application also identifies second exam SPs who are returning to the MEC and assigns the second exam SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the second exam SP into the application, and performs venipuncture to collect the second exam venipuncture protocol tubes, which includes the two 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer administers a short questionnaire.

The laboratory processes, stores, and ships the primary SP's VOC blood tubes, badge, and water specimens, and the second exam SP's blood tubes. The blood samples must be refrigerated within 15 minutes after completion of the venipuncture. Blood, water, and exposure monitors (in their original canister) are shipped once a week via next day courier in insulated containers with enough ice packs to maintain their refrigerated temperature.

There are only two situations that exclude the primary SP from participating in the VOC study. Exclude a primary SP if they are not going to be staying in their primary residence during the following 48 hours and/or exclude them if their selection occurs during the last 2 days of the stand. The second exam SP is not selected for a second exam if they were eligible for VOC as a primary SP.

There are four types of QC; one of each is performed weekly. The four types of QC are: repeat participant, field monitoring, positive control, and office air monitoring.

## A.2 Supplies

The VOC equipment and supplies are listed in Exhibit A-1.

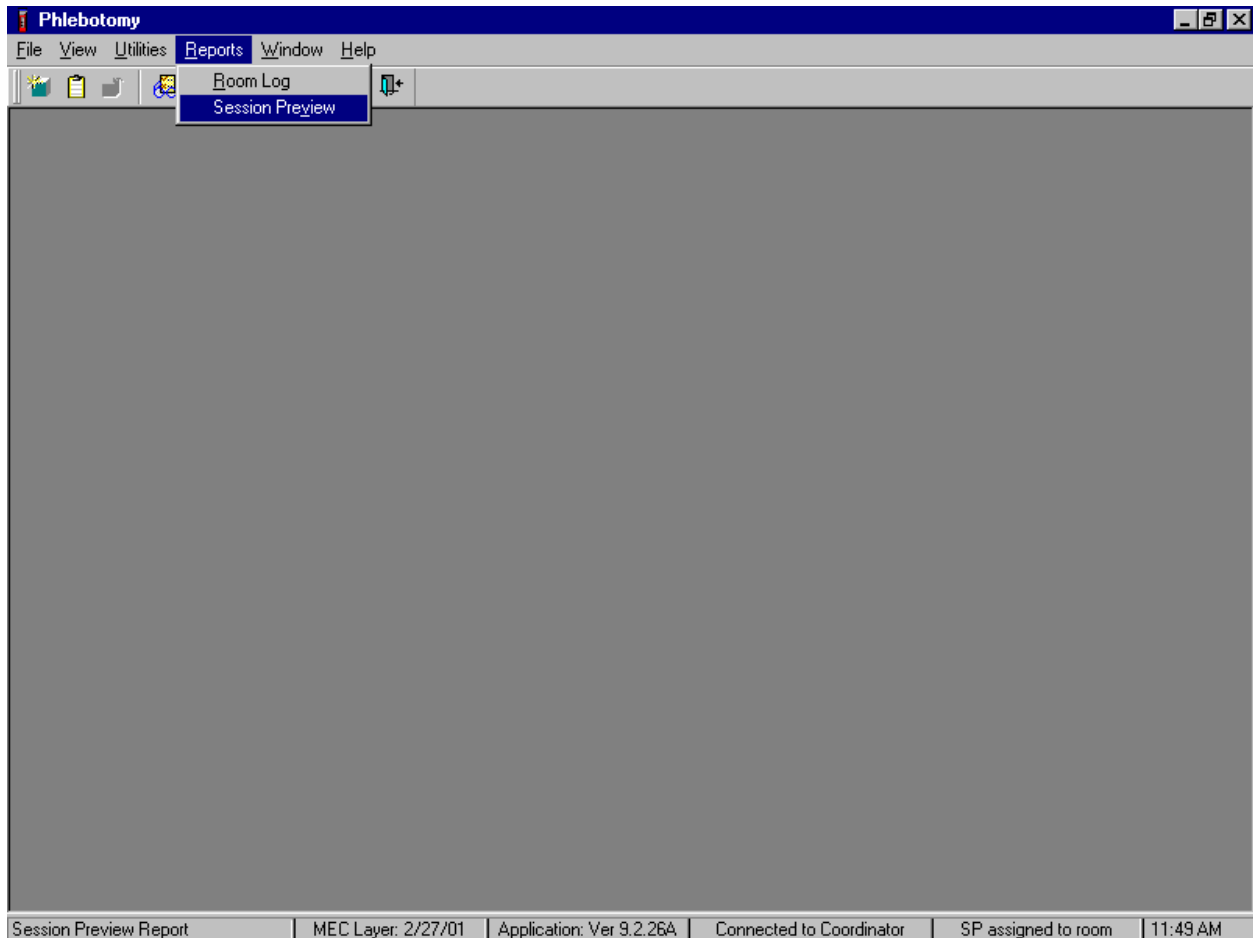
Exhibit A-1. Equipment and supplies - VOC

7-mL gray top blood tubes	Directions for wearing the badge – English
Exposure monitoring badge	Directions for wearing the badge – Spanish
10-mL water collection vessel	Water collection instructions – English/Spanish
50-mL conical tube	Reminder cards – English/Spanish
Small plastic zip sealing bags (VOC water)	Primary SP VOC questionnaire – English
5 place Styrofoam mailer	Primary SP VOC questionnaire – Spanish
3 place Styrofoam mailer	Second exam SP VOC questionnaire – English
Hard-sided cooler	Second exam SP VOC questionnaire – Spanish
12 x 12 plastic bags	Refrigerant gel pack
Refrigerant gel-packs	Cardboard shipper
Empty VOC canisters	Rubber bands
Packing tape	Absorbent pads

At the start of each stand, prepare 50 water collection kits. Enter the current field office telephone number in the blank space on the water collection instructions. Place one 10-mL glass water collection vessel into a 50-mL conical tube. Place the 50-mL conical tube into a zip closable bag and add one hard copy of the instructions for wearing the badge in English or Spanish. Store the collection kits in the phlebotomy cabinet. Discard any remaining water vials at the end of each stand; do not ship them back to the warehouse.

### A.3 Session Preview

Access the Session Preview report to view all SPs scheduled into any session including the current session.

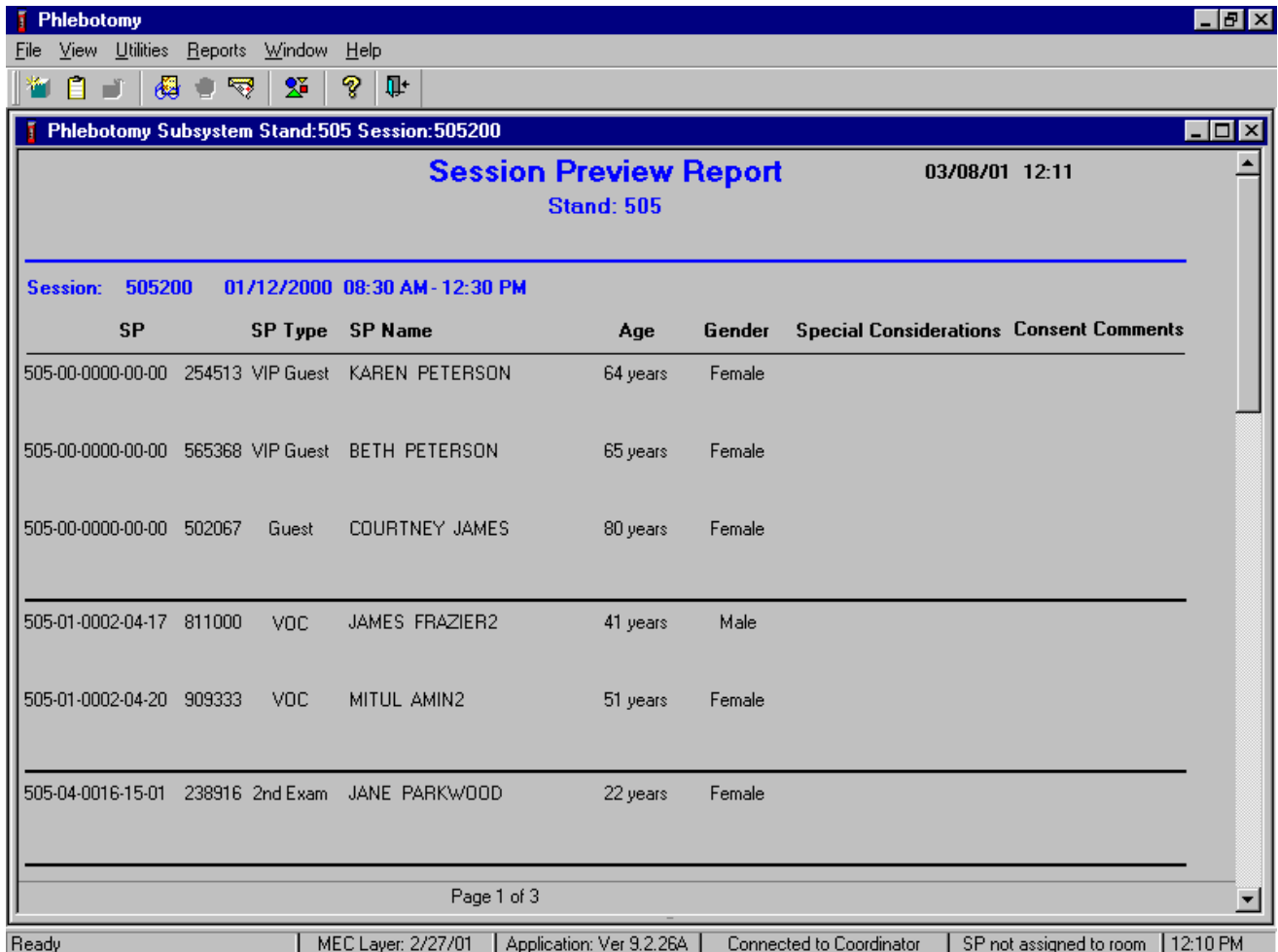


To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Session Preview} and left click, or type [Alt] [R/r], [V/v].

Select the session.

The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to drag the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the  button and left click, or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the  button and left click.

The Session Preview report displays.



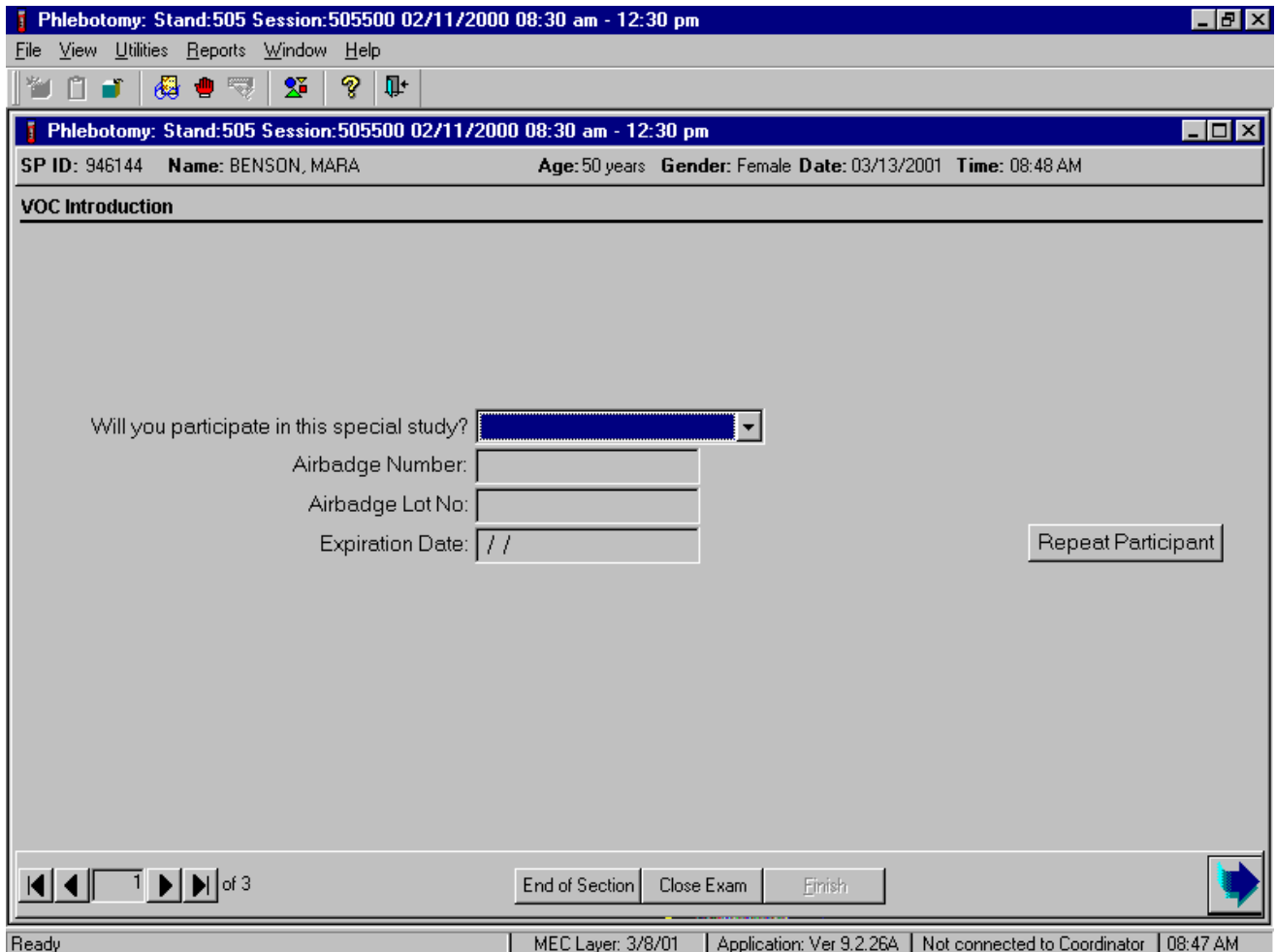
The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any Special Considerations or Consent Comments. A blue asterisk (\*) in front of a name indicates that the SP is eligible for the VOC component. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the \_ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

#### A.4 Recruiting Primary SPs

The MEC phlebotomist is responsible for recruiting a primary SP for the VOC study, recording the recruitment response, SP ID, badge and water lot and expiration dates. The phlebotomist

prints labels for the badge canister, labels and stores the canister, and reviews both the badge and water instructions with the primary SP. It is the MEC interviewer's responsibility to attach the badge to the primary SP as they are leaving the MEC. Always use an exposure badge with a shorter expiration date first.

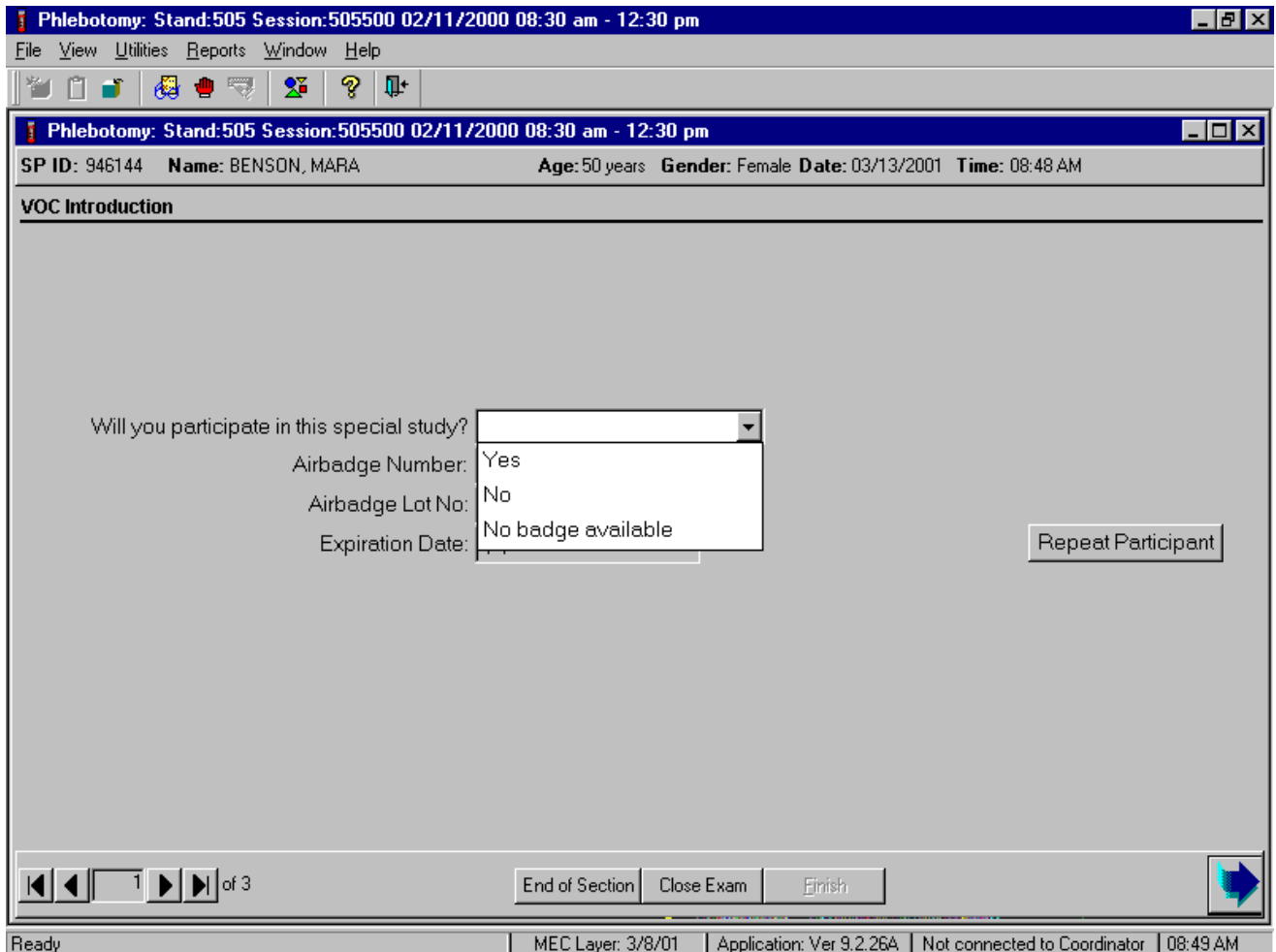
Following the venipuncture, the VOC Introduction window displays for VOC eligible primary SPs.



Personalize the recruitment approach to address each primary SP's specific style. Use language naturally to convey enthusiasm and excitement. Express a positive attitude and explain to the primary SP that the VOC is the next part of their examination. Do not ask the recruitment question, rather state, "I see that you have been selected to participate in the VOC special study." Explain the VOC study as an opportunity for the SP and move forward, making sure, all questions are addressed. Allow the primary SP to refuse, if necessary.

Explain that the primary MEC appointed SP is eligible to receive \$30.00 remuneration when they return to the MEC 46-76 hours later. Explain that the home appointed SP is eligible to receive \$30.00 remuneration when the home examiner conducts the home VOC exam. They receive this amount if they do not refuse the blood draw and the exam is conducted in the SP's home. Second exam SPs are not recruited and are not eligible for any additional remuneration.

Record the response to the recruitment question, "Will you participate in this special study?"



Record the response by typing [Y/y] for "Yes," [N/n] for "No," or [N/n] a second time for "No badge available." Alternatively to record the response, use the mouse to direct the mouse arrow to the drop down arrow on the drop-down list, left click to display the responses, drag the arrow to "Yes," "No," or "No badge available" and left click.

If the recruitment response is "Yes," the following three text boxes are activated.

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM

VOC Introduction

Will you participate in this special study? Yes

Airbadge Number: 946144

Airbadge Lot No: 067815

Expiration Date: 10/31/2002

Repeat Participant

1 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.26A | Not connected to Coordinator | 08:50 AM

Locate the badge lot number and expiration date on the bottom of the canister. Always use an exposure badge with a shorter expiration date first. Record the primary SP's SP ID as the airbadge number and record the badge lot number and expiration date. Type the primary SP's SP ID in the **Airbadge Number:** text box using the keyboard's numeric keys and select [Tab]. Enter the information into the **Airbadge Lot No:** and the **Expiration Date:** boxes using the keyboard. To progress to the appointment (next) window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or press [Enter] when the bright blue arrow is highlighted.



NCHS has established priorities for VOC specimen collection and established guidelines for rescheduling missed VOC appointments.

Scheduling VOC appointments in the MEC and HO (home):

- When the primary SP is recruited, the database captures the start time. The primary SP is eligible to return to the MEC (or have the home examiner conduct a home VOC exam if there are no MEC sessions available) 46-76 hours after recruitment. The MEC phlebotomist must encourage all SPs to return to the first available MEC session at the 46-hour time limit. When there are no MEC sessions, schedule the primary SP into a HO session. When the primary SP refuses to commit to either appointment, leave the session date field blank. The field office staff or the home examiner will contact the SP to schedule the exam. The MEC phlebotomist gives the SP a reminder card that lists the SP's return location, date, and time.
- The phlebotomy application actually displays all MEC and HO sessions that start after a 44-hour time limit and before the 76-hour time limit. SPs actual return appointments are scheduled two hours after the start of the session so the actual exposure time should be 46 and not 44 hours.

Priorities and collecting specimens in the MEC and HO:

- When the primary SP returns to the MEC, attempt to collect the blood, badge, water, and administer the questionnaire. When conducting a VOC home exam attempt to collect the blood, badge, water, and administer the questionnaire.
- If the SP does not return to the MEC (no show) and the 76-hour time frame has not expired the field office staff attempts to contact the SP to reschedule the SP into another MEC session or to schedule the exam in the SP's home.

Rescheduling missed appointments and collecting specimens beyond the 76-hour window or collecting specimens with exposure times less than 46 hours:

- NCHS has determined that, if a primary SP does not show up for the VOC appointment and the 76-hour time frame has expired, the badge is no longer useful, and should not be collected. If the primary SP provides a badge and the 76-hour time frame has expired, dispose of the badge (outside the presence of the SP). Likewise, NCHS has determined that the time and effort involved with rescheduling no-show primary SPs to collect the water and administer the questionnaire after the 76 hour time frame has expired will not produce useful data. Therefore, NCHS does not recommend rescheduling no-show return primary SPs to the MEC or conducting a VOC home exam after the 76-hour time frame has expired.
- NCHS has determined that specimens (badge, blood and/or water) collected before the 46-hour exposure window will not produce useful data. Do not collect specimens when the exposure time is less than 46 hours. Do not administer the VOC questionnaire to primary SPs when the exposure time is less than 46 hours.

Schedule the VOC return visit appointment.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar with various icons. Below the toolbar, a header bar displays patient information: "SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM". The main content area is titled "Appointments" and contains the text: "I now need to make an appointment for you two days from now to have the results of this test read." Below this text, a section titled "Household Members in This Session:" contains a table with the following data:

SP Name	Age	VOC	Session Date	Start Time	Reason
MARA BENSON	50 y Y				

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow icon. The status bar at the very bottom shows "Ready", "MEC Layer: 3/8/01", "Application: Ver 9.2.26A", "Not connected to Coordinator", and "08:51 AM".

To view the available MEC and HO sessions for the return appointment, use the mouse to direct the mouse arrow to the drop-down list and left click to display MEC sessions for which the primary SP is eligible to return to have the additional blood drawn and the water and badge collected.

Review the appointment choices.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm". The patient information is: SP ID: 946144, Name: BENSON, MARA, Age: 50 years, Gender: Female, Date: 03/13/2001, Time: 08:48 AM. The "Appointments" section contains the text: "I now need to make an appointment for you two days from now to have the results of this test read." Below this, a table lists household members in the session. A dropdown menu is open for the first member, MARA BENSON, showing the following appointment options:

SP Name	Age	VOC	Session Date	Start Time	Reason
MARA BENSON	50 y	Y			

Appointment options for MARA BENSON:

- HO 2/13/00 08:30 AM
- MEC 2/13/00 10:30 AM
- MEC 2/13/00 03:30 PM
- MEC 2/13/00 07:30 PM
- HO 2/14/00 08:30 AM

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows: "Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.26A | Not connected to Coordinator | 08:51 AM".

Primary SPs are eligible for return appointments 46-76 hours after they were recruited. Only sessions that fall within this time frame are displayed. MEC appointment times are adjusted so that they begin 2 hours after the start of a MEC session. Returning primary VOC SPs should arrive at the MEC after a routine MEC session is underway.

Post a copy of the home examiner's stand calendar in the phlebotomy room. Use this calendar to schedule SPs into MEC or home (HO) sessions. Schedule SPs into home sessions (HO) only on days indicated as VOC/HE on the calendar. The home examiner contacts SPs appointed into home sessions and schedules the exam.

	Feb 25	Feb 26	Feb 27	Feb 28	Mar 1	Mar 2	Mar 3
<b>Home examiner</b>	X	X	VOC/HE	NO HAD/OFF	X Off		X
Morning	AM	AM			AM *ACD	AM	AM
Afternoon	PM	Ship/*ACD	Off	Off		PM	PM
Evening		EVE			EVE		
	Mar 4	Mar 5	Mar 6	Mar 7	Mar 8	Mar 9	Mar 10
<b>Home examiner</b>	X	X					
Morning	AM	AM *ACD	Ship/*ACD				
Afternoon	PM		Teardown	Off	Off	Travel	Travel
Evening		EVE					

**Calendar key:**

**X** = VOC exams in the MEC

**NO HAD/OFF** = Close the home all day session (home examiner is off)

**Off** = Close the home all day session (home examiner is off)

**VOC/HE** = Home examiner conducts home VOC exams 11-8 and/or home exams

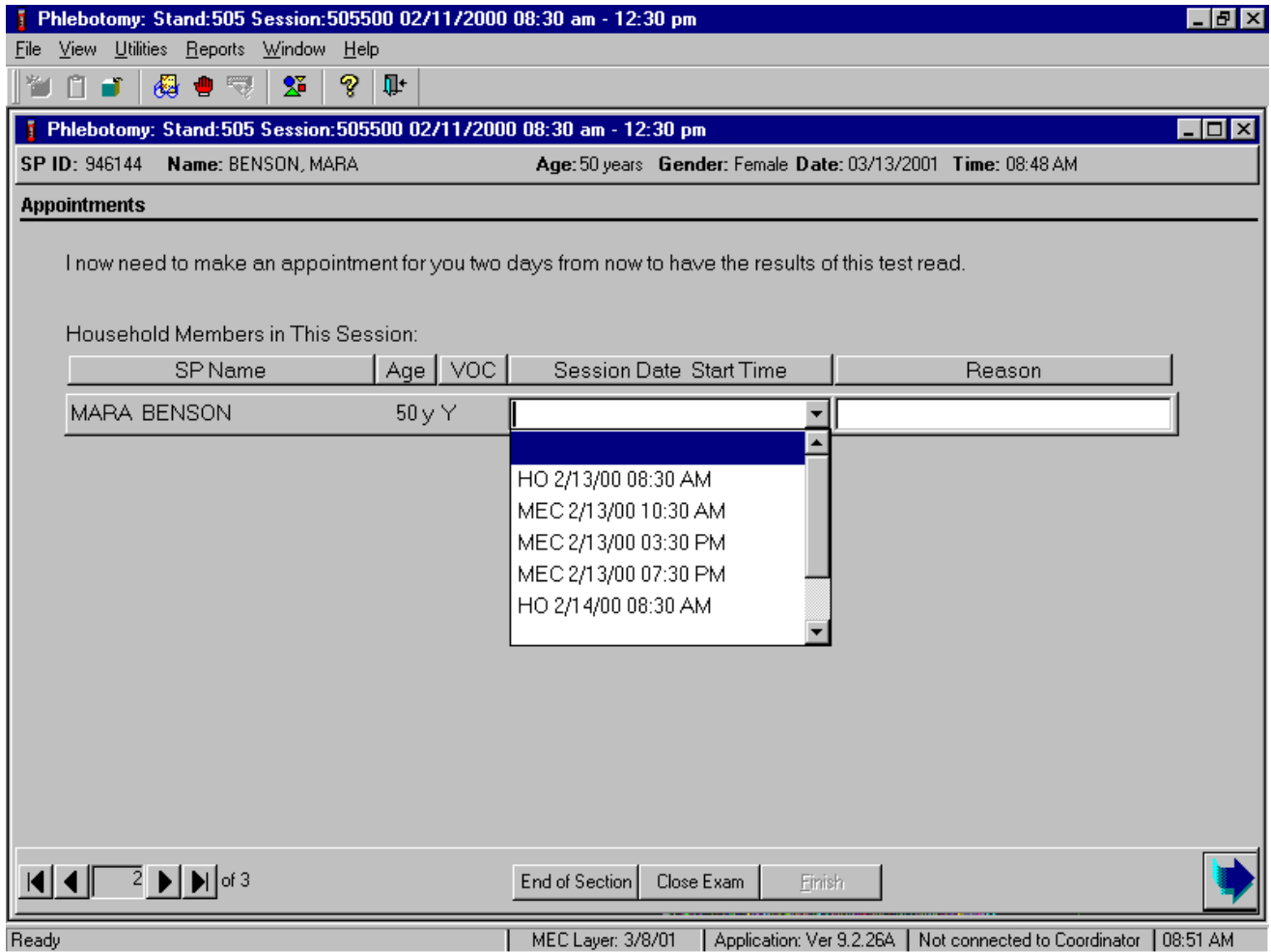
**Do not recruit VOC** = MEC phlebotomist does not recruit SP during the last 2 days at each stand

**Ship** = The lab ships all specimens from the MEC to the contract labs weekly

**\*ACD** = The lab ships the special ACD blood tube to the genetics laboratory twice per week

The home examiner does not have the same 2 days off as the MEC staff; one of their 2 days off is the same as the MEC staff but the second day off is different. The laboratory shipping schedule is also included in these calendars.

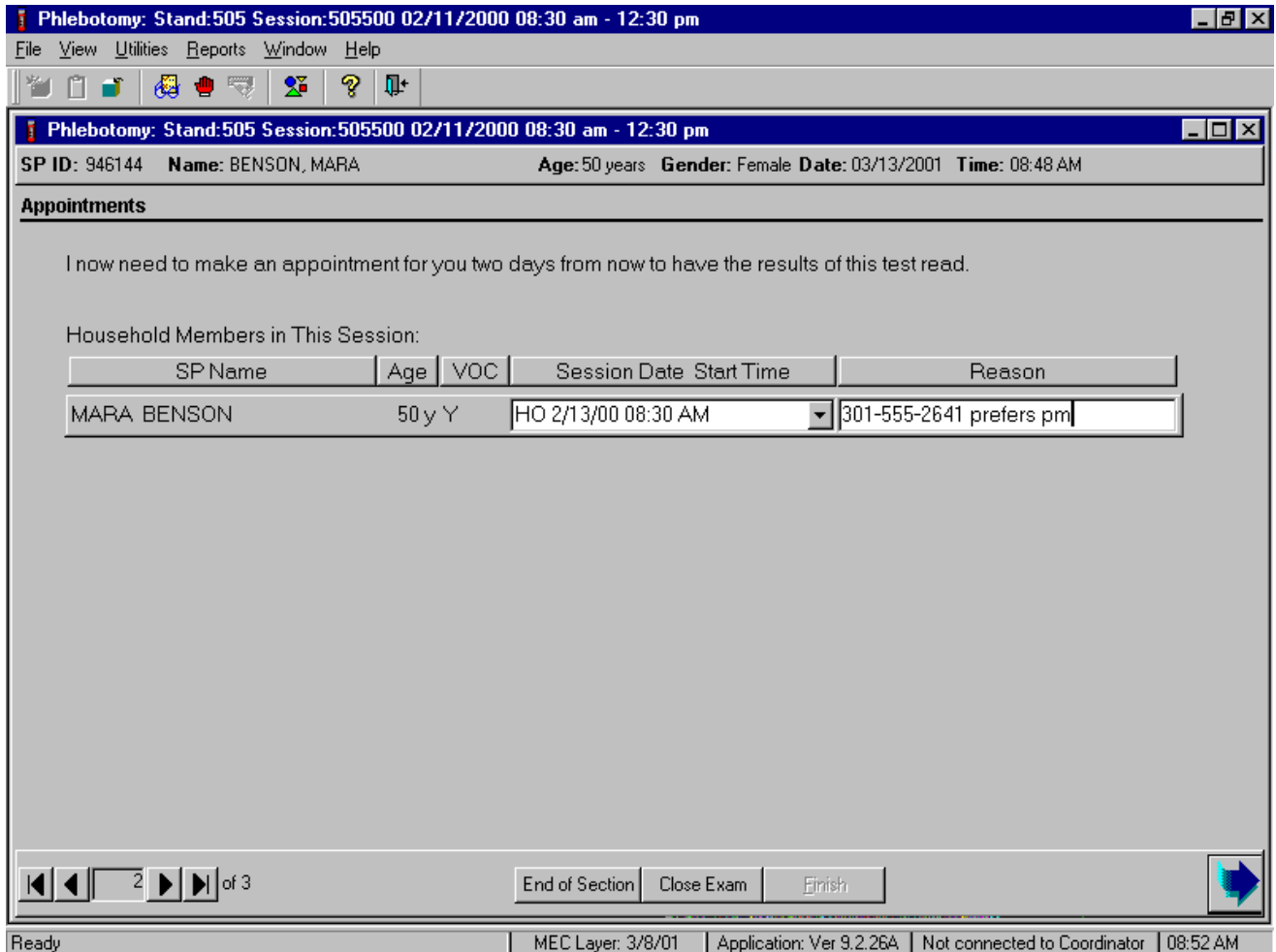
Select a specific MEC or HO session.



To select or highlight a specific MEC or HO session, use the mouse to drag the mouse arrow to the desired choice, and left click. The MEC date and time are inserted into the appointment text box.

Verbally verify the SP's telephone numbers. Enter this number in the "reason" text box on the Appointment screen. Verbally ask the SP to state when they are generally available or ask them for a preferred exam time and enter this information in the "Reason" text box. Enter:

- "am" for times from 8:00 AM to 12:00 PM
- "pm" for times from 12:00 PM to 5:00 PM
- "eve" for times from 5:00 PM to 8:00 PM



The home examiner uses this information if the SP does not show up for their scheduled MEC appointment. Attach specific reasons to an appointment, when necessary.

Write the appointment date and time on the bottom of the VOC reminder card and review this information with the SP. If this is a VOC home exam, explain to the SP that the home examiner will contact them to set up a specific time on this date. Write the date in the space provided on the reminder card.

<b>National Health and Nutrition Examination Survey</b>	
<b>VOC Return Appointment Reminder</b>	
Thank you for participating in the VOC (volatile organic compound) portion of the study. Please remember to wear your badge as instructed by the health study representative and bring the water vial with you when you return. Your return appointment is scheduled:	
<input type="checkbox"/> <b>At this medical exam center</b>	
Date _____	Time _____
<input type="checkbox"/> <b>At your home</b>	
Date _____	
The home health examiner will contact you to set up an appointment time.	
_____	

Store the reminder card with the SP's canister and water vial.

Review the examination status of the VOC section of the phlebotomy examination.

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM

VOC status

Status

Complete  
 Partial  
 Not Done

Comments

Other text

3 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.26A | Not connected to Coordinator | 08:53 AM

The VOC status is complete if the primary SP was successfully recruited and not done if the primary SP was not recruited. To complete a successful VOC recruitment on a primary SP, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted.

Review the water collection instructions (Exhibit A-2), instructions for wearing the badge and the activity log (Exhibits A-3 - English or A-4 – Spanish) with the primary SP. Use a demonstration badge to address any specific concerns that the primary SP may have.



Exhibit A-2. Water collection instructions – English and Spanish

**Water Collection Instructions**  
(To be given to each SP with the glass tube.)

Instructions for collecting tap water sample:

1. Collect the water sample from the bathtub or an outside faucet ONLY.
2. Turn on the cold water.
3. Let the cold water run for 3 minutes.
4. Unscrew the red top cap.
5. Take the glass tube out of the plastic container.
6. 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.)
7. Fill the tube with water until it overflows.
8. Screw the black cap tightly on the tube.
9. Turn the tube upside down to make sure it does not leak. (If the tube does leak, empty it and refill.)
10. Put the glass tube back into the plastic container with the black cap toward the top.
11. Screw the red top cap tightly onto the plastic container.
12. Bring the water sample with you when you return to the examination trailer.

Call the Field Office at \_\_\_\_\_ if you have questions.

**Water Collection Instructions**  
(To be given to each SP with the glass tube.)

Instrucciones para recolectar la muestra de agua de la llave:

1. Tome la muestra de agua de la (bañadera/bañera/tina) o de una llave de afuera SOLAMENTE.
2. Abra la llave del agua fría.
3. Deje que el agua fría corra por 3 minutos.
4. Destornille la tapa roja.
5. Saque el tubo de vidrio del envase plástico.
6. Saque la tapa negra del tubo de vidrio. (Si la cubierta blanca de la tapa se sale, póngala nuevamente en el interior de la tapa. El lado brillante debe quedar a la vista.)
7. Llène el tubo con agua hasta que se derrame.
8. Atornille bien apretada la tapa negra al tubo.
9. Dé vuelta el tubo al revés para asegurarse que no se sale. (Si el tubo gotea, vacíelo y llénelo nuevamente.)
10. Ponga el tubo de vidrio nuevamente dentro del envase de plástico con la tapa negra hacia arriba.
11. Atornille la tapa con la superficie roja bien apretada sobre el envase de plástico.
12. Traiga la muestra de agua cuando vuelva al centro móvil de examen.

Llame al centro de operaciones en \_\_\_\_\_ si desea hacer alguna pregunta.

**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY**

**DIRECTIONS FOR WEARING EXPOSURE BADGES**

- We would like you to use the exposure badge continuously from the time you leave the Mobile Examination Center until you either return to the MEC in 2 or 3 days or the home examiner collects the badge from you.
- Wear the exposure badge as you would wear a name tag -- attached to your clothing in the area of your upper chest. Make sure the white membrane is facing outward and try not to touch the white membrane.
- Wear the exposure badge on your outermost layer of clothing. For example, if you start out wearing a shirt and have the badge attached to your shirt and then put on a jacket, remove the badge and place it so it is attached to the jacket.
- Place the exposure badge on a bedside table or clipped to a nearby lampshade while you are sleeping. Make sure the white membrane is exposed to the air.
- When taking a shower or a bath, leave the exposure badge in another room. The steam from the hot shower or bath may cause the badge to not work properly. A good place to leave the badge might be the same place you leave it while you are sleeping.
- When you return the badge, we will ask you some questions about the amount of time that you spent indoors both at home and at work or school and we will ask you about the amount of time you spent outdoors. Please use the Activity Log on the reverse side to help you remember where you have been during the time you are wearing the exposure badge. You may also wish to keep notes in the space on the reverse side.

(See other side of page.)

You may use the Activity Log to mark hours spent indoors at home, indoors at work or school, and outdoors, and in other places (for example, in a vehicle) for each day that you use the exposure badge.

Activity Log																
	Day 1				Day 2				Day 3				Day 4			
	Indoors (home)	Indoors (work/school)	Outdoors	Other	Indoors (home)	Indoors (work/school)	Outdoors	Other	Indoors (home)	Indoors (work/school)	Outdoors	Other	Indoors (home)	Indoors (work/school)	Outdoors	Other
TIME																
12:00																
Midnight																
1:00 am																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 am																
12:00 Noon																
1:00 pm																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 pm																

**NOTES:**

## **ENCUESTA NACIONAL DE EXAMEN DE SALUD Y NUTRICIÓN**

### **INSTRUCCIONES PARA USAR LAS CAJAS DE EXPOSICIÓN**

- Quisiéramos que usara la pequeña caja de exposición continuamente desde el momento en que sale del Centro Móvil de Examen hasta que vuelva al CME en dos o tres días o el examinador en el hogar pase a pedirle la caja de exposición.
- Use la caja de exposición de la misma manera que usted usaría una etiqueta de identificación -- sujeta a su ropa en la parte superior del pecho. Asegúrese de que la membrana blanca quede hacia afuera y trate de no tocar la membrana blanca.
- Use la caja de exposición en su ropa más externa. Por ejemplo, si usted empieza con una camisa y tiene la caja sujeta a la camisa y luego se pone una chaqueta, quítese la caja y póngala en la chaqueta.
- Ponga la caja de exposición en una mesa de noche al lado de la cama o sujétela a una pantalla de lámpara cercana mientras está durmiendo. Asegúrese de que la membrana blanca esté expuesta al aire.
- Cuando esté dándose una ducha o baño, deje la caja de exposición en otra habitación. El vapor de la ducha o del baño caliente puede causar que la caja no funcione apropiadamente. Un buen lugar para dejar la caja podría ser el mismo lugar en que la deja mientras duerme.
- Cuando devuelva la caja, le haremos algunas preguntas acerca de la cantidad de tiempo que usted pasó adentro, tanto en la casa como el trabajo o la escuela, y le preguntaremos acerca de la cantidad de tiempo que pasó afuera. Por favor use el Registro de Actividades que aparece en el reverso para ayudarse a recordar dónde ha estado durante el tiempo que estaba usando la caja de exposición. Posiblemente también quiera hacer anotaciones en el espacio al reverso.

(Mire el otro lado de la página)

- Usted puede usar el Registro de Actividades para marcar las horas pasadas adentro de la casa, adentro en el trabajo o la escuela, afuera, y en otros lugares (por ejemplo, en un vehículo) para cada día que use la caja de exposición.

*Registro de Actividades*

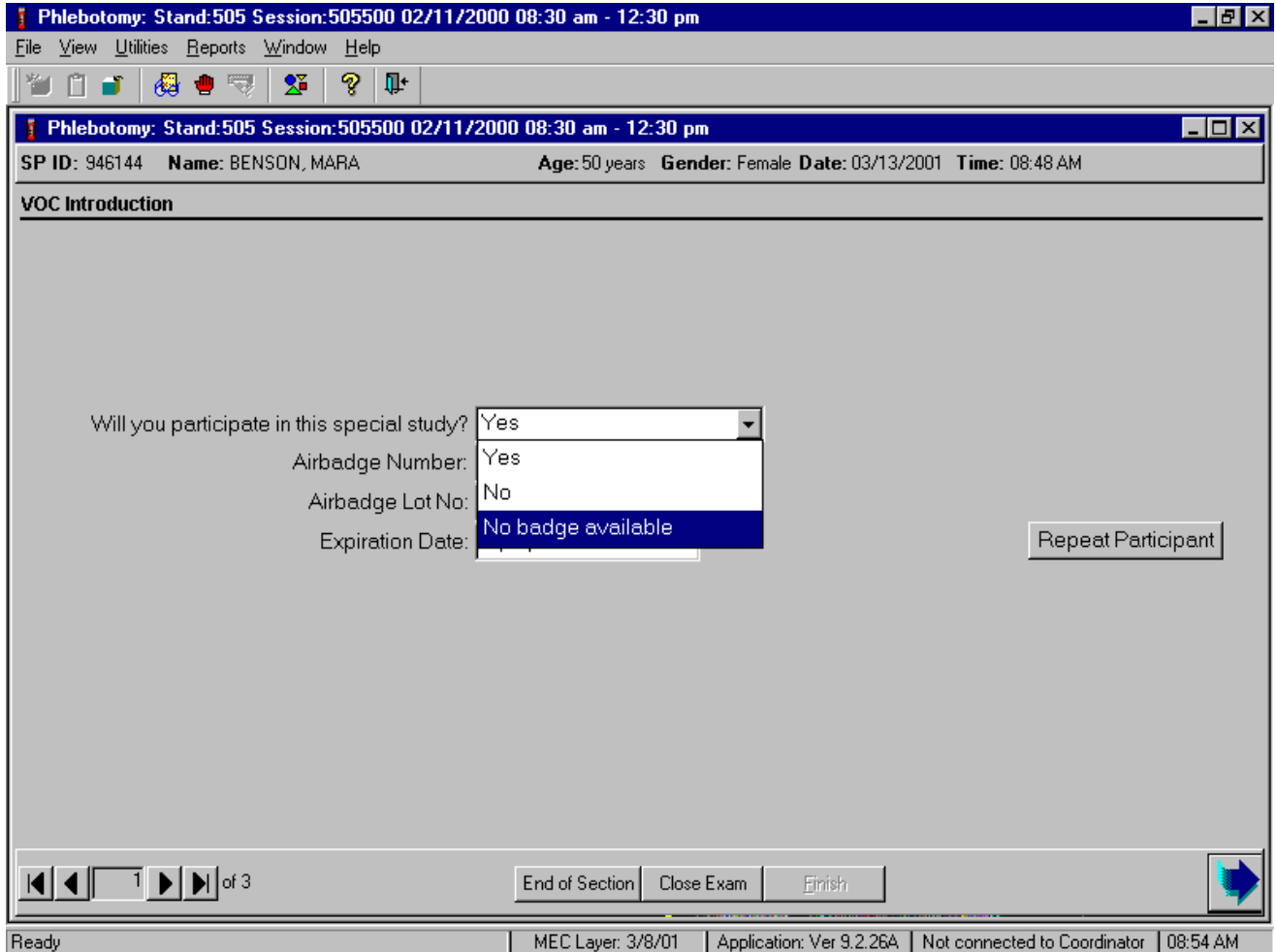
HORA	Día 1				Día 2				Día 3				Día 4			
	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro	Adentro (casa)	Adentro (trabajo/escuela)	Afuera	Otro
12:00 Medianoche																
1:00 am Mañana																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00																
8:00																
9:00																
10:00																
11:00 am																
12:00 Mediodía																
1:00 pm Tarde																
2:00																
3:00																
4:00																
5:00																
6:00																
7:00 Noche																
8:00																
9:00																
10:00																
11:00 pm Noche																

**NOTAS:**

Escort the recruited primary SP to the coordinator or to the next component. Store the appointment reminder card, canister and instructions, and the water vial and instructions with the primary SP's clothes. When the primary SP is ready to leave the MEC they change back into their street clothes, attach the badge with the assistance of the MEC interviewer, and take home the water collection kit and directions for wearing the exposure badge. Finally, remind the primary SP to please remember to bring the badge and the water sample when they return to the MEC.

Do not discard the empty canister. Store the unlabeled empty canister in the cabinet above the phlebotomy computer terminal. Use this canister when the primary SP returns 46-76 hours later. If the primary SP does not return for their scheduled MEC or HO appointment, recycle the empty canister.

The phlebotomist is responsible for checking the availability of badges before the start of the stand. If no badges are available, do not attempt to recruit the primary SP. Enter "No badges available" in the "Will you participate in this special study?" response text box. Proceed to the next window.



If there are no badges available, record this information by typing [N/n] for "No badge available." Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, drag the arrow to "No badge available," and left click. The Airbadge Number, Airbadge Lot No, and Expiration Date boxes remain grayed out. Only badges with an expiration date of "today" or earlier are eligible for use.

Attempt refusal conversion on all primary VOC eligible primary SPs.

Try to convert all primary SPs who provided a negative response to the recruitment question. Use the following information or "talking points" to convert primary SPs.

*Component:* Volatile Organic Compounds (VOC)  
*Who Examined:* Selected participants ages 20-59  
*Examination:* An air monitoring badge, worn by the participant for 46 - 76 hours  
A water sample  
A blood sample  
*Results:* Reported only if levels are high  
*Why we do this:*

1. There are chemicals and pollutants in the air we breathe every day. Since many of these chemicals have no odor or color, we do not know they are there. Some of these chemicals are known or thought to cause health problems. In 1990, the Clear Air Act Amendment required the government to take a closer look at these hazardous air pollutants.
2. For this test, we are interested in a group of chemicals called volatile organic compounds, or VOCs. They are commonly used in the manufacture of many household items and things we use every day. Some examples of products that contain VOCs are: household cleaners, furniture polish, gasoline, hair spray, nail polish and remover, air fresheners, mothballs, and paint.
3. We have very little information on the levels of VOCs in the air that we breathe. Our survey is the first time that national levels are being collected to measure how much of these chemicals people are exposed to. We expect that the levels of these chemicals will be low, but need to collect information to determine what the true levels are. From the information collected, we will be able to describe what the levels are in the U.S. and compare them with high levels from places like waste sites and factories.
4. If you are selected to be part of this test, you will be asked to wear a small air-monitoring badge for 46 - 76 hours. When you come back to have your TB reading, you should bring a sample of water from your home. At that time, we will collect the badge, and take a small blood sample. We will ask you about some of your activities during the time that you wore the badge. There are no harmful chemicals in the badges that can affect you or any people in your household.
5. This is an important test because it is not currently known how much of these chemicals are in the air that people breathe. You will be part of the first nationwide residential group to have these measurements done.



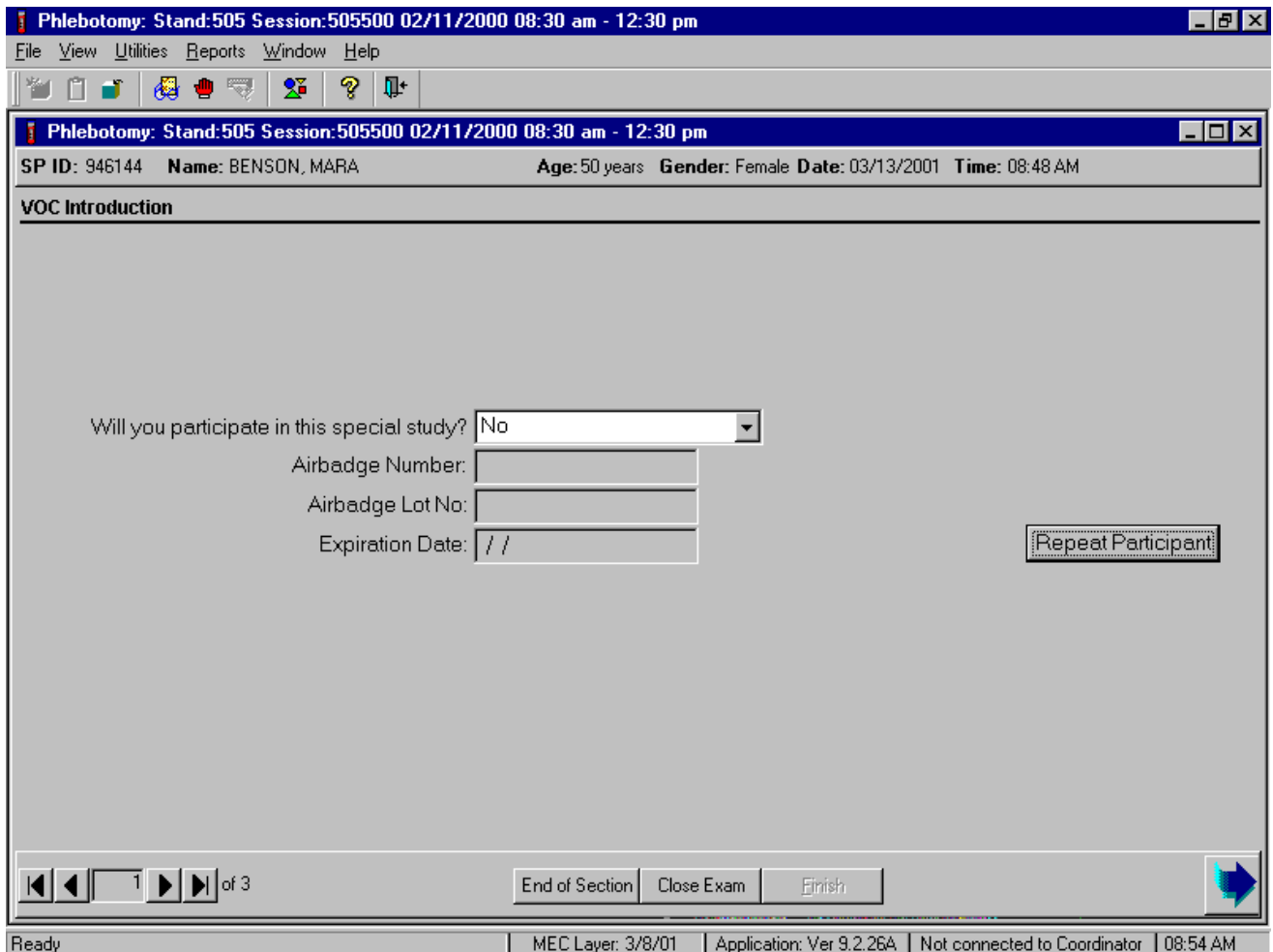
In addition, use the following information to convert primary SPs.

- This is the only opportunity you will have to join this special study group. I would like to include you as a volunteer.
- This research is sponsored by The Mickey Leland National Urban Air Toxics Research Center (NUATRC), located in the Texas Medical Center. The NUATRC was authorized by the U.S. Congress in the Clean Air Act Amendments of 1990, and incorporated in 1991. It is named after the late Congressman Mickey Leland, whose efforts on behalf of public health contributed significantly to the passage of key amendments to the Clean Air Act.
- The NUATRC is a research facility that has been specifically charged to sponsor and gather scientific information on the human health effects caused by exposure to air toxics. By law, it is a nonprofit corporation, financed by government and private funds.
- As established by law, the NUATRC is governed by a nine-member Board of Directors, and receives scientific guidance from a nationally based thirteen-member Scientific Advisory Panel.
- The primary research mission of the NUATRC is to contribute meaningful and relevant data to the peer-reviewed scientific literature on the potential human health effects of air toxics. NUATRC views this mission as a fundamental component in the national regulatory effort to develop cost-effective and balanced regulations to protect the public from the potential risk from air toxics. NUATRC believes that the participation of all segments of our society is critical to the success of this effort. This includes Federal, state, and local governments, private sector representatives, and public interest organizations. NUATRC has determined that it will be able to effectively meet its mission by pursuing research activities not being adequately addressed by other organizations and which will contribute data relevant to the national understanding of the human health effects of air toxics. Thus, at this time NUATRC has decided to focus on the following research areas.
  1. Noncancer health effects, primarily those affecting the human respiratory and immune systems; and
  2. Determination of actual human exposures to air toxics in urban environments.
- This study is an epidemiologic data analysis of a population-based study of personal exposures to volatile organic compounds among a subset of participants in a statistically designed national survey.
- The NUATRC is collaborating with the National Center for Health Statistics (NCHS) on a study to collect environmental exposure data for a subset of the US population, as part of a comprehensive nationally based health study.
- The 1,000 participants in this 3-year study constitute a subset of approximately 15,000 subjects selected by NCHS for a national survey of the residential U.S. population for whom household and health status data are collected and physical examinations are

performed. The purpose of the national survey is to obtain nationally representative data on the health and nutritional status of the population.

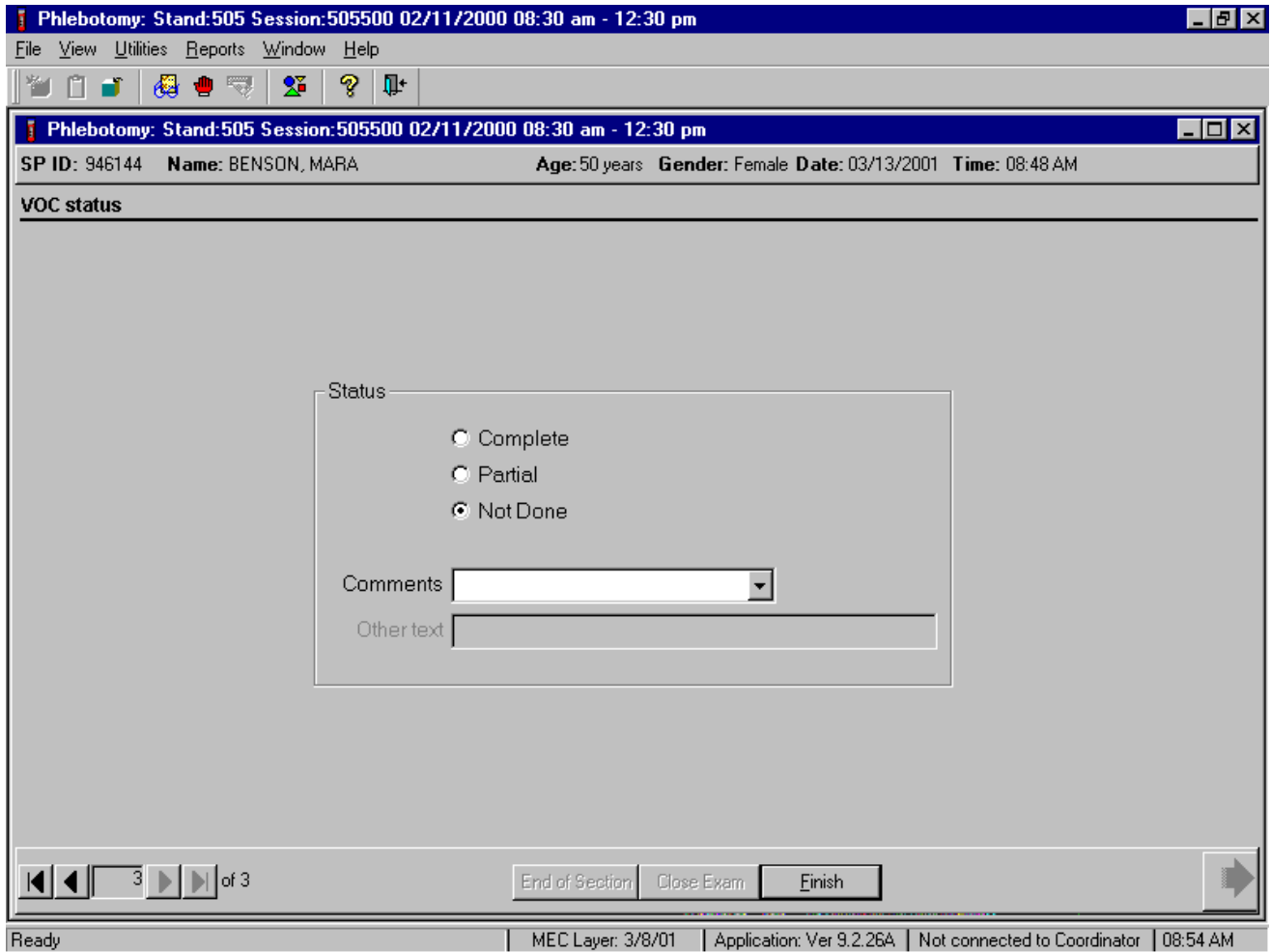
- The 1,000 subjects in the collaborative NCHS-NUATRC study are selected to be a representative subset of the larger study population. Thus, they will provide household and personal data about themselves to the survey regarding socioeconomic, behavioral, demographic, and occupational factors.
- The primary aims of the study are:
  1. To characterize the distribution of exposures to selected VOCs within a subpopulation;
  2. To examine the relationship between personal exposures to the VOCs and socio-economic, behavioral, demographic, and occupational characteristics;
  3. To investigate possible associations between personal exposures to VOCs and some selected indicators of health status for which data are collected as part of the larger study; and
  4. To investigate the relationships between local sources of VOCs in subject communities (such as industrial emissions) and personal exposures using available data.
- The purpose of the analysis will be to assess the 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. It is known that an individual's exposure to any form of air pollution is affected by the indoor and outdoor environment, as well as by factors that are related to lifestyle (socioeconomic, behavioral, demographic, and occupational).
- Associations of VOC 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 elucidate any patterns which are consistent with published studies of health outcomes.

If the recruitment is unsuccessful, record the negative response as "No" in the "Will you participate in this special study?" text box.



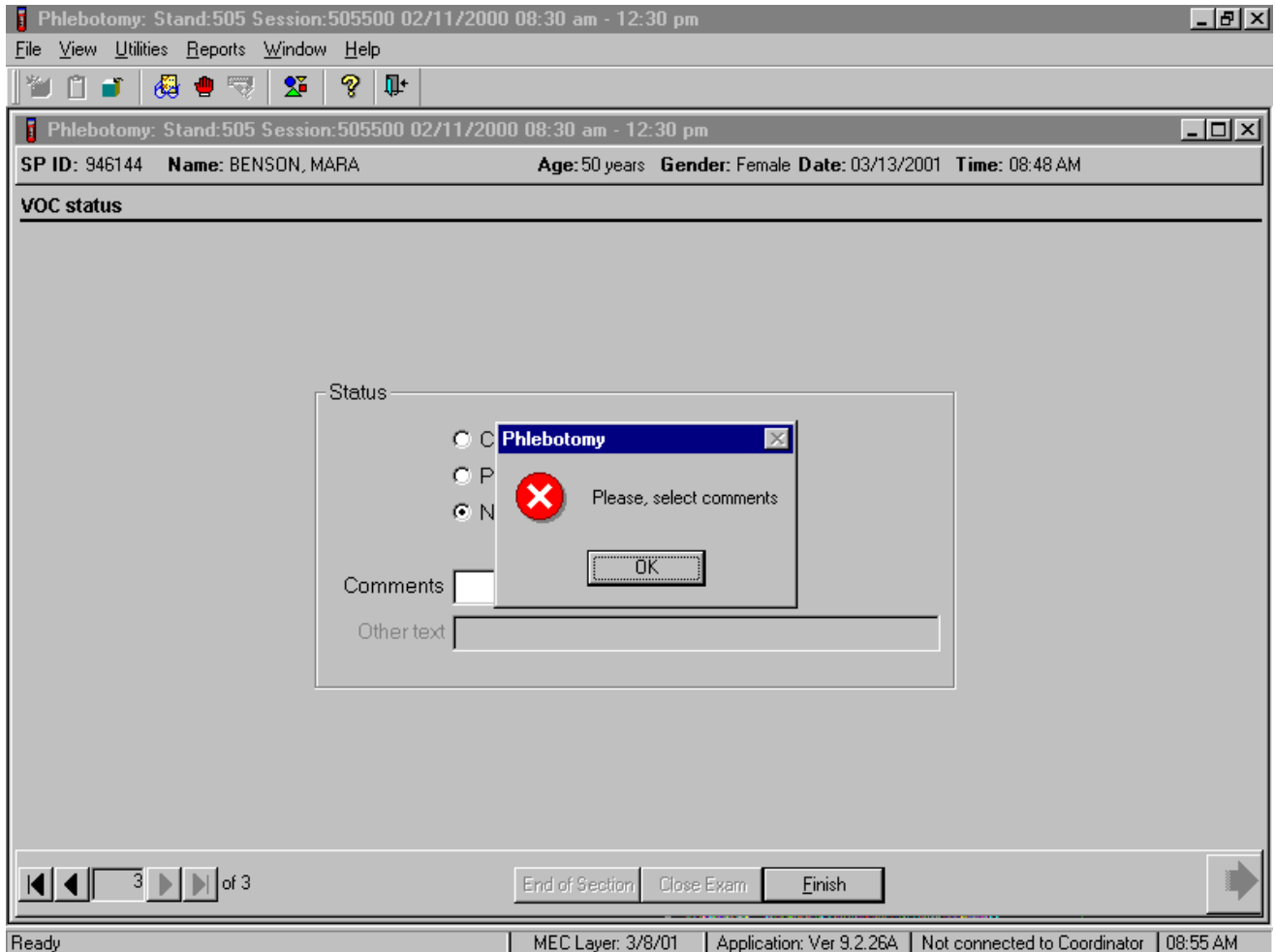
Record the "No" response by typing [N/n]. Alternatively, to record a negative response, use the mouse to direct the mouse arrow to the drop down arrow on the drop-down list, left click to display the responses, drag the arrow to "No" and left click. The Airbadge Number, Airbadge Lot No, and Expiration Date boxes remain grayed out. To progress to the next window, use the mouse to direct the mouse arrow to the bright blue right arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Review the examination status of the VOC section of the phlebotomy examination.



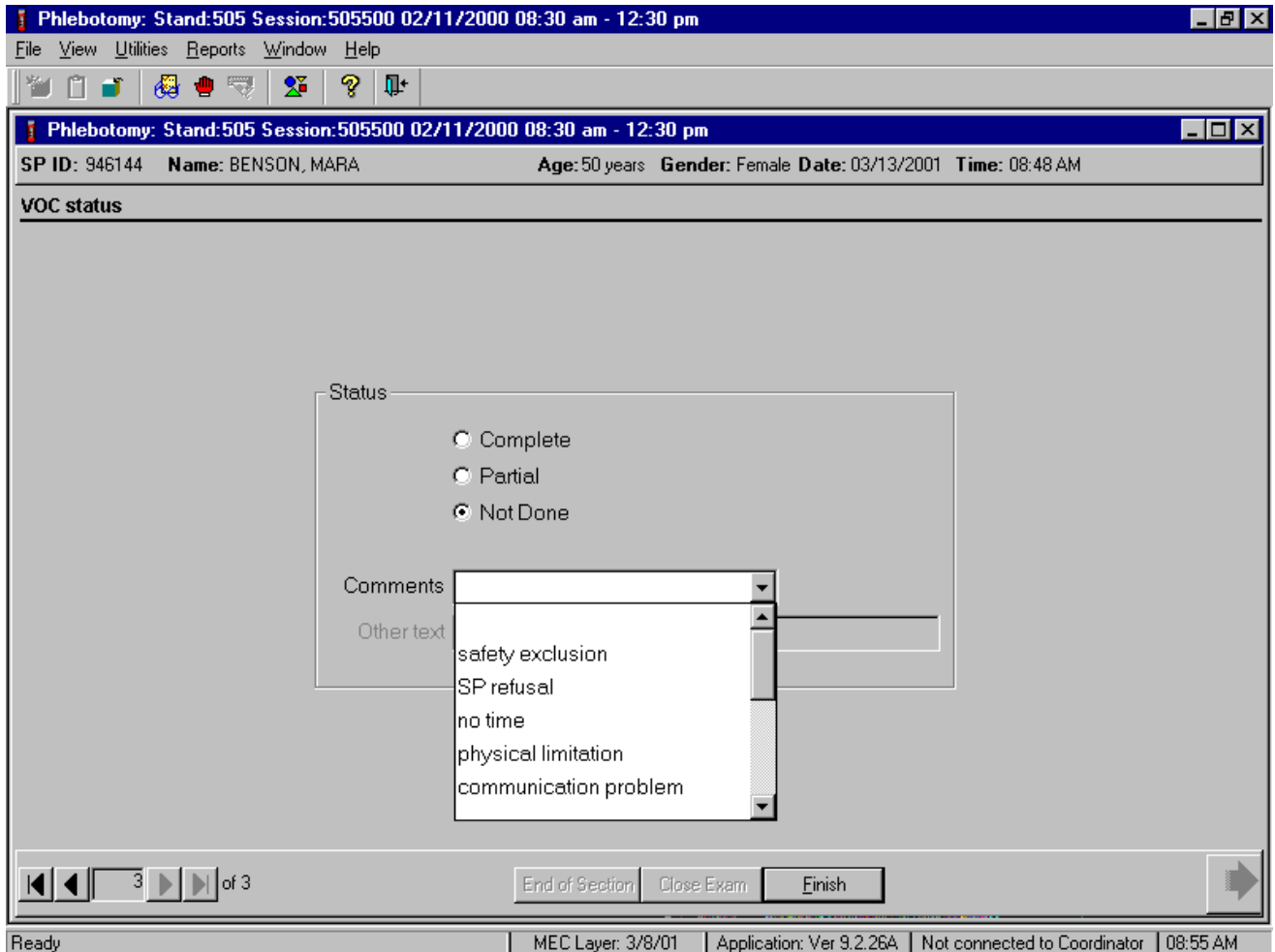
The VOC status is Not Done if the SP was not recruited. Use mandatory comments to explain the not done status.

An error message text box displays if a comment is not selected.



A Not Done VOC exam status requires a comment. If [Enter] is selected before a comment has been entered, an error message text box displays. To remove this window, use the mouse to direct the mouse arrow to the **OK** button and left click. Enter the comment.

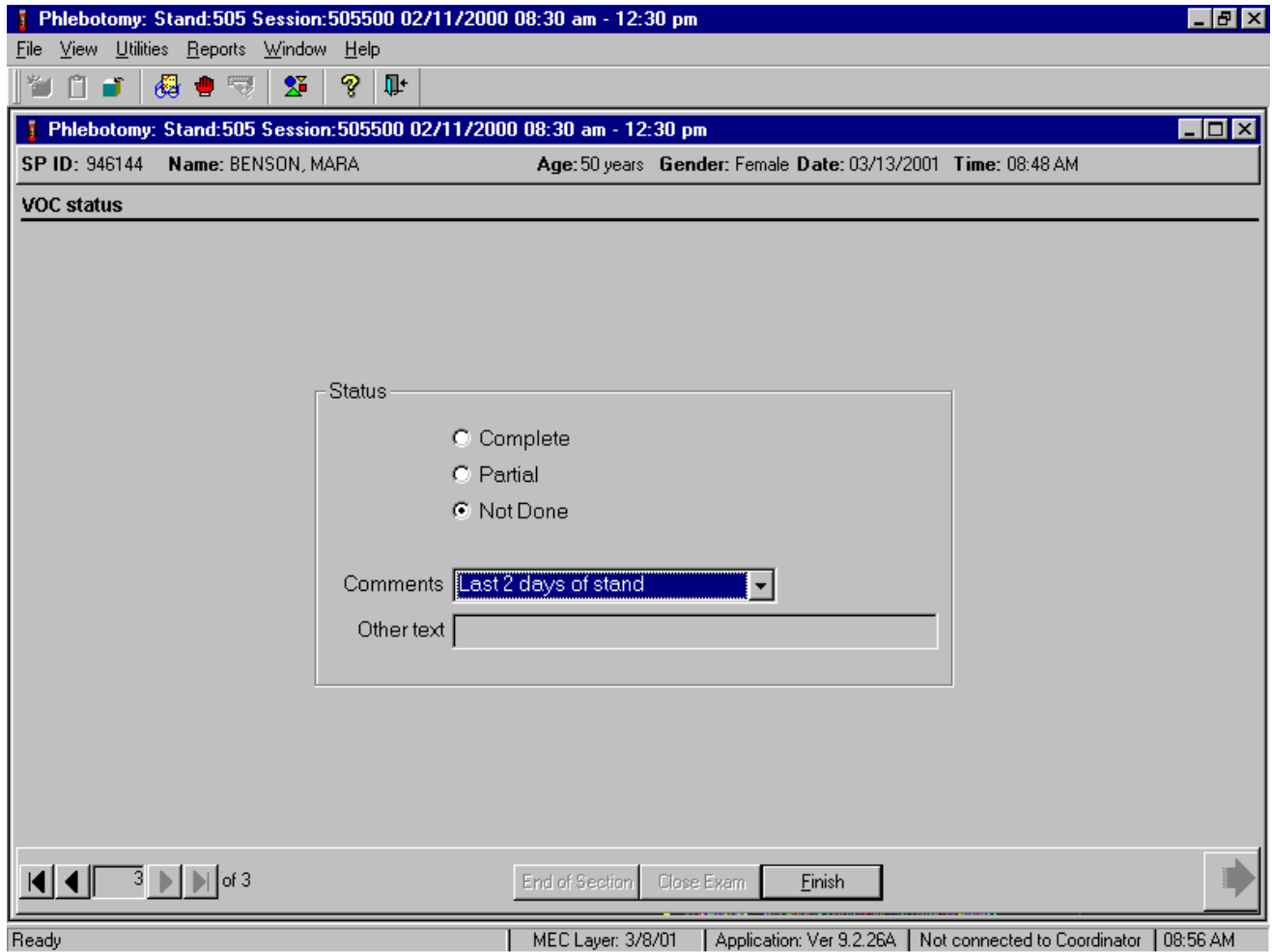
Enter a comment for all primary VOC exams with a Not Done section status.



Choose and enter the appropriate comment code when the VOC section status is Not Done. To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice, and left click. Be sure to view all choices by using the scroll bar on the right side of the drop-down list. Alternatively, to select a comment, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code. When the correct choice is highlighted, left click.

Comment Code	Use when:
Safety exclusion	Not applicable; <i>Application should code these</i>
SP refusal	The primary SP refuses to participate in the special study or wear the badge. This is SP initiated nonresponse due to refusal. The primary SP refuses the component.
No time	Not applicable; <i>Coordinator should code these</i>
Physical limitation	Not applicable
Communication problem	Not applicable; <i>Coordinator should code these</i>
Equipment failure	Not applicable; <i>Data manager should code these</i>
SP ill/emergency	The primary SP became ill or an emergency occurred and the test could not be performed on the primary SP
Interrupted	Not applicable; <i>Coordinator should code these</i>
Error (technician/software/supplies)	The phlebotomist creates a human error, the software malfunctions or supplies affect the ability to complete the exam
SP Out of town next 48 hours	The SP is out of town the next 48 hours
Last 2 days of stand	It is the last 2 days of a stand
SP not staying in primary residence	The SP is not staying in their primary residence for the next 2 days
Other, specify	Choose "other, specify" to free text information

Exit the module.



To complete the VOC section of the phlebotomy examination for an unsuccessful VOC recruitment, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted. Escort the primary SP to the coordinator or to the next component.



## **A.5 The Return Visit - Primary VOC SPs**

Complete VOC data collection consists of the following: two 7-mL blood tubes, exposure badge, tap water sample, and answering the questions asked during the questionnaire. The first priority for VOC data capture is the MEC so that the blood can be collected. If the primary SP cannot come to the MEC or there are no MEC sessions available, the home examiner conducts a VOC home exam to collect the blood tubes, badge and water, and administers the questionnaire.

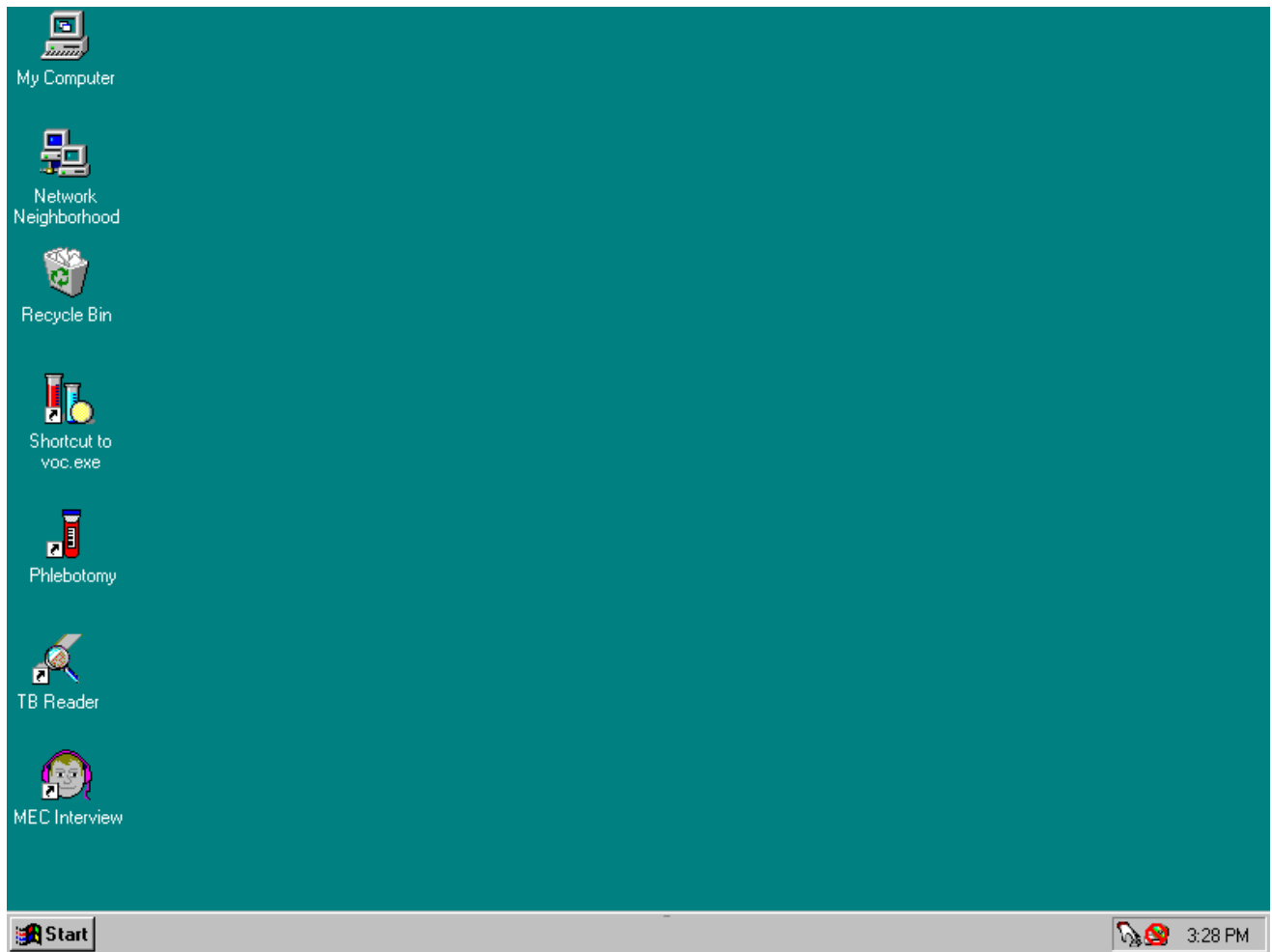
The coordinator application identifies primary SPs who are returning to the MEC 46-76 hours later for the VOC return visit and assigns the primary SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the primary SP into the application, and performs venipuncture to collect the two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer collects the exposure monitor and water sample, and administers a short questionnaire. Labels for the badge and water samples print on the Intermec printer in the phlebotomy room.

The home examiner can conduct a VOC home visit to collect the blood tubes, badge and water, and administer the questionnaire. Before conducting the home VOC exam, access the laboratory application and print the blood tube, water vial, and canister labels. For each home VOC exam, take at least two 7-mL gray top tubes, an empty canister, a spare water collection kit and copies of both the English and Spanish questionnaires. Prepare and take the Thermos cooler with ice cubes and thermometer. Refrigerate the VOC blood tubes within 30 minutes after the blood draw. Access the VOC application, draw the blood, collect the water vial and the badge, label the specimens, store the blood tubes in the Thermos, administer the questionnaire, pay the SP, and transport the specimens to the MEC laboratory. Process the specimens using the head-up display in the Laboratory application. Store the specimens in refrigerator #2.

The MEC phlebotomist, home examiner, and MEC interviewers have access to the complete VOC collection module.

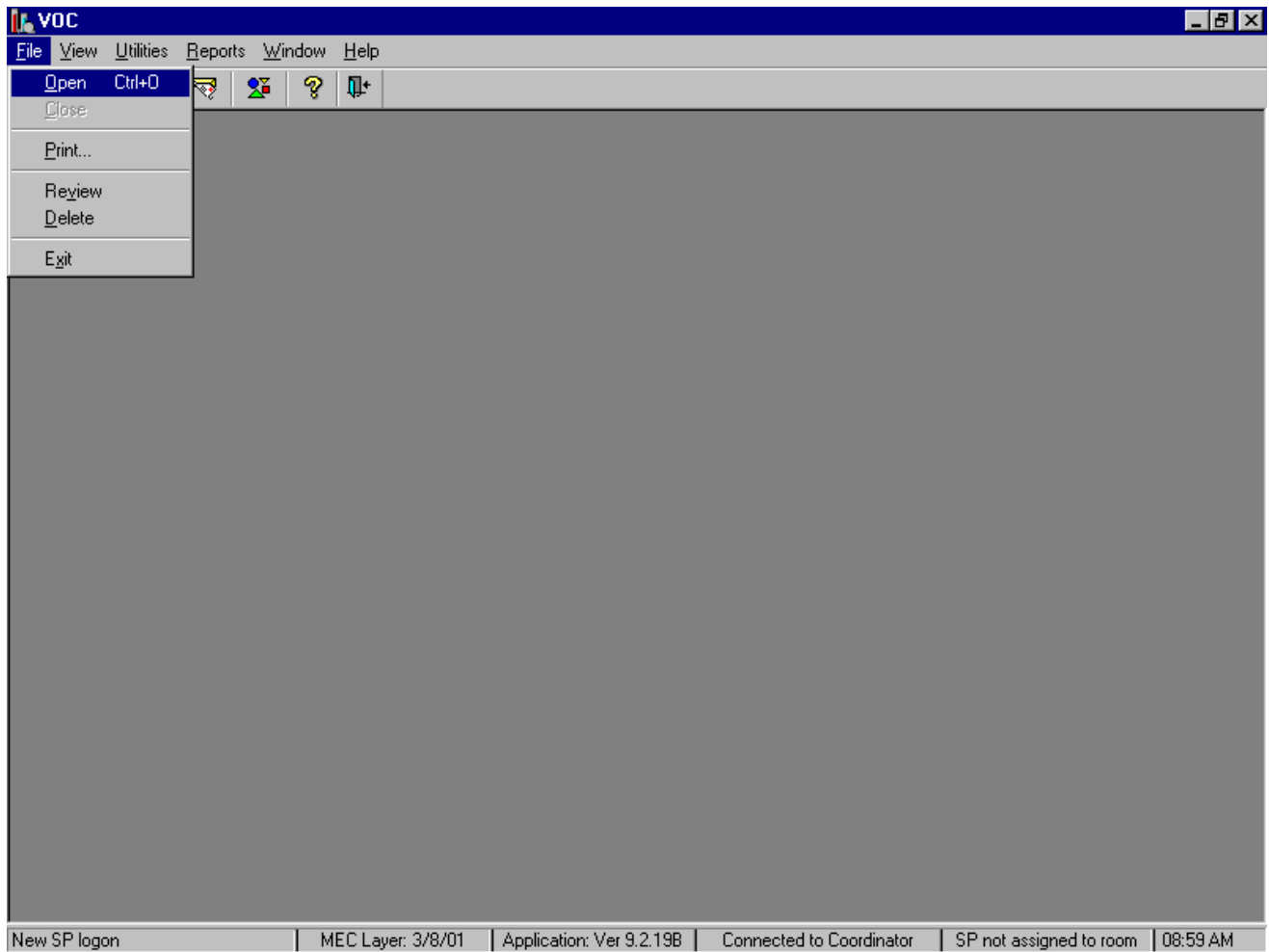
**A.5.1 Open the VOC Exam and Log the Primary VOC SP into the Component - MEC and HO**

Access the VOC application.



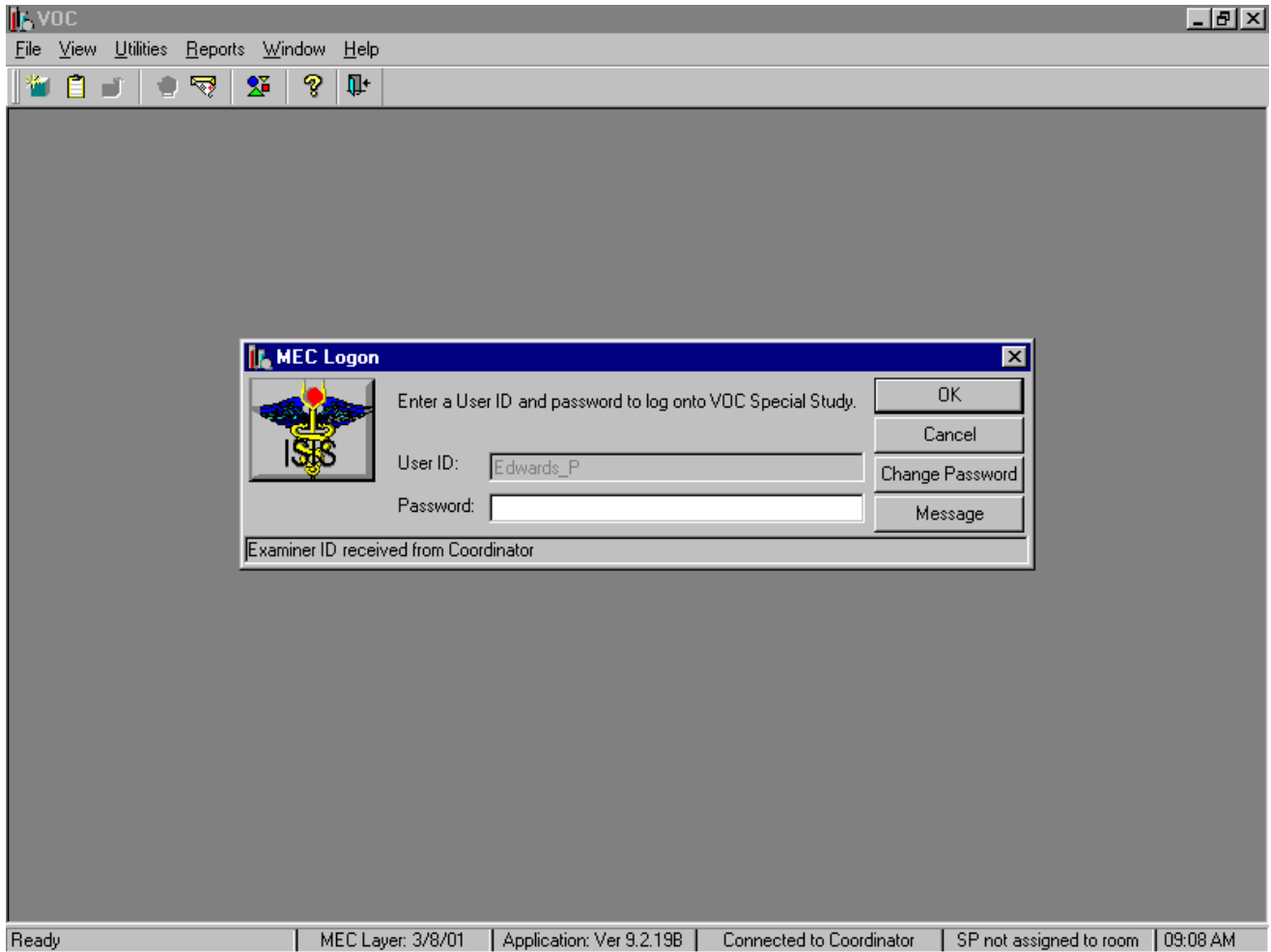
To open the VOC application, use the mouse to direct the mouse arrow to the VOC icon on the desktop and double click.

The VOC application opens. Open a primary VOC return examination.



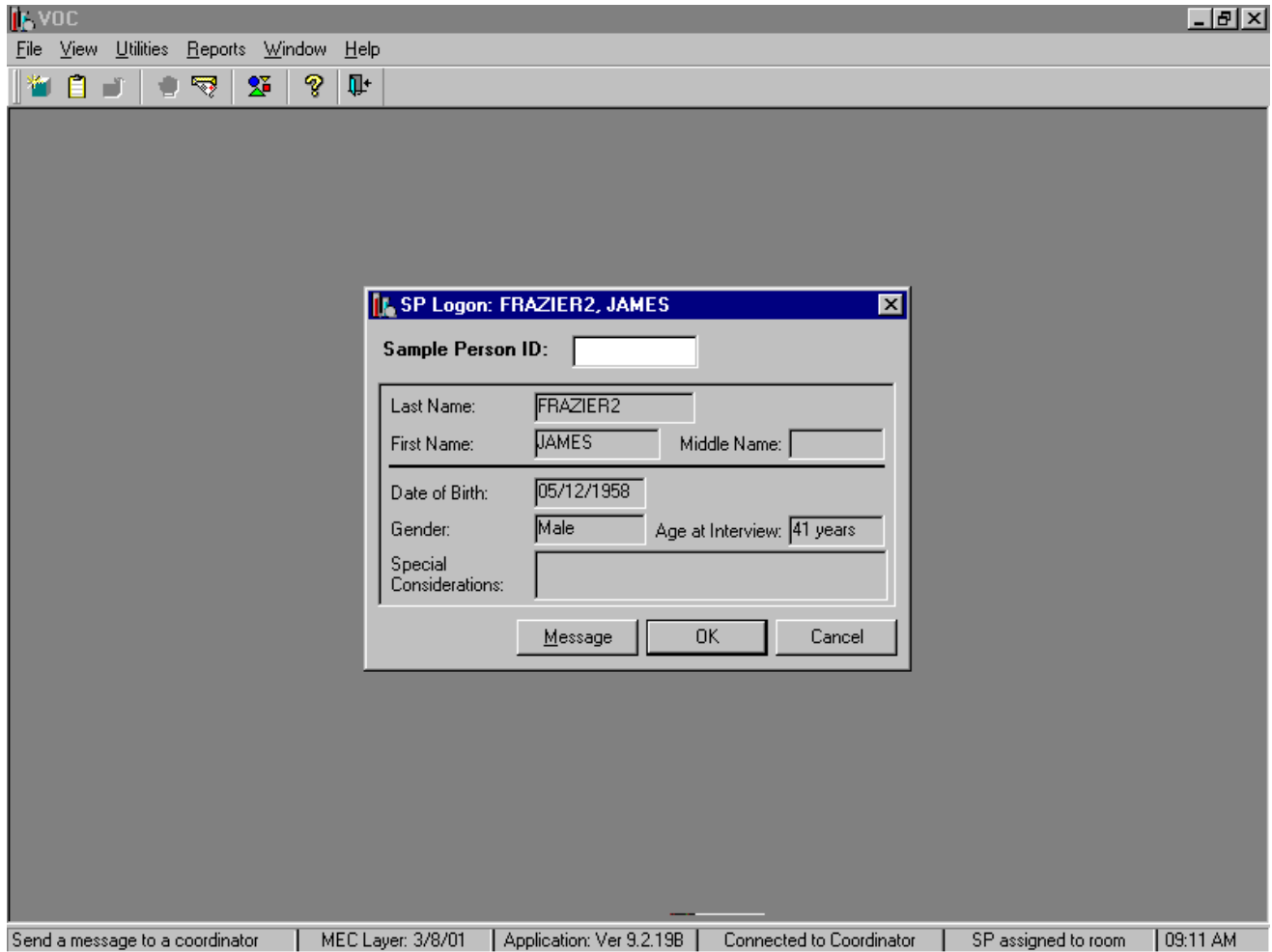
To open a VOC return examination for a primary VOC SP, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Open} and left click, or type [Alt] [F] [O/o] or [Ctrl] [O/o].

Log onto the VOC application.



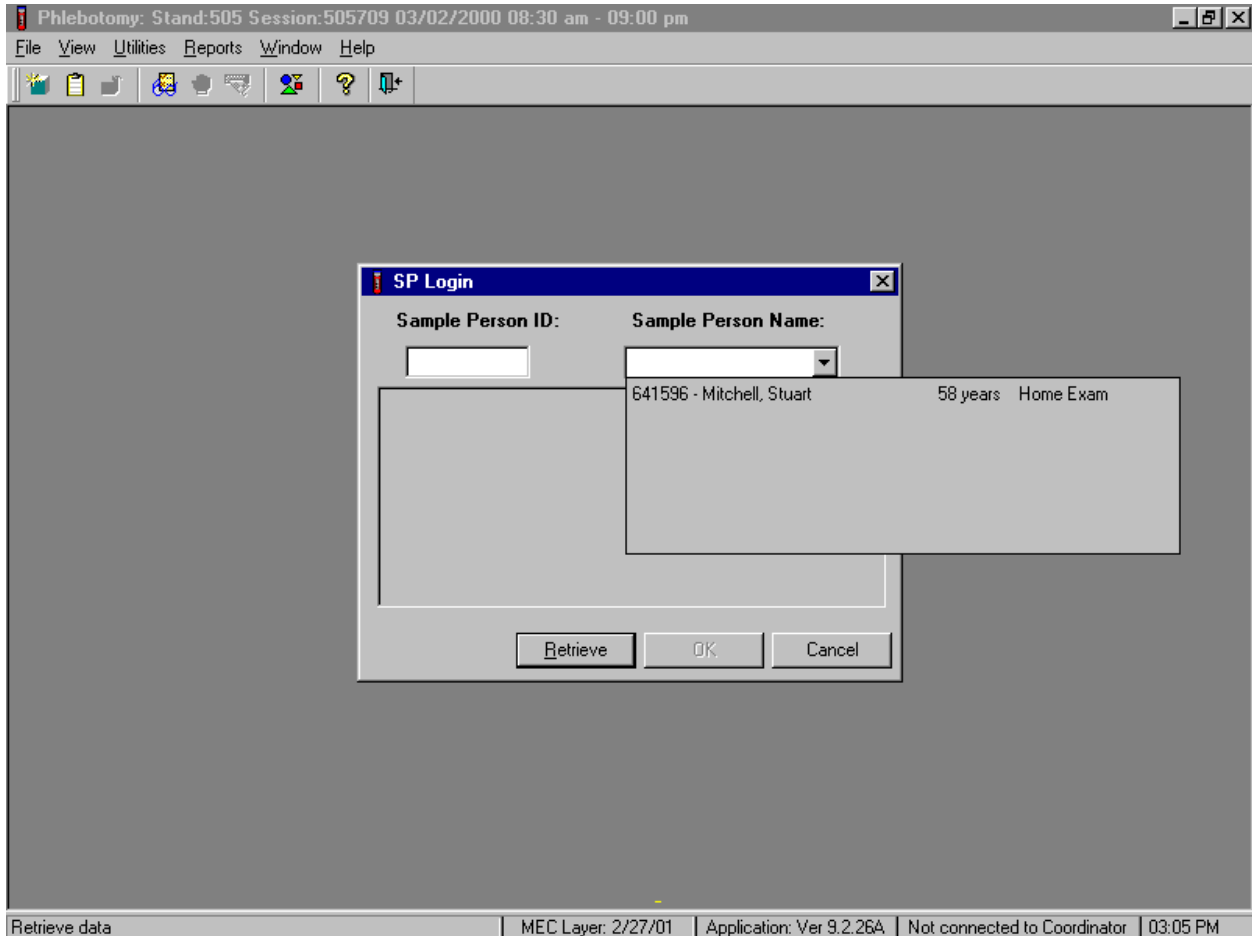
The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the mouse arrow to the Cancel button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the Message button and left click.

The SP Logon window displays in the MEC.



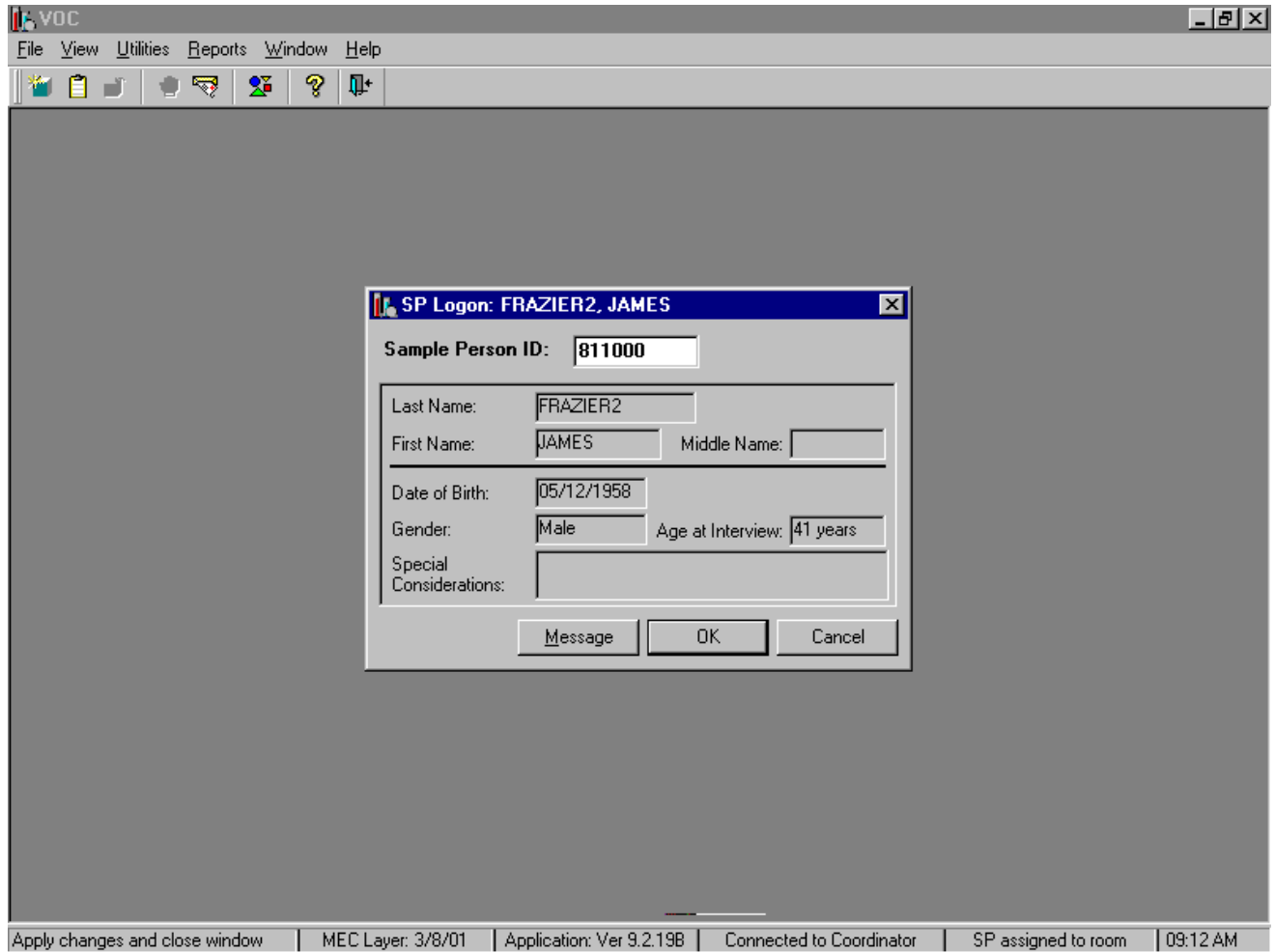
The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

In the home, the SP login window displays.



To view the list of eligible SPs, use the mouse to direct the mouse arrow to the pull down menu on the right side of the **Sample Person Name:** box and right click. The **Sample Person ID:** and the **Sample Person Name:** boxes fill in for the highlighted choice.

Continue to log the SP into the exam. Verify the information.



Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

To move forward to the primary VOC sample collection window, press [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the SP Login process, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

### **A.5.2 The Primary SP VOC Blood Collection – Phlebotomist and Home Examiner**

The home examiner conducts VOC home exams. Before conducting the exam, access the laboratory application and print the VOC blood tube, water vial, and canister labels. For each exam, take at least two 7-mL gray top tubes, an empty canister, a spare water collection kit, and copies of both the English and Spanish questionnaires. Prepare and take the Thermos cooler with ice cubes and thermometer. Refrigerate the VOC blood tubes within 30 minutes after the blood draw.

Once in the home, the home examiner accesses the VOC application, draws the blood tubes, collects the water vial and badge, labels the specimens, stores the blood tubes in the Thermos, administers the questionnaire, pays the SP, and transports the specimens to the MEC laboratory. They process the specimens using the heads up display in the laboratory application and store the specimens in refrigerator #2.

CDC prescreens the gray-top tubes used for the VOC protocol for this study. The following is the procedure for preparing the 7-mL gray Vacutainer® VOC blood collection tubes and a statement of their purpose. Dr. David Ashley at the CDC provided this procedure.

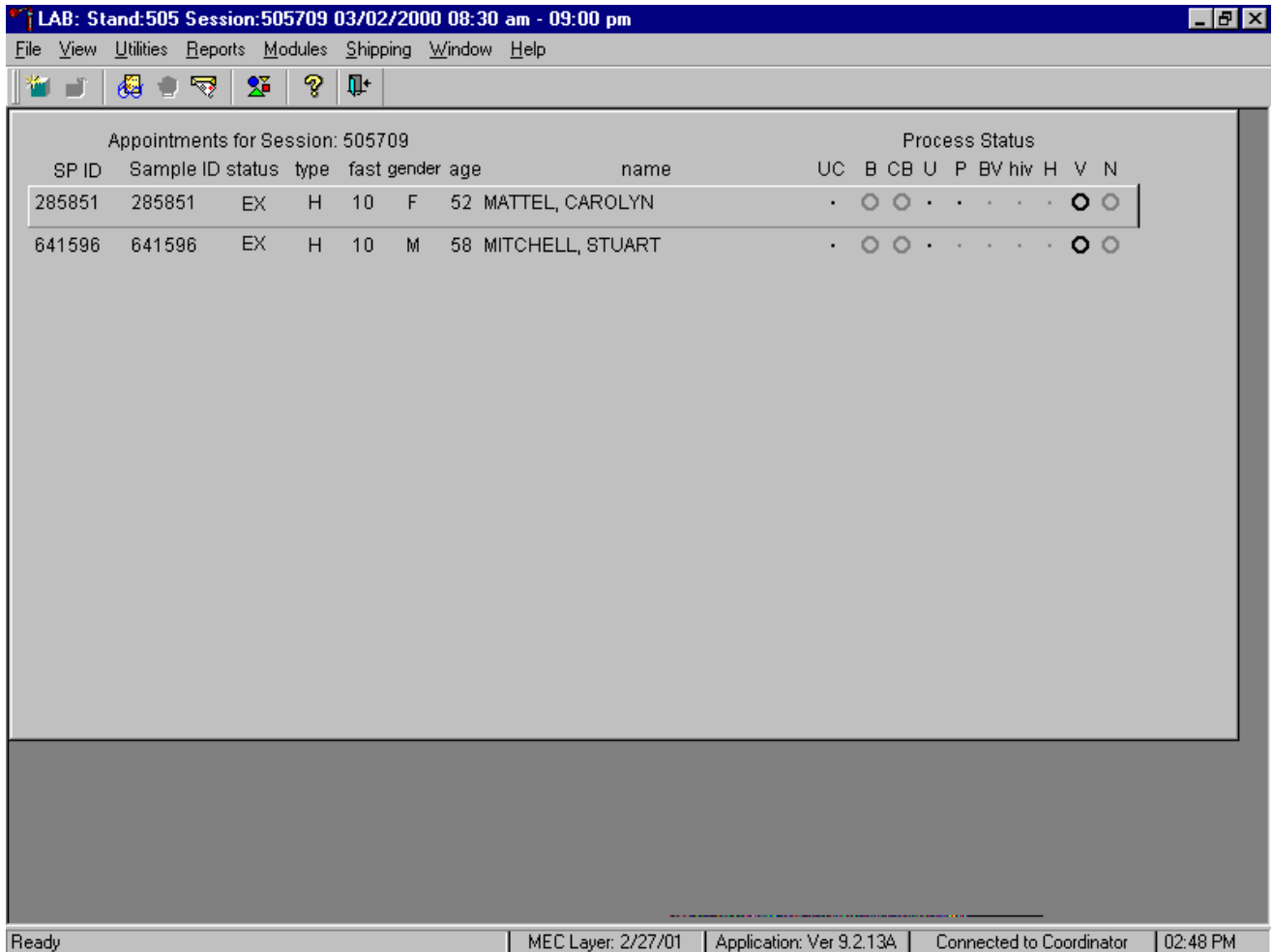
#### **Procedure for preparing the 7-mL gray Vacutainer® Tubes**

- 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 time frame necessary for their use.

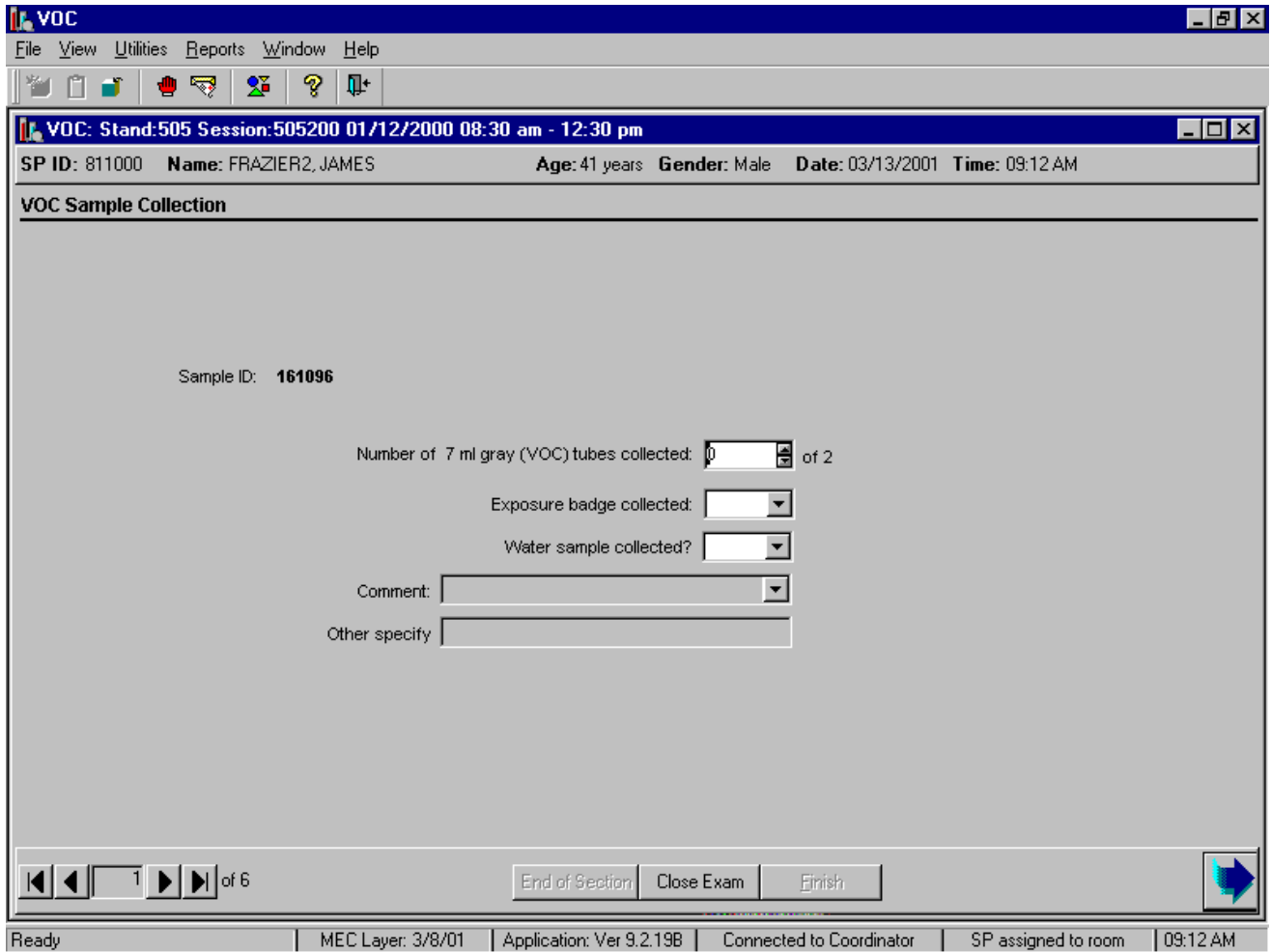


The home examiner must print labels in the MEC before leaving to conduct the VOC home exam.



Access the laboratory application in the MEC. Select the correct home exam session for the SP. Once the heads-up display is presented, select, {File}, {Print Labels}, and {VOC Processing} or type [F/f], [L/l], [V/v].

Proceed to the first primary SP's VOC window, "VOC Sample Collection."

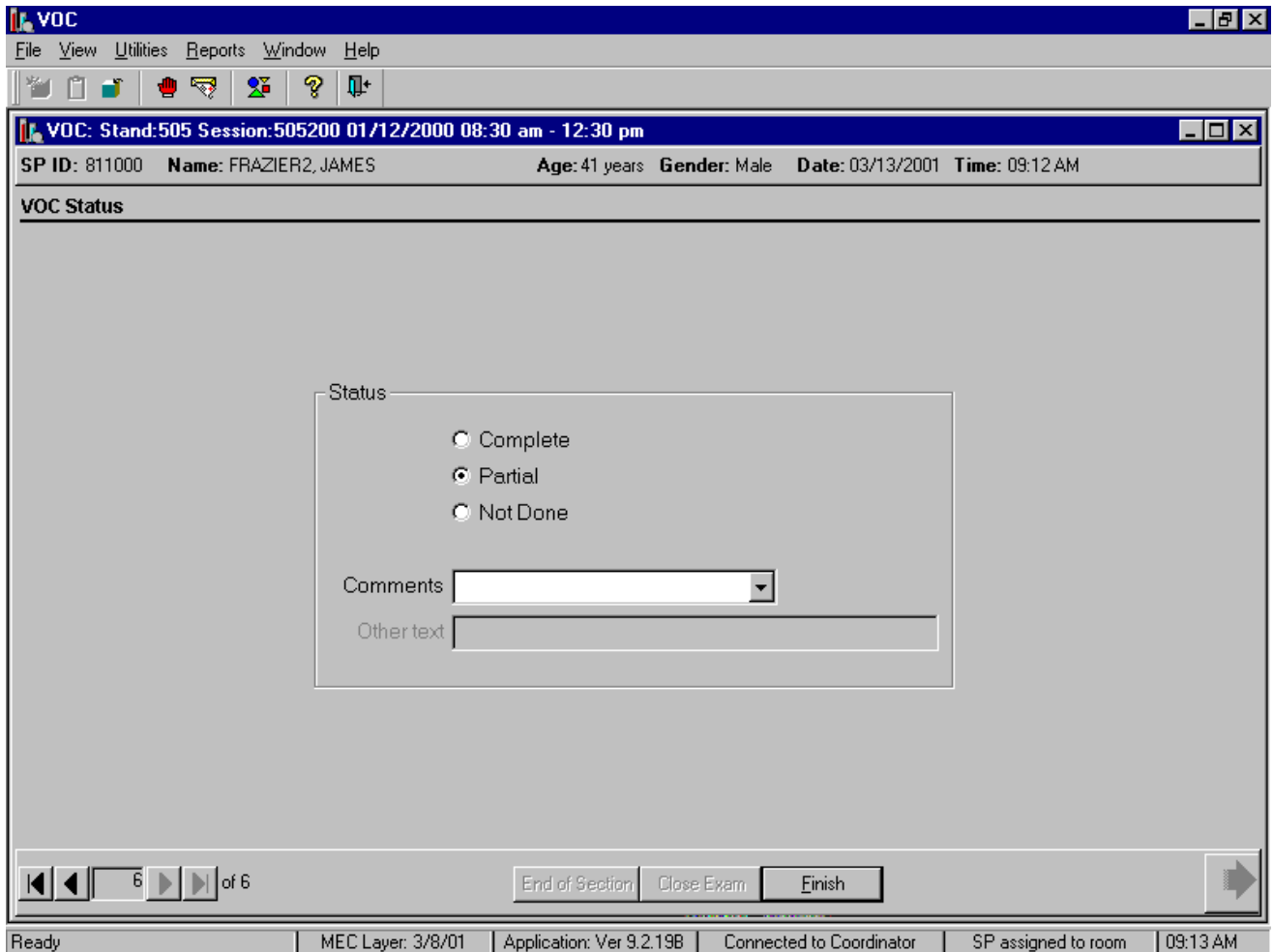


The window displays the appropriate venipuncture protocol for returning primary VOC SPs. Draw two 7-mL gray top tubes using procedures described in Chapter 4.

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes by placing the bar coded label on the tube. Pass the blood tubes through the window to the laboratory.

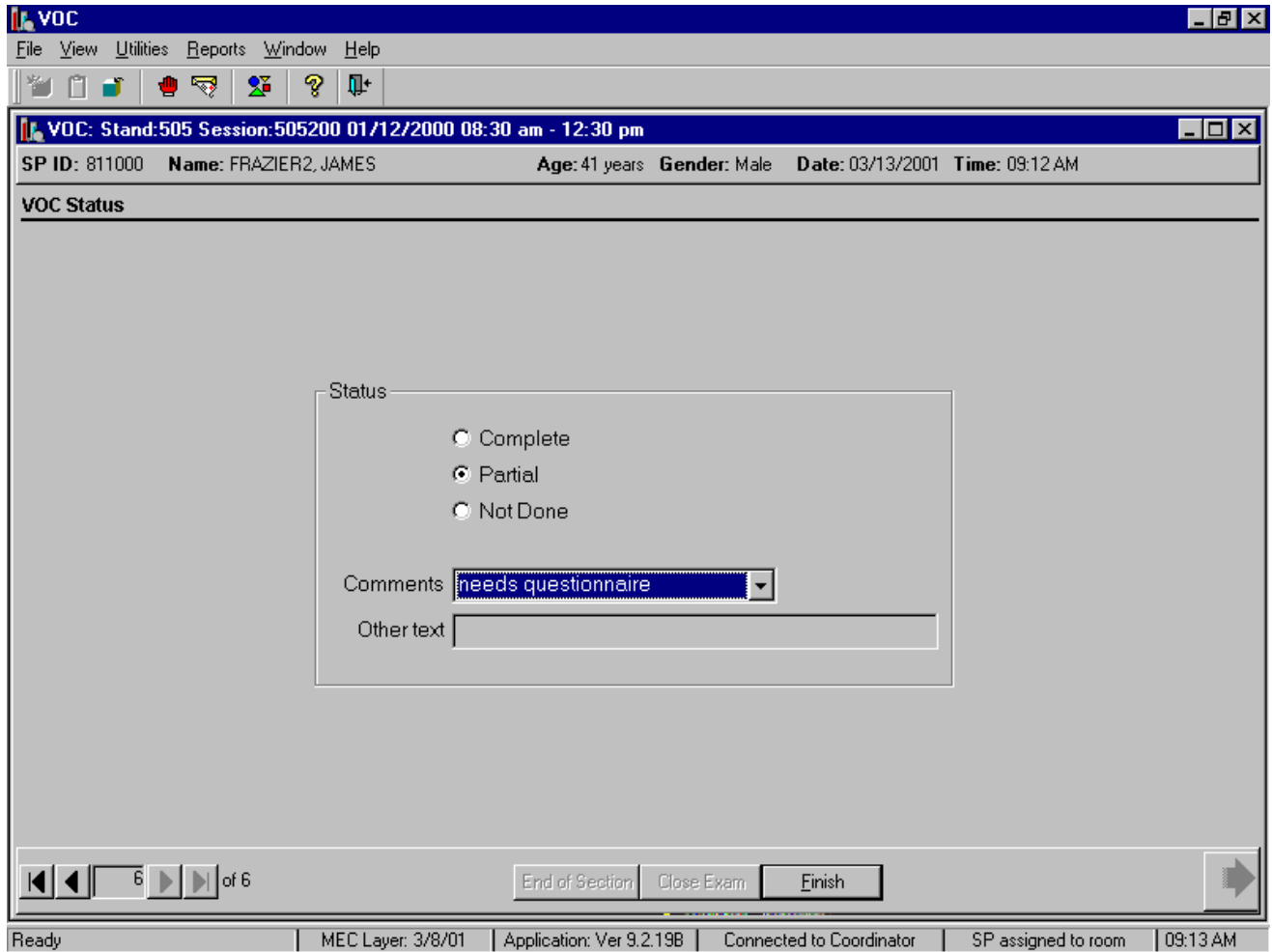
The slide navigation bar provides a means to move forward and back through an examination. To move forward to the last window in the exam, use the mouse to direct the mouse arrow to the black right arrow with the line on the right side on the navigation bar and left click.

Review the examination status.



Use comment codes to explain partial and not done status codes. Exams are partial if one or more of the blood tubes, the water, or the badge are collected and not done if none of these specimens is collected.

Record the comment “SP needs questionnaire” if the SP has not been to MEC interview.



Choose and enter the appropriate comment code when the VOC section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

The home examiner must perform a weekly data search to identify SPs who did not show up for their MEC appointment and the exposure time was greater than 76 hours. The home examiner must code these exams as “Not Done” and mark the appointments as “No Show.”

1. Using the AMS search function, search for “ALL persons given a VOC appointment.”
2. Click on the “Appt Status” column header to sort on all No Show appointments.
3. Identify all SPs who were VOC and have a No-show status.
4. Drag the Sp into the Home All Day session and select the same home session date as the original No Show date.
5. Perform a data transfer.
6. Open the VOC application on the laptop and access the SP.
7. Select the “Close Exam” button on the bottom of the screen.
8. Code the exam as SP refusal.
9. Perform a data transfer.
10. Using the AMS, select the calendar for Home Appointments
11. In the AMS, select Session Appointments for VOC, and highlight the correct SP.
12. Use the “hand” to change the appointment status to “No Show.”
13. Print and review a VOC Reconciliation report at least weekly.

### A.5.3 The Primary SP's VOC Badge and Water Collection – MEC Interviewers and Home Examiner

The MEC interviewer or the home examiner collects the primary VOC SP's badge and water samples and administers the questionnaire.

Record collection of the primary VOC SP's exposure badge.

The screenshot shows a software window titled "VOC" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window displays the following information:

- Header: VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm
- Subject Info: SP ID: 811000 Name: FRAZIER2, JAMES Age: 41 years Gender: Male Date: 03/13/2001 Time: 09:12 AM
- Section Title: VOC Sample Collection
- Sample ID: 161096
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: [Dropdown menu]
- Water sample collected? [Yes/No dropdown menu]
- Comment: [Text input field]
- Other specify: [Text input field]

At the bottom of the window, there are navigation buttons (back, forward, 1 of 6), "End of Section", "Close Exam", and "Finish" buttons. A status bar at the very bottom shows: Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.19B | Connected to Coordinator | SP assigned to room | 09:15 AM

To record yes or no type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. In the MEC, the labels generate automatically on the printer in the phlebotomy room for "Yes" responses.

Reassemble the badge. Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.

Record collection of the water sample.

The screenshot displays the VOC software interface. At the top, there is a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main window title is 'VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm'. Below the title bar, there is a header section with the following information: 'SP ID: 811000', 'Name: FRAZIER2, JAMES', 'Age: 41 years', 'Gender: Male', 'Date: 03/13/2001', and 'Time: 09:12 AM'. The main content area is titled 'VOC Sample Collection'. It contains the following fields and controls:

- Sample ID: **161096**
- Number of 7 ml gray (VOC) tubes collected:  of 2
- Exposure badge collected:
- Water sample collected?:  (dropdown menu with 'Yes' and 'No' options)
- Comment:
- Other specify:

At the bottom of the main content area, there is a navigation bar with 'End of Section', 'Close Exam', and 'Finish' buttons. The status bar at the very bottom shows 'Ready', 'MEC Layer: 3/8/01', 'Application: Ver 9.2.19B', 'Connected to Coordinator', 'SP assigned to room', and '09:16 AM'.

Record collection of the primary VOC SP's water vessel. To record yes or no type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. In the MEC, a label prints automatically in the phlebotomy room for "Yes" responses.

If the water collection response is "No," the Comment text box highlights.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

SP ID: 811000 Name: FRAZIER2, JAMES Age: 41 years Gender: Male Date: 03/13/2001 Time: 09:12 AM

VOC Sample Collection

Sample ID: **161096**

Number of 7 ml gray (VOC) tubes collected: 2 of 2

Exposure badge collected: Yes

Water sample collected? No

Comment: SP did not return the water  
Other specify  
Broken  
Other

1 of 6

End of Section Close Exam Finish

Ready MEC Layer: 3/8/01 Application: Ver 9.2.19B Connected to Coordinator SP assigned to room 09:16 AM

To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the mouse arrow to select or highlight the most appropriate choice and left click. Alternatively to select a code, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, then use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and, when the correct choice is highlighted, left click. If "Other" is chosen, type a short explanation in the "Other specify" text box. To proceed to the VOC questionnaire, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click.

Reject the specimen if the water is not returned in the glass tube. The only acceptable container is the 10-mL glass vial. Do not pour the water from the plastic conical tube into the glass tube.



Label and store or transport the specimen to the MEC lab.

In the MEC:

- Label both sides of the exposure badge and the outside of the canister with the labels. Return the exposure badge sections to the canister and replace the canister plastic lid. Label the glass water sample vessel vertically with bar coded labels. The badge and water are ready for transport to the laboratory.

In the home:

- Access the VOC application, draw the blood, collect the water vial and the badge, label the specimens with the preprinted labels, store the blood tubes in the Thermos, administer the questionnaire, pay the SP, and transport the specimens to the MEC laboratory. Process the specimens using the heads-up display in the laboratory application. Store the specimens in refrigerator #2.

#### **A.5.4 The Primary SP's VOC Questionnaire – MEC Interviewers and Home Examiner**

The MEC interviewers administer the primary VOC SP's questionnaire after collecting the badge and water and before or after the phlebotomist collects the blood in the MEC. The home examiner collects the blood, badge, and water, and administers the questionnaire. The questionnaire collects data about the primary SP's home, activities, and amount of time spent in various locations, and exposure to different chemicals over the past 46-76 hours. Administer the questionnaire by reading each question to the primary VOC SP. Record the primary VOC SP's response to each question either by selecting the response from a list of acceptable responses or by entering a numeric value in the space indicated. A description for each of the questions from the primary VOC questionnaire and specifications for answers are listed below.

Only SPs who have had at least one blood tube, the badge, or water collected are eligible for the VOC questionnaire. Verify the following conditions when using the VOC application:

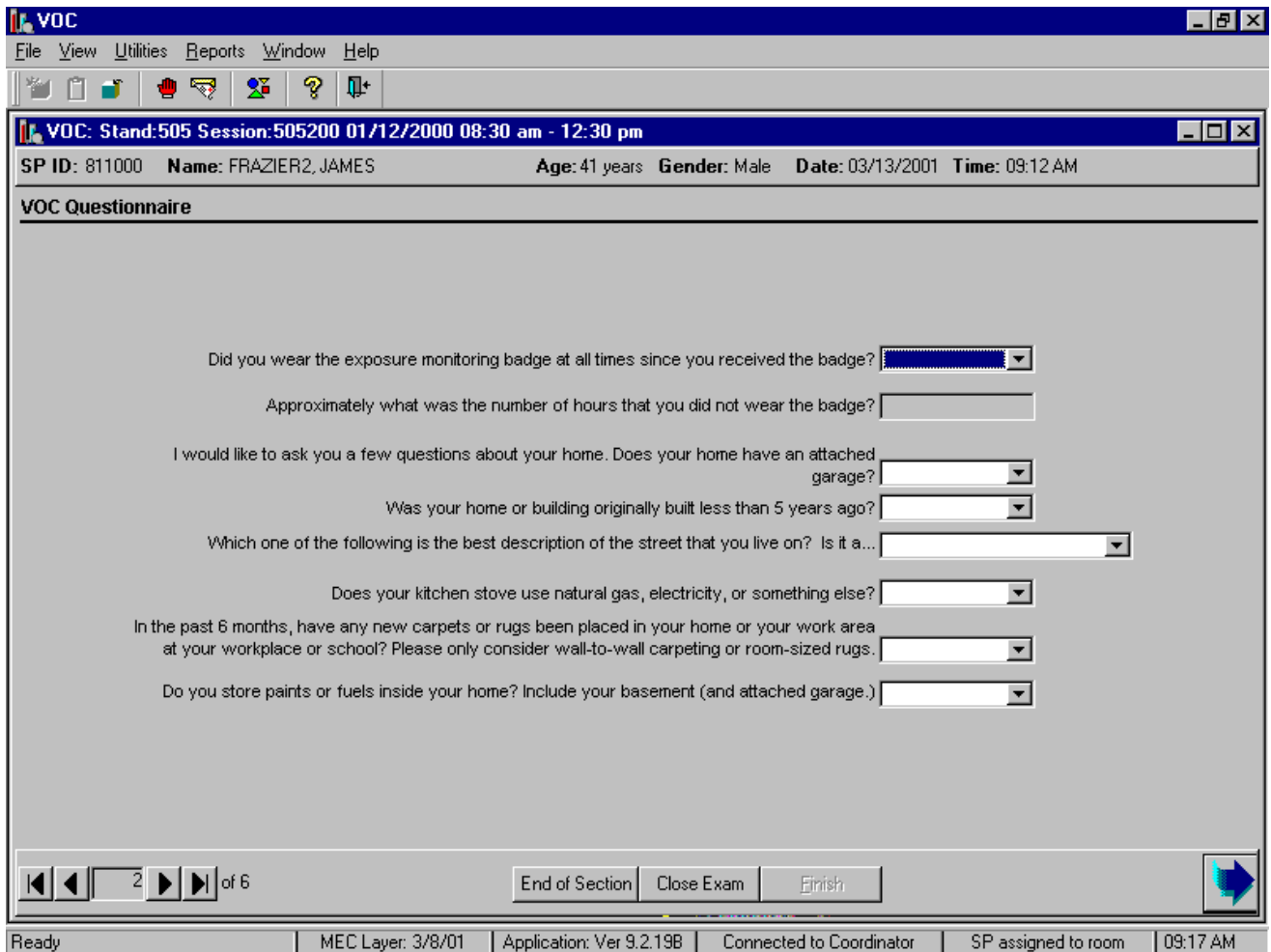
- If both the blood and badge are not collected, the application skips to the status screen and does not display the questionnaire.

- If the exposure time is greater than 76 hours, the application does not allow the VOC badge to be collected but does permit collection of the blood and water and does display the questionnaire.
- If the exposure time is less than 46 hours, the application does not allow collection of the VOC blood tubes, badge or water and does not display the questionnaire.

Record the various text and numeric responses by using one of the following two methods.

- Record text responses either by typing the first letter of the choice, or select or highlight the correct choice by using the mouse to direct the mouse arrow to the drop-down list, left click, drag the mouse arrow to the correct choice, and left click when the correct choice is highlighted. Select [Tab] to move to the next question.
- Record numeric responses by using the keyboard's numeric keys to enter the number and select [Tab] to move to the next question.

Begin to administer the primary SP's VOC questionnaire. Ask each question exactly as presented on the window.



**Did you wear the exposure monitoring badge at all times since you received the badge? [Yes, No]**

<p>This initial question determines the length of time the primary SP actually wore the badge since the time they left the MEC and returned for their MEC appointment.</p>	<p>"At all times" means that the primary SP wore the badge from the time they left the MEC to the present time. This includes time spent sleeping, bathing, and showering. Select "Yes," if they wore the badge the entire time, "No" if they wore the badge less than the entire time. If "No" is selected, the next text box is enabled.</p>
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**If no: Approximately what was the number of hours that you did not wear the badge?  
[Number of hours]**

<p>This question documents the actual number of hours that the primary SP did not wear the badge between the time they received the badge and the time they returned to their MEC appointment.</p>	<p>Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the SP's best estimate.</p>
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**Q1: I would like to ask you a few questions about your home. Does your home have an attached garage? [Yes, No, Refused, Don't know]**

<p>Q1: This question refers to the primary residence where the primary SP spent the last 46-76 hours and specifically refers to whether or not the home has a garage and if it does, is it attached.</p>	<p>Home refers to the building where the primary SP lives. This can be a mobile trailer, apartment, townhouse, single, or multiple family building. An attached garage refers to a building or wing of a building in which a car is parked that is also attached or connected as a part to the home. Select "Yes," if the home has an attached garage, "No" if it does not; "Refused" if the primary SP refuses to answer the questions; and "Don't know" if the primary SP is unsure.</p>
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**Q2: Was your home or building originally built less than 5 years ago? [Yes, No, Refused, Don't know]**

<p>Q2: This question asks the age of the primary SPs home or primary residence.</p>	<p>Ask the primary SP to state the age of their home or when they believe their home was built. If the home was built less than 5 years ago, select "Yes." If the home is older than 5 years, select "No." If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know or cannot estimate the age of their home select "Don't know."</p>
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**Q3: Which one of the following is the best description of the street that you live on? Is it a [Rural or country road, Dead-end residential street, Through residential street, Commercial street, Major highway, Refused, Don't know]**

<p>Q3: This question asks the primary SPs to describe the street on which their house or primary residence is located.</p>	<p>Ask the primary SP to decide which of the choices best describe the street on which their home is located. Rural or country refers to country as opposed to urban or suburban. This includes farming and agriculture areas. Dead-end residential refers to a street in a suburban or small area that does not go through to another street. Through residential describes a street in a suburb, city, or small town that does go through to another street. A commercial street is a street that has commercial businesses located on it. A major highway is any state-designated highway or Federal interstate highway. Select the primary SP's response. If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know select "Don't know."</p>
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**Q4: Does your kitchen stove use natural gas, electricity, or something else? [Natural gas, Electricity, Something else, Refused, Don't know]**

Q4: This question asks the primary SP to describe the energy source for their kitchen stove.	Ask the primary SP to decide if the source of power or energy for their kitchen stove is one of the choices. Natural gas refers to propane and other natural gases used as fuel. Electricity refers to electric current used or regarded as a source of power. "Something else" refers to any other known energy source other than natural gas or electricity such as a wood stove or coal furnace. Select the primary SP's response. If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know select "Don't know."
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**Q5: In the last 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? [Yes, No, Refused, Don't know]**

Q5: This question asks the primary SP to decide if the carpets or rugs in any of the three environments are new within the last 6 months.	If the carpets or rugs in any of these three environments are less than 6 months old, select "Yes." If the carpets or rugs are older than 6 months select "No." If the primary SP refuses to answer the question select "Refused" and if the primary SP does not know or cannot estimate the age of their carpets and rugs select "Don't know."
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**Q6: Do you store paints or fuels inside your home? Include your basement (and attached garage.) [Yes, No, Refused, Don't know]**

<p>Q6: This question asks the primary SP to decide if they currently have any paints or fuels stored inside their home. Include the basement and attached garage if the primary SP reports having an attached garage.</p>	<p>Include areas of the home like the basement and attached garage. Do not include separate storage facilities like barns or sheds on the same property. Include all paints, both indoor and outdoor, and fuels like propane or butane. Do not include wood or coal. If the primary SP indicates they store paint or fuels in any of these locations select "Yes." If the primary SP reports they do not store these items in these locations select "No." If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know select "Don't know."</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

SP ID: 811000 Name: FRAZIER2, JAMES Age: 41 years Gender: Male Date: 03/13/2001 Time: 09:12 AM

VOC Questionnaire

Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge 74 hours ago up until this appointment.

During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping.

Were any windows open in your home?

About how many hours did you spend indoors at work or at school?

About how many hours did you spend outdoors?

Did you pump gas into a car or other motor vehicle yourself?

3 of 6

End of Section Close Exam Finish

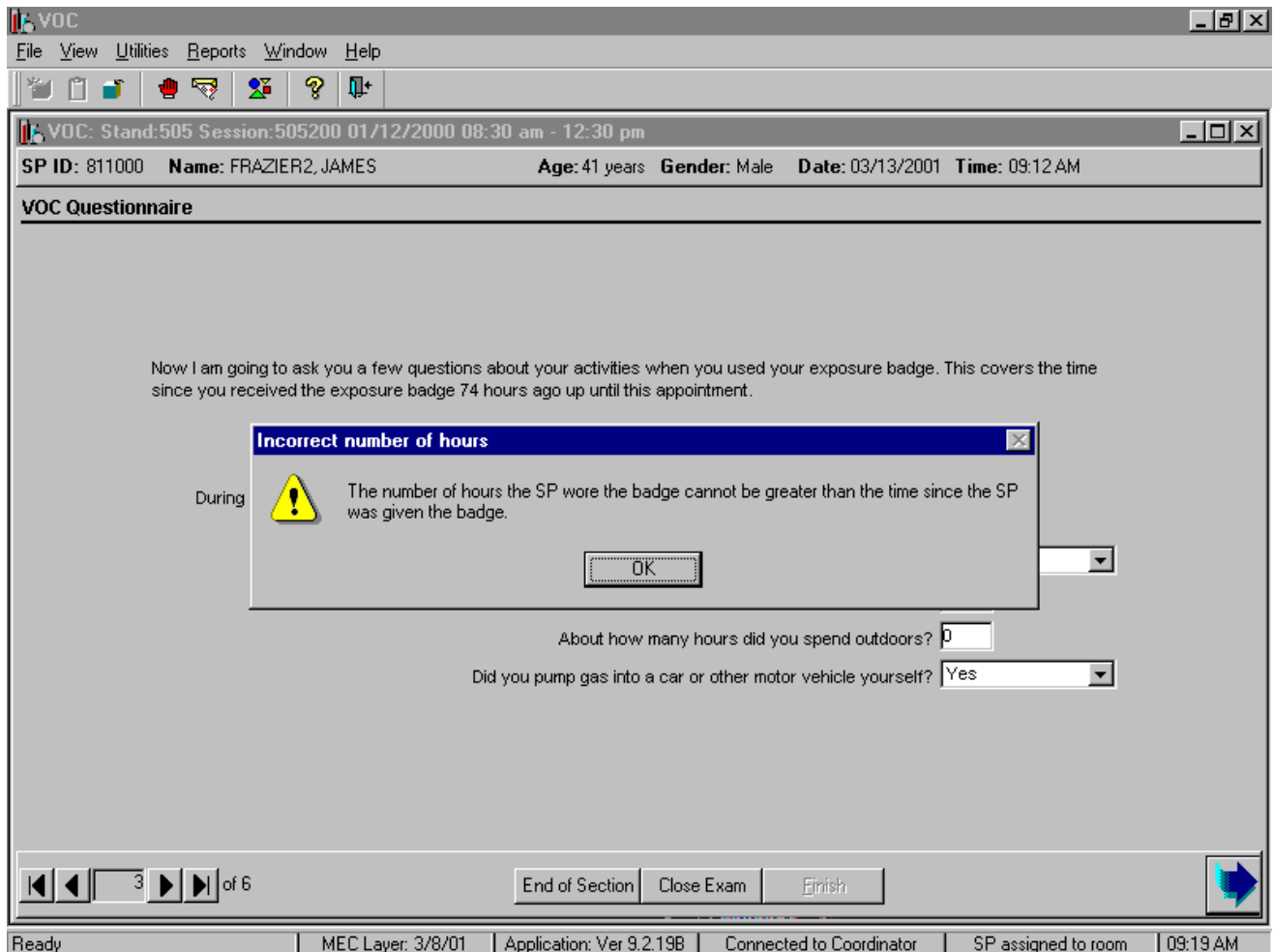
Ready MEC Layer: 3/8/01 Application: Ver 9.2.19B Connected to Coordinator SP assigned to room 09:18 AM

The number of hours since the initial MEC appointment displays. The beginning time is based on the time the primary VOC SP was recruited in the MEC.

Read the script to the primary SP. "Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge (number of hours inserted here) hours ago up until this appointment." Encourage the primary SP to refer to the activity log to assist in the calculations.



The total number of hours reported in Q7 through Q10 must not total more than the number of hours since the badge was issued.



An error message text box displays if the number of hours reported in questions Q7, Q9, and Q10 exceed the total number of hours since the badge was issued. Review the reported information with the primary VOC SP and probe to clarify any responses. Correct any responses so that the number hours reported in questions Q7, Q9, and Q10 are less than the total number of hours. To remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

**Q7: During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping. [Number of hours]**

<p>Q7: This question asks the primary SP to report the total number of hours spent in their home during the time they used the exposure badge.</p>	<p>Type the number of whole hours that the primary SP reports they spent indoors in their home while using the exposure badge. Record answers to two digits. If the answer is 0 type "00." Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP's best estimate.</p>
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**Q8: Were any windows open in your home? [Yes, No, Refused, Don't know]**

<p>Q8: This question asks the primary SP to report if any windows were open in their home during the time that they used the exposure badge.</p>	<p>Include open doors, e.g., sliding doors to patios and house doors with screens. If the primary SP reports that any windows were open, select "Yes." If no windows were open, select "No." If the primary SP refuses to answer the question, select "Refused" and if the primary SP does not know or recall select "Don't know."</p>
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**Q9: About how many hours did you spend indoors at work or school? [Number of hours]**

<p>Q9: This question asks the primary SP to report the total number of hours spent indoors at work or school during the time they used the exposure badge.</p>	<p>Type the number of hours the primary SP reports they spent indoors in their home while using the exposure badge. Record answers to two digits. If the answer is 0, type "00." Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP's best estimate.</p>
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**Q10: About how many hours did you spend outdoors? [Number of hours]**

<p>Q10: This question asks the primary SP to report the total number of hours spent outdoors during the time they used the exposure badge.</p>	<p>Type the number of hours the primary SP reports they spent outdoors while using the exposure badge. Record answers to two digits. If the answer is 0, type "00." Enter the number of hours reported by the primary SP. If the number of hours is less than 1, enter 0. In general, round &lt;30 minutes down to nearest whole number, if &gt;30 minutes round up to nearest whole number, if exactly 30 minutes round to nearest even whole number. For example, 2 hours 30 minutes, round to 2 hours; 3 hours and 30 minutes round to 4 hours. Since primary SPs are required to answer this question, get the primary SP's best estimate.</p>
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**Q11: Did you pump gas into a car or other motor vehicle yourself? [Yes, No, Refused, Don't know]**

<p>Q11: This question asks the primary SP to report if they pumped gas into a car or other motor vehicle during the time that they used the exposure badge.</p>	<p>Include any grade of gas but do not include natural gas. Include pumping gas into a container, such as a lawn mower container. Do not record "Yes" if the primary SP reports being a passenger in a car into which gas was pumped. If the primary SP reports actually pumping gas into any car or motor vehicle, select "Yes." If the primary SP reports they did not pump gas into a car or other motor vehicle, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know if they pumped gas into any car or other motor vehicle, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

**Q12: Did you spend any time at a swimming pool? [Yes, No, Refused, Don't know]**

<p>Q12: This question asks the primary SP to report if they spent any time at a swimming pool during the time they used the exposure badge.</p>	<p>Determine if the primary SP spent time at a swimming pool. The SP did not have to swim in the pool. If the primary SP reports being at or in a swimming pool, select "Yes." If the primary SP reports that they were not at a swimming pool, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall if they were at a swimming pool, select "Don't know."</p>
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**Q13: Did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week? [Yes, No, Refused, Don't know]**

<p>Q13: This question asks the primary SP to report if they visited a dry cleaning shop or wore clothes that had been dry cleaned within the last week.</p>	<p>The cleaning process cleans clothing with chemical solvents having little or no water. Determine if the primary SP visited a dry cleaning shop during the time they used the exposure badge or if they wore clothes that had been dry-cleaned within the last week or 7 days. If the primary SP meets either criterion, select "Yes." If the primary SP reports that they were not at a dry cleaners and have not worn clothes dry-cleaned within the last week, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot remember if they were at a dry cleaning shop or wore clothes dry-cleaned within the last week, select "Don't know."</p>
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**Q14: Did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors? [Yes, No, Refused, Don't know]**

<p>Q14: This question asks the primary SP to report if either they have spent 10 or more minutes near wood-burning fires indoors or outdoors during the time they used the exposure badge.</p>	<p>Include wood-burning devices such as wood stoves, fireplaces and outdoor pits or fires. If the primary SP meets any of these criteria, select "Yes." If the primary SP reports that they have not been around any of these sources of wood fires, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall if they spent any time near wood burning fires while using the exposure badge, select "Don't know."</p>
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**Q15: Did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe? [Yes, No, Refused, Don't know]**

<p>Q15: This question asks the primary SP to report if they have spent 10 or more minutes near any person who was smoking cigarettes, cigars, or a pipe during the time they used the exposure badge.</p>	<p>Include any brand of cigarette, any size of cigar, or any style of pipe. If the primary SP meets any of these criteria, select "Yes." If the primary SP reports that they have not been around any of these sources of smoke, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall if they spent any time near someone who was smoking these forms of tobacco while using the exposure badge, select "Don't know."</p>
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**Q16: Even though you did not use the badge when taking a hot shower, did you take a hot shower for five minutes or longer during this time period? [Yes, No, Refused, Don't know]**

<p>Q16: This question asks the primary SP to report if they took a hot shower of at least 5 minutes during the time that they used the exposure badge.</p>	<p>Determine if the primary SP took a hot shower for at least 5 minutes. If the primary SP reports taking a hot shower for a total of at least 5 minutes, select "Yes." If the primary SP reports taking a cold or warm shower or a hot shower for less than 5 minutes, select "No." If the primary SP refuses to answer, select "Refused." If the primary SP does not know or cannot recall taking a hot shower for at least 5 minutes, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.







**Q17: During the time you used the exposure badge, did you breathe fumes from any of the following? [Yes, No, Refused, Don't know]**

<p>Q17: This question asks the primary SP to report if they breathed fumes from a variety of sources during the time that they used the exposure badge.</p>	<p>Individually determine if the primary SP breathed fumes from each source. Record each answer. If the primary SP reports breathing fumes from an item while using the exposure badge, select "Yes." If the primary SP reports s/he did not breath fumes while using the exposure badge, select "No." If at any point during the interview the primary SP refuses to answer any further questions, select the "Refused" square. If the primary SP does not know or cannot recall breathing fumes while using the exposure badge, select "Don't know" or if the primary SP reports they do not know the answer to all the remaining choices, select the "Don't know" square. Select the bright blue arrow to proceed to the last window.</p>
<p>Paints</p>	<p>Include all interior and exterior paints, spray paints used in arts and crafts, and oil-based artist paints.</p>
<p>Mothballs, moth crystals, or mothflakes</p>	<p>Mothballs are composed of a ball of camphor or naphthalene. They are used for protection of clothes from moths.</p>
<p>Household disinfectant or degreasing cleaners</p>	<p>Consider all disinfectants including Lysol® and PineSol®.</p>
<p>Furniture polish</p>	<p>Consider Pledge®, Liquid Gold, and lemon polish and all other brands of furniture polish.</p>
<p>Hairspray</p>	<p>Consider all brands of hairspray.</p>
<p>Fingernail polish or fingernail polish remover</p>	<p>Nail polish and nail polish remover contains acetone.</p>
<p>Diesel fuel or kerosene</p>	<p>Diesel fuel is a crude oil. Kerosene is a hydrocarbon oil, chiefly of the methane series, used for burning in lamps. It is also called coal oil.</p>
<p>Gasoline</p>	<p>Gasoline is a distillate of crude petroleum.</p>

Paint thinner, brush cleaner, or furniture stripper	These items contain turpentine.
Air fresheners or room deodorizers	Consider all spray types of air fresheners such as Airwick®, Glade®, and Lysol® and include the type that affixes to a wall or toilet or stands upright in a dispenser.
Dry-cleaning fluid or spot remover	Consider all spot removers like K2R.
Glues or adhesives used for hobbies or crafts	Glue is a viscid cement or adhesive preparation and is usually an impure gelatin derived from boiling certain animal substances. Hobby glue contains a significant amount of toluene.

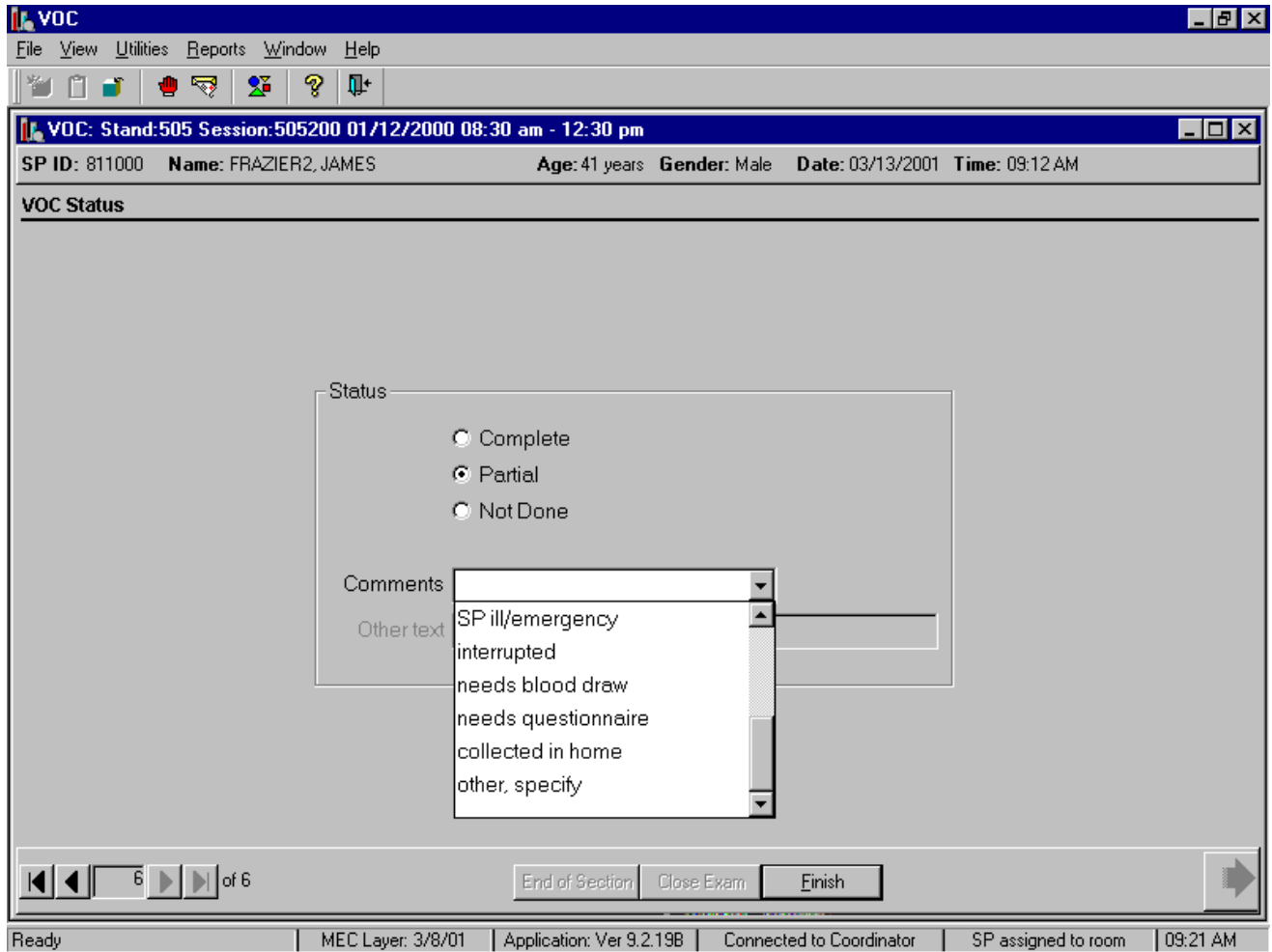
To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Verify the status for the primary VOC exam.

The screenshot shows the VOC software interface. At the top, the title bar reads "VOC". Below it is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains several icons. The main window title is "VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below this, a header displays "SP ID: 811000", "Name: FRAZIER2, JAMES", "Age: 41 years", "Gender: Male", "Date: 03/13/2001", and "Time: 09:12 AM". The main area is titled "VOC Status" and contains a "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below the radio buttons are two text input fields: "Comments" and "Other text". At the bottom of the main area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 3/8/01", "Application: Ver 9.2.19B", "Connected to Coordinator", "SP assigned to room", and "09:20 AM".

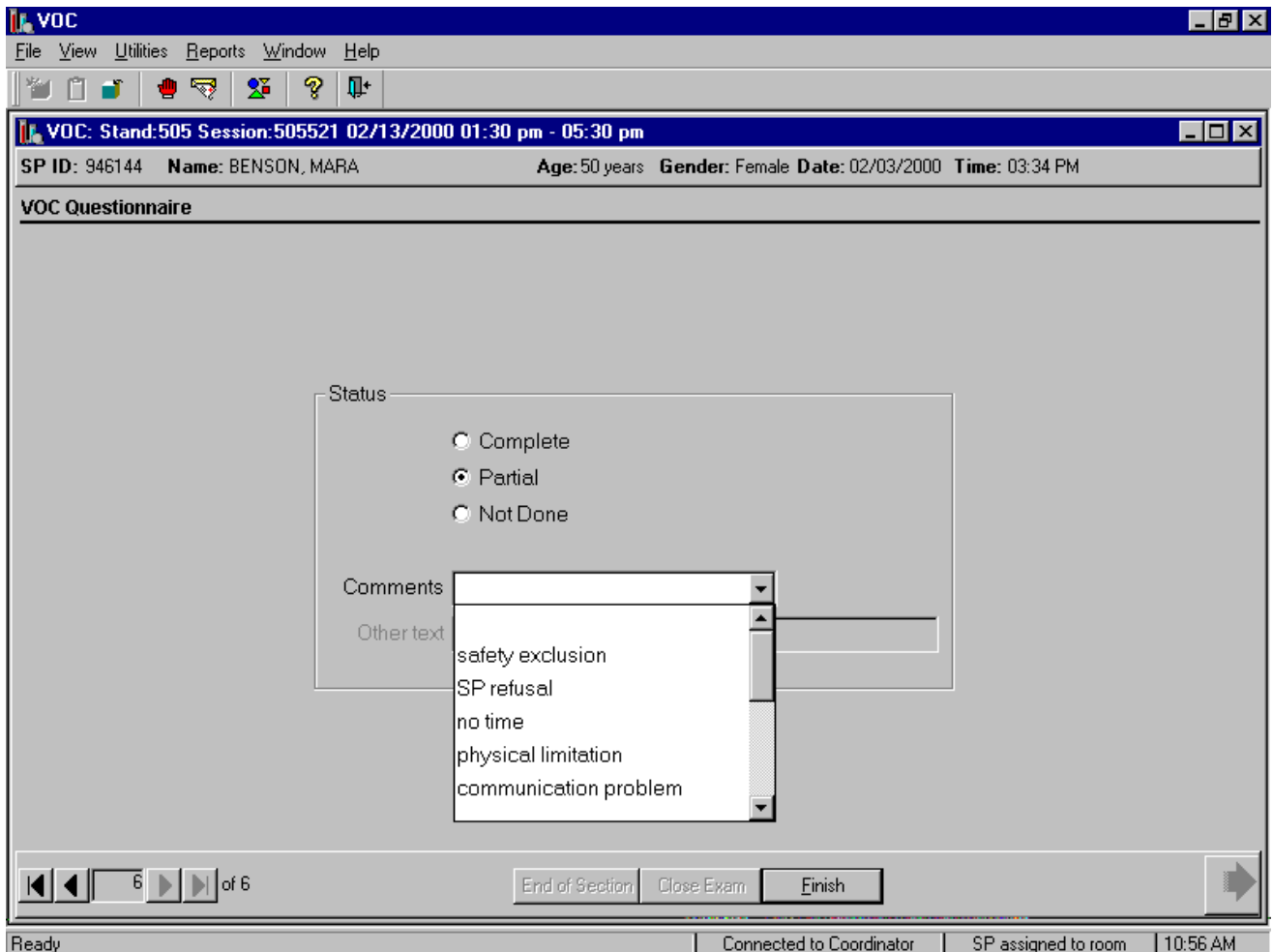
The exam is complete if blood tubes, water, and badge were collected, and the questionnaire was completed.

Use comment codes to explain a partial status or not done status.



Comment codes are used to explain partial and not done status codes. Exams are partial if either of the blood tubes, the water, or the badge were collected and not done if none of the specimens is collected.

Choose and enter the appropriate comment code when the examination status is partial or not done.



To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice, and left click. Alternatively to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If "Other, specify" is chosen, type a short explanation in the "Other text" text box.

Comment Code	Use when:
Safety exclusion	Not applicable
SP refusal	This is SP initiated nonresponse due to refusal. The primary SP refuses the component for any reason other than an illness or emergency. If the primary SP refuses in the reception area, the coordinator codes the exam. If the primary SP refuses after starting the exam, the examiner codes the exam.
No time	Not applicable
Physical limitation	The venipuncture is unsuccessful.
Communication problem	Not applicable
Equipment failure	Not applicable
SP ill/emergency	The primary SP became ill or an emergency occurred and the test could not be performed on the SP.
Interrupted	Not applicable
Needs blood draw	The SP went to MEC interview first and the venipuncture is still pending.
Needs questionnaire	The SP went to phlebotomy first and the questionnaire is still pending.
Collected in home	Not applicable
Other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the VOC examination, use the mouse to direct the mouse arrow to the Finish button in the navigation bar and left click or press [Enter] when the Finish button is highlighted. If the SP is in the MEC, escort them back to the coordinator.

## **A.6 The Return Visit Second Exam SPs**

MEC examinees are recruited to return for a second MEC exam. The coordinator asks examinees as they exit the MEC if they would be willing to return for a dietary day 2 interview, a second exam, or both. Only examinees who had their blood drawn, had most components completed, and agree to have phlebotomy again will be recruited for a second exam.

Approximately 16-20 second exams are performed at each stand for quality control purposes. The field office determines if the examinee is eligible for a second exam. Some examinees may not be eligible because of participation in other components such as the mental health CATI. Second exams may be scheduled beginning 1 week after the primary exam, and will generally be scheduled towards the end of a stand schedule when exam sessions are lighter. In the event of a conflict in obtaining a primary MEC exam component or a second exam component, the primary MEC exam component should always be given preference.

The coordinator application identifies second exam SPs who are returning to the MEC and assigns the second exam SP to both the phlebotomy room and the MEC interview room. In phlebotomy, the phlebotomist logs the second exam SP into the phlebotomy exam, and performs venipuncture to collect the second exam venipuncture protocol tubes, which includes two blood tubes using 7-mL gray-top Vacutainers®. Labels print automatically for the blood specimens. The MEC interviewer administers a unique second exam VOC questionnaire.

### **A.6.1 Open the Phlebotomy Application and Log the Second Exam VOC SP into the Phlebotomy Component**

Open the Phlebotomy application.

- To open the phlebotomy application, use the mouse to direct the mouse arrow to the phlebotomy icon on the desktop and double click.

Log onto the Phlebotomy application.

- The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the **OK** button and left click. To exit this window without entering a password, use the mouse to direct the mouse arrow to the **Cancel** button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the **Message** button and left click.



The Message Center window identifies the SP assigned to phlebotomy.

- A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component displays. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the **Send** button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the **Close** button and left click, or select [Enter].

Open the phlebotomy exam.

- To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

The SP Logon window displays.

- The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the **OK** button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Verify the information.

- Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

## **A.6.2 The Second Exam VOC Blood Collection - Phlebotomist**

Conduct the phlebotomy interview, administer the fasting questionnaire, perform the venipuncture, and review the exam section status.

The Phlebotomy application opens. Access or open a second exam phlebotomy examination.

- To open a phlebotomy exam for a second exam, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Open} and left click, or type [F/f] [O/o] or [Ctrl] [O/o].

Conduct the phlebotomy interview. Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly and record the responses.

- Record the response by typing [Y/y] for "Yes," [N/n] for "No," [R/r] if they refuse, or [D/d] for "Don't know." Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to "Yes," "No," "Refused," or "Don't Know" and left click. If the response is "Yes," "Refused," or "Don't Know," use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the window and left click.

Administer the fasting questionnaire.

- Read the text exactly and record the time. Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to "AM" or "PM" and left click.
- 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, select [F2]. 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 up-down 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.
- Continue administering the questionnaire. Verify the initial time response by asking the remaining questions.

The window displays the appropriate venipuncture protocol for returning second exam SPs. Only second exam SPs ages 20-59 are eligible for the two additional VOC blood tubes. Complete the second exam venipuncture procedure (Exhibit A-5) using procedures described in Chapter 4.

Exhibit A-5. Venipuncture protocol – second exam

Age in Years	12-19	20-59	60-69
Tube Type – Priority			
5-mL Lavender	2	2	2
3-mL Gray (Morning sessions only)	1	1	1
3-mL Blue (40+)		1	1
15-mL Red	2	2	2
7-mL Gray		2	

Enter the blood draw results.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area displays patient information: "SP ID: 238916", "Name: PARKWOOD, JANE", "Age: 22 years", "Gender: Female", "Date: 03/13/2001", and "Time: 09:31 AM". Below this is a section titled "Venipuncture". It contains four rows of data: "5 ml EDTA" with a spin box set to "0" of 2, "3 ml gray" with a spin box set to "0" of 1, "15 ml red" with a spin box set to "0" of 2, and "7 ml gray" with a spin box set to "0" of 2. To the right of these rows is a checkbox labeled "Obtained all" which is currently unchecked. Below the checkbox is the number "232636". At the bottom of the main content area is a "Comment:" label followed by a text input field. At the very bottom of the window is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish", along with a blue arrow icon. The status bar at the bottom of the screen shows "Ready", "MEC Layer: 3/8/01", "Application: Ver 9.2.26A", "Not connected to Coordinator", and "09:31 AM".

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes and pass to the laboratory. To collectively mark all tubes as collected, use the mouse to direct the mouse arrow to the Obtained all check box and left click to insert a check mark or type [Alt] [B/b].

To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue are arrows are highlighted.

Review the examination status.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays patient information: "SP ID: 238916 Name: PARKWOOD, JANE Age: 22 years Gender: Female Date: 03/13/2001 Time: 09:31 AM". The main area is titled "Venipuncture Status" and contains a "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below the status section are two text input fields: "Comments" and "Other text". At the bottom of the window, there is a navigation bar with a page indicator "4 of 4" and buttons for "End of Section", "Close Exam", and "Finish". The system tray at the very bottom shows "Ready", "MEC Layer: 3/8/01", "Application: Ver 9.2.26A", "Not connected to Coordinator", and "09:32 AM".

Use comment codes to explain partial and not done status codes. Exams are partial if one or more of the blood tubes are collected and not done is none of these specimens is collected.

### **A.6.3 The Second Exam VOC Questionnaire – MEC Interviewers**

The MEC interviewer administers the unique second exam VOC questionnaire. Access the VOC application, open a VOC examination, and log the second exam SP into the exam. Verify all information that appears on the SP Logon window. The second exam VOC questionnaire displays on the subsequent windows.

Record the various text and numeric responses by using one of the following two methods.

- Record text responses either by typing the first letter of the choice, or select or highlight the correct choice by using the mouse to direct the mouse arrow to the drop-down list, left click, drag the mouse arrow to the correct choice, and left click when the correct choice is highlighted. Select [Tab] to move to the next question.
- Record numeric responses by using the keyboard's numeric keys to enter the number and select [Tab] to move to the next question.

Begin to administer the second exam VOC questionnaire. Ask each question exactly as presented on the window.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

SP ID: 238916 Name: PARKWOOD, JANE Age: 22 years Gender: Female Date: 03/13/2001 Time: 09:36 AM

VOC Questionnaire

I would like to ask you a few questions about your home. Does your home have an attached garage?

Was your home or building originally built less than 5 years ago?

Which one of the following is the best description of the street that you live on? Is it a...

Does your kitchen stove use natural gas, electricity, or something else?

In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please only consider wall-to-wall carpeting or room-sized rugs.

Do you store paints or fuels inside your home? Include your basement (and attached garage.)

1 of 4

End of Section Close Exam Finish

Ready MEC Layer: 3/8/01 Application: Ver 9.2.19B Connected to Coordinator SP assigned to room 09:36 AM

**Q1: I would like to ask you a few questions about your home. Does your home have an attached garage? [Yes, No, Refused, Don't know]**

<p>Q1: This question refers to the primary residence where the second exam SP lives and specifically refers to whether or not the home has a garage and if it does, is it attached.</p>	<p>Home refers to the building where the second exam SP lives. This can be a mobile trailer, apartment, townhouse, single, or multiple family building. An attached garage refers to a building or wing of a building in which a car is parked that is also attached or connected as a part to the home. Select "Yes," if the home has an attached garage, "No" if it does not, "Refused" if the second exam SP refuses to answer the questions, and "Don't know" if the second exam SP is unsure.</p>
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**Q2: Was your home or building originally built less than 5 years ago? [Yes, No, Refused, Don't know]**

<p>Q2: This question asks the age of the second exam SP's home or primary residence.</p>	<p>Ask the second exam SP to state the age of their home or when they believe their home was built. If the home was built less than 5 years ago, select "Yes." If the home is older than 5 years, select "No." If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know or cannot estimate the age of their home, select "Don't know."</p>
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**Q3: Which one of the following is the best description of the street that you live on? Is it a [Rural or country road, Dead-end residential street, Through residential street, Commercial street, Major highway, Refused, Don't know]?**

<p>Q3: This question asks the second exam SP to describe the street on which their house or primary residence is located.</p>	<p>Ask the second exam SP to decide which of the choices best describes the street on which their home is located. Rural or country refers to country as opposed to urban or suburban. This includes farming and agriculture areas. Dead-end residential refers to a street in a suburban or small area that does not go through to another street. Through residential describes a street in a suburb, city, or small town that does go through to another street. A commercial street is a street that has commercial businesses located on it. A major highway is any state-designated highway or Federal interstate highway. Select the SP response. If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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**Q4: Does your kitchen stove use natural gas, electricity, or something else? [Natural gas, Electricity, Something else, Refused, Don't know]**

<p>Q4: This question asks the second exam SP to describe the energy source for their kitchen stove.</p>	<p>Ask the second exam SP to decide if the source of power or energy for their kitchen stove is one of the choices. Natural gas refers to propane and other natural gases used as fuel. Electricity refers to electric current used or regarded as a source of power. "Something else" refers to any other known energy source other than natural gas or electricity such as a wood stove or coal furnace. Select the second exam SP's response. If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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**Q5: In the last 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? [Yes, No, Refused, Don't know]**

<p>Q5: This question asks the second exam SP to decide if the carpets or rugs in any of the three environments are new within the last 6 months.</p>	<p>If the carpets or rugs in any of these three environments are less than 6 months old, select "Yes." If the carpets or rugs are older than 6 months select "No." If the second exam SP refuses to answer the question, select "Refused" and if the SP does not know or cannot estimate the age of their carpets and rugs, select "Don't know."</p>
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**Q6: Do you store paints or fuels inside your home? Include your basement (and attached garage.) [Yes, No, Refused, Don't know]**

<p>Q6: This question asks the second exam SP to decide if they currently have any paints or fuels stored inside their home. Include the basement and attached garage if the second exam SP reports having an attached garage.</p>	<p>Include areas of the home like the basement and attached garage. Do not include separate storage facilities like barns or sheds on the same property. Include all paints, both indoor and outdoor, and fuels like propane or butane. Do not include wood or coal. If the second exam SP indicates they store paint or fuels in any of these locations, select "Yes." If the second exam SP reports they do not store these items in these locations, select "No." If the second exam SP refuses to answer the question, select "Refused" and if the second exam SP does not know, select "Don't know."</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

SP ID: 238916 Name: PARKWOOD, JANE Age: 22 years Gender: Female Date: 03/13/2001 Time: 09:36 AM

VOC Questionnaire for Day 2 Exam

Now I am going to ask you a few questions about your activities over the last three days. This means today, yesterday, or the day before yesterday.

In the last three days, did you pump gas into a car or other motor vehicle yourself?

In the last three days, did you spend any time at a swimming pool?

In the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

In the last three days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors?

In the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

In the last three days, did you take a hot shower for five minutes or longer?

2 of 4

End of Section Close Exam Finish

Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.19B | Connected to Coordinator | SP assigned to room | 09:37 AM

Read the script to the second exam SP. "Now I am going to ask you a few questions about your activities over the last 3 days. This means today, yesterday, or the day before yesterday."

**Q7: In the last three days, did you pump gas into a car or other motor vehicle yourself? [Yes, No, Refused, Don't know]**

<p>Q7: This question asks the second exam SP to report if they pumped gas into a car or other motor vehicle during the last 3 days.</p>	<p>Include any grade of gas but do not include natural gas. Include pumping gas into a container, such as a lawn mower container. Do not record "Yes" if the second exam SP reports being a passenger in a car into which gas was pumped. If the second exam SP reports actually pumping gas into any car or motor vehicle, select "Yes." If the second exam SP reports they did not pump gas into a car or other motor vehicle, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know if they pumped gas into any car or other motor vehicle, select "Don't know."</p>
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**Q8: During the last three days, did you spend any time at a swimming pool? [Yes, No, Refused, Don't know]**

<p>Q8: This question asks the second exam SP to report if they spent any time at a swimming pool during the last 3 days.</p>	<p>Determine if the second exam SP spent time at a swimming pool. The second exam SP did not have to swim in the pool. If the second exam SP reports being at or in a swimming pool, select "Yes." If the second exam SP reports that they were not at a swimming pool, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they were at a swimming pool, select "Don't know."</p>
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**Q9: During the last three days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week? [Yes, No, Refused, Don't know]**

<p>Q9: This question asks the second exam SP to report if they visited a dry cleaning shop or wore clothes that had been dry cleaned within the last week.</p>	<p>The cleaning process cleans clothing with chemical solvents having little or no water. Determine if the second exam SP visited a dry cleaning shop during the time they used the exposure badge or if they wore clothes that had been dry-cleaned within the last week or 7 days. If the second exam SP meets either criterion, select "Yes." If the second exam SP reports that they were not at a dry cleaners and have not worn clothes dry-cleaned within the last week, select "No." If the second exam SP refuses to answer, select "Refused." If the SP second exam does not know or cannot remember if they were at a dry cleaning shop or wore clothes dry-cleaned within the last week, select "Don't know."</p>
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**Q10: During the last three days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors? [Yes, No, Refused, Don't know]**

<p>Q10: This question asks the second exam SP to either report if they have spent 10 or more minutes near wood-burning fires indoors or outdoors during the last 3 days.</p>	<p>Include wood-burning devices such as wood stoves, fireplaces, and outdoor pits or fires. If the second exam SP meets any of these criteria, select "Yes." If the second exam SP reports that they have not been around any of these sources of wood fires, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they spent any time near wood burning fires while using the exposure badge, select "Don't know."</p>
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**Q11: During the last three days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe? [Yes, No, Refused, Don't know]**

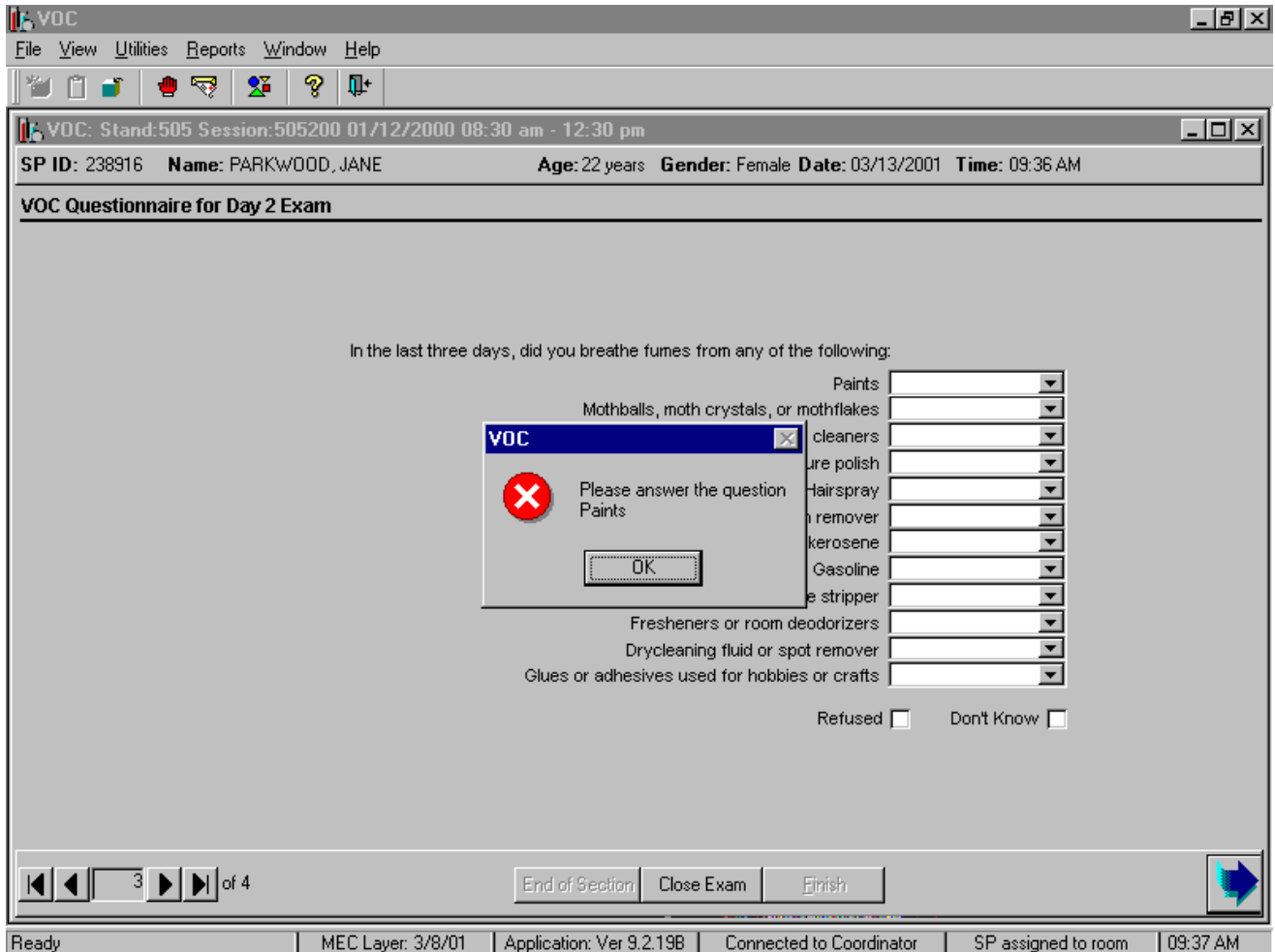
<p>Q11: This question asks the second exam SP to report if they have spent 10 or more minutes near any person who was smoking cigarettes, cigars or a pipe during the last 3 days.</p>	<p>Include any brand of cigarette, any size of cigar, or any style of pipe. If the second exam SP meets any of these criteria, select "Yes." If the second exam SP reports that they have not been around any of these sources of smoke, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall if they spent any time near someone who was smoking these forms of tobacco while using the exposure badge, select "Don't know."</p>
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**Q12: In the last three days, did you take a hot shower for five minutes or longer? [Yes, No, Refused, Don't know]**

<p>Q12: This question asks the second exam SP to report if they took a hot shower for at least 5 minutes during the last 3 days.</p>	<p>Determine if the second exam SP took a hot shower for at least 5 minutes. If the second exam SP reports taking a hot shower for a total of at least 5 minutes, select "Yes." If the second exam SP reports taking a cold or warm shower or a hot shower for less than 5 minutes, select "No." If the second exam SP refuses to answer, select "Refused." If the second exam SP does not know or cannot recall taking a hot shower for at least 5 minutes, select "Don't know." Select the bottom right blue arrow to proceed to the next window.</p>
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To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

The next window displays.



Continue to enter responses for each item. If the bright blue arrow in the navigation bar or [Enter] is inadvertently selected, an error message text box displays. Review the text and, to remove the message text box, use the mouse to direct the mouse arrow to the **OK** button and left click, or select [Enter].

**Q13: In the last three days, did you breathe fumes from any of the following? [Yes, No, Refused, Don't know]**

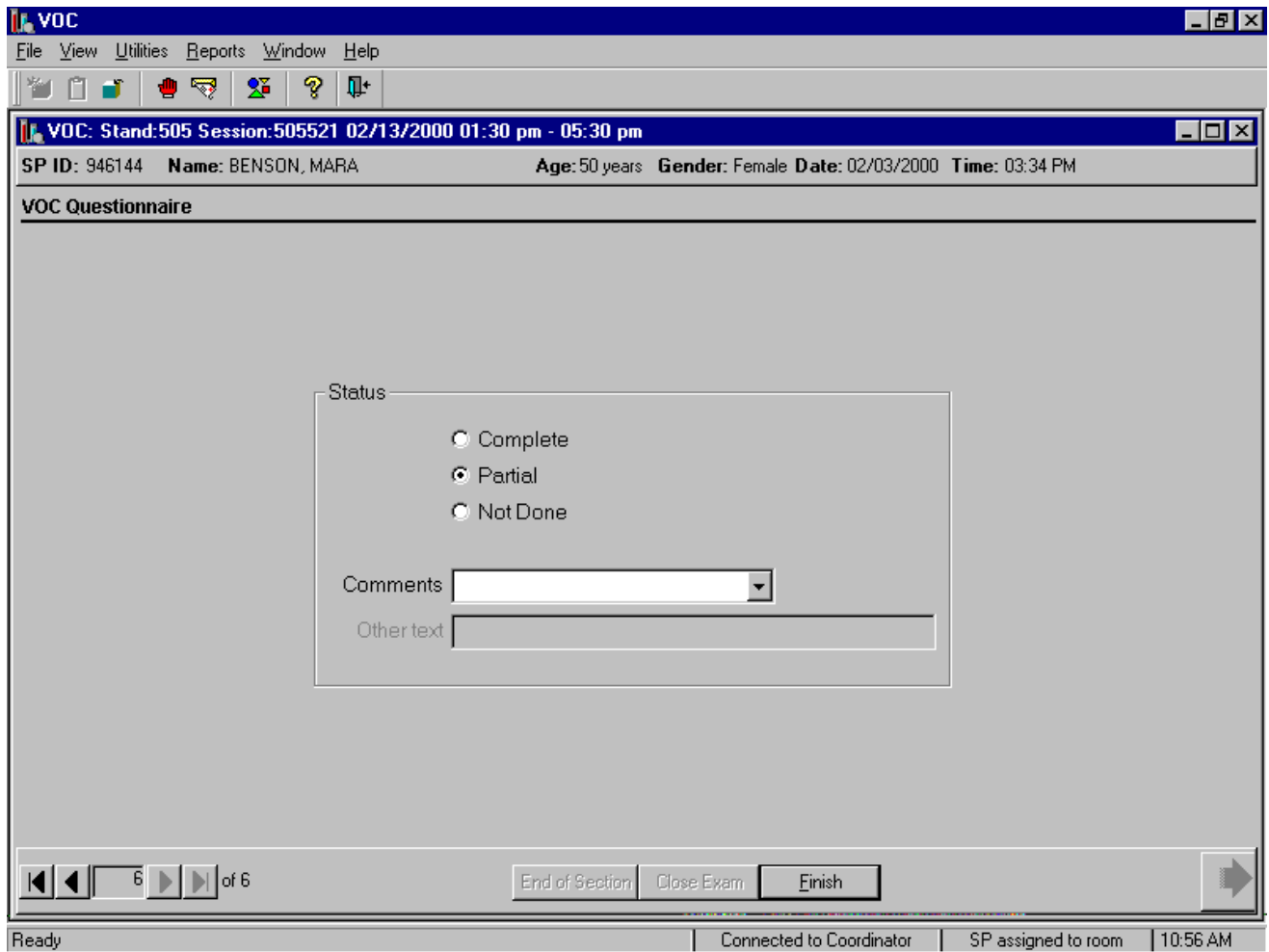
<p>Q13: This question asks the second exam SP to report if they breathed fumes from a variety of sources during the last 3 days.</p>	<p>Individually determine if the second exam SP breathed fumes from each source. Record each answer. If the second exam SP reports breathing fumes from an item while using the exposure badge, select "Yes." If the second exam SP reports s/he did not breath fumes while using the exposure badge, select "No." If at any point during the interview the second exam SP refuses to answer any further questions, select the "Refused" square. If the second exam SP does not know or cannot recall breathing fumes while using the exposure badge, select "Don't know" or if the second exam SP reports they do not know the answer to all the remaining choices, select the "Don't know" square. Select the bright blue arrow to proceed to the last window.</p>
<p>Paints</p>	<p>Include all interior and exterior paints, spray paints used in arts and crafts, and oil-based artist paints.</p>
<p>Mothballs, moth crystals, or mothflakes</p>	<p>Mothballs are composed of a ball of camphor or naphthalene. They are used for protection of clothes from moths.</p>
<p>Household disinfectant or degreasing cleaners</p>	<p>Consider all disinfectants including Lysol® and PineSol®.</p>
<p>Furniture polish</p>	<p>Consider Pledge®, Liquid Gold, and lemon polish and all other brands of furniture polish.</p>
<p>Hairspray</p>	<p>Consider all brands of hairspray.</p>
<p>Fingernail polish or fingernail polish remover</p>	<p>Nail polish and nail polish remover contains acetone.</p>
<p>Diesel fuel or kerosene</p>	<p>Diesel fuel is a crude oil. Kerosene is hydrocarbon oil, chiefly of the methane series, used for burning in lamps. It is also called coal oil.</p>
<p>Gasoline</p>	<p>Gasoline is a distillate of crude petroleum.</p>



Paint thinner, brush cleaner, or furniture stripper	These items contain turpentine.
Air fresheners or room deodorizers	Consider all spray types of air fresheners such as Airwick®, Glade®, and Lysol® and include the type that affixes to a wall or toilet or stands upright in a dispenser.
Dry-cleaning fluid or spot remover	Consider all spot removers like K2R.
Glues or adhesives used for hobbies or crafts	Glue is a viscid cement or adhesive preparation and is usually an impure gelatin derived from boiling certain animal substances. Hobby glue contains a significant amount of toluene.

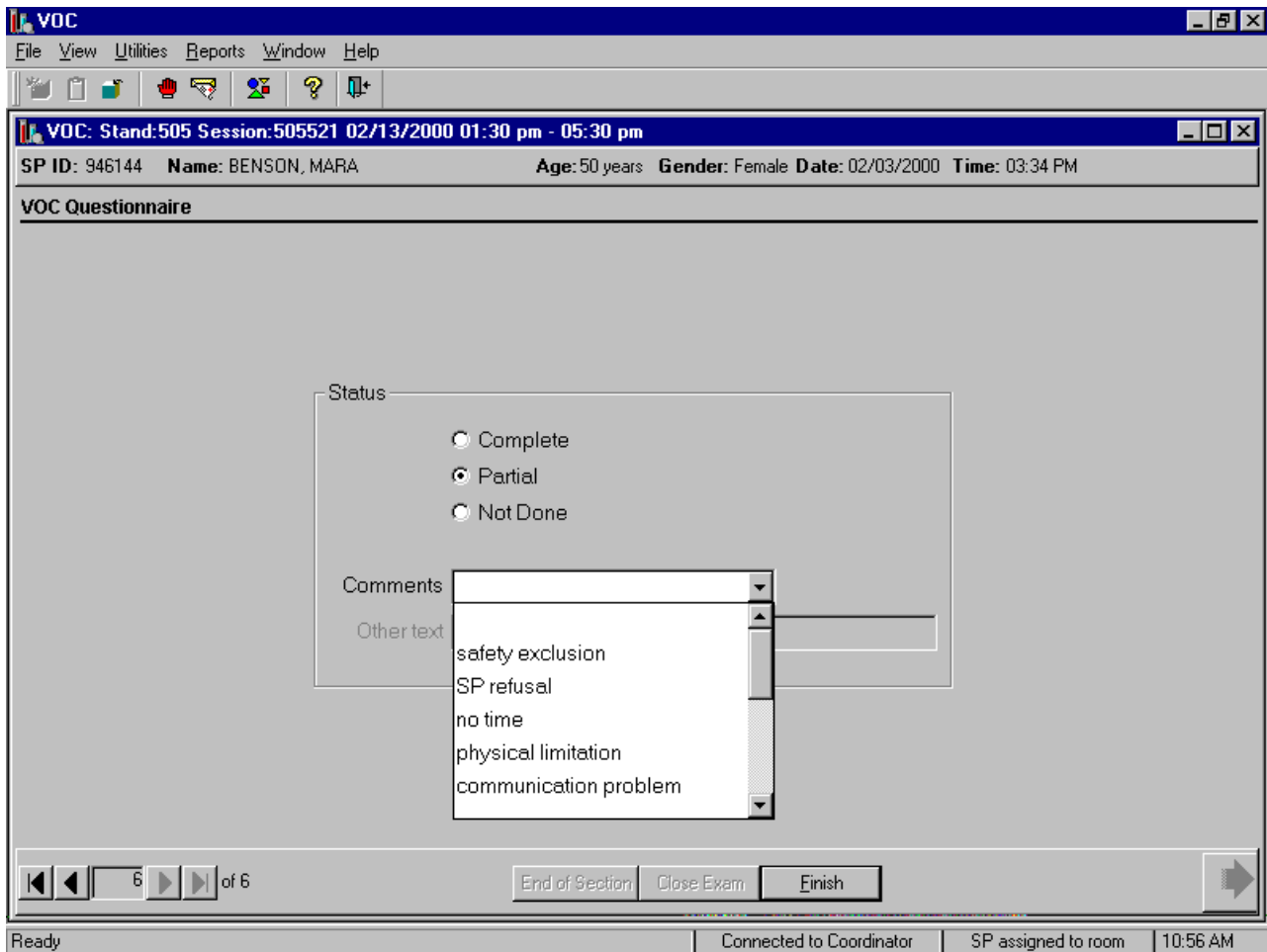
To move to the next window, use the mouse to direct the mouse arrow to the bright blue arrow in the navigation bar and left click or select [Enter] when the bright blue arrow is highlighted.

Verify the status code for the second exam VOC examination.



Comment codes are used to explain partial and not done status codes.

Choose and enter the appropriate Comment Code when section status is partial or not done.



To select a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the codes, drag the arrow to select or highlight the most appropriate choice and left click. Alternatively to select a comment code, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click. If "Other, specify" is chosen, type a short explanation in the "Other text" text box.

Comment Code	Use when:
Safety exclusion	Not applicable
SP refusal	This is SP initiated nonresponse 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 codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.

No time	Not applicable
Physical limitation	The venipuncture is unsuccessful.
Communication problem	Not applicable
Equipment failure	Not applicable
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
Interrupted	Not applicable
Other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

To complete the VOC examination, use the mouse to direct the mouse arrow to the **Finish** button in the navigation bar and left click or press [Enter] when the **Finish** button is highlighted. Escort the SP back to the coordinator.

## A.7 Reviewing an Exam

Review a completed exam. Access the Review module.

- To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F/f], [V/v]. The Session PickUp list displays.

Select the session.

- The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Select the SP.

- The SP Login window displays. To view a list of previously examined SPs, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.

- The Sample Person ID and Sample Person Name text boxes fill in with the SP ID and SP ID-last name. To continue, use the mouse to direct the mouse arrow to the **Retrieve** button and left click, or select [Enter]. To exit, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Continue to select the SP.

- Once the **Retrieve** button is selected, the remaining data in the SP Login box fills in. To move forward and to review the exam, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. The phlebotomy exam windows with results are displayed. To progress through the windows, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

After the phlebotomy protocol window is displayed and the bright blue arrow in the bottom right hand corner is selected, a Print Labels message text box displays.

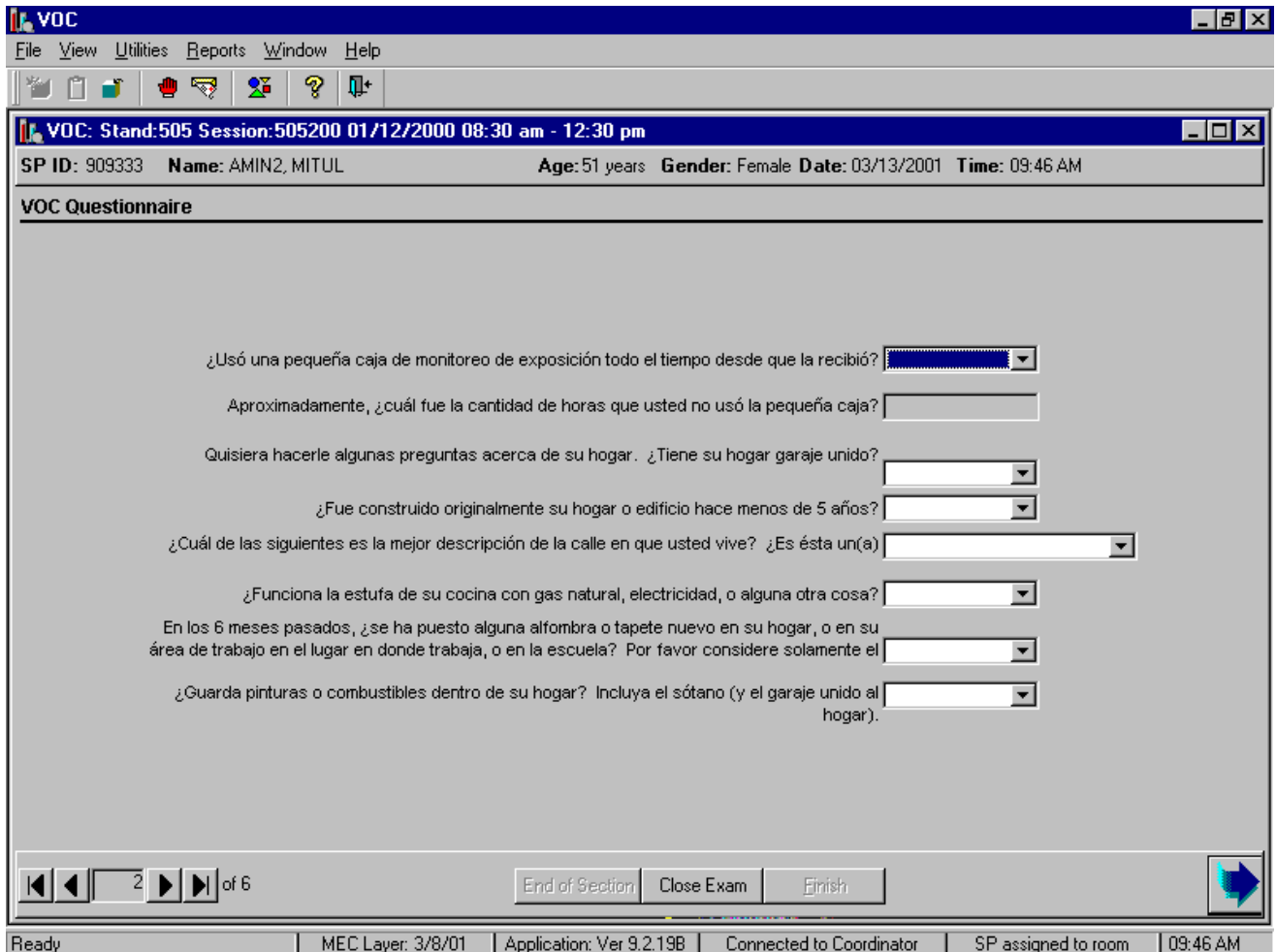
- The Print Labels informational message text box displays the following message; "Data is already present. Do you wish to print labels?" To reprint the labels, use the mouse to direct the mouse arrow to the **Yes** button and left click, or select [Enter]. To decline the opportunity to reprint labels, use the mouse to direct the mouse arrow to the **No** button and left click. The venipuncture status window displays. To finish, select [Enter] or use the mouse to direct the mouse arrow to the **End of Section** button and left click.

## **A.8 Performing the Venipuncture, and Administering the Primary and Second Exam Questionnaire on SPs Who Do Not Speak English**

When the phlebotomist or home examiner performs the venipuncture procedure on a primary or second exam SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the SP's language assists the phlebotomist. When the MEC interviewer or home examiner must administer either the primary or second exam questionnaire to a SP who does not speak English and the MEC interviewer or home examiner does not speak the language of the SP, a translator who does speak the SP's language assists them.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the venipuncture.

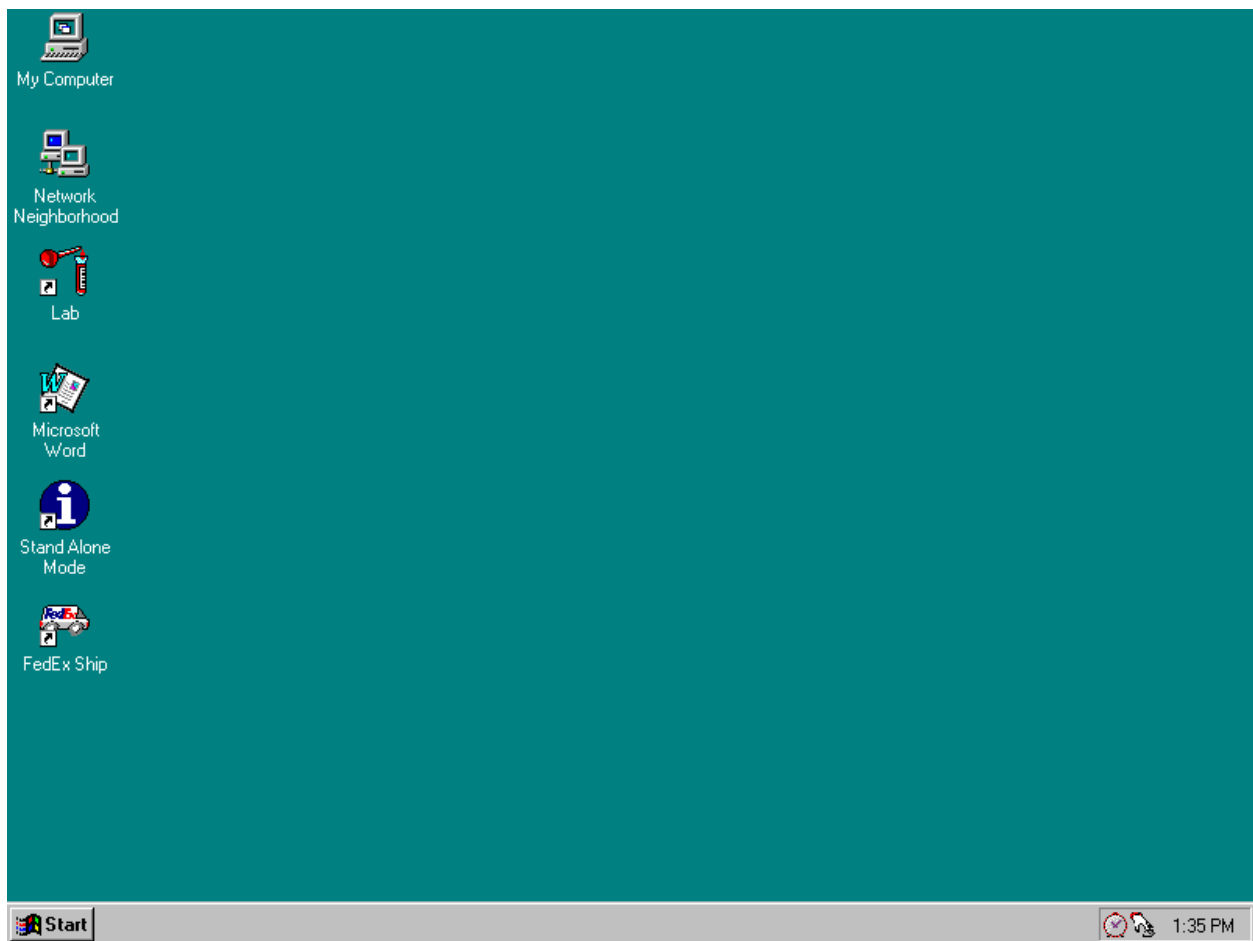
Convert the phlebotomy interview and fasting questionnaire text from English to Spanish or from Spanish to English at any time before, during, or after an exam.



To view the phlebotomy interview, fasting questions, or questionnaires in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S/s]. To return the phlebotomy interview, fasting questions, or questionnaire to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E/e].

## A.9 Processing VOC Specimens (Vessels) in the Laboratory

Open the laboratory application, select the correct session, and review the heads-up display.



To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Use the set session function to retrieve home sessions. The process steps are identical for both MEC and home sessions. Review the heads-up display.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status												
								UC	B	CB	U	P	BV	hiv	H	V	N			
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	○	○	○	○	○	○	○	○	○	○	○	○
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	○	○	○	○	○	○	○	○	○	○	○	○	○
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	○	○	○	○	○	○	○	○	○	○	○	○	○
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	○	○	○	○	○	○	○	○	○	○	○	○	○
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	○	●	○	●	○	○	○	○	○	○	○	○
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	○	○	○	○	○	○	○	○	○	○	○	○	○
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	○	○	○	○	○	○	○	○	○	○	○	○	○
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	○	○	○	○	○	○	○	○	○	○	○	○	○
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	○	○	○	○	○	○	○	○	○	○	○	○	○
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	○	○	○	○	○	○	○	○	○	○	○	○	○
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	○	○	○	○	○	○	○	○	○	○	○	○	○
811000	161096	SC	V		M	41	FRAZIER2, JAMES	○	○	○	○	○	○	○	○	○	○	○	○	○
865168	865168	SC	P	N	F	1	LAWLESS, SARA	○	○	○	○	○	○	○	○	○	○	○	○	○
909333	140929	SC	V		F	51	AMIN2, MITUL	○	○	○	○	○	○	○	○	○	○	○	○	○

MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 11:38 AM

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run, V=VOC), fast (M=morning, A=afternoon, E=evening, N=none), Gender (M=male, F=female), Age, and Name (last, first.)

The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible for a module when the process status is ○. The SP is eligible for a module but no results have been recorded when the process status is ●. The SP is eligible for a module and some results



have been recorded when the process status is **⊙**. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is **●**. The SP is eligible for a module but the process status is **O** until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from **O** to **⊙**. The SP is eligible for the hiv module but the status is **O** until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from **O** to **⊙**. The process status updates and changes after each result is saved.

The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP for urine collection. Select a different SP if active SP is not the SP of choice.

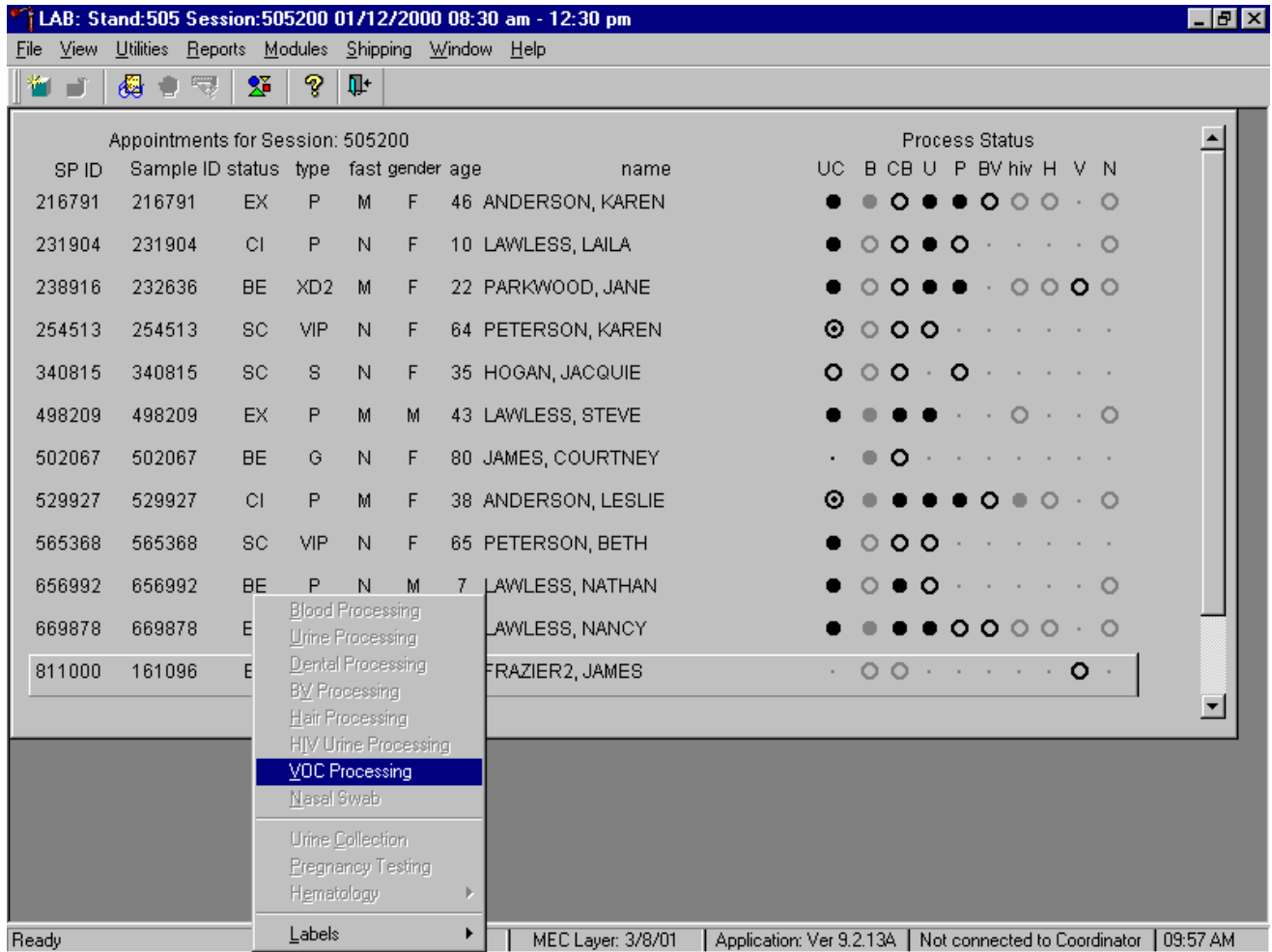
To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down. Alternatively, to view all SPs use the mouse to direct the mouse arrow to the bottom of the heads-up display, right click, and drag the display up or down.

Table A-1 illustrates the VOC processing and storage protocol.

Table A-1. VOC processing and storage protocol

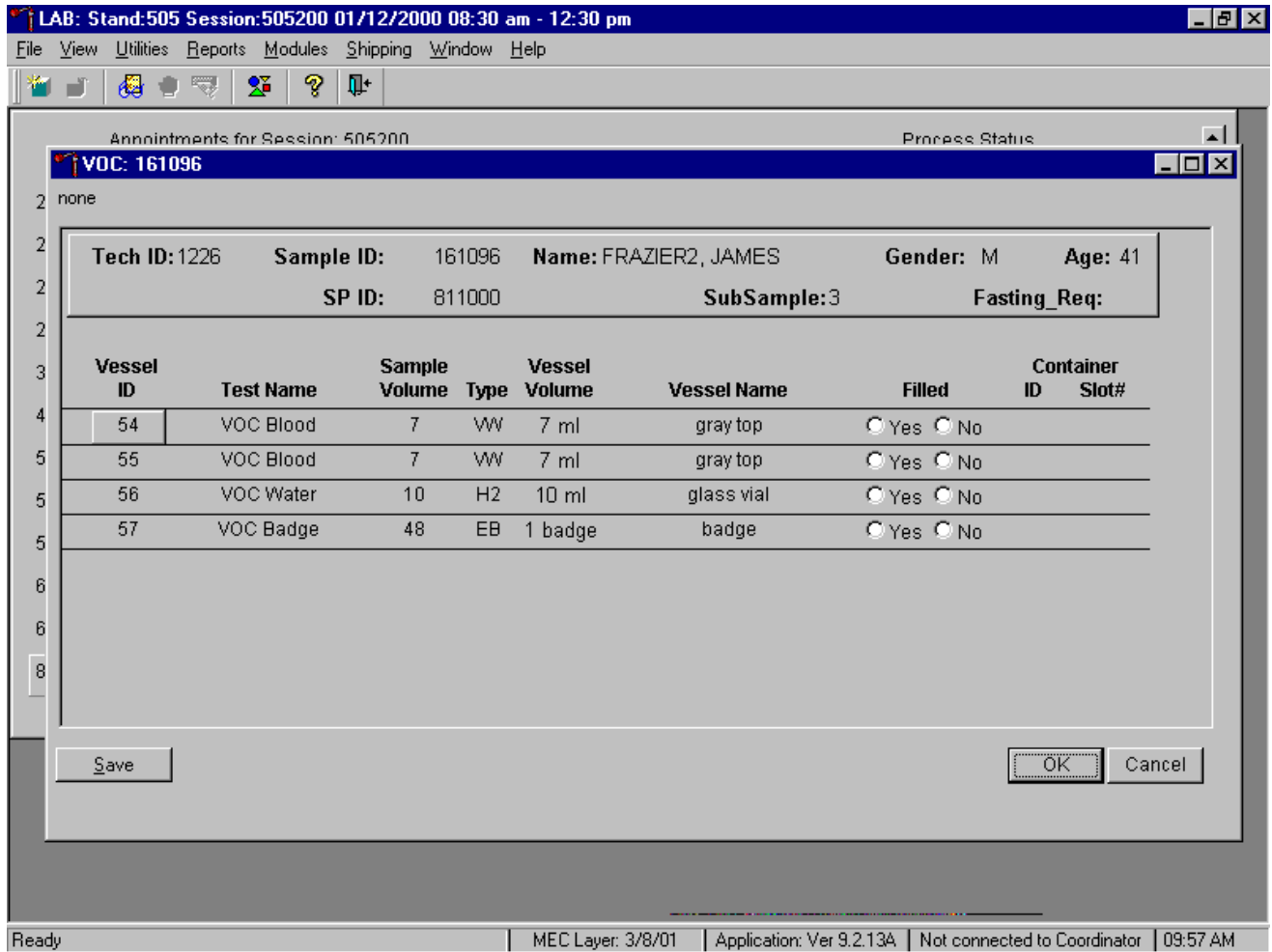
Vessel No	Assay	Age in years	Sample size mL	Collection Type	Vessel Storage
54	VOC Blood	20-59	7	7-mL Gray top	1 x 5 foam mailer
55	VOC Blood	20-59	7	7-mL Gray top	1 x 5 foam mailer
56	VOC Water	20-59	10	10-mL Glass	1 x 3 foam mailer
57	VOC Badge	20-59	48 hour	Badge	12 x 12 Plastic bag

Access the VOC processing module.



To access the VOC processing module, use the mouse to direct the mouse arrow to the correct SP and right click, drag the mouse arrow to {VOC Processing} and right click or right click and type [V/v]. Alternatively to access the VOC processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {VOC Processing} and left click or type [V/v].

The VOC processing window displays.



Compare the Sample ID on the window to the bar code label on the vessels.



Review the heads-up display.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

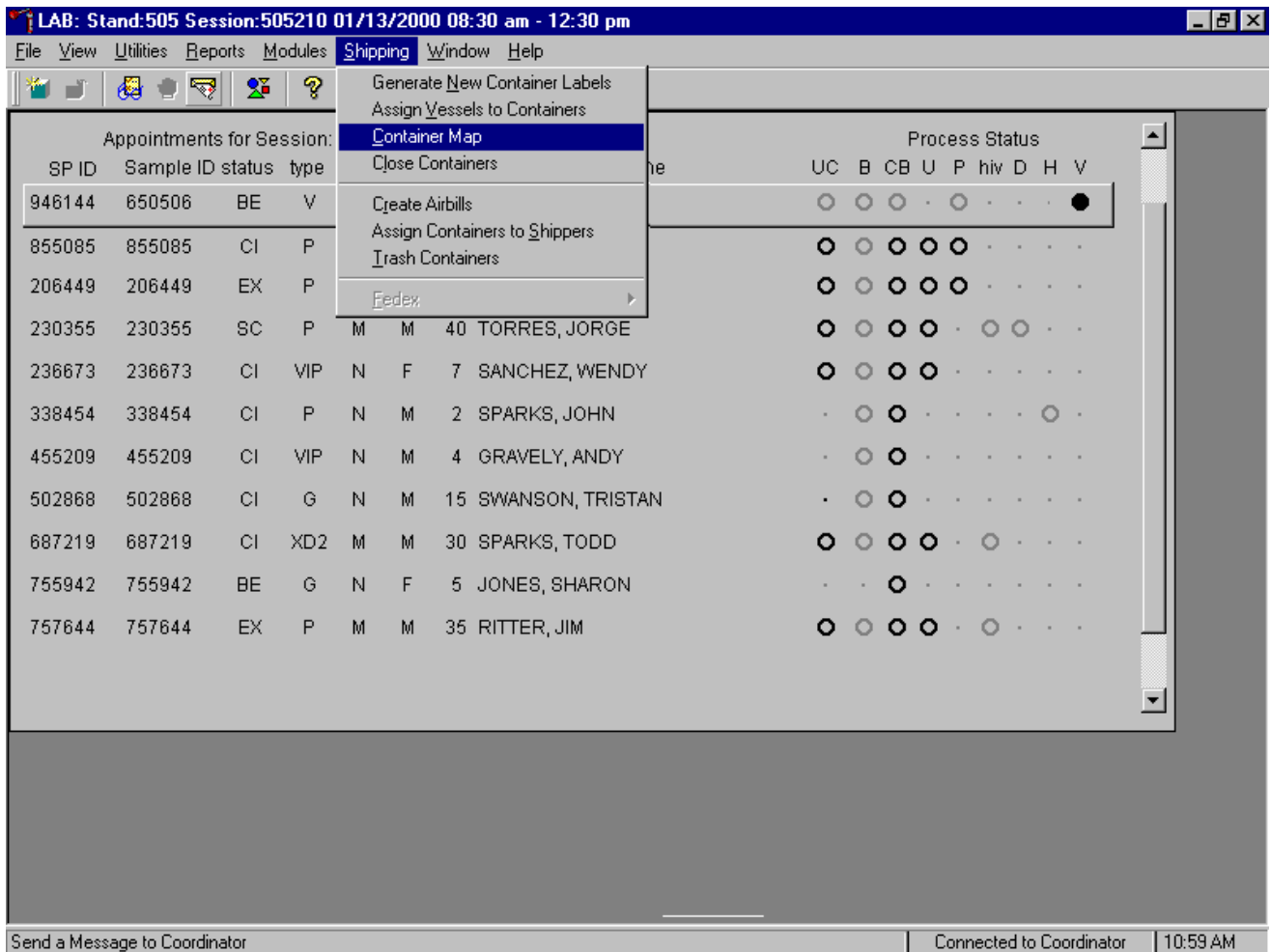
Appointments for Session: 505200

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status												
								UC	B	CB	U	P	BV	hiv	H	V	N			
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	-	●	●	-	-	-	-	-	●	-	●	-	●
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	-	●	●	●	●	●	●	●
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●	-	-	-	-	-	-	-	-	-
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	-	●	-	-	-	-	-	-	-	-
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	-	-	●	-	-	-	-	●	-
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	-	●	●	-	-	-	-	-	-	-	-	-	-
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	●	●	●	-	●
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●	-	-	-	-	-	-	-	-	-
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	-	-	-	-	-	-	-	-	●
669878	669878	BE	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	●	●	-	●
811000	161096	SC	V		M	41	FRAZIER2, JAMES	-	●	●	-	-	-	-	-	-	-	-	●	-
865168	865168	SC	P	N	F	1	LAWLESS, SARA	-	●	●	-	-	-	-	-	●	-	-	-	●
909333	140929	SC	V		F	51	AMIN2, MITUL	●	●	●	-	●	-	-	-	-	-	-	●	-

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Connected to Coordinator | 11:38 AM

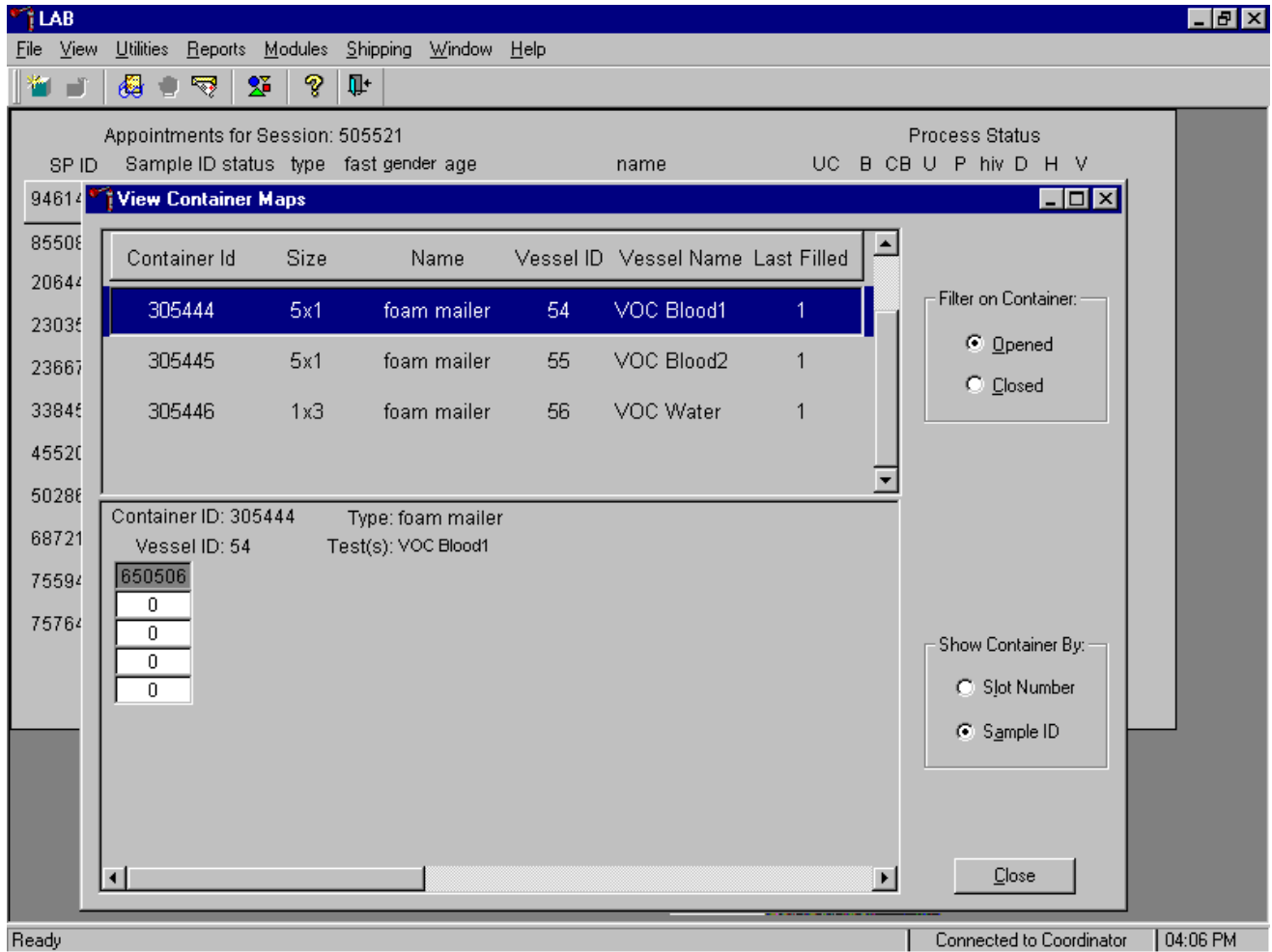
Verify that the heads-up display is updating correctly.

Check the slot assignment of containers associated with vessels 54-57, at the end of each session.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping}, drag the arrow to {Container Map} and left click or type [Alt] [S/s], [C/c].

Verify the contents of each container against the container map.



- Set the Filter on Container to "Opened" by using the mouse to direct the mouse arrow to "Opened" and left click.
- Set the Show Container By to "Sample ID" by using the mouse to direct the mouse arrow to "Sample ID" and left click.
- Highlight or select the container ID for vessel 54 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 54.
- Verify the container ID on the box against the container ID listed on the window and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.

- Continue checking each container map report for vessels 55, 56, and 57.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

## **A. 10      Quality Control**

The are four types of weekly VOC quality control (QC): repeat participant, field monitoring, positive control, and office air monitoring. Conduct one of each QC type weekly according to the following schedule. The phlebotomist is responsible for the repeat participant, the laboratory is responsible for the positive control, and the MEC interviewers are responsible for the field monitoring and the room air monitoring.

### **A.10.1      Week 1 – Repeat Participant**

The phlebotomist recruits two SPs who are asked to wear two badges for the entire 46-76 hours, one on each side of the lapel. The SP returns to the MEC 46-76 hours later. The phlebotomist collects two tubes of blood, both badges, one water sample and administers the VOC questionnaire. Labels print on the Intermec printer in the phlebotomy room and all specimens are delivered to the laboratory. The laboratory processes the samples using the heads-up screen (identical to dry run samples since the duplicate badge is blinded to the analysis laboratory). Only SPs who are eligible for MEC return appointments are eligible to be recruited as the repeat participant.



Recruit two SPs per stand as repeat participants.

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM

VOC Introduction

Will you participate in this special study? Yes

Airbadge Number: 946144

Airbadge Lot No: 067815

Expiration Date: 10/31/2002

Repeat Participant

1 of 3

End of Section Close Exam Finish

Ready MEC Layer: 3/8/01 Application: Ver 9.2.26A Not connected to Coordinator 09:23 AM

Enter the initial recruitment response, record the airbadge number, airbadge lot number, and expiration date in a manner identical to routine VOC SPs. Assess the SPs return appointment date and time and their willingness to participate. If the SP is eligible to return to the MEC and appears interested, ask if they would be willing to wear two badges, one on each side of their lapel.

Access the repeat participant QC function.

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM

VOC Introduction

Will you participate in this special study? Yes

Airbadge Number: 946144

Airbadge Lot No: 067815

Expiration Date: 10/31/2002

Cancel

1 of 3

End of Section Close Exam Finish

Ready MEC Layer: 3/8/01 Application: Ver 9.2.26A Not connected to Coordinator 09:24 AM

To access the repeat participant QC function, use the mouse to direct the mouse arrow to the **Repeat Participant** button and left click. A second set of response boxes appears. If the SP then decides they do not want to wear two badges, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Enter the information for the second badge.

Phlebotomy: Stand:505 Session:505500 02/11/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 946144 Name: BENSON, MARA Age: 50 years Gender: Female Date: 03/13/2001 Time: 08:48 AM

VOC Introduction

Will you participate in this special study? Yes

Airbadge Number: 946144 946144

Airbadge Lot No: 067815 067815

Expiration Date: 10/31/2002 10/31/2002

Cancel

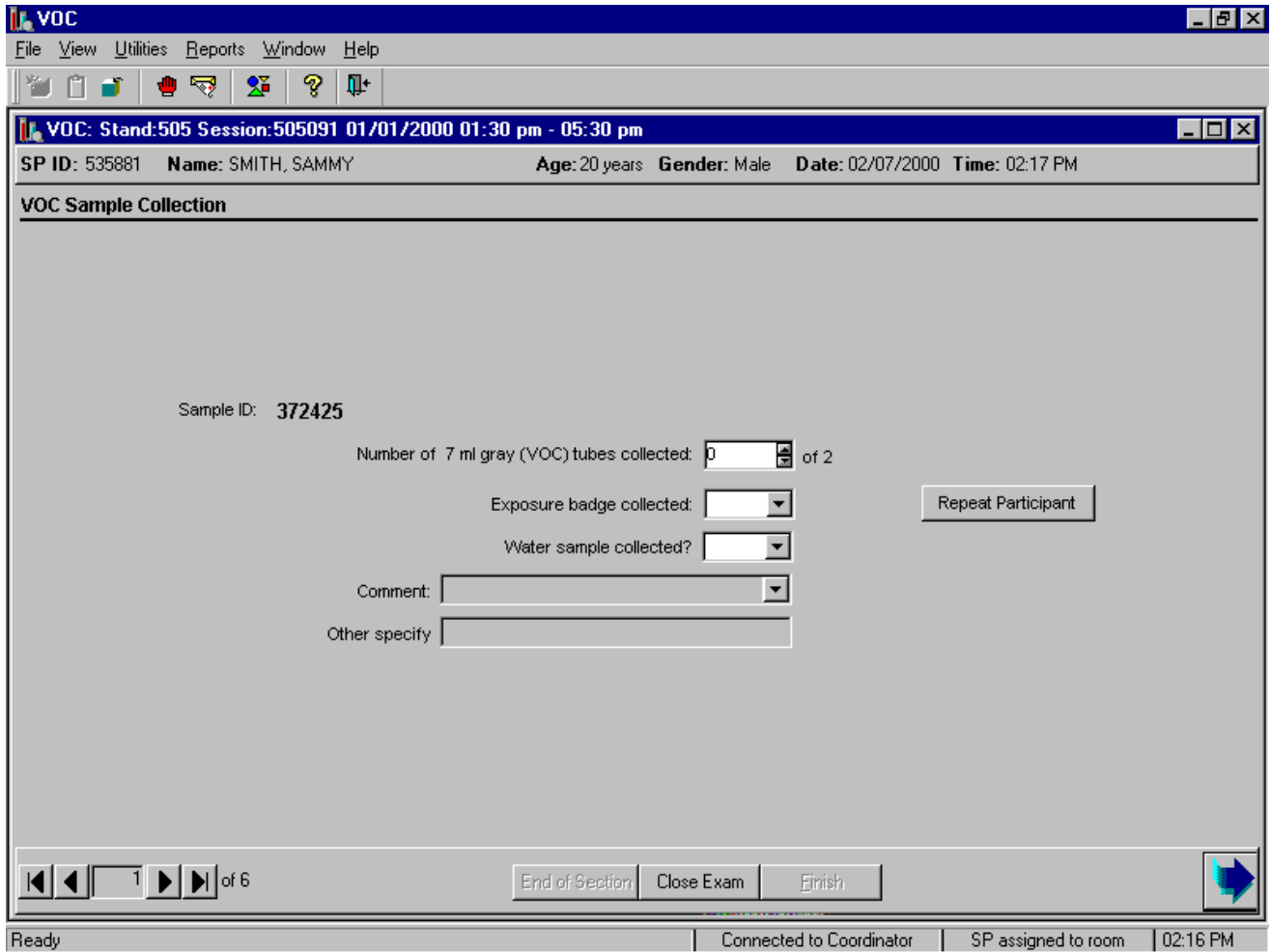
1 of 3

End of Section Close Exam Finish

Ready MEC Layer: 3/8/01 Application: Ver 9.2.26A Not connected to Coordinator 09:24 AM

Enter the information for the second badge including the airbadge number, airbadge lot number, and expiration date in a manner identical to all routine primary VOC SPs. If the SP changes their decision, use the mouse to direct the mouse arrow to the **Cancel** button and left click. The second set of response boxes disappears and the **Repeat Participant** button becomes bold or active again. Continue to recruit two primary SPs as repeat participants. Once the second primary SP is recruited, the **Repeat Participant** button disappears. Continue the routine recruitment process by scheduling the return appointment, verifying the examination status, and escorting the primary SP back to the coordinator. The MEC interviewer attaches both badges to the primary SP as the SP exits the MEC.

The repeat participant returns to the MEC for their return appointment.



Log the repeat participant into the VOC application. The window displays the appropriate venipuncture protocol. Draw two 7-mL gray top tubes using procedures described in Chapter 4.

Immediately after completing the venipuncture, enter the results of the blood draw. To record either zero, one, or two tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up or down or type the correct number using the numeric keys. Label the blood tubes by placing the bar coded label on the tube. Pass the blood tubes through the window to the laboratory.

Record collection of the repeat participant's first exposure badge.

The screenshot shows the VOC software interface. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below the title bar, the participant information is displayed: "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The main area is titled "VOC Sample Collection" and contains the following fields and controls:

- Sample ID: 372425
- Number of 7 ml gray (VOC) tubes collected: 2 of 2
- Exposure badge collected: Yes (dropdown menu)
- Water sample collected? (dropdown menu)
- Comment: (text input field)
- Other specify (text input field)
- Repeat Participant (button)

At the bottom of the window, there are navigation controls: "End of Section", "Close Exam", "Finish", and a blue arrow button. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:17 PM".

To record yes or no type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. In the MEC, the labels generate automatically on the printer in the phlebotomy room for "Yes" responses.

Reassemble the badge. Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.

Record collection of the repeat participant's water vessel.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm

SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM

VOC Sample Collection

Sample ID: 372425

Number of 7 ml gray (VOC) tubes collected: 2 of 2

Exposure badge collected: Yes

Water sample collected? Yes

Comment: Yes

Other specify: No

Repeat Participant

1 of 6

End of Section Close Exam Finish

Ready | Connected to Coordinator | SP assigned to room | 02:17 PM

Record collection of the repeat participant's water vessel. To record yes or no, type [Y/y] for "Yes," or [N/n] for "No." Alternatively, to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. A label prints for "Yes" responses.

Record collection of the second (repeat) exposure badge.

VOC

File View Utilities Reports Window Help

VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm

SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM

VOC Sample Collection

Sample ID: 372425

Number of 7 ml gray (VOC) tubes collected: 2 of 2

Exposure badge collected: Yes  Repeat Participant

Water sample collected? Yes

Comment:

Other specify

1 of 6

End of Section Close Exam Finish

Ready | Connected to Coordinator | SP assigned to room | 02:19 PM

To record collection of the second (repeat) exposure badge, use the mouse to direct the mouse arrow to the **Repeat Participant** button and left click. A second response text box displays next to the original text box.

Continue recording collection of the second (repeat) exposure badge.

The screenshot shows the VOC software interface. The title bar reads "VOC". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". Below this, participant information is displayed: "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/07/2000 Time: 02:17 PM". The section is titled "VOC Sample Collection". The current sample ID is "372425". The number of 7 ml gray (VOC) tubes collected is "2" of 2. The "Exposure badge collected" dropdown is set to "Yes", and the "Water sample collected?" dropdown is also set to "Yes". A "Repeat Participant" button is visible. There are input fields for "Comment:" and "Other specify". At the bottom, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "02:19 PM".

To record yes or no, type [Y/y] for "Yes," or [N/n] for "No." Alternatively to record yes or no, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes" or "No" and left click. Labels generate automatically on the printer for "Yes" responses.



A second unique sample ID is assigned to the second badge.

The screenshot shows the VOC software interface. The main window title is "VOC: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm". The participant information is: "SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 02/09/2000 Time: 08:24 AM". The section is titled "VOC Sample Collection". The data entered includes: "Sample ID: 372425", "Sample ID: 376097", "Number of 7 ml gray (VOC) tubes collected: 2 of 2", "Exposure badge collected: Yes Yes", "Water sample collected? Yes", "Comment:" (empty), and "Other specify" (empty). At the bottom, there are navigation buttons: "End of Section", "Close Exam", "Finish", and a blue arrow button. The status bar at the very bottom shows "Ready", "Connected to Coordinator", "SP assigned to room", and "08:29 AM".

Note that there are two sample IDs, one for each badge. Reassemble and label the exposure monitoring badges.

- Snap elution cap onto the top of the primary monitor body. Separate the primary body and secondary body sections. Snap the bottom cup (no plugs) into bottom of the primary section. Snap the elution cap on the secondary body.
- Label one exposure badge with one set of labels and the second exposure badge with the second set of labels; each label set contains unique numbers. Label both sides of the exposure badge and the outside of the canister with the labels. Return the exposure badge sections to the canister and replace the canister plastic lid. Label the glass water sample vessel vertically with bar coded labels. The badges and water are ready for transport to the laboratory.

Administer the VOC questionnaire, verify the status of the examination, and escort the SP back to the coordinator.

Process the repeat participant's samples in the laboratory in a manner identical to dry run vessels.

LAB: Stand:505 Session:505091 01/01/2000 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

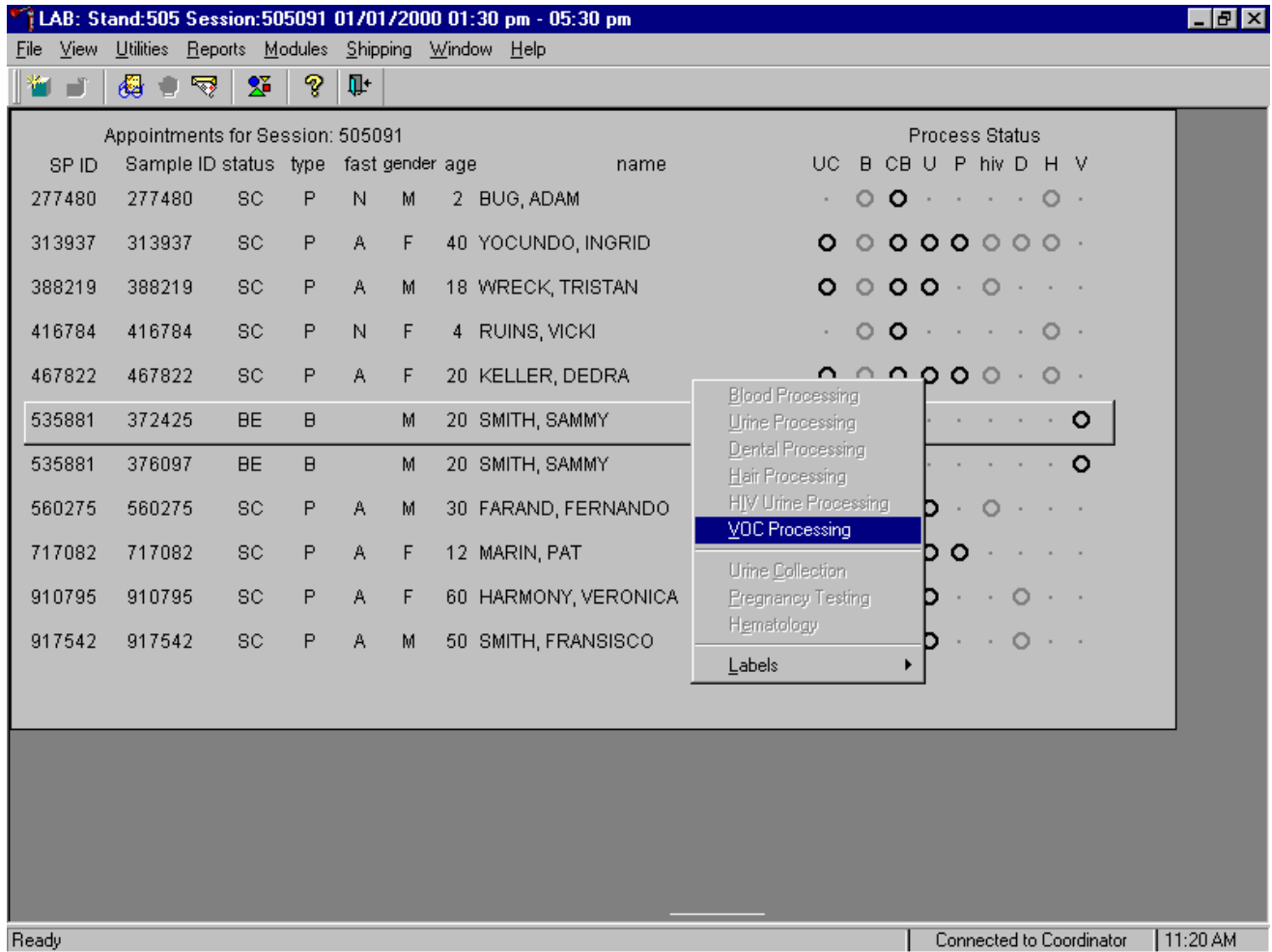
Appointments for Session: 505091

SP ID	Sample ID	status	type	fast	gender	age	name	Process Status								
								UC	B	CB	U	P	hiv	D	H	V
277480	277480	SC	P	N	M	2	BUG, ADAM	.	○	●	.	.	.	.	○	.
313937	313937	SC	P	A	F	40	YOCUNDO, INGRID	●	○	○	○	○	○	○	○	.
388219	388219	SC	P	A	M	18	WRECK, TRISTAN	○	○	○	○	.	○	.	.	.
416784	416784	SC	P	N	F	4	RUINS, VICKI	.	○	○	.	.	.	.	○	.
467822	467822	SC	P	A	F	20	KELLER, DEDRA	○	○	○	○	○	○	.	○	.
535881	372425	BE	B		M	20	SMITH, SAMMY	.	○	○	.	.	.	.	.	○
535881	376097	BE	B		M	20	SMITH, SAMMY	.	○	○	.	.	.	.	.	○
560275	560275	SC	P	A	M	30	FARAND, FERNANDO	○	○	○	○	.	○	.	.	.
717082	717082	SC	P	A	F	12	MARIN, PAT	○	○	○	○	○	.	.	.	.
910795	910795	SC	P	A	F	60	HARMONY, VERONICA	○	○	○	○	.	.	○	.	.
917542	917542	SC	P	A	M	50	SMITH, FRANCISCO	○	○	○	○	.	.	○	.	.

Ready | Connected to Coordinator | 11:17 AM

Locate the repeat participant on the laboratory heads-up display. Note that the SP is listed twice; one record is linked to the SP's blood, badge, and water samples and the second record is linked to the second badge. Each record is assigned unique sample IDs.

Select the correct SP and access the VOC Processing module.

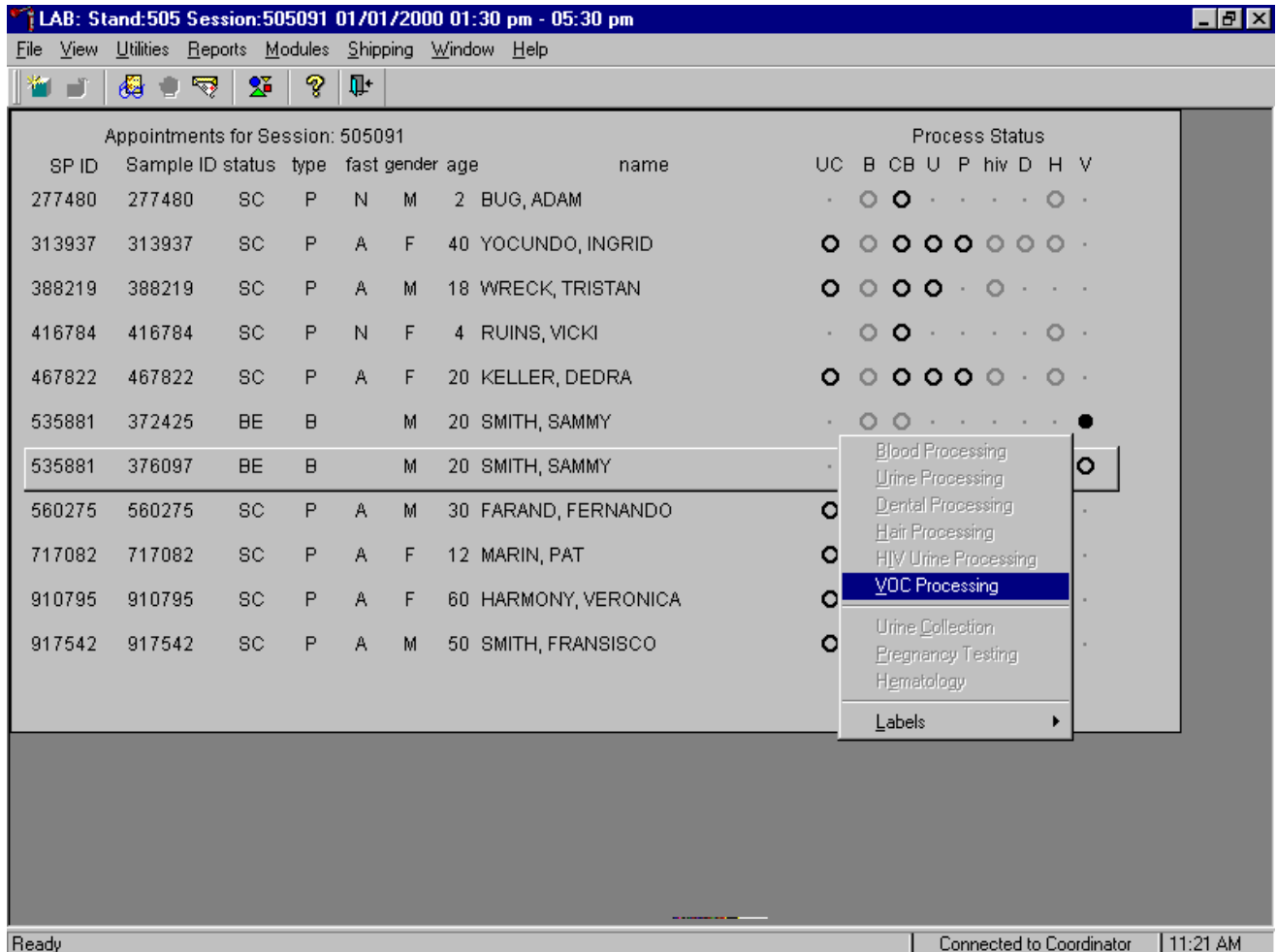


To access the VOC Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {VOC Processing} and right click or type [V/v]. Alternatively to access the VOC processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {VOC Processing}, and right click or type [V/v].



left click or select [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Record the processing results for the second badge.



To access the VOC Processing module for the second badge, use the mouse to direct the mouse arrow to the SP's second line, right click, drag the mouse arrow to {VOC Processing} and right click or type [V/v]. Alternatively to access the VOC processing module for this SP, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {VOC Processing}, and right click or type [V/v].

The SP's second VOC processing screen displays.

Appointments for Session: 505091

SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	hiv	D	H	V
27748	VOC: 376097															
31390	none															

Tech ID: 1226    Sample ID: 376097    Name: SMITH, SAMMY    Gender: M    Age: 20

SP ID: 535881    SubSample: 4    Fasting\_Req:

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
57	VOC Badge	48	EB	1 badge	badge	<input type="radio"/> Yes <input type="radio"/> No		

Save    OK    Cancel

Ready    Connected to Coordinator    11:22 AM

Individually mark this vessel as Filled - "Yes" or Filled - "No." To mark this individual VOC vessel as collected or Filled - "Yes" use the mouse to direct the mouse arrow to 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. To mark this individual badge as not collected or Filled - "No," use the mouse to direct the mouse arrow to the "No" radio button and left click. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this 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 this action or to save this 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 close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

### **A.10.2 Weeks 2 and 4 - Field Monitoring**

MEC interview - Perform this QC during the first day of the second and fourth work week. New (unopened and unexposed) badges are shipped to the MEC at the beginning of each stand. Open one canister in the phlebotomy room, immediately separate the front and back sections of the badge, immediately cap the front and back sections, and put both sections back into the canister. Snap the lid onto the canister. Write the current data, time, and “field monitoring” on the top of the canister. Allow the canister to remain in the phlebotomy room for 48 hours. After 48 hours, collect the canister, write the collection date and time on the top of the canister, and deliver it to the laboratory. In the laboratory, print labels for the field monitoring using the VOC QC Label module. Retrieve the start and end date and time from the top of the canister and record this information in the VOC QC Label module. Record the sample type as “field monitoring.” Process the field monitoring using the VOC QC module. Label the badge, immediately store in the refrigerator, and ship with routine samples.

### **A.10.3 Week 5 - Office Air Monitoring**

MEC interview – Perform this QC during the first day of the fifth workweek. New (unopened and unexposed) badges are shipped to the MEC at the beginning of each stand. Open one canister in the area where the SPs clothes are stored and place or clip the badge in a space where it will not be disturbed or disrupted. Write the current date and time on the top of the canister. Collect the canister 46-76 hours later. Separate the front and back sections of the badge, immediately cap the front and back sections, and put both sections back into the canister. Snap the lid onto the canister. Write the data, time and “office air” on the top of the canister. Deliver the canister immediately to the laboratory. In the laboratory, print labels for the office air monitor using the VOC QC Label module. Retrieve the start and end date and time from the top of the canister and record this information in the VOC QC Label module. Record the sample type as “office air monitoring.” Process the office air monitor badge using the VOC QC module. Label the badge, immediately store in the refrigerator, and ship with routine samples.

### **A.10.4 Week 3 - Positive Control**

4<sup>th</sup> or 6<sup>th</sup> MEC exam day at even numbered stands

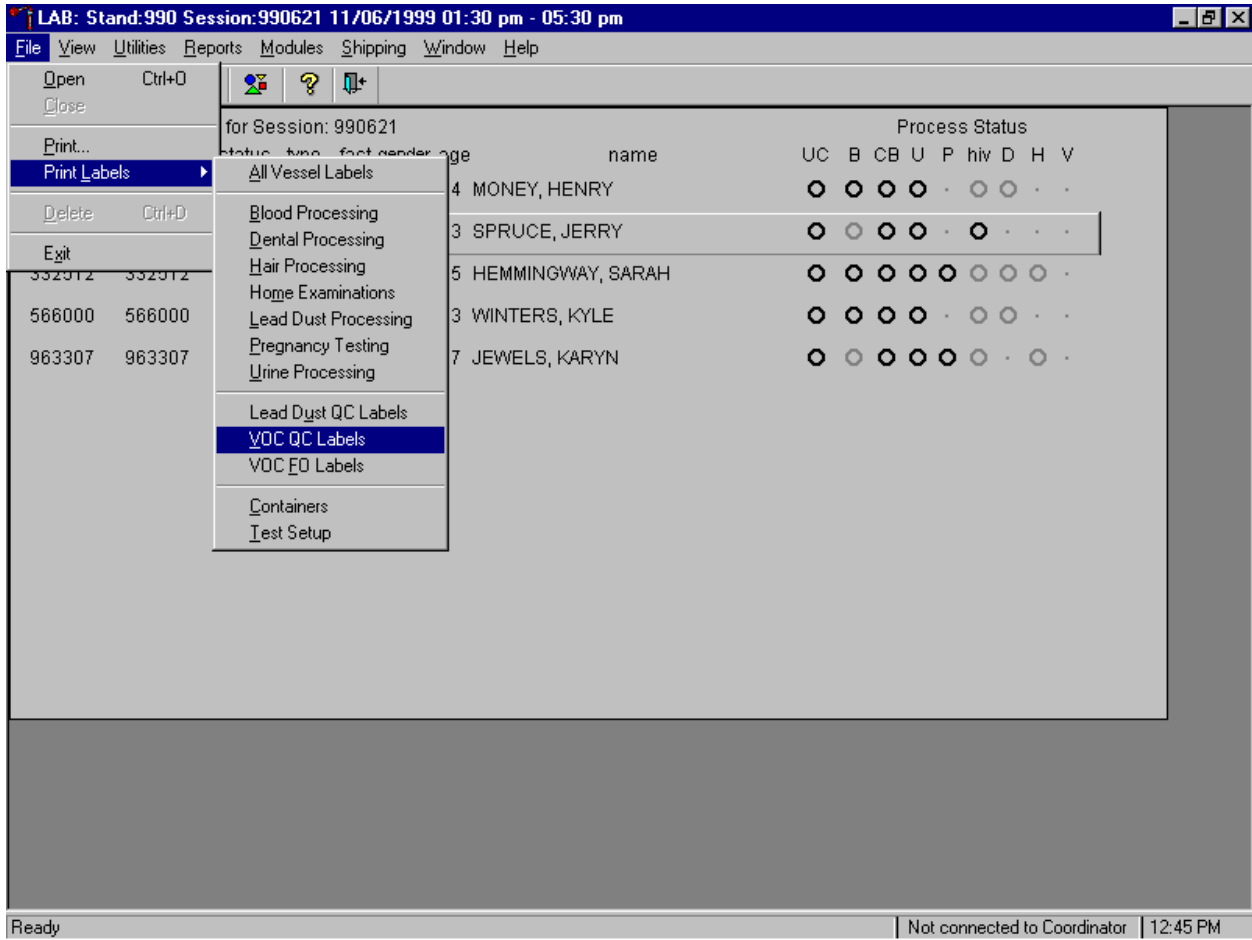
5<sup>th</sup> or 7<sup>th</sup> day at odd numbered stands

Laboratory – One positive control is received at the MEC at the beginning of each stand. Transfer the badge sections to a canister that includes no identifying marks. Initially process the positive control using the Print VOC QC Labels module. Enter the lot number and expiration date from the current MEC badges. Enter the current date and time as the end date and time. Subtract approximately 50-60 hours from the end date and time and enter this date and time as the start date and time. Record the sample type as “positive control.” Document collection using the VOC QC module; place the labeled canister in the laboratory refrigerator, and ship with routine badges.



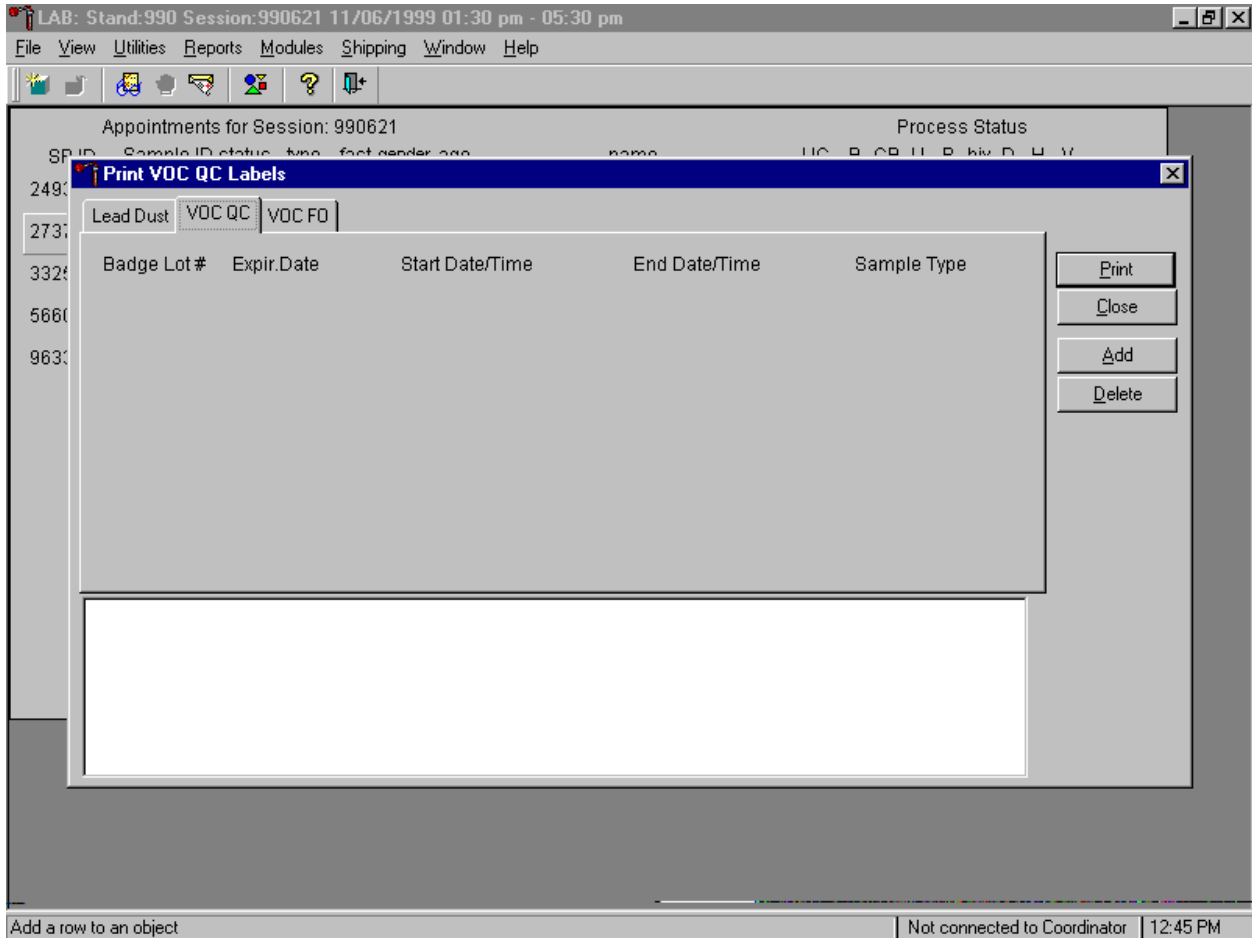
## A.10.5 Processing QC Specimens (Vessels) in the Laboratory

Access the VOC QC Label functions.



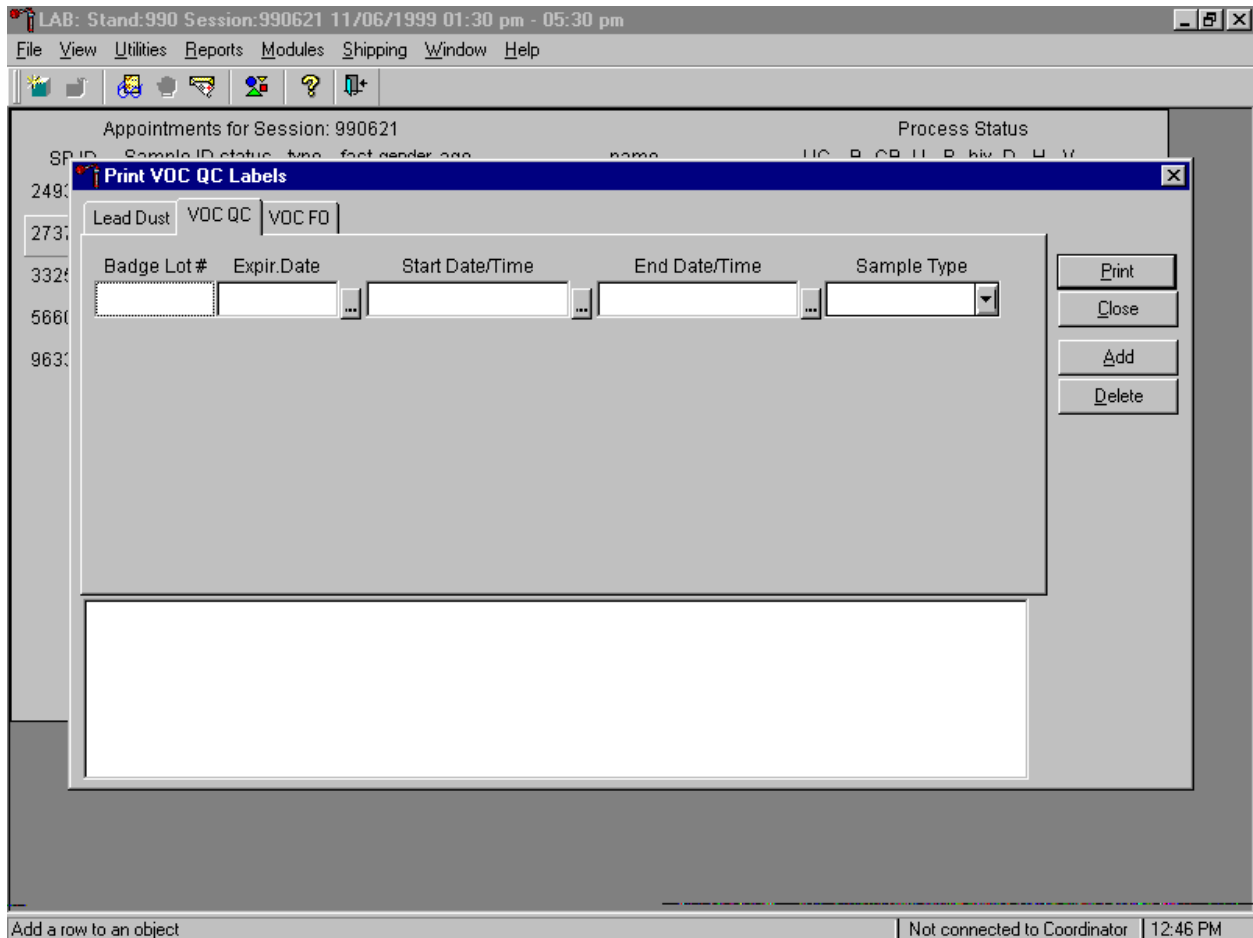
To access the VOC QC label function, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Print Labels}, then to {Print VOC QC labels}, and left click or type [Alt] [F/f] [L/l] [V/v].

The Print VOC QC Labels window displays.



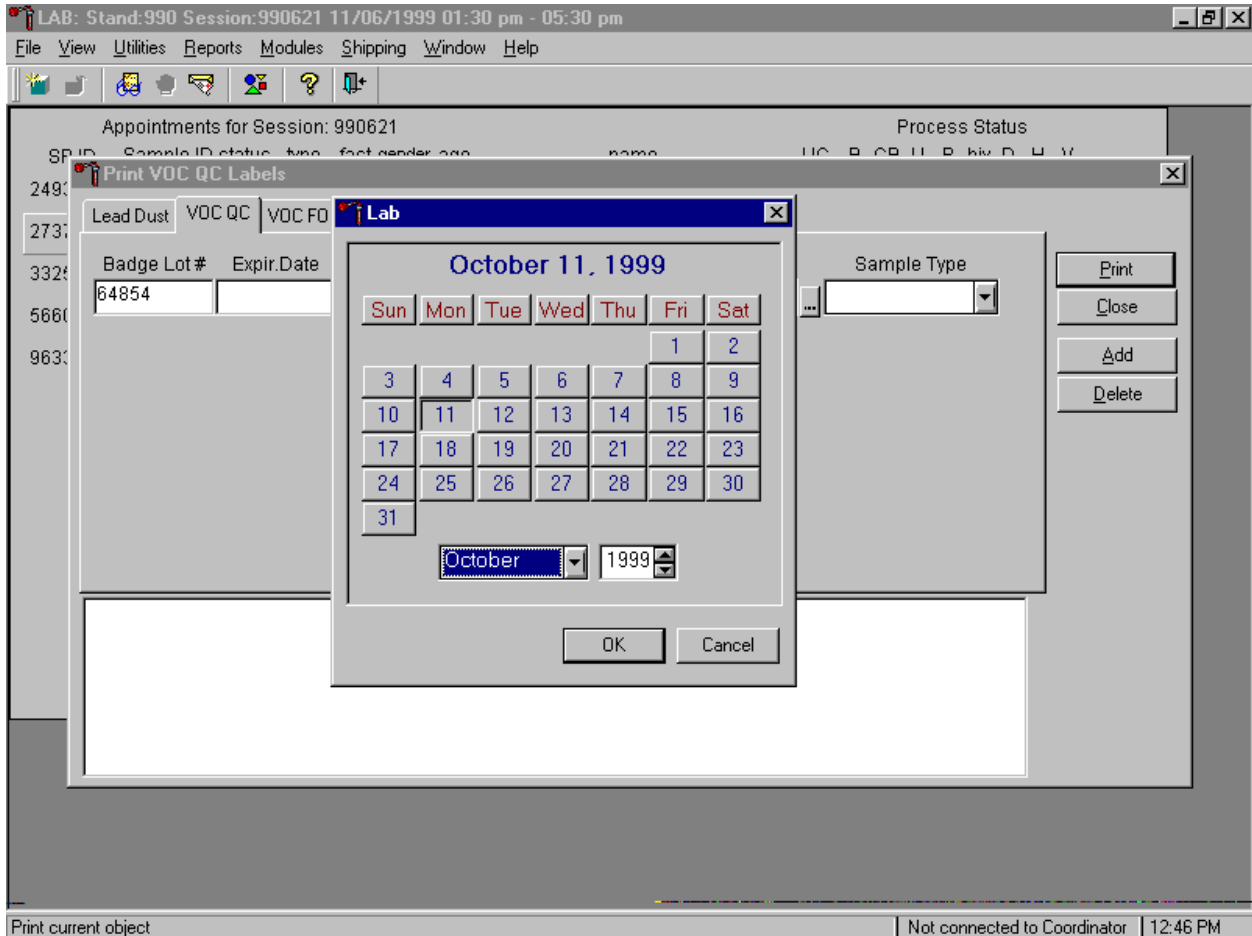
Use this module to print three types of QC labels: positive control, field monitoring, and office air monitoring. To print labels for VOC QC badges, use the mouse to direct the mouse arrow to the VOC QC file header and left click.

Continue to print labels for the VOC QC badges.



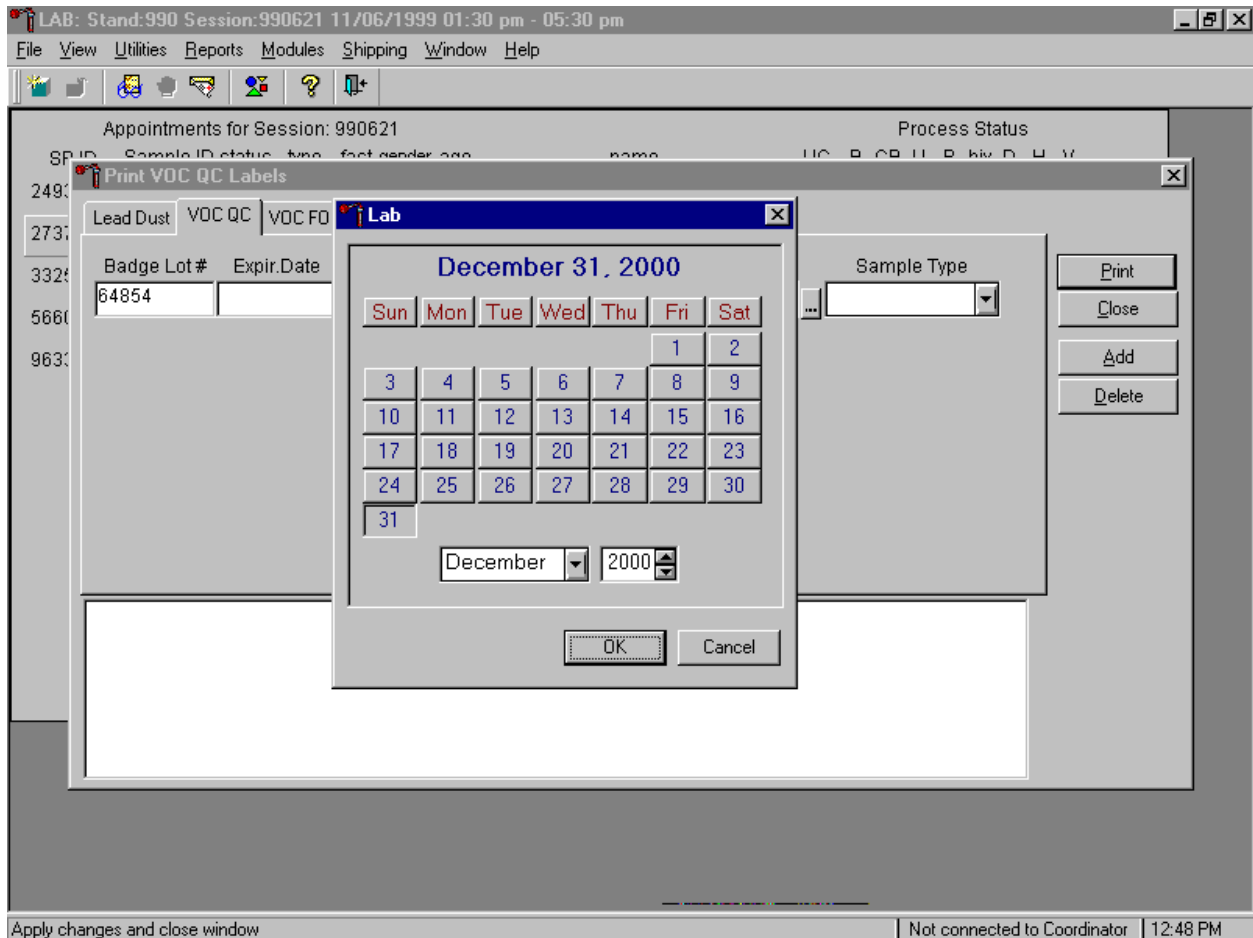
To continue the process, use the mouse to direct the mouse arrow to the **Add** button and left click or type [A/a]. One line is added to the VOC QC file.

Continue to print labels for the VOC QC badges.



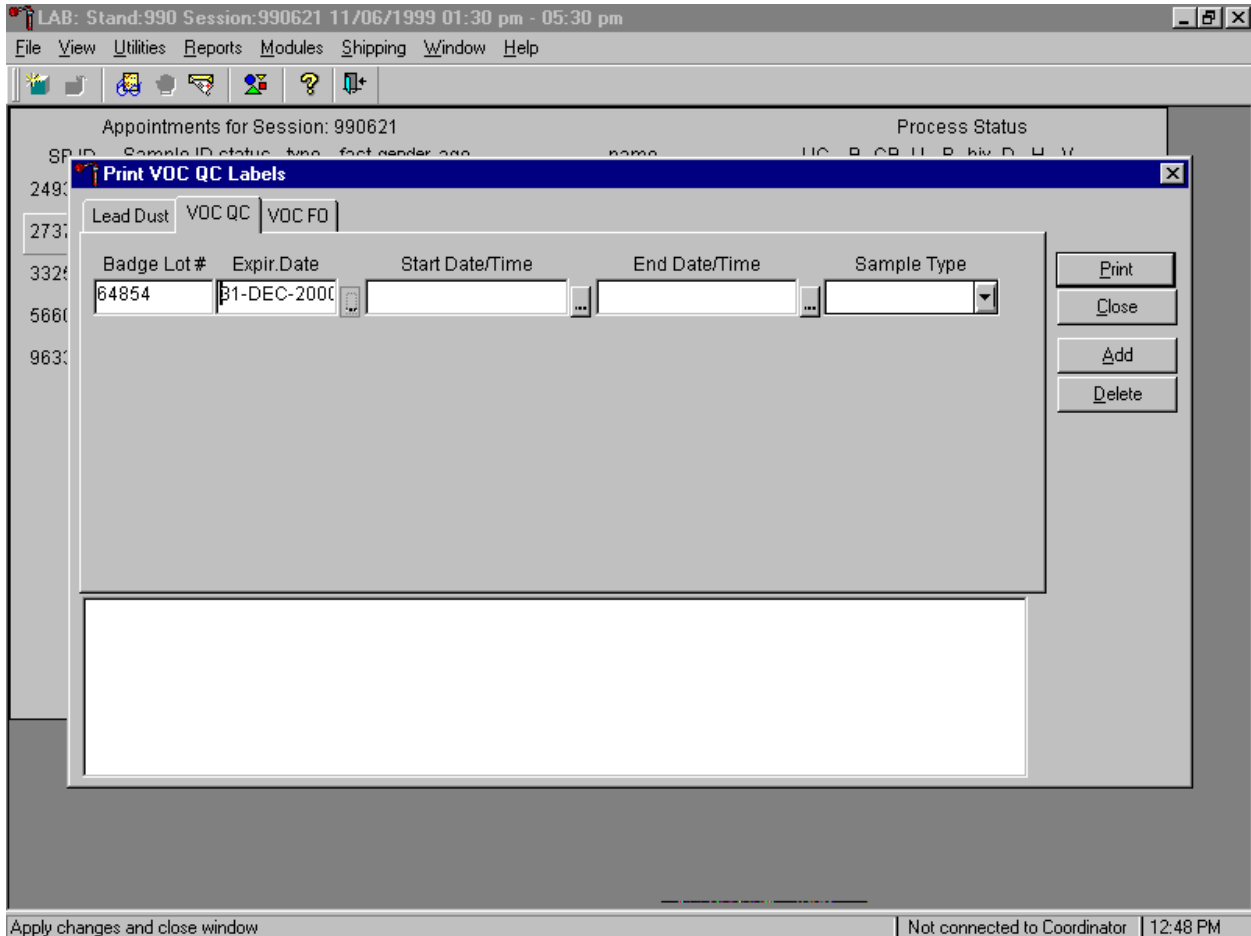
To continue the print QC label process, type the lot number located on the bottom of the canister into the badge lot # response text box and select [Tab] to move to the next text box. Enter the badge expiration date by using the calendar. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the Expire date text box and left click. The lab calendar displays.

Continue to print labels for the VOC QC badges.



For field monitoring and office air monitoring QC, enter the hand written start and end dates and times. For the positive control, enter the current date and time as the start and end date and time. Enter the date by using the calendar. 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 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 up-down 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.

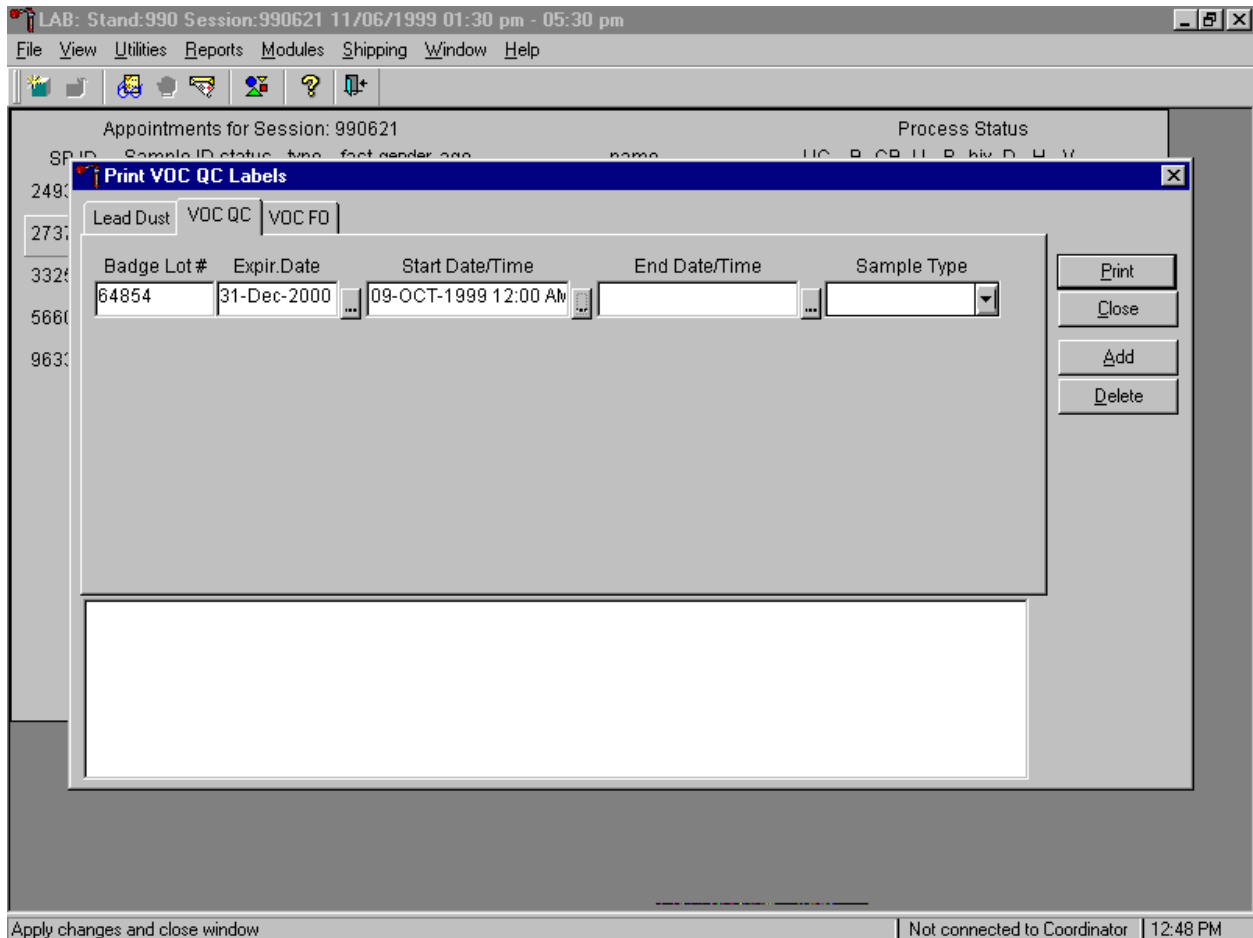
Enter the beginning exposure date and time into the Start Date/Time text box.



The date and time format is dd-mmm-yyyy xx:xxAM or dd-mmm-yyyy xx:xxPM. Use the calendar to enter the exposure date and manually correct the hours. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the Start Date/Time text box and left click. The lab calendar displays. 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 up-down 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. The calendar time defaults to 12:00AM. To correct the exposure start time, use the mouse to direct the cursor to the insertion point in the Start Date/Time text box and begin to type the hours, minutes, and AM or PM using the keyboard.

Alternatively, type in the date and time using the character and numeric keys and the dd-mmm-yyyy xx:xxAM or dd-mmm-yyyy xx:xxPM format and select [Tab].

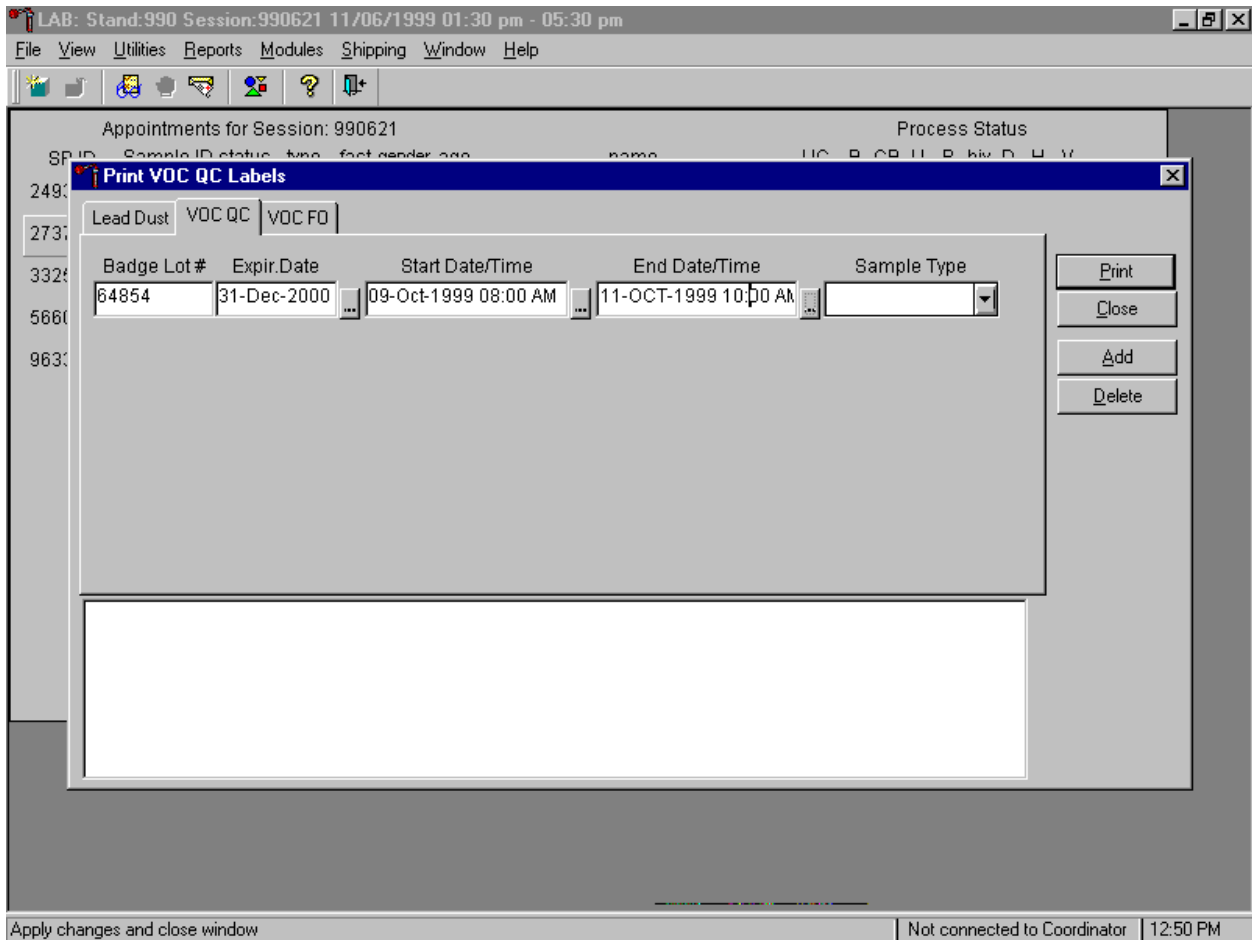
Enter the end exposure date and time into the End Date/Time text box.



The date and time format is dd-mm-yyyy xx:xxAM or dd-mm-yyyy xx:xxPM. Use the calendar to enter the exposure date and manually correct the hours. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis button located next to the End Date/Time text box and left click. The lab calendar displays. 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 up-down 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. The calendar time defaults to

12:00AM. To correct the exposure start time, use the mouse to direct the cursor to the insertion point in the End Date/Time text box and begin to type the hours, minutes, and AM or PM using the keyboard. Alternatively, type in the date and time using the character and numeric keys and the dd-mm-yyyy xx:xxAM or dd-mm-yyyy xx:xxPM format and select [Tab].

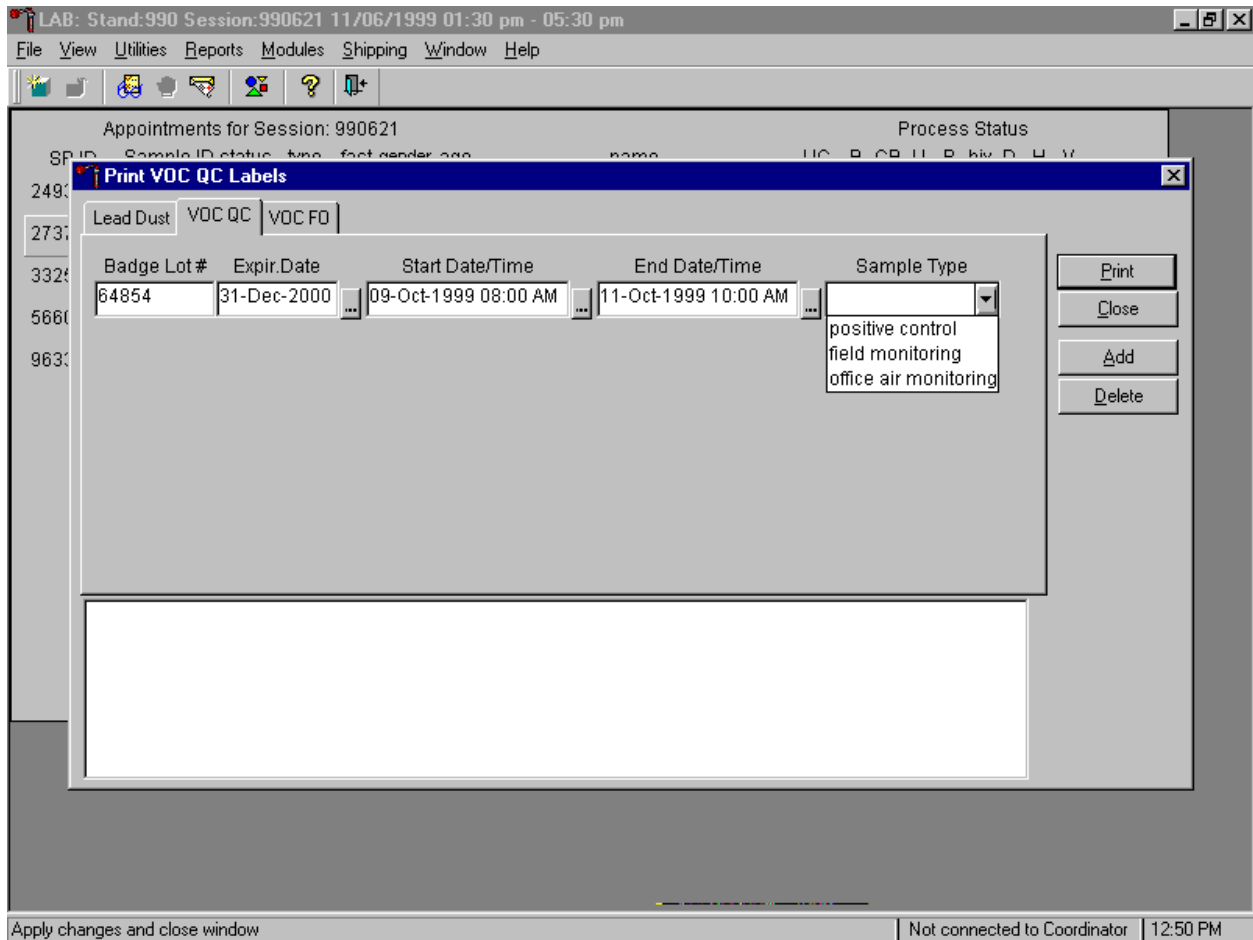
Continue to print labels for the VOC QC badges.



Verify and review the start and end exposure date and times displayed in the window. Compare these dates and times to the start and end date and time documented on the canister.

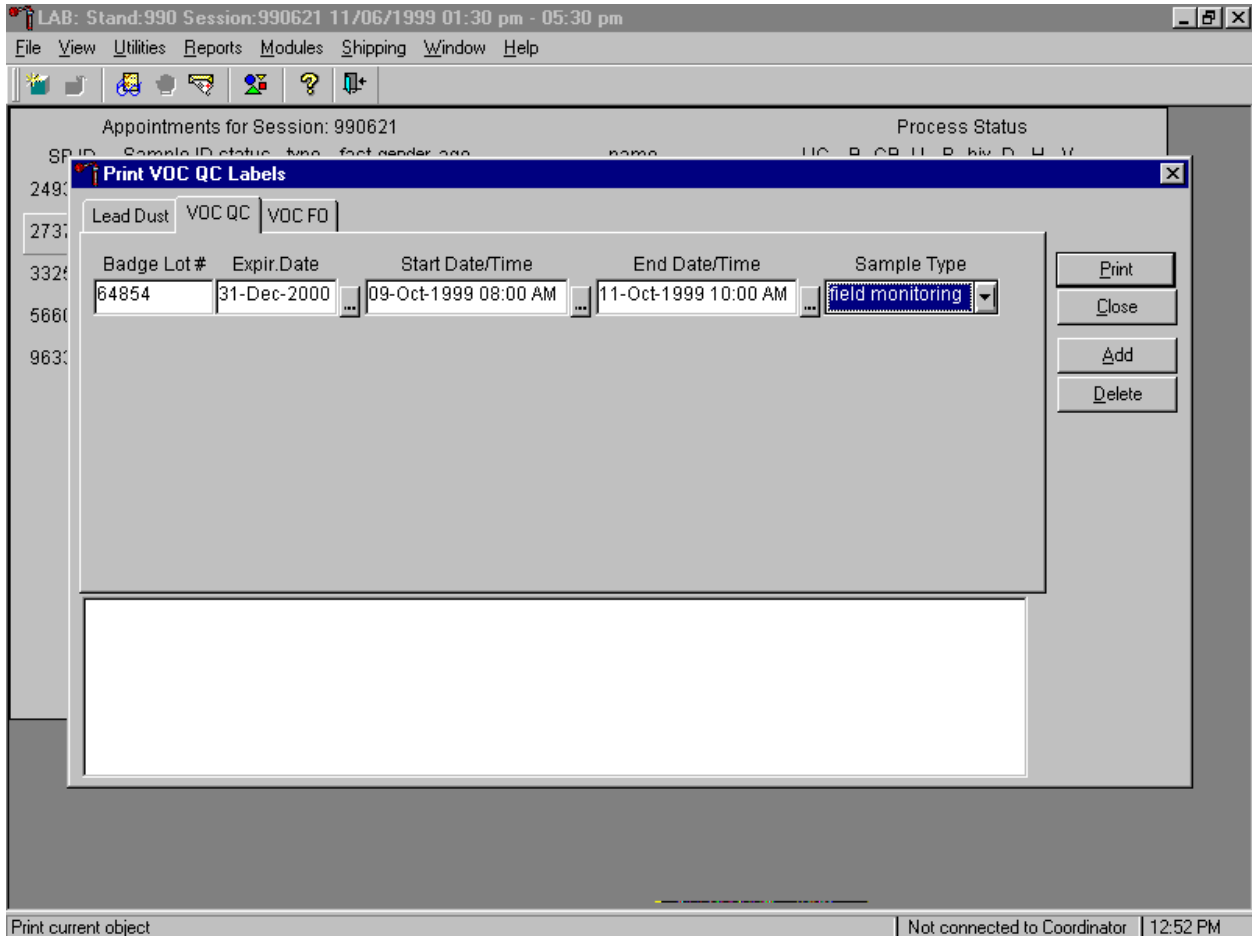


Select the type of VOC QC sample.



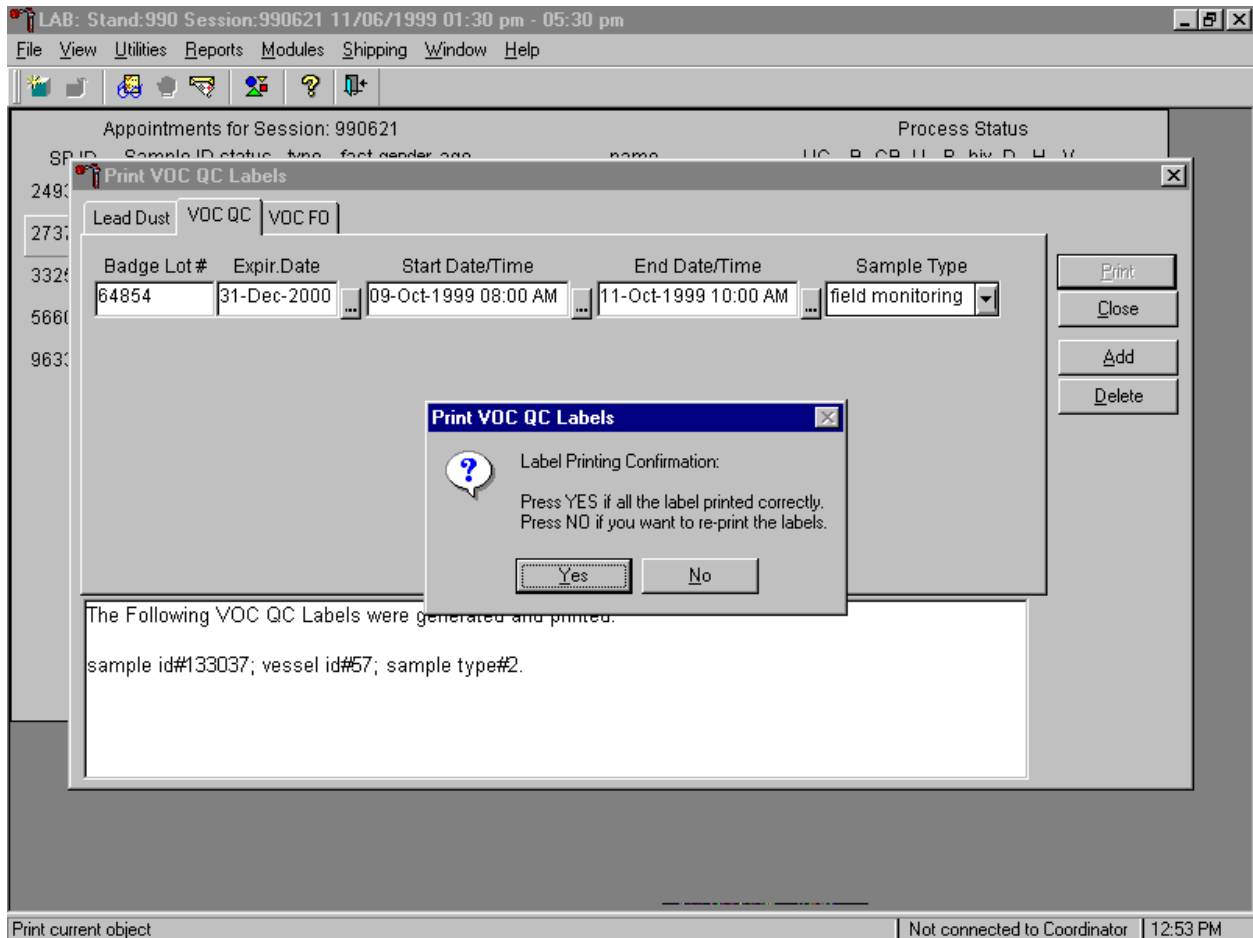
To select the VOC QC sample type, use the mouse to direct the mouse arrow to the drop-down list, left click, drag the arrow to the correct choice and left click.

Continue to print labels for the VOC QC badges.



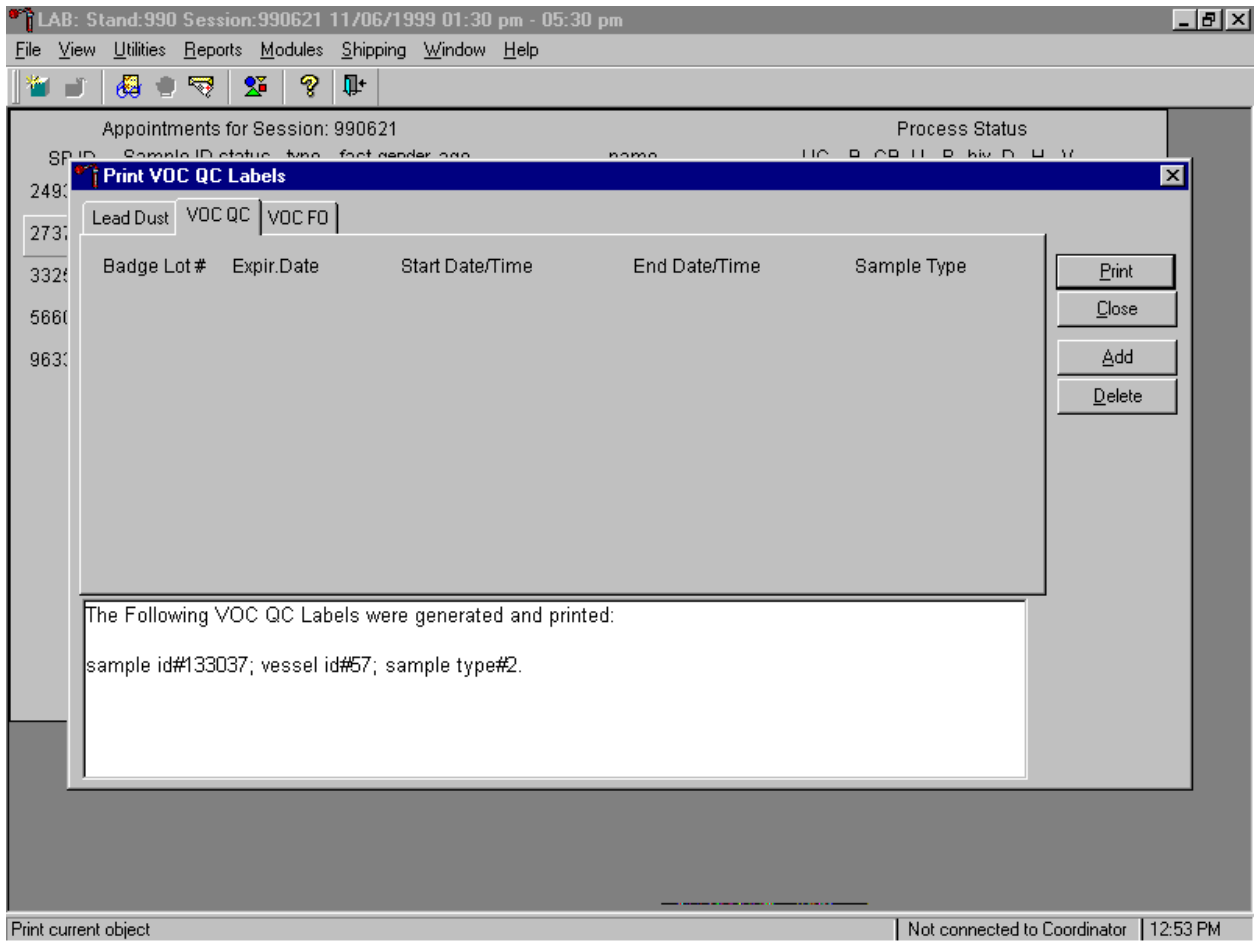
The sample type, positive control, field monitoring, or office air monitoring, displays in the sample type text box. Verify the accuracy of the information in the Print VOC QC Labels window. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click or type [Shift] [P/p]. Labels print on the printer in the label/ship area of the laboratory. To close the window without saving any information to the database and to exit the VOC QC label module, use the mouse to direct the mouse arrow to the **Close** button and left click, or type [Shift] [Cc]. To add an additional VOC QC line, use the mouse to direct the mouse arrow to the **Add** button and left click, or type [Shift] [A/a]. To delete the information in the window, use the mouse to direct the mouse arrow to the **Delete** button and left click, or type [Shift] [D/d].

Confirm that the labels printed correctly before continuing.



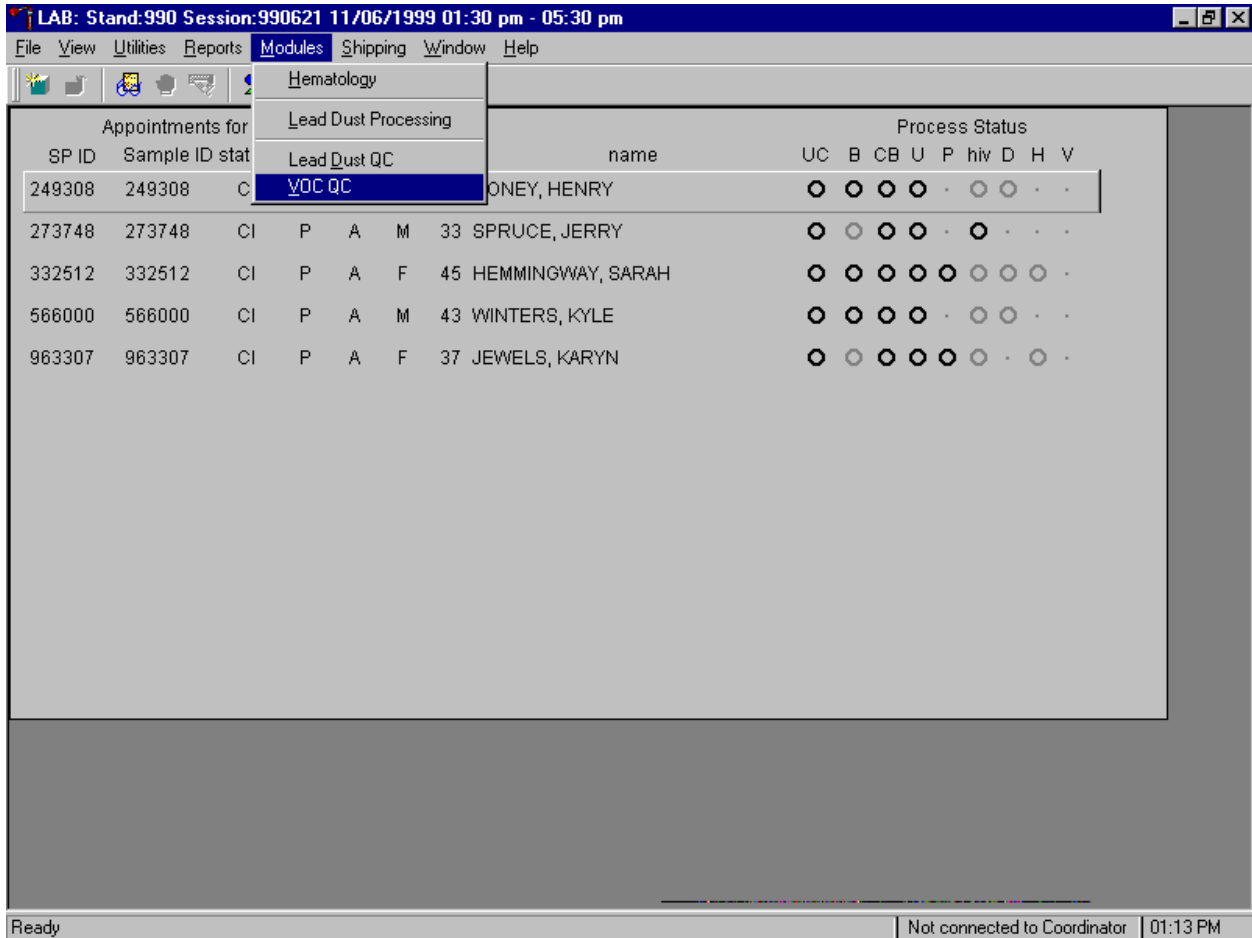
The Print VOC QC Labels message text window displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to **Yes** button and left click or type [Shift] [Y/y] or select [Enter]. If any of the labels did not print correctly and/or to reprint the labels, use the mouse to direct the mouse arrow to the **No** button and left click or type [Shift] [N/n]. All data is erased from the window once a response is recorded to this question.

Verify the information contained in the lower white section of the Print VOC QC labels window.



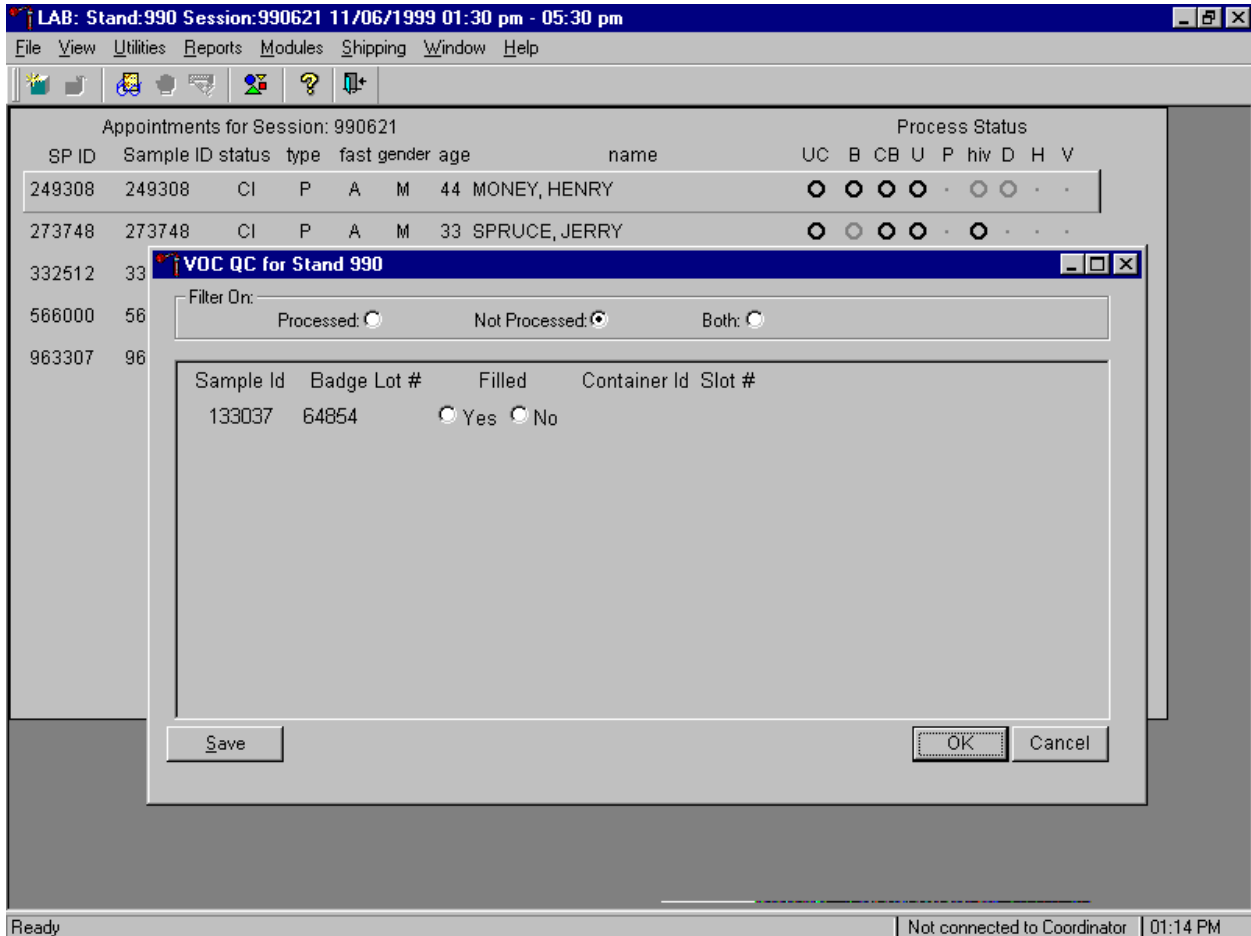
The lower white section of the Print VOC QC Labels window displays the sample ID #, vessel ID #, and sample type #.

Access the VOC QC module to process the QC specimens.



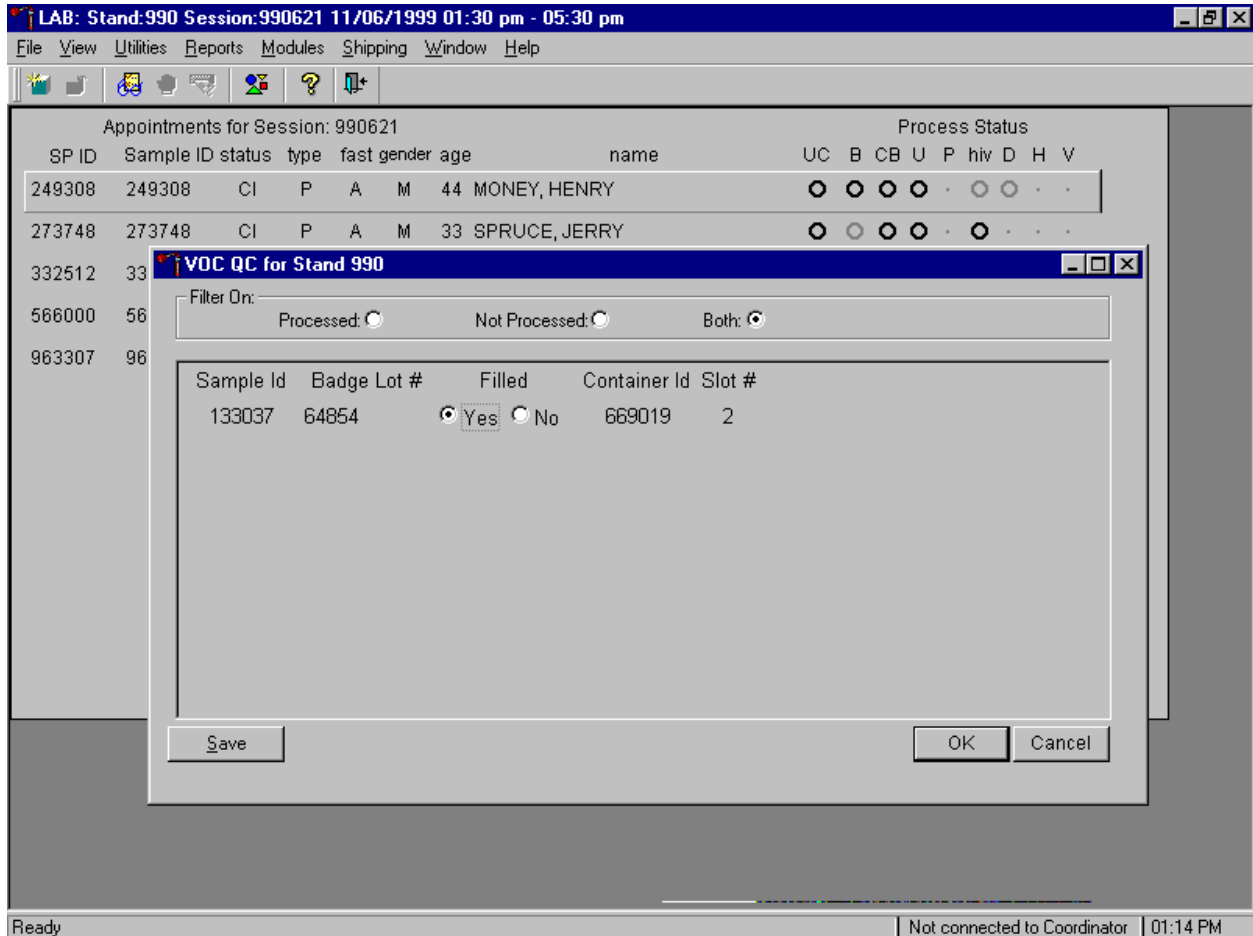
To access the VOC QC module, use the mouse to direct the mouse arrow to {Modules} in the menu bar, right click, drag the arrow to {VOC QC} and left click or type [Alt] [M/m] [V/v].

The VOC QC processing window displays.



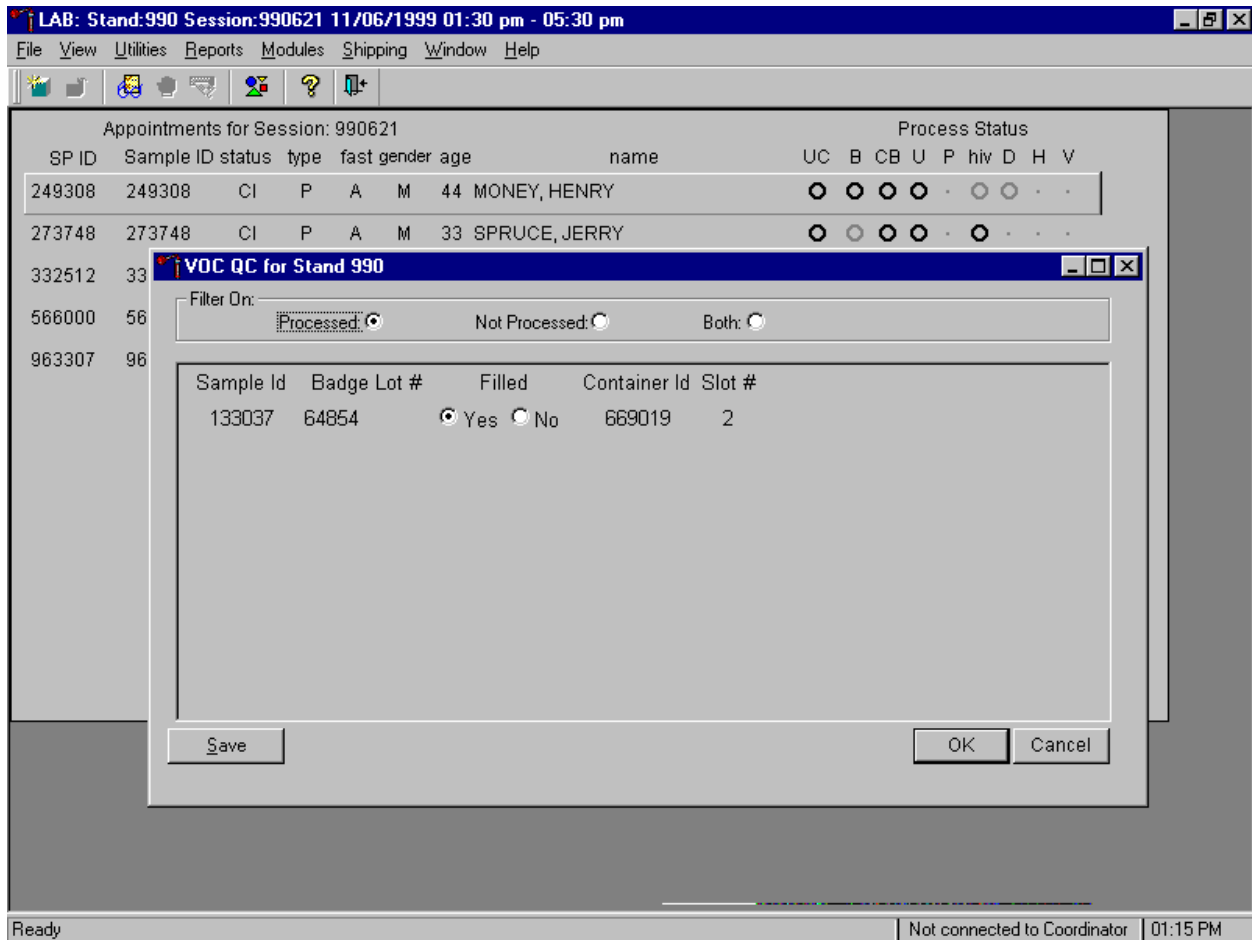
The VOC QC for Stand XXX window displays. Filter on "Processed" to view previously processed vessels, "Not Processed" to view current unprocessed vessels, or "Both" to view previously processed and unprocessed vessels. Verify that the correct filter is selected. Select the "Not Processed" filter to mark vessels as collected and to assign these vessels to containers. The VOC QC window contains the following data items: Sample ID, Badge Lot #, Filled – Yes, Filled - No, Container ID, and Slot #.

Mark the VOC QC badge as collected or Filled – "Yes."



Compare the Sample ID on the window to the bar code label on the vessels. To mark the badge as collected or Filled – "Yes," use the mouse to direct the mouse arrow to the Filled "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.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S]. To record this action or to save this 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 this action and to exit the module, use the mouse to direct the mouse arrow to the **Cancel** button and left click.



## A.11 Shipping VOC Specimens

Ship VOC blood, badges, and water vessels to two contract laboratories in double-sided Styrofoam and corrugated cardboard shippers or hard-sided coolers using wet ice (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 A-6, the Shipping Protocol, illustrates the specifications for the shipment of biological specimens to each of the two contract laboratories.

Exhibit A-6. Shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
<b>VOC</b>				
CDC/Air Toxicant Branch	VOC Blood	Refrigerated	1 x 5 foam mailer	Weekly
CDC/Air Toxicant Branch	VOC Blood	Refrigerated	1 x 5 foam mailer	Weekly
CDC/Air Toxicant Branch	VOC Water	Refrigerated	1 x 3 foam mailer	Weekly
RWJMS/UMDNJ	VOC Badge	Refrigerated	12 x 12 plastic bag	Weekly

The integrity of laboratory specimens, including the VOC vessels, is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contract 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.

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 home examiner assist in performing each of the steps listed below to complete the shipping procedures.

- On the day before a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software.
- On the morning of a shipping day, close all containers, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted "warning" labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers and hard sided coolers 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.
- Place the appropriate paper manifest and the FedEx return airbill in a 12 x 12 plastic bag and place the plastic bag on the Styrofoam lid of shipper and place the lid on 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 either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

Follow the instructions in Chapter 9, Sections 9.8 to create the two airbills; create one for airbill for CDC/Air Toxicant Branch and a second airbill for RWJMS/UMDNJ. Follow instructions in Section 9.10 to close containers for vessels 54, 55, 56 and 57. Follow instructions in Section 9.11 to assign the airbills to the shippers. Vessels 54, 55, and 56 are assigned to the same shipper. Vessel 57 is assigned to the airbill associated with RWJMS/NMDNJ.

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 9.12 to prepare the paper manifest and to send the electronic file.

All of these shipments require reusable refrigerant packs to keep specimens cold but not frozen during transit. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.)

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. The Federal regulations include the use of the following items:

- A watertight primary receptacle e.g., sealed cryovial, sealed Vacutainer®, and sealed Falcon tubes;
- A watertight secondary packaging e.g., a sealed plastic storage bag;
- Sufficient absorbent material between the primary receptacle and the secondary receptacle to absorb the entire contents of all primary receptacles;

- Individually wrapped glass primary receptacles if multiple receptacles are placed in a secondary packaging; this ensures that contact between them is prevented; and
- A sturdy outside packaging constructed of corrugated fiberboard.

Store the blood and water vessels in foam 1 x 5 or 1 x 3 mailers. Secure the top of each mailer to the bottom with a rubber band. Place the mailers for vessels 54 and 55 in a plastic bag, add one absorbent paper, and seal the bag. Place the mailer for vessel 56 in a separate plastic bag. Store the VOC canisters (badges) in a 5-inch tall empty box in the refrigerator or in a 12 x 12 plastic bag. When ready to pack, transfer canisters from the 5-inch tall empty box to a 12 x 12 zip plastic bag. Exhibit A-7 illustrates the contract laboratory addresses for the VOC Laboratories.

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand.

Exhibit A-7. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact Person(s) Telephone number
CDC/Air Toxicant Branch 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341	VOC Blood #1 VOC Blood #2 VOC Water	Refrigerated	Dr. Ben Blount 770-488-7962
RWJMS/UMDNJ Room #309 170 Frelinghuysen Road Piscataway, NJ 08855-1179	VOC Badge	Refrigerated	Dr. Clifford Weisel 732-445-0154

These 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 Medium Shipping Container for CDC/Air Toxicant Branch**

- Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.
- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper.

- Place the sealed mailers (vessels 54, 55 and 56) on top of the refrigerant packs.
- Pack the sides with crumbled newsprint.
- Add two or three additional refrigerant packs.
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the Styrofoam lid.
- Seal the shipper.
- 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.
- 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.
- Add one additional strip of tape across the FedEx pouch.

**Pack Medium Shipping Container for RWJMS/UMDNJ**

- Pack the specimen storage bag tightly in the hard-sided cooler to prevent movement.
- Place at least one large or two small frozen refrigerant packs around the sealed bag.
- Fill any remaining space with crumbled newsprint.
- Place the hard-sided cooler inside an empty corrugated shipper.
- Fill any remaining space with crumbled newsprint.
- Place a plastic envelope containing the appropriate shipping manifest and the return address label on top of the hand sided cooler.
- Seal the shipper.
- 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.
- 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.
- Add one additional strip of tape across the FedEx pouch.

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:

- Label shippers containing refrigerant packs with a "Refrigerate" label.
- Label shippers containing whole blood, with a "Biohazard" label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- 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

#### **A.12 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. Smoking outside the MEC should be confined to areas where there are no air intake vents and there is no possibility of second-hand smoke entering the interior of the MEC. Thermostats should be adjusted 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:

- A 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 set up and teardown activities. (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.)

### **A.13 How to Deal With System Failure**

If the computer system fails, conduct the English or Spanish primary or second exam VOC questionnaire using a hard copy document (Appendix A.1-A.4), and note the time and number and type of specimens collected (water, badge, and/or blood). Complete the questionnaire and enter the collection and questionnaire results after the system is operational. These documents are available in the blank forms directory in the MEC and the shared directory in the field office. Contact the data manager with questions about how to access and print these documents.

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _    AM PM
	TECH ID  __ _ _ _

**APPENDIX A.1 – VOC QUESTIONNAIRE**

Did you wear the exposure monitoring badge at all times since you received the badge?

- YES ..... 1
- NO ..... 2

If no: Approximately what was the number of hours that you did not wear the badge?

|\_\_|\_|  
HOURS

- If less than 1 hour ..... 0

Q1. I would like to ask you a few questions about your home. Does your home have an attached garage?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q2. Was your home or building originally built less than 5 years ago?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q3. Which one of the following is the best description of the street that you live on? Is it a...

- Rural or country road ..... 1
- Dead-end residential street ..... 2
- Through residential street ..... 3
- Commercial street ..... 4
- Major highway ..... 5
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q4. Does your kitchen stove use natural gas, electricity, or something else?

- Natural gas..... 1
- Electricity..... 2
- Something else ..... 3
- REFUSED..... 7
- DON'T KNOW ..... 9

Q5. In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please consider wall-to-wall carpeting or room-sized rugs.

- YES..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW ..... 9

Q6. Do you store paints or fuels inside your home? Include your basement (and attached garage.)

- YES..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW ..... 9

Now I am going to ask you a few questions about your activities when you used your exposure badge. This covers the time since you received the exposure badge \_\_\_ hours ago up until this appointment.

Q7. During the time you used your exposure badge, about how many hours did you spend indoors at home? Include time spent sleeping.

\_\_\_\_\_  
HOURS

Q8. Were any windows open in your home?

- YES..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW ..... 9

Q9. About how many hours did you spend indoors at work or school?

\_\_\_\_\_  
HOURS

Q10. About how many hours did you spend outdoors?



□□□  
HOURS

Q11. Did you pump gas into a car or other motor vehicle yourself?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q12. Did you spend any time at a swimming pool?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q13. Did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q14. Did you spent 10 or more minutes near a wood-burning fire in a fireplace, wood stove, or outdoors?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q15. Did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q16. Even though you did not use the exposure badge when taking a hot shower, did you take a hot shower for 5 minutes or longer during this time period?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q17. During the time you used the exposure badge, did you breathe fumes from any of the following:

	<u>Yes</u>	<u>No</u>
Paints .....	1	2
Mothballs, moth crystals, or moth flakes.....	1	2
Household disinfectant or degreasing cleaners.....	1	2
Furniture polish .....	1	2
Hairspray.....	1	2
Fingernail polish or fingernail polish remover .....	1	2
Diesel fuel or kerosene .....	1	2
Gasoline .....	1	2
Paint thinner, brush cleaner, or furniture stripper .....	1	2
Air fresheners or room deodorizers .....	1	2
Dry-cleaning fluid or spot remover.....	1	2
glues or adhesives used for hobbies or crafts .....	1	2
REFUSED .....	7	
DON'T KNOW .....	9	

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _    AM PM
	TECH ID  __ _ _ _

**APPENDIX A.2 – SPANISH VOC QUESTIONNAIRE**

¿Usó una pequeña caja de monitoreo de exposición todo el tiempo desde que la recibió?

- SI..... 1
- NO..... 2

Si no: Aproximadamente, ¿cuál fue la cantidad de horas que usted no usó la pequeña caja?

- |\_\_|\_|  
(cantidad de horas);
- 0 si es menos de 1 hora HOURS ..... 0

Q1. Quisiera hacerle algunas preguntas acerca de su hogar. ¿Tiene su hogar garaje unido?

- SI..... 1
- NO..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q2. ¿Fue construido originalmente su hogar o edificio hace menos de 5 años?

- SI..... 1
- NO..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q3.Cuál de las siguientes es la mejor descripción de la calle en que usted vive? ¿Es ésta un(a)

- Camino rural o del condado..... 1
- Calle residencial sin salida..... 2
- Calle residencial con salida ..... 3
- Calle comercial ..... 4
- Autopista principal..... 5
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q4. ¿Funciona la estufa de su cocina con gas natural, electricidad, o alguna otra cosa?

- Natural gas..... 1
- Electricidad ..... 2
- Alguna otra cosa ..... 3
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q5. En los 6 meses pasados, ¿se ha puesto alguna alfombra o tapete nuevo en su hogar, o en su área de trabajo en el lugar en donde trabaja, o en la escuela? Por favor considere solamente el alfombrado de pared a pared o alfombras del tamaño de la habitación

- SI..... 1
- NO..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q6. ¿Guarda pinturas o combustibles dentro de su hogar? Incluya el sótano (y el garaje unido al hogar).

- SI..... 1
- NO..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Texto

Ahora le voy a hacer algunas preguntas acerca de sus actividades cuando usó su caja de exposición. Esto cubre el tiempo desde que recibió la caja de exposición hace XX horas hasta esta cita.

Q7. Durante el tiempo que usó la caja de exposición, ¿cuántas horas más o menos pasó dentro de la casa? Incluya el tiempo que pasó durmiendo.

|||  
Cantidad de horas

Q8. ¿Había alguna ventana abierta en su hogar?

- SI..... 1
- NO..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q9. ¿Cuántas horas más o menos pasó adentro en el trabajo o en la escuela?

|||  
Cantidad de horas

Q10. ¿Cuántas horas más o menos pasó afuera?

□□□  
Cantidad de horas

Q11. ¿Le echó gasolina usted mismo a un automóvil u otro vehículo de motor?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q12. ¿Pasó algún tiempo en una (alberca/piscina)?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q13. En la última semana, ¿visitó una lavandería de lavado en seco o usó ropa que había sido limpiada al seco?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q14. ¿Pasó 10 minutos o más cerca del fuego de una chimenea de leña, una estufa de leña, o fuera del hogar?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q15. ¿Pasó 10 minutos o más cerca de una persona que estaba fumando cigarrillo, cigarro, puro, o pipa?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q16. Aunque usted no usó la caja de exposición cuando se estaba dando una ducha o baño caliente, ¿se dio una ducha o baño caliente por cinco minutos o más durante este período de tiempo?

SI.....	1
NO.....	2
REFUSED.....	7
DON'T KNOW .....	9

Q17. Durante el tiempo que usó la placa de exposición, ¿aspiró los gases de cualquiera de los artículos siguientes?:

	<u>Yes</u>	<u>No</u>
Pinturas .....	1	2
Bolas de naftalina para las polillas, cristales para las polillas, o escamas para las polillas.....	1	2
Desinfectantes caseros o limpiadores para sacar la grasa .....	1	2
Lustre para muebles .....	1	2
Atomizador de líquido para el pelo .....	1	2
Esmalte para las uñas o removedor de esmalte para las uñas.....	1	2
Combustible de diesel o querosén.....	1	2
Gasolina .....	1	2
Líquido para diluir pintura, limpiador de brochas, o removedor de pintura para muebles .....	1	2
Refrescantes de aire o desodorantes para habitaciones. ....	1	2
Líquidos para limpiar en seco o removedor de manchas.....	1	2
Gomas o adhesivos usados para pasatiempos o obras manuales (artesanías) .....	1	2
REFUSED .....	7	
DON'T KNOW .....	9	

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _  AM
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _    PM
	TECH ID  __ _ _ _

**APPENDIX A.3 – VOC EXPOSURE MONITORING QUESTIONNAIRE: SECOND EXAMINATION**

(to be administered by MEC interviewer)

Q1. I would like to ask you a few questions about your home. Does your home have an attached garage?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q2. Was your home or building originally built less than 5 years ago?

- YES ..... 1
- NO ..... 2
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q3. Which one of the following is the best description of the street that you live on? Is it a:

- Rural or county road ..... 1
- Dead-end residential street..... 2
- Through residential street ..... 3
- Commercial street..... 4
- Major highway ..... 5
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q4. Does your kitchen stove use natural gas, electricity, or something else?

- Natural gas..... 1
- Electricity..... 2
- Something else ..... 3
- REFUSED ..... 7
- DON'T KNOW ..... 9

Q5. In the past 6 months, have any new carpets or rugs been placed in your home or your work area at your workplace or school? Please only consider wall-to-wall carpeting or room-sized rugs.

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q6. Do you store paints or fuels inside your home? Include your basement (attached garage, if applicable).

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Now I am going to ask you a few questions about your activities over the last 3 days. This means today, yesterday, or the day before yesterday.

Q7. In the last 3 days, did you pump gas into a car or other motor vehicle yourself?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q8. In the last 3 days, did you spend any time at a swimming pool?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9

Q9. In the last 3 days, did you visit a dry cleaning shop or wear clothes that had been dry-cleaned within the last week?

YES ..... 1  
NO ..... 2  
REFUSED ..... 7  
DON'T KNOW ..... 9



Q10. In the last 3 days, did you spend 10 minutes or more near a wood-burning fire in a fireplace, wood stove, or outdoors?

YES ..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q11. In the last 3 days, did you spend 10 or more minutes near a person who was smoking a cigarette, cigar, or pipe?

YES ..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q12. In the last 3 days, did you take a hot shower for 5 minutes or longer?

YES ..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q13. In the last 3 days, did you breathe fumes from any of the following:

	<u>YES</u>	<u>NO</u>	<u>DK</u>	
	<u>REFUSED</u>			
a. Paints .....	1	2	7	9
b. Mothballs, moth crystals, or mothflakes.....	1	2	7	9
c. Household disinfectant or degreasing cleansers .....	1	2	7	9
d. Furniture polish.....	1	2	7	9
e. Hair spray .....	1	2	7	9
f. Fingernail polish or fingernail polish remover .....	1	2	7	9
g. Diesel fuel or kerosene .....	1	2	7	9
h. Gasoline .....	1	2	7	9
i. Paint thinner, brush cleaner, or furniture stripper.....	1	2	7	9
j. Fresheners or room deodorizers.....	1	2	7	9
k. Drycleaning fluid or spot remover .....	1	2	7	9
l. Glues or adhesives used for hobbies or crafts.....	1	2	7	9

SP Name _____	Date  __ _  -  __ _  -  __ _ _ _ _
SP ID  __ _ _ _ _ _ _ _ _	Time  __ _  :  __ _    AM PM
	TECH ID  __ _ _ _

**APPENDIX A.4 – SPANISH VOC EXPOSURE MONITORING QUESTIONNAIRE:  
SECOND EXAMINATION**  
(to be administered by MEC interviewer)

Q1. Quisiera hacerle algunas preguntas acerca de su hogar. ¿Tiene su hogar un garaje unido?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW ..... 9

Q2. ¿Fue construido originalmente su hogar o edificio hace menos de 5 años?

- SI..... 1
- NO..... 2
- REFUSED..... 7
- DON'T KNOW ..... 9

Q3. ¿Cuál de las siguientes es la mejor descripción de la calle en que usted vive? ¿Es ésta un(a):

- Camino rural o del condado..... 1
- Calle residencial sin salida..... 2
- Calle residencial con salida ..... 3
- Calle comercial ..... 4
- Autopista principal..... 5
- REFUSED..... 7
- DON'T KNOW ..... 9

Q4. ¿Funciona la estufa de su cocina con gas natural, electricidad, o alguna otra cosa?

- Gas natural ..... 1
- Electricidad ..... 2
- Alguna otra cosa ..... 3
- REFUSED..... 7
- DON'T KNOW ..... 9

Q5. En los últimos 6 meses, ¿se ha puesto alguna alfombra o tapete nuevo en su hogar, o en su área de trabajo en el lugar en donde trabaja, o en la escuela? Por favor considere solamente el alfombrado de pared a pared o alfombras del tamaño de la habitación

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q6. ¿Guarda pinturas o combustibles dentro de su hogar? Incluya el sótano (y el garaje unido al hogar, si corresponde).

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

**Texto**

***"Ahora le voy a hacer algunas preguntas acerca de sus actividades durante los últimos tres días. Esto significa hoy, ayer, o antes de ayer."***

Q07. En los últimos tres días, ¿le echó gasolina usted mismo a un automóvil u otro vehículo de motor?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q08. En los últimos tres días, ¿pasó algún tiempo en una (alberca/piscina)?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q09. En los últimos tres días, ¿visitó una lavandería de lavado en seco o usó ropa que había sido limpiada al seco dentro de la última semana?

SI..... 1  
NO..... 2  
REFUSED..... 7  
DON'T KNOW ..... 9

Q10. En los últimos tres días, ¿pasó 10 minutos o más cerca del fuego de una chimenea de leña, una estufa de leña, o fuera del hogar?

SI..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q11. En los últimos tres días, ¿pasó 10 minutos o más cerca de una persona que estaba fumando (cigarro/cigarrillo), (puro/cigarro/tabaco), o pipa?

SI..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q12. En los últimos tres días, ¿se dio una ducha o baño caliente por cinco minutos o más?

SI..... 1  
 NO..... 2  
 REFUSED..... 7  
 DON'T KNOW ..... 9

Q13. En los últimos tres días, ¿aspiró los gases de cualquiera de los artículos siguientes?:

	<u>Yes</u>	<u>No</u>
Pinturas .....	1	2
Bolas de naftalina para las polillas, cristales para las polillas, o escamas para las polillas.....	1	2
Desinfectantes caseros o limpiadores para sacar la grasa .....	1	2
Lustre para muebles .....	1	2
Atomizador de líquido para el pelo .....	1	2
Esmalte para las uñas o removedor de esmalte para las uñas.....	1	2
Combustible de diesel o querosén.....	1	2
Gasolina .....	1	2
Líquido para diluir pintura, limpiador de brochas, o removedor de pintura para muebles .....	1	2
Refrescantes de aire o desodorantes para habitaciones. ....	1	2
Líquidos para limpiar en seco o removedor de manchas.....	1	2
Gomas o adhesivos usados para pasatiempos o obras manuales (artesanías) .....	1	2
REFUSED .....	7	
DON'T KNOW .....	9	

Appendix B  
Hair, MRSA, and Bacterial Vaginosis  
Processing, Storage, and Shipping

## APPENDIX B

### HAIR, MRSA, AND BACTERIAL VAGINOSIS PROCESSING, STORAGE, AND SHIPPING

#### B.1 Introduction

The purpose of hair collection is to obtain a suitable biological sample to determine total mercury levels in hair. Relationships exist between the concentrations of mercury in human scalp hair and dietary methylmercury exposures. Use the hair to characterize recent exposure to methylmercury over a relatively uniform time interval.

The purpose of collecting a nasal swab is to obtain a suitable biological sample to culture for the presence of *Staphylococcus aureus* (*S. aureus*). *Staphylococcus aureus* is one of the most common causes of skin and soft tissue infection in both the health care and community settings. Antimicrobial resistance in *S. aureus* has increased dramatically, particularly in the hospital, where the rapid emergence of methicillin-resistant *S. aureus* (MRSA) has left only one intravenous antimicrobial, vancomycin, as a treatment option; the appearance of *S. aureus* isolates with resistance to vancomycin (VISA) has led to concern that this organism may become untreatable with currently available antimicrobials. Previously limited to hospitals, MRSA infections have been increasingly reported in the community, and it is unclear whether resistance is spreading from hospitals or another unidentified source. Risk factors for MRSA infection include hospitalization, antimicrobial use, underlying medical illness, and proximity to individuals with MRSA infection or colonization, including health care workers. The carrier state is asymptomatic, and transmission of MRSA can occur from any individual colonized with MRSA. In order to estimate the potential for spread of MRSA in the community, it is important to measure the MRSA carriage rate through a population-based study. However, no prospective, population-based prevalence study has been done to measure the prevalence of MRSA in the community, and no national surveillance exists to provide a reliable national population estimate. Therefore, NHANES participants who consent are cultured for MRSA.

The Specimen Collection component consists of two sections, hair collection and nasal swab collection. The MEC coordinator assigns a SP to the specimen collection/balance room. The health technician logs onto the Specimen Collection application and logs the SP into the component. The

Specimen Collection application presents the correct section screens according to the SPs person type, age, and gender. Primary male and female SPs age 1-5 and females age 16-49 are eligible for hair collection. Primary, home exam, and second exam SPs age 1+ are eligible for nasal swab collection. Health technicians collect the hair and/or nasal swab on primary and second exam SPs, record the results in ISIS, escort the SP back to the coordinator, and transport the specimens to the MEC laboratory. The home examiner collects the nasal swab in the SP's home, records the collection results in the Specimen Collection application, and transports the nasal swab back to the MEC. The medical technologist logs the specimen into the MEC laboratory using the laboratory application, stores the specimens, and ships them to contract laboratories weekly.

The purpose of collecting two vaginal swabs is to have suitable biological specimens to perform a pH test, make a gram stain, and to test for *Trichomonas vaginalis*. Recent studies have linked bacterial vaginosis (BV) and trichomoniasis to adverse pregnancy and gynecologic outcomes such as preterm labor and delivery, low birth weight, premature rupture of membranes, post-Cesarean endometritis, and post-abortal and post-hysterectomy infections. No reliable national population estimate of BV or trichomoniasis exists. NHANES is assessing the prevalence of BV and *Trichomonas vaginalis* (TV) infections in the general population, identifying and confirming risk factors, and monitoring trends in prevalence as detection and treatment programs are established and expanded.

Primary female SPs ages 14-49 are eligible for the BV component. New BV-related questions have been added to the reproductive health section of the MEC Interview. The physician collects two preprinted labels from the grid in the label/ship area at the start of each session. Each label includes the test name, SP's six digit SP ID concatenated with the vessel ID, and a corresponding bar code. The physician counsels each eligible SP and introduces them to the vaginal collection technique. The physician uses a prepared collection kit and a preprinted instruction sheet to help explain the collection technique. The physician removes two swabs from the collection kit and prelabels the red-capped tube (containing a cotton swab with a wood shaft) with the label displaying the vessel ID #72 and the Puritan® swab (Dacron with a white plastic shaft) with the label displaying the vessel ID #73. The physician then places the swabs back into the collection kit and gives the collection kit to the eligible SP.

The SP self collects the two swabs in the MEC bathroom and places each swab back into its original red-capped tube or transport sleeve. The SP hands the red-capped conical tube and the Dacron swab in the transport sleeve to the assistant coordinator who delivers them to the laboratory. One additional glass slide label prints as part of each eligible SP's set of processing labels. The laboratory uses

the red-capped cotton swab (vessel 72) to determine pH and to make a slide for gram stain. The SP ID and the vessel ID on the label of the Dacron swab are verified in the laboratory and the swab is refrigerated. The laboratory ships the glass slide and the Dacron swab weekly.

Document specimen collection using the Laboratory application; process hair samples, nasal, and vaginal swabs, and store the vessels. Ship the specimens to the contract laboratories weekly.

**B.2 Supplies**

The supplies needed for hair, MRSA, and bacterial vaginosis processing and storage are listed in Exhibit B.1

Exhibit B-1. Equipment and supplies - hair, MRSA, and bacterial vaginosis processing and storage

BBL Culture swab	Bitran bag (6 x 6 clear)
PH paper, EM ColorpHast range 4-7	Bitran bag (12 x 12 clear)
Slides, Microscope – Single Side Frosted 3 x 1	Large padded envelope
Micro slide box - Blue	Medium shippers
Refrigerant gel packs	Small shippers

**B.3 Protocols**

Exhibit B-2 illustrates the SP’s protocol for hair, nasal swab, and BV processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit B-2. Hair, nasal swab, and BV processing protocol

ID	Test name	Ages	Sample	Sample type	Vessel type	Person types
59	Methylmerc	1-5 both sexes 16-49 females	100 mg	Hair	6 x 6 plastic bag	Primary only
72	Vaginosis	14-49 females	1 swab	Vaginal swab	Cotton swab	Primary only
73	T vaginalis	14-49 females	1 swab	Vaginal swab	Dacron swab	Primary only
76	MRSA	1+	1 swab	Nasal swab	Culturette swab	Primary Home Exam Second Exam



#### **B.4 Labeling Vessels**

The appropriate bar code labels automatically print for each SP based on the SP's age, sex, and person type. The label/ship technologist at workstation 3 prints the labels at least one session in advance. The printing procedure is described in Chapter 9.

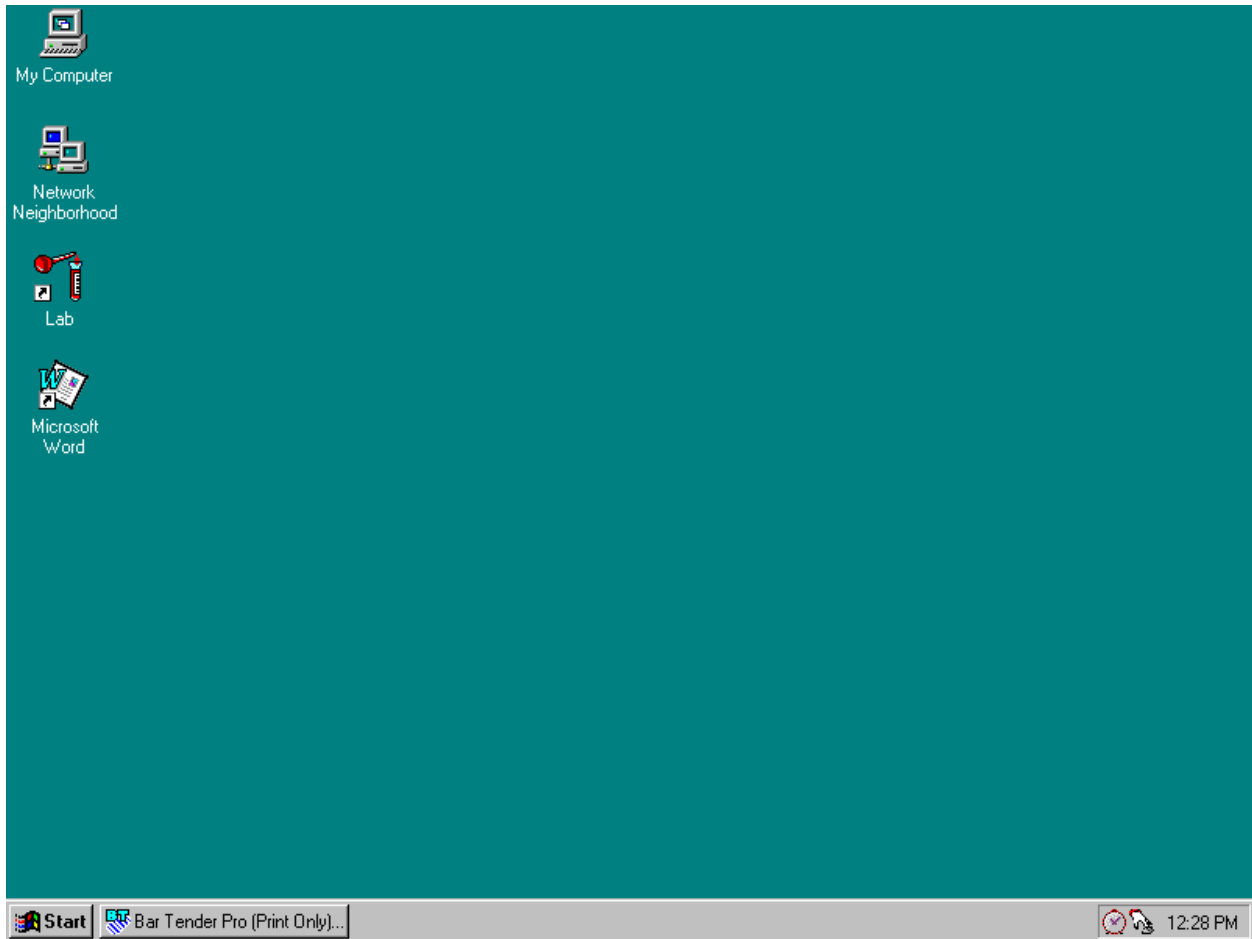
On label prints for each hair vessel hair vessel #59 and nasal swab #76. Place these labels on the grid in the label/ship area. The health technicians collect these labels before each session starts.

A total of three labels print for each SP—one label for vessel #72, one label for vessel #73, and one additional label for the glass slide. Place the two vessel labels on the grid in the label/ship area. The physician collects these labels before each session begins.

One additional label prints for the gram stain slide. This label contains the words “Vaginosis,” the SP ID concatenated with the vessel ID (#72), and a bar code that is shifted toward the bottom of the label's white opaque area. Place this label at workstation 2 with the other urine vessel and pregnancy test labels.

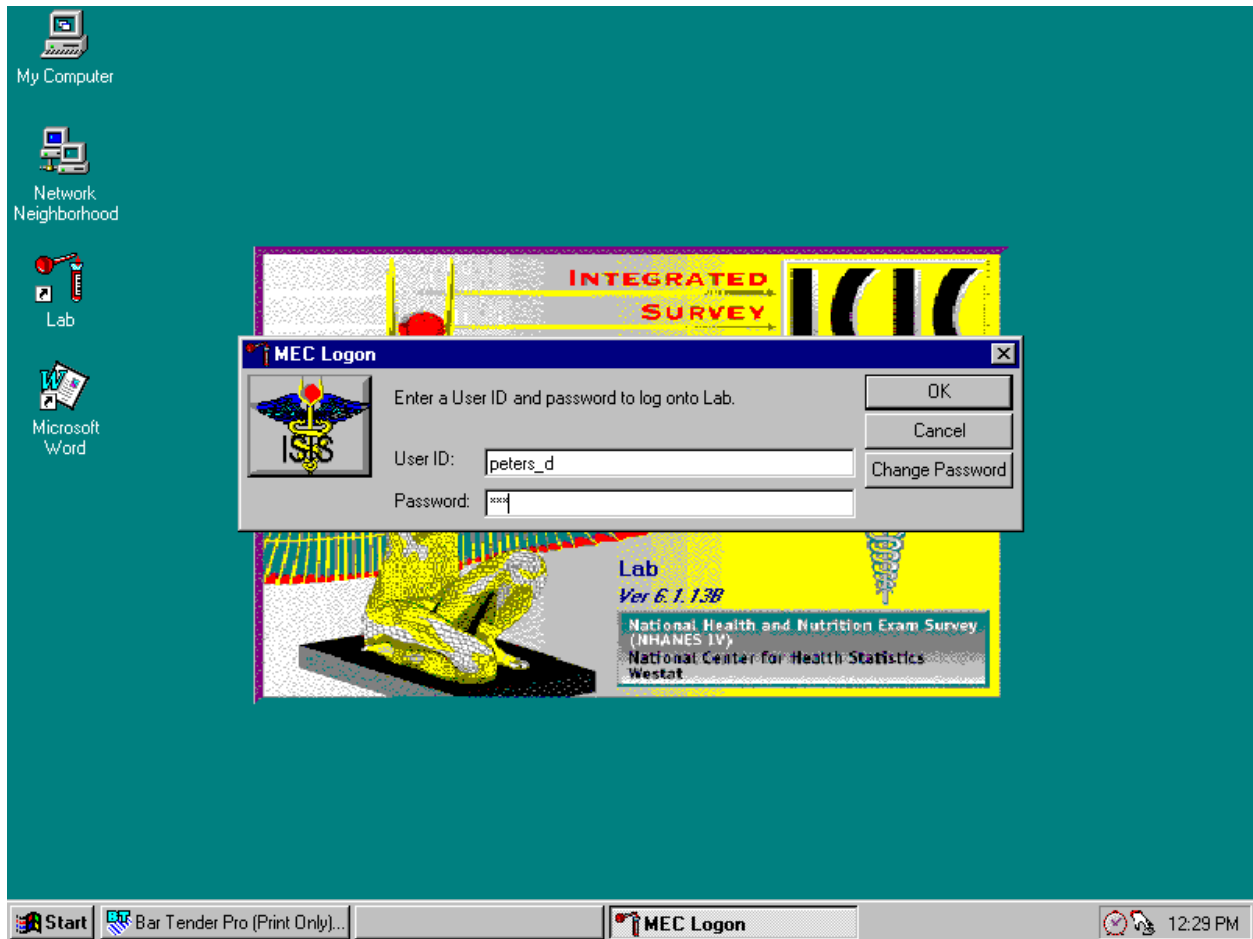
## B.5 Document Hair, MRSA and BV Collection

Open the Laboratory application.



To open the Laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Log onto the laboratory application.



The MEC Logon window displays. Type last name, underscore first initial in the User ID space, and [Tab] or [Enter]. Enter password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the **OK** button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the **Cancel** button and left click.

Use the MEC heads-up display to view the SPs scheduled into the session, the modules for which they are eligible, and their current process status.

Appointments for Session: 505200								Process Status										
SP ID	Sample ID	status	type	fast	gender	age	name	UC	B	CB	U	P	BV	hiv	H	V	N	
216791	216791	EX	P	M	F	46	ANDERSON, KAREN	●	●	●	●	●	●	●	●	●	●	●
231904	231904	SC	P	N	F	3	LAWLESS, LAILA	.	●	●	.	.	.	.	●	.	●	
238916	232636	CI	XD2	M	F	22	PARKWOOD, JANE	●	●	●	●	●	.	●	●	●	●	
254513	254513	SC	VIP	N	F	64	PETERSON, KAREN	●	●	●	●	.	.	.	.	.	.	
340815	340815	SC	S	N	F	35	HOGAN, JACQUIE	●	●	●	.	●	.	.	.	.	.	
498209	498209	SC	P	M	M	43	LAWLESS, STEVE	●	●	●	●	.	.	●	.	.	●	
502067	502067	SC	G	N	F	80	JAMES, COURTNEY	.	●	●	.	.	.	.	.	.	.	
529927	529927	CI	P	M	F	38	ANDERSON, LESLIE	●	●	●	●	●	●	●	●	●	●	
565368	565368	SC	VIP	N	F	65	PETERSON, BETH	●	●	●	●	.	.	.	.	.	.	
656992	656992	SC	P	N	M	7	LAWLESS, NATHAN	●	●	●	●	.	.	.	.	.	●	
669878	669878	CI	P	M	F	40	LAWLESS, NANCY	●	●	●	●	●	●	●	●	●	●	
811000	161096	SC	V		M	41	FRAZIER2, JAMES	.	●	●	.	.	.	.	.	.	●	
865168	865168	SC	P	N	F	1	LAWLESS, SARA	.	●	●	.	.	.	.	●	.	●	
909333	140929	SC	V		F	51	AMIN2, MITUL	●	●	●	.	●	.	.	.	.	●	

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run, V=VOC), fast (M=morning, A=afternoon, E=evening, N=none), Gender (M=male, F=female), Age, and Name (last, first.)

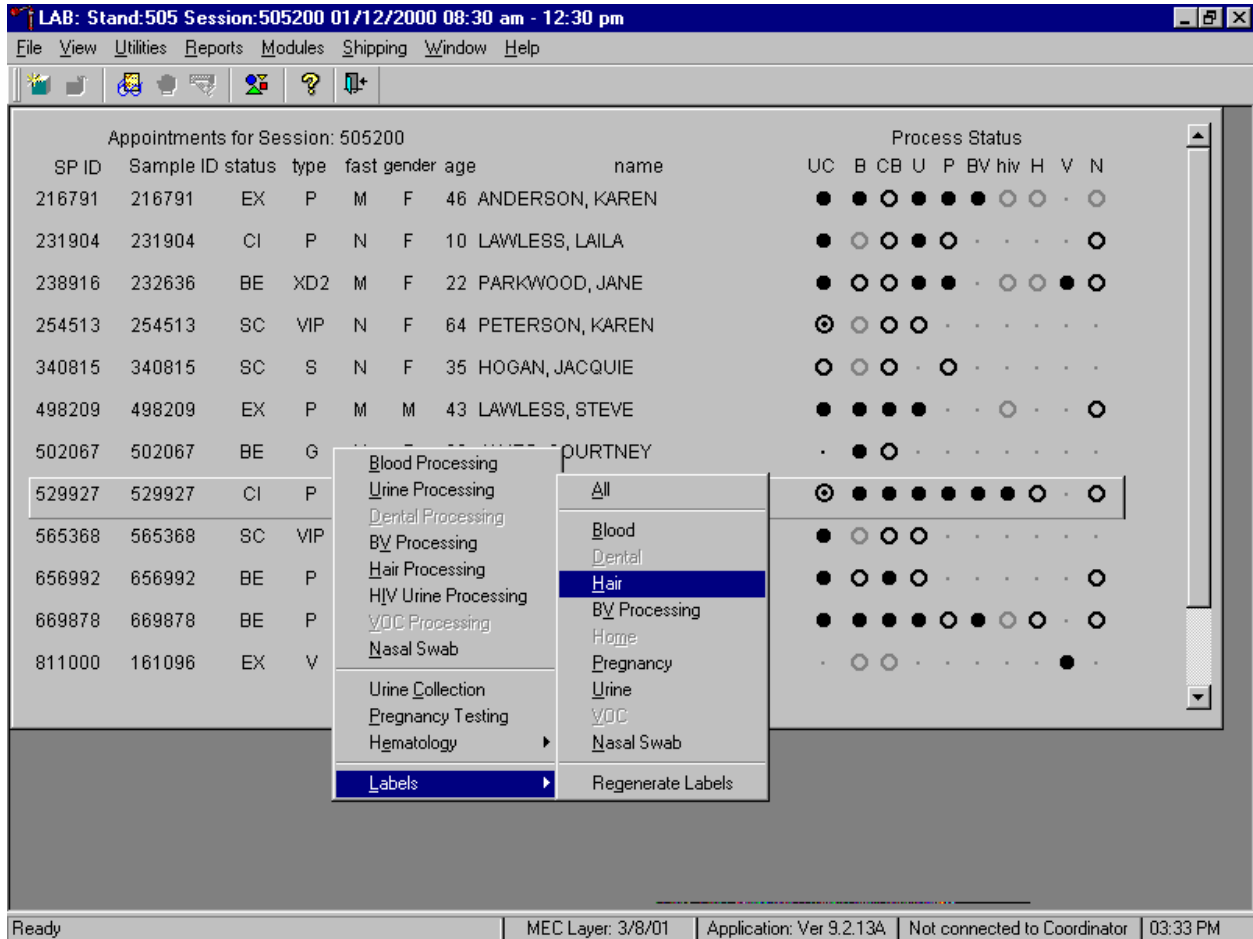
The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible for a module when the process status is . The SP is eligible for a module but no

results have been recorded when the process status is **O**. The SP is eligible for a module and some results have been recorded when the process status is **⊙**. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is **●**. The SP is eligible for a module but the process status is **O** until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from **O** to **⊙**. The SP is eligible for the HIV module but the status is **O** until the SP's blood processing HIV result is recorded. If the quantity of HIV serum is insufficient, the status changes from **O** to **⊙**. The process status updates and changes after each result is saved.

The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP for urine collection. Select a different SP if active SP is not the SP of choice.

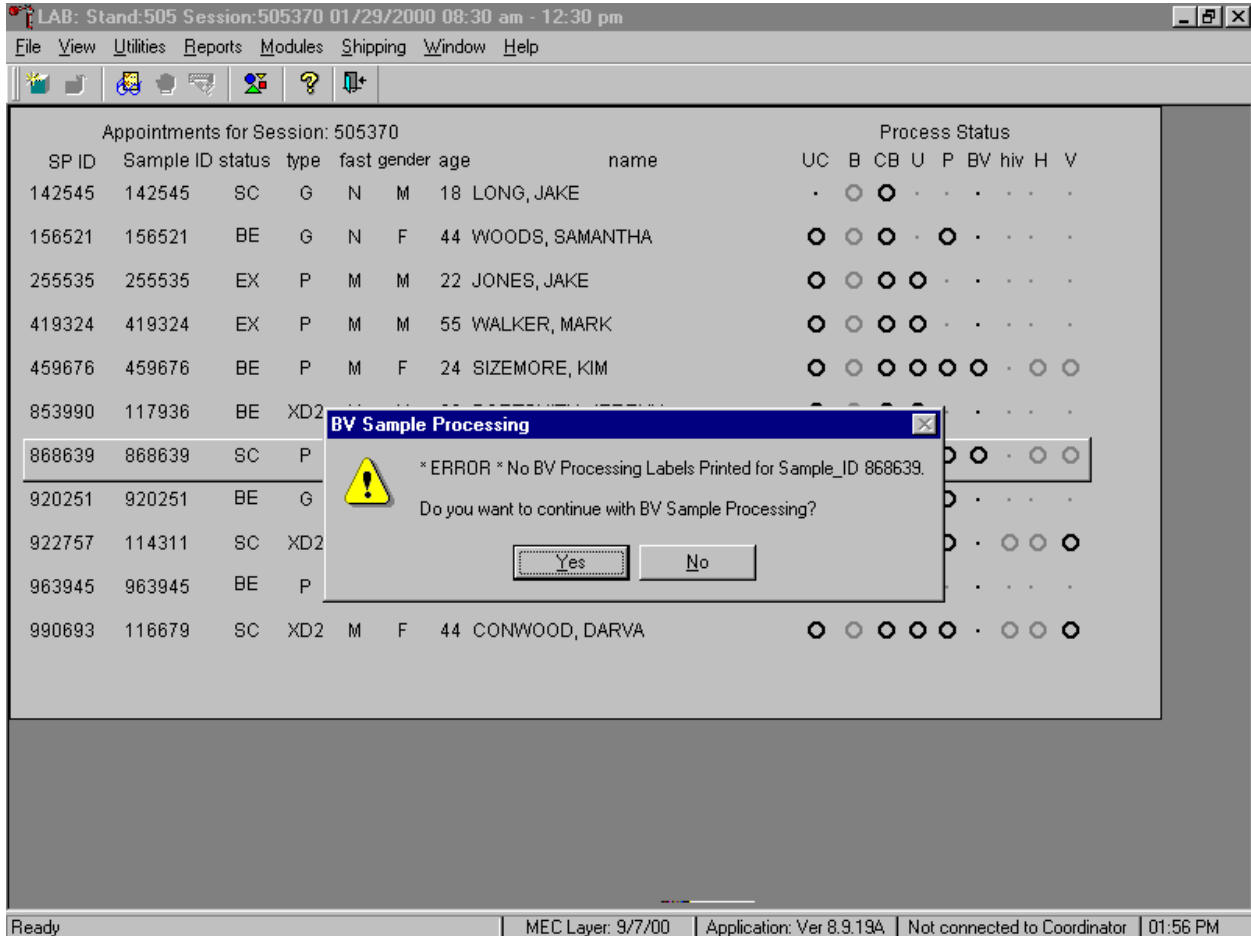
To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down. Alternatively, to view all SPs use the mouse to direct the mouse arrow to the bottom of the heads-up display, right click, and drag the display up or down.

Print additional hair, nasal swab, or BV labels for a particular SP using the heads-up display.



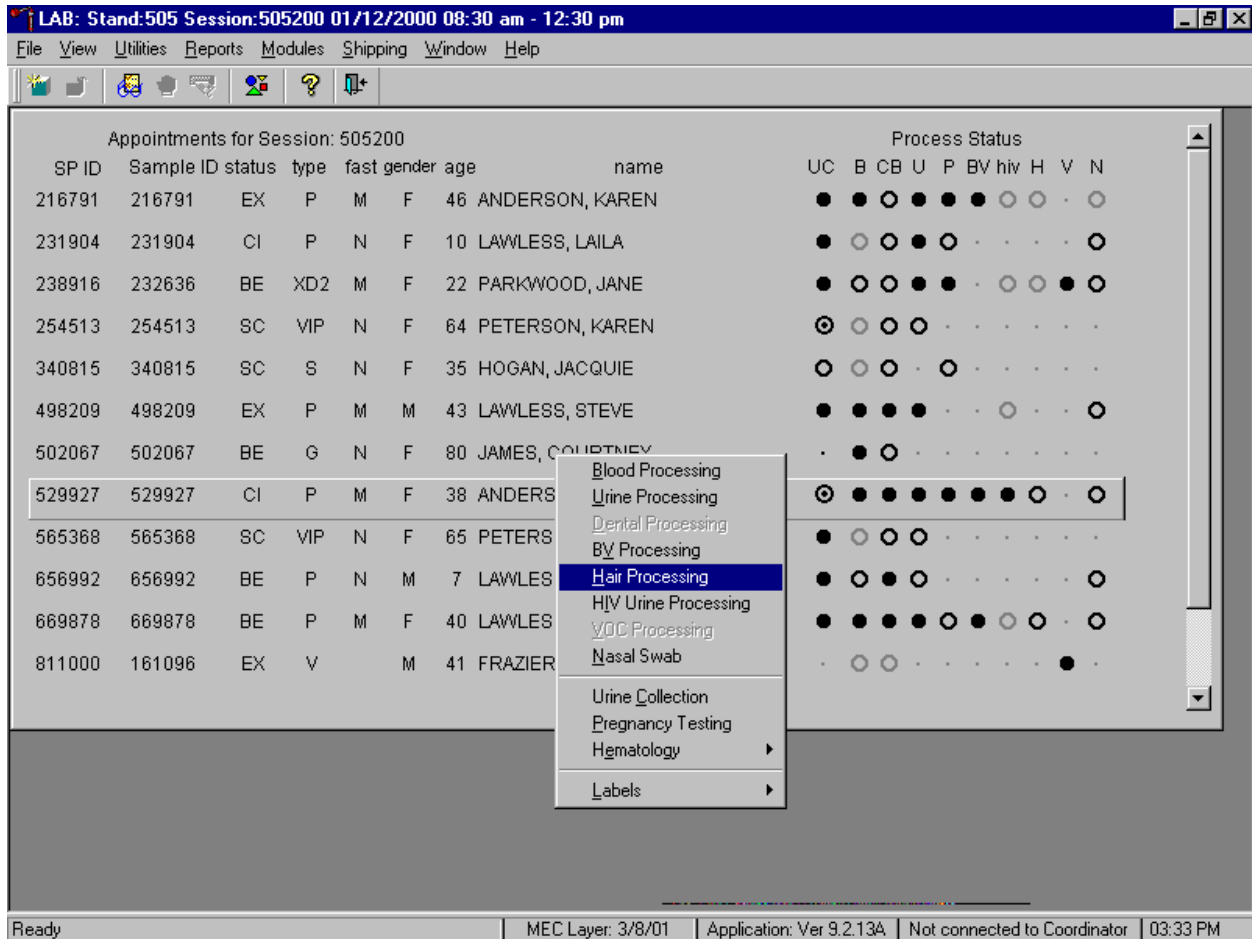
To print additional labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {Hair}, {BV Processing}, or {Nasal Swab} and right click. Alternatively, to print additional labels, use the mouse to direct the mouse arrow to the correct SP, right click, and type [L/l] [H/h] for hair labels, [L/l] [V/v] for BV processing labels or [L/l] [N/n] for nasal swab labels. The labels print in the Label/Ship area.

If labels have not been printed in advance, a Hair Sample Processing, BV Sample Processing, or Nasal Swab Processing message box displays.



Hair, nasal swab, or BV processing cannot occur unless labels have been printed in advance. To remove the Sample Processing message box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter]. Reprint the labels for all SPs or an individual SP in a session.

Select the correct SP and access the Hair, BV Processing, or Nasal Swab module. Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.



To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Hair Processing module, drag the mouse arrow to {Hair} and left click or right click and type [H/h]. To access the BV Processing module, drag the mouse arrow to {BV Processing} and left click or right click and type [V/v]. To access the NS (nasal swab) processing module, drag the mouse arrow to {Nasal Swab} and left click or right click and type [N/n]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to correct module and left click or type [H/h], [V/v] or [N/n].



## **B.6 Processing Hair Specimens**

Process hair specimens in the lab. Process these specimens using the Hair processing module and store specimens for shipment.

The health technicians collect hair samples in the designated room in trailer 1 and transport the samples to the laboratory in 6 x 6 plastic bags. The health technicians attach a SP ID bar coded label to the outside of the plastic bag after collecting the sample. Record the collection in the Hair processing module and store the specimen.

The Hair processing window displays.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hair: 529927

none

Tech ID: 1226    Sample ID: 529927    Name: ANDERSON, LESLIE    Gender: F    Age: 38  
 SP ID: 529927    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
59	Methylmerc	100	H	100 mg	plastic bag	<input type="radio"/> Yes <input type="radio"/> No		

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:33 PM

The Hair processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type (H=hair), Vessel Volume, Vessel name, Container ID/Slot #, and Filled “Yes” or “No” radio buttons.

Mark each vessel as Filled “Yes” or “No.”

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hair: 529927

none

Tech ID: 1226    Sample ID: 529927    Name: ANDERSON, LESLIE    Gender: F    Age: 38  
SP ID: 529927    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Container ID	Slot#
59	Methylmerc	100	H	100 mg	plastic bag	<input checked="" type="radio"/> Yes <input type="radio"/> No	0306018	1

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:33 PM

To mark an individual hair vessel as collected or “filled,” use the mouse to direct the mouse arrow to 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. To mark an individual hair vessel as not collected or Filled - “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click.

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this 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 type [Enter]. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

## B.7 Processing BV Specimens

Process the swab in the red-capped tube for:

1. pH
2. Gram stain slide

Process the Dacron swab in the transport sleeve for:

1. *Trichomonas vaginalis*

If the laboratory receives only the Dacron swab in the transport sleeve, perform the pH, make the gram stain, and process the swab for *Trichomonas vaginalis*. If the laboratory receives only one red-capped swab, perform the pH, and make the gram stain, but do not process the red-capped swab for *Trichomonas vaginalis*.

Verify that the correct swab is in the correct tube before processing the specimens. If the swabs are in the incorrect tubes, correct the situation before proceeding. Table B-3 summarizes the BV processing protocol. Process the red-capped swab first. Perform the pH measurement and then make the gram stain slide. Refrigerate the Dacron swab in the transport sleeve.

Table B-3. BV processing protocol

Vessel No	Assay	Age in Years	Sample Type	Collection Type	Vessel Type
72	Vaginosis	Women 14-49	Cotton swab in a red-capped tube	Genital swab	(pH) Glass slide
73	T vaginalis	Women 14-49	Puritan Dacron swab in a transport sleeve	Genital swab	Dacron swab in a transport sleeve

- Perform a pH on the cotton swab in the red-capped tube. Touch the pH strip to the side of the cotton tip. Use the fluid on the tip of the swab if necessary. Record the pH to one decimal.
- Cut (trim) the label at the margin between the opaque and clear sections and discard the clear portion. Label one glass slide with the vessel 72 label. Make a smear for gram stain using the cotton swab in the red-capped tube. Roll the swab across the surface of the frosted-edge glass slide. (Do not dab the tip of the cotton swab on the slide.) Allow the slide to air dry. Record the processing results. Store the glass slide at room temperature in a slide box.
- Verify that the shaft of the swab inside the plastic transport sleeve is white plastic and not wood. Record the processing result and refrigerate the Dacron swab in the transport sleeve.
- Discard the red-capped cotton swab that was used for the pH and gram stain in the biohazard trash.

Remember if the laboratory receives only the Dacron swab in the transport sleeve, perform the pH, make the gram stain, and process the swab for *Trichomonas vaginalis*. If the laboratory receives only one red-capped swab perform the pH and make the gram stain, but do not process the red-capped swab for *Trichomonas vaginalis*.

The BV Processing window displays.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input type="radio"/> Yes <input type="radio"/> No	(none)			
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)			

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:23 PM

The BV Processing window contains the following information for a SP: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample (designation), and Fasting\_Req. There are additional columns that display the Vessel ID, Test Name, Sample Volume, (specimen) Type, Vessel Volume, Vessel Name, Filled (Yes or No), Comment, pH and Container ID and Slot#. Use radio buttons to record the processing results, Filled “Yes” or “No”, attach a comment using the Comment text window, record the pH result in the text box, and store the vessel in the assigned Container ID and Slot#.

Record the pH either before or after recording the vessel as Filled “Yes” or Filled “No.”

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	<4.0	0306029	1
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)	4.0		

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:23 PM

To record the pH, use the mouse to direct the mouse arrow to the pH drop-down list, left click to display the choices, drag the mouse arrow to the correct value, and left click. Use the scroll bar to view all the possible values. Alternatively, to record the pH type [Tab], [Tab], and [Tab] to advance to the pH text box, and type the whole number value using the keyboard’s numeric keys. To enter a decimal value, type the whole number value a second time.

Each of the two vessels is “filled” if the swab was collected. Individually mark each vessel as Filled – “Yes” or Filled – “No.”

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	4.0	0306029	1
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)			

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:23 PM

To mark an individual BV vessel as collected or Filled – “Yes” or Filled – “No” use the mouse to direct the mouse arrow to the “Yes” or “No” 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. A comment is not required to exit this screen.



Enter a quality control comment for vessel 72 and/or 73 when the swab is dry and the judgment is that the SP did not attempt to collect the sample(s).

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Vessel Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)	4.0		
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none) inadequate sample			

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:25 PM

To record an “inadequate sample” comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “inadequate sample,” and left click. Alternatively, to record the comment “inadequate sample,” [Tab] to advance to the Comment text box and type [I/I] and [Enter].

Record the comment to vessel 72, “dacron swab used” when appropriate.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	4.0	0306029	1
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)			

bloody swab  
 dacron swab used

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:25 PM

Record the “dacron swab used” comment when vessel #72 is collected or Filled – “Yes”, and the laboratory receives only the Dacron swab in the transport sleeve. To record this comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “dacron swab used,” and left click. Alternatively, to record the comment “dacron swab used,” [Tab] to advance to the Comment text box and type [D/d] and [Enter].

There are no comments available for vessel 73 when the vessel is marked as Filled “Yes” because it is not permissible to use the cotton swab for the *T vaginalis* test.

LAB: Stand:505 Session:505370 01/29/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 505370 Process Status

SP ID Sample ID status type fast gender age name UC B CB U P BV hiv H V

**BV: 459676**

none

Tech ID: 1226 Sample ID: 459676 Name: SIZEMORE, KIM Gender: F Age: 24  
 SP ID: 459676 SubSample: 1 Fasting\_Req: 1

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		30575	2
73	T vaginalis	1	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		30575	2

Save OK Cancel

Ready | MEC Layer: 9/7/00 | Application: Ver 8.9.19A | Not connected to Coordinator | 01:52 PM

Never use the cotton (red-capped) swab for the T vaginalis (vessel 73) test.

Use the quality control comment code to indicate if blood is present.

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	4.0	0306029	1
73	T vaginalis	1	SW	1 swab	swab	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)			

To enter the quality control comment “blood present” for a filled vessel 72 and/or 73, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present} and left click.

Store the glass slide in the assigned slot in the slide box at room temperature and store the Dacron swab in the 12 x 12 plastic bag in refrigerator #2, review the information in the BV-processing window, and save the data to the database.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

BV: 216791

none

Tech ID:1226    Sample ID: 216791    Name: ANDERSON, KAREN    Gender: F    Age: 46  
 SP ID: 216791    SubSample: 1    Fasting\_Req: 1

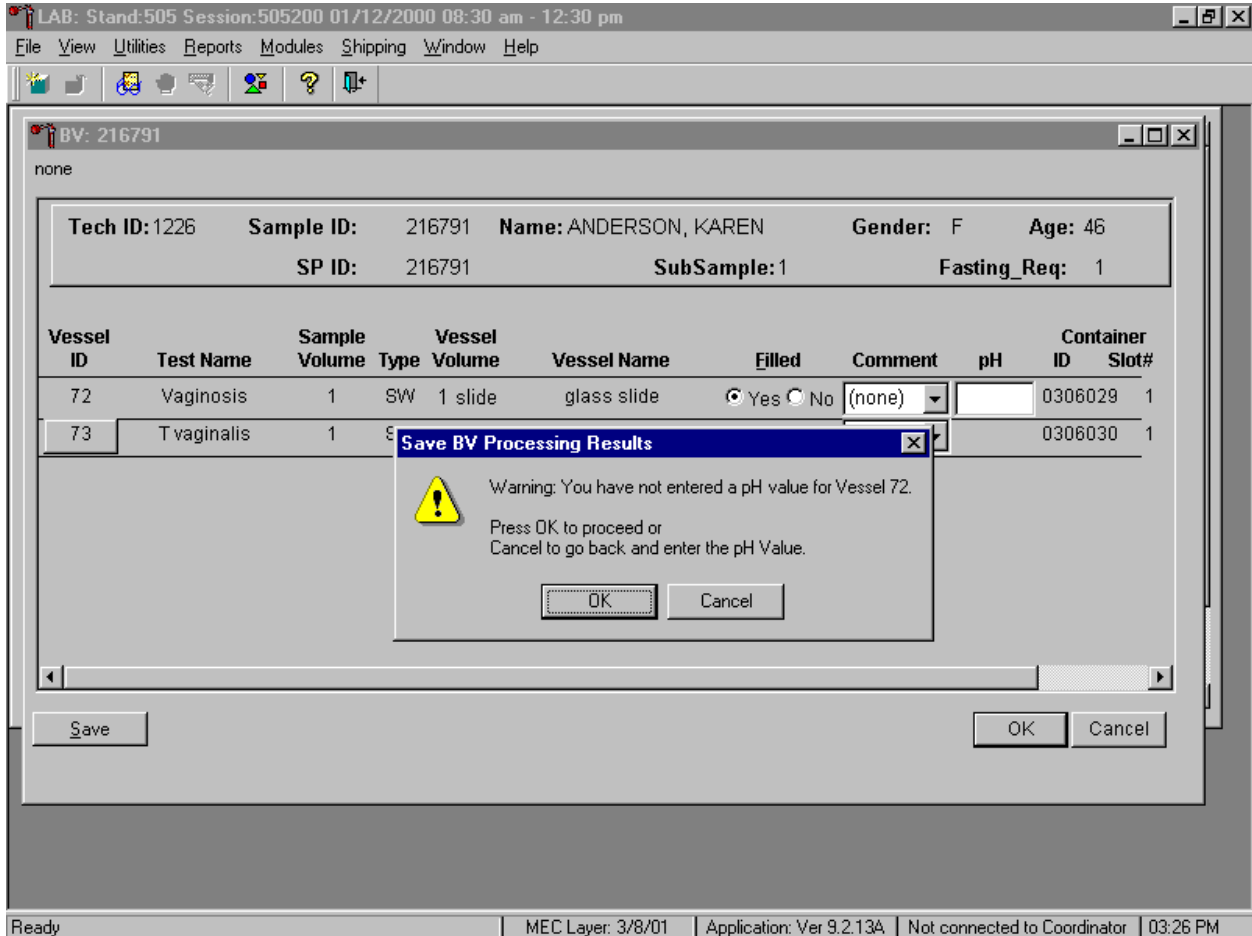
Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	pH	Container ID	Slot#
72	Vaginosis	1	SW	1 slide	glass slide	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)	4.0	0306029	1
73	T vaginalis	1	SW	1 swab	swab	<input checked="" type="radio"/> Yes <input type="radio"/> No	(none)		0306030	1

Save    OK    Cancel

Ready    MEC Layer: 3/8/01    Application: Ver 9.2.13A    Not connected to Coordinator    03:23 PM

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click or type [S/s]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

If the **Save** or the **OK** button is selected and the pH has not been recorded, a Save BV Processing Results warning message box displays requesting a value for this test.



To remove the warning message box and return to the heads-up screen, use the mouse to direct the mouse arrow to the **OK** button and left click. To remove the warning message box and return to the current processing screen, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

The process status circle in the heads-up fills in completely for SPs who have both swabs recorded as collected or Filled - “yes.” The process status circle partially fills in for SPs who have one vessel marked as Filled – “Yes” and the other vessel marked as Filled – “No.”

Do not enter a result until the swabs arrive in the laboratory. At the end of each session, review the results for each SP. Access each record and enter Filled - “No” for both vessels for all SPs for whom no swabs were received.

## B.8 Processing Nasal Swab Specimens

The nasal swab (NS) processing window displays.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The main window is titled "NS: 231904" and contains the following information:

none

Tech ID: 1226	Sample ID: 231904	Name: LAWLESS, LAILA	Gender: F	Age: 10
	SP ID: 231904	SubSample: 1	Fasting_Req: 4	

Vessel ID	Test Name	Sample Volume	Type	Vessel Volume	Vessel Name	Filled	Comment	Container ID	Slot#
76	MRSA	1	NS	1 swab	swab	<input type="radio"/> Yes <input type="radio"/> No	(none)		

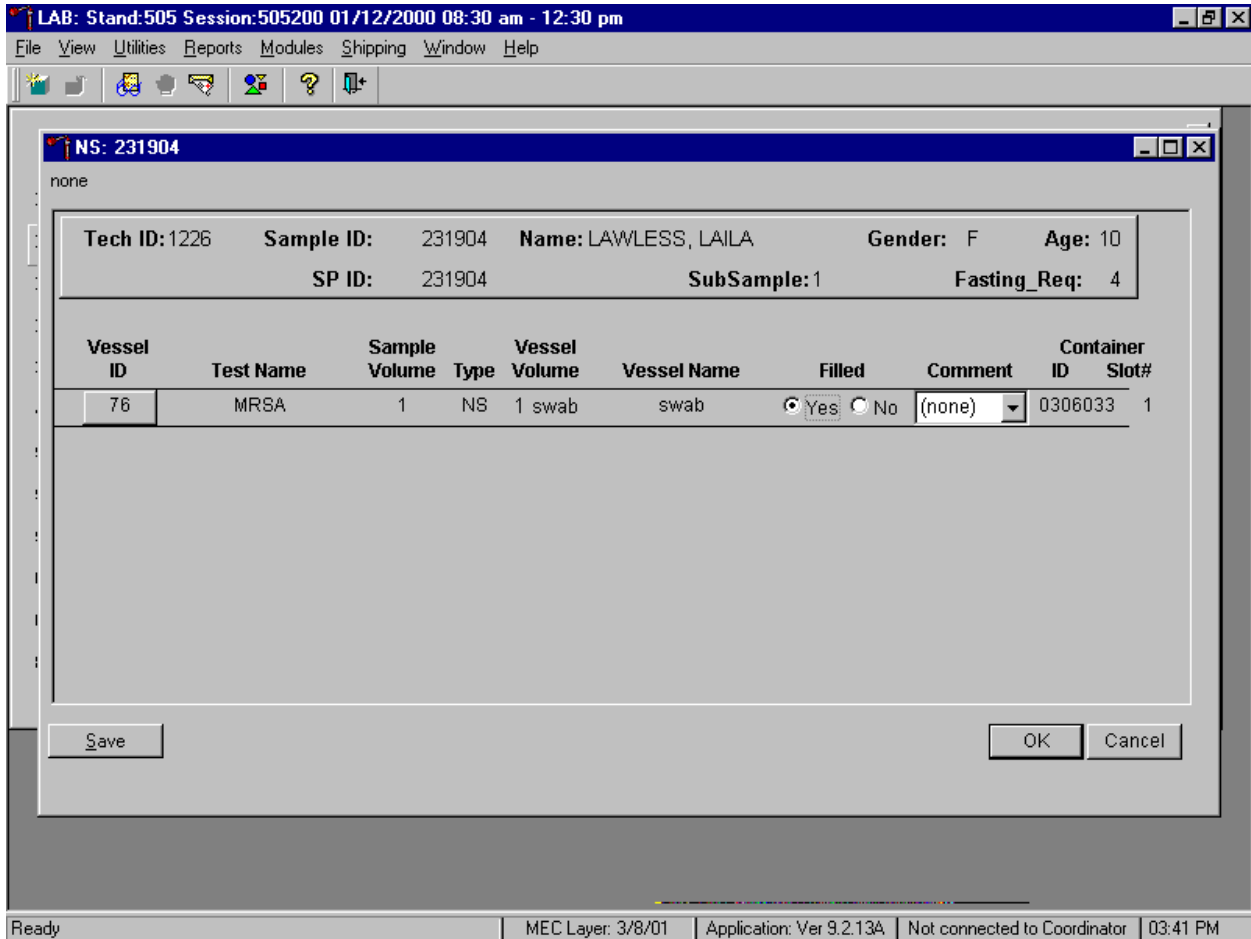
Buttons: Save, OK, Cancel

System tray: Ready | MEC Layer: 3/8/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 03:41 PM

The nasal processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting\_Req, columns for Vessel ID, Test Name, Sample Volume, Type (NS), Vessel Volume, Vessel Name, Container ID/Slot #, and Filled “Yes” and “No” radio button and a Comments text box.



Mark each vessel as Filled “Yes” or “No.”



To mark an individual NS vessel as collected or “filled,” use the mouse to direct the mouse arrow to 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. To mark an individual NS vessel as not collected or Filled - “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. There are no comments available for either a Filled – “Yes” or Filled – “No” result.

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **S**ave button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click or type [Enter]. To close the window without

saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

## **B.9 Specimen Storage**

Record the hair processing results and prepare to store the vessel. Store the hair collection plastic bag in a 12 x 12 plastic bag at ambient temperate at workstation 2. Record the MRSA processing results and store the nasal swab in a 12 x 12 plastic bag in the refrigerator at workstation 2.

Perform the BV pH measurement, make the gram stain slide, store the glass slide in a plastic slide box, and store the slide box at room temperature at workstation 2. Record the processing results for the Dacron swab, store the swab in a 12 x 12 plastic bag, and refrigerate the Dacron swab (in the transport sleeve) in refrigerator #2.

Store vessels in numbered storage containers according to test as indicated in Exhibit B-4.

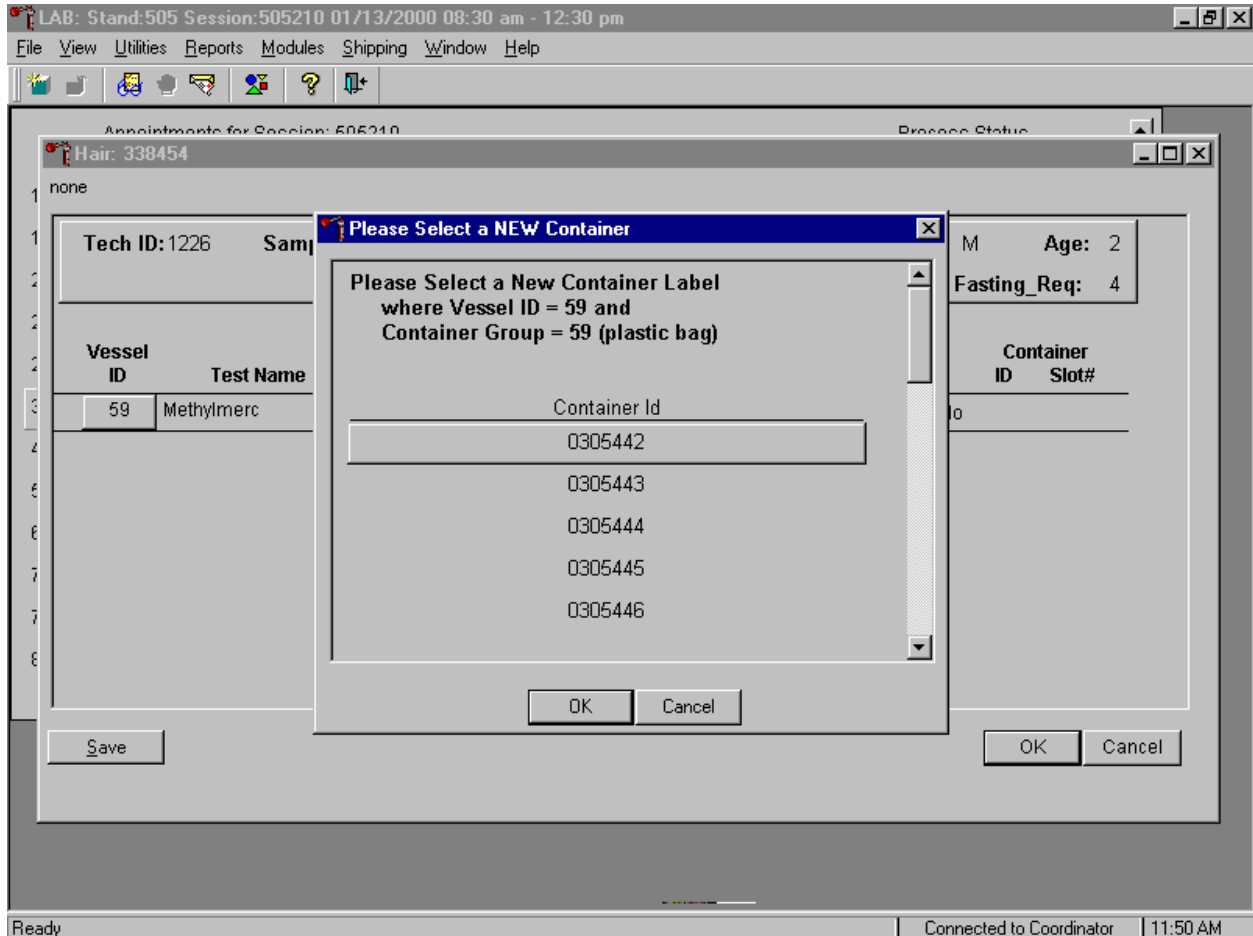
At the beginning of each stand, generate and print a series of bar coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process “opens” a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Exhibit B-4. Storage protocol for hair, MRSA, and BV

<b>Shipping Location</b>	<b>Vessel</b>	<b>Condition</b>	<b>Vessel Storage</b>
Research Triangle Institute	59 Methymerc	Room temperature	12 x 12 plastic bag
Magee Womens Hospital	72 Vaginosis	Room temperature	1 x 25 slide box
Magee Womens Hospital	73 T vaginosis	Refrigerated	12 x 12 plastic bag
CDC/Dr. Sigrid McAllister	76 MRSA	Refrigerated	12 x 12 plastic bag

## B.9.1 Opening New Containers

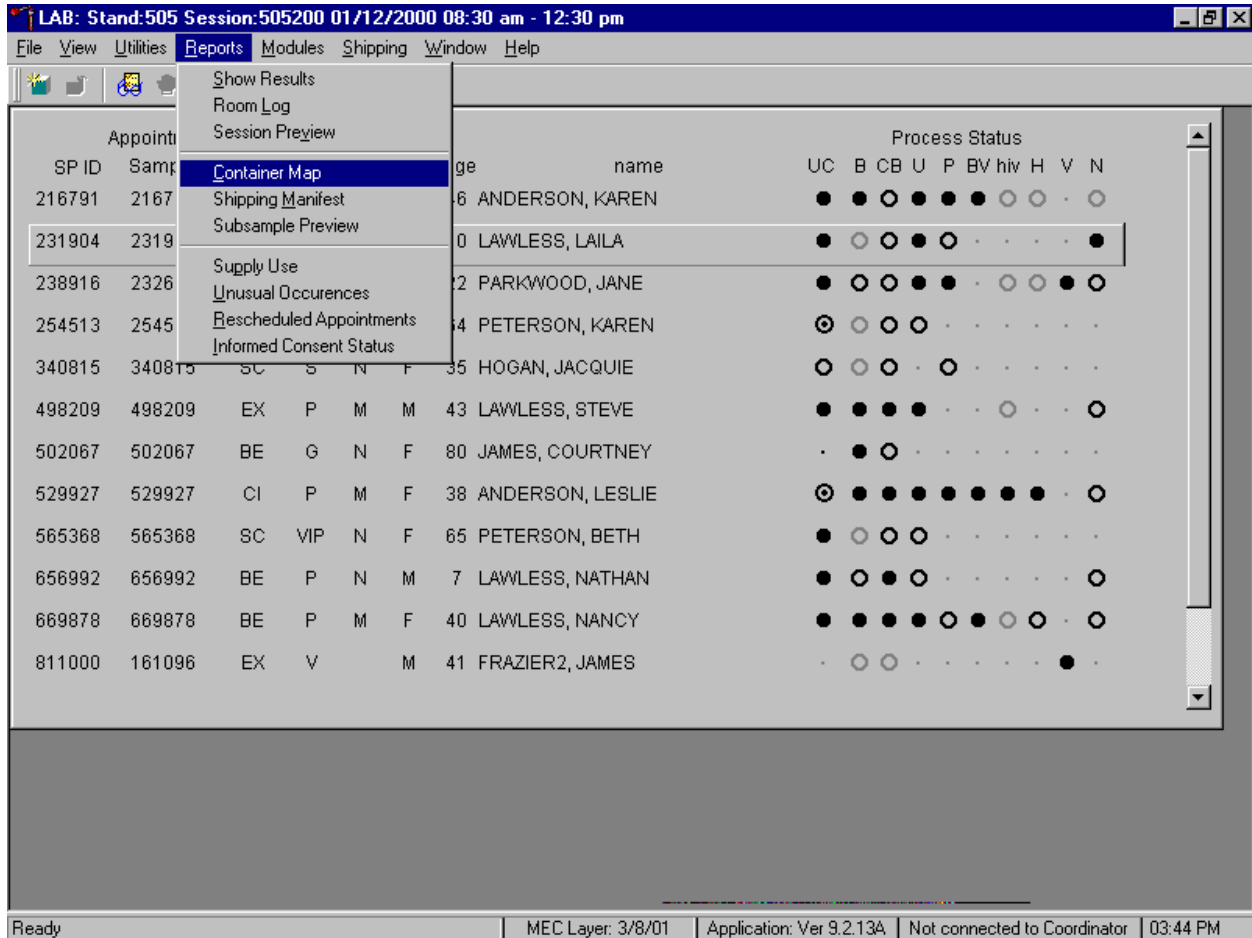
When a container is full, the container will automatically “close.” Open a new container when prompted.



When a container is full, an opportunity to open a new container is automatically displayed on the “Please Select a NEW Container” window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

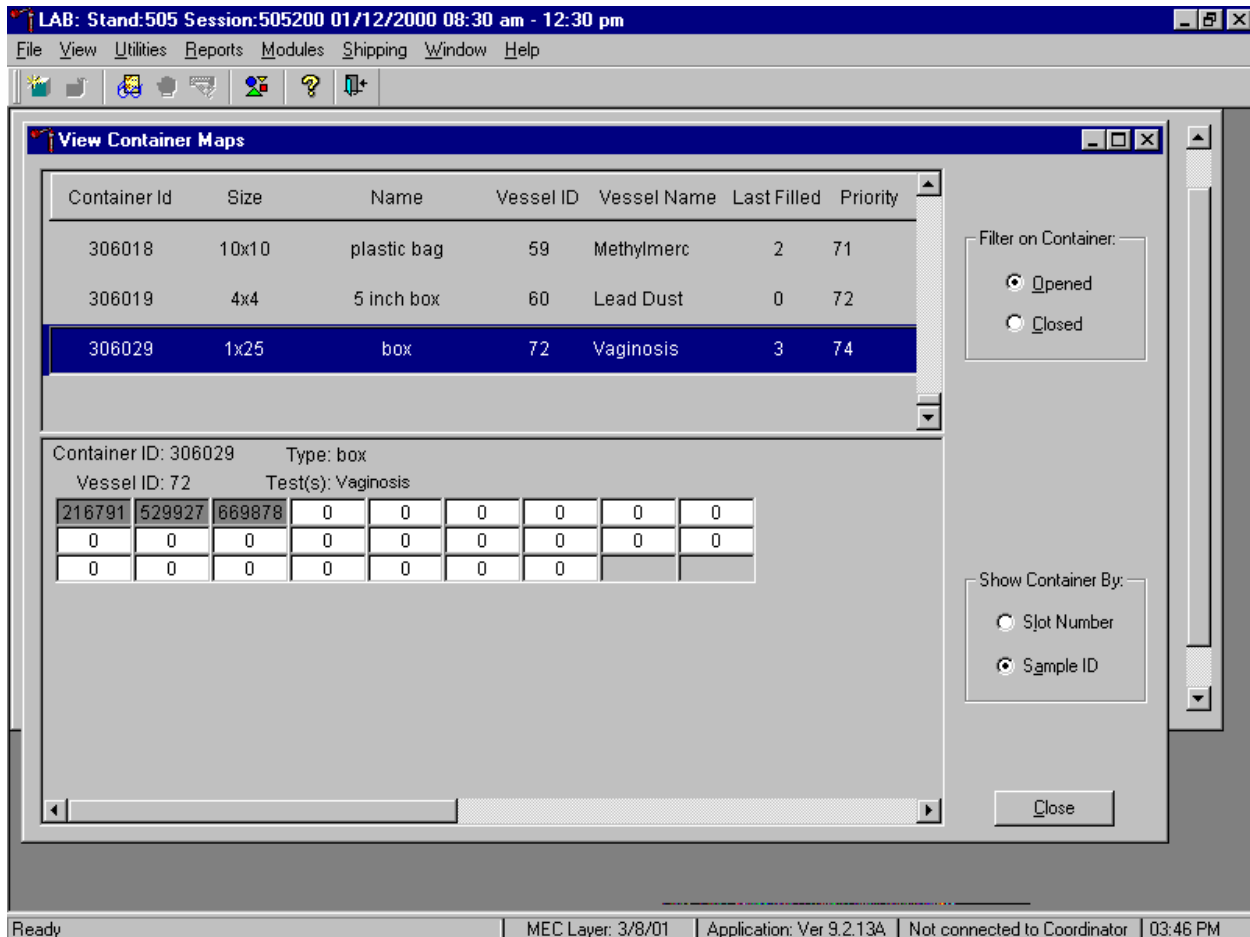
## B.9.2 Check Storage Containers

Check the slot assignment of containers associated with vessels 59, 72, 73, and 76 at the end of each session. Access the Container Map report.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping} in the menu bar, drag the arrow to {Container Map}, and left click or type [Alt] [R/r] [C/c] or [Alt] [S/s], [C/c].

Verify the contents of each container against the container map.



- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to “Opened” and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to “Sample ID” and left click.
- Highlight or select the first container ID for vessel 59 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 59.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.

- Continue checking each container map report for vessels 72, 73, and 76.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

## B.10 Shipping Procedures

The technologists ship vessels 72, 73, and 76 to a variety of contract laboratories in double-sided Styrofoam and corrugated cardboard shippers using wet ice (refrigerant packs). Ship vessel 59 at ambient temperature using padded envelopes. 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 B.5, the Shipping Protocol, illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Send the hair specimens in a padded envelope at ambient temperature weekly. Ship the nasal swab in small shipper with sufficient refrigerant gel packs to maintain refrigerated conditions and ship weekly. Pack both the plastic slide box and the Dacron swabs in a small shipper with sufficient refrigerant gel packs to maintain refrigerated conditions and ship weekly. Exhibit B-5 illustrates the shipping protocol.

Exhibit B-5. Shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Research Triangle Institute	59	Methylmerc	Room Temperature	Weekly
Mcgee Womens Hospital	72 73	Vaginosis <i>T vaginalis</i>	Refrigerated	Weekly
CDC/Sigrid K. McAllister	76	MRSA	Refrigerated	Weekly

### B.10.1 Packing Procedures

Some of the shipments require reusable refrigerant packs to keep specimens cold but not frozen. For these shipments, use reusable refrigerant packs. Store reusable refrigerant packs in the

freezers, replacing as necessary. (Distribute the refrigerant packs across all freezers.) The technologists ship room temperature specimens in padded envelope. Exhibit 9-3 in Chapter 9 contains a list of all contract laboratory addresses.

Add enough frozen refrigerant packs to the shipper to keep vessels 72, 73, and 76 cold for at least 48-72 hours. Pack all refrigerated containers in Styrofoam shippers. Pack the specimens tightly in the Styrofoam container to prevent movement.

For all destinations except vessel 59 (hair) include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand. Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand.

#### **Pack Small Shipping Container for Refrigerated Shipment (vessels 72 and 73)**

- Place a rubber band around the slide box (vessel 72) to prohibit the slides from falling out of the slide box.
- Place the slide box in a padded envelope.
- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper.
- Place the sealed plastic bag containing the swabs on top of the refrigerant pack.
- Pack the sides with crumbled newsprint.
- Place two or three additional refrigerant packs on top of the swabs.
- Place additional crumpled newsprint on top of the refrigerant gel pack.
- Place the padded envelope containing the slide box on top of the crumpled newsprint.
- Close the container lid.
- Place a plastic envelope containing the appropriate shipping manifest and the return FedEx preprinted airbill 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 airbill.
- Seal the shipper with several tape strips.

### **Pack Small Shipping Container for Refrigerated Shipment (vessels 76)**

- Place at least two large or three small frozen refrigerant packs in the bottom of a shipper.
- Place the sealed 12 x 12 plastic bag on the refrigerant packs.
- Pack the sides with crumbled newsprint.
- Place two or three additional refrigerant packs on top of the container.
- Place additional crumpled newsprint on top of the refrigerant gel pack.
- Close the container lid.
- Place a plastic envelope containing the appropriate shipping manifest and the return FedEx preprinted airbill 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 airbill.
- Seal the shipper with several tape strips.

### **Pack Ambient Temperature Padded Envelope (vessel 59)**

- Place the bag of hair specimens in a padded envelope.
- Place a plastic envelope containing the appropriate shipping manifest in the envelope.
- Assume the package weighs 1 pound.
- Record the total weight of the envelope (1 pound) on the appropriate FedEx airbill.
- Seal the envelope.



## Label Shippers

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

- Label shippers containing refrigerant packs with a “Refrigerate” label.
- 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.
- Place one additional strip of tape across the FedEx pouch.

### B.11 How to Deal With System Failure

If the computer system fails, record results on a preprinted Miscellaneous Processing Worksheet (Exhibit B-6). Complete a Workstation 2 worksheet for each SP while processing the hair, MRSA and/or BV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit B-6. Miscellaneous processing worksheet

#### HAIR, MRSA, AND BV PROCESSING

SP ID \_\_\_\_\_

ID	Name	Ages	Sample mL	Sample Type	pH	Filled ✓	Slot #
72	Vaginosis	14-49 females	cotton swab				
72	Vaginosis			Glass slide			
59	Methylmerc	15 both genders 16-49 females	100 mg	Hair			
76	MRSA	1+	cotton swab	Swab			

Appendix C  
Lead Dust Processing and Quality Control

## APPENDIX C

### LEAD DUST PROCESSING AND QUALITY CONTROL

#### C.1 Overview

Field interviewers collect lead dust samples in households with children ages 1-5. Associate a dust sample with a specific SP when it is collected; collect the sample in the room where the SP spends most of their time. There are five possible sample types: floor, floor replicate, windowsill, windowsill replicate, and field blank. Collect both floor and windowsill samples in each eligible home. In 10 percent of homes, collect one replicate sample. This replicate is randomly selected as either a floor or windowsill sample. In those households chosen for a replicate sample, the interviewer must also collect a field blank.

Each lead dust sample consists of one dust collection wipe in a 50-mL skirted conical tube. Label lead dust samples in the field with preprinted randomly assigned specimen identification numbers. Place samples from each household in a sample storage bag and return to the field office. Store samples at room temperature in a box with a lid to prevent excessive exposure to light. The MEC manager delivers lead dust samples and the corresponding Lead Dust Transmittal form to the MEC weekly. Samples are relabeled, assigned to specific slots in storage containers, and shipped weekly to the analysis laboratory. Send the Lead Dust Transmittal form back to the home office at the end of each stand.

The warehouse maintains a supply of spiked positive controls. At the start of each stand, the warehouse manager sends four spiked positive samples to the MEC. Process one pair of spiked samples; designate one control as a floor sample and designate the second positive control as a window sample. Process this pair of samples at the start of weeks 1 and 3. Print labels for these specimens, process, and insert the relabeled samples into the assigned slot in the storage containers.

Blood lead levels are reported to all SPs who were tested. The test is performed on all primary SPs age 1+, all dry run volunteers age 12+, VIP guests age 1+, home exam SPs age 50+, and second exam SPs age 12-69. If the blood level is greater than the threshold, which is age dependent, an early reporting letter is sent to the SP. If the result is less than the threshold, it is reported in the final Report of Findings. If the lead level of the household lead dust wipes exceeds Federal guidelines, a report

is sent to the household along with EPA (Environmental Protection Agency) or HUD Housing and Urban Development) informational brochures. Only abnormal lead dust levels in an environmental sample are reported to an SP but all blood levels are reported.

**C.2 MEC Laboratory Lead Dust Processing**

The conical tubes that hold each lead dust sample are labeled in the field with bar-coded labels that contain a preprinted randomly assigned specimen identification number and an indication of the sample type. Once these tubes reach the MEC, the laboratory staff matches the vessels to the Lead Dust Transmittal form, prints laboratory labels that contain the sample ID associated with each SP and the vessel ID, removes the original field office label, and labels each sample with the new laboratory label. Process the relabeled samples using the Lead Dust Processing module, store the samples at room temperature, and ship weekly. Field blanks are blinded to the analysis laboratory. Label field blanks with “virtual” sample IDs as designated by ISIS.

The supplies needed for lead dust processing and storage are listed in Exhibit C.-1

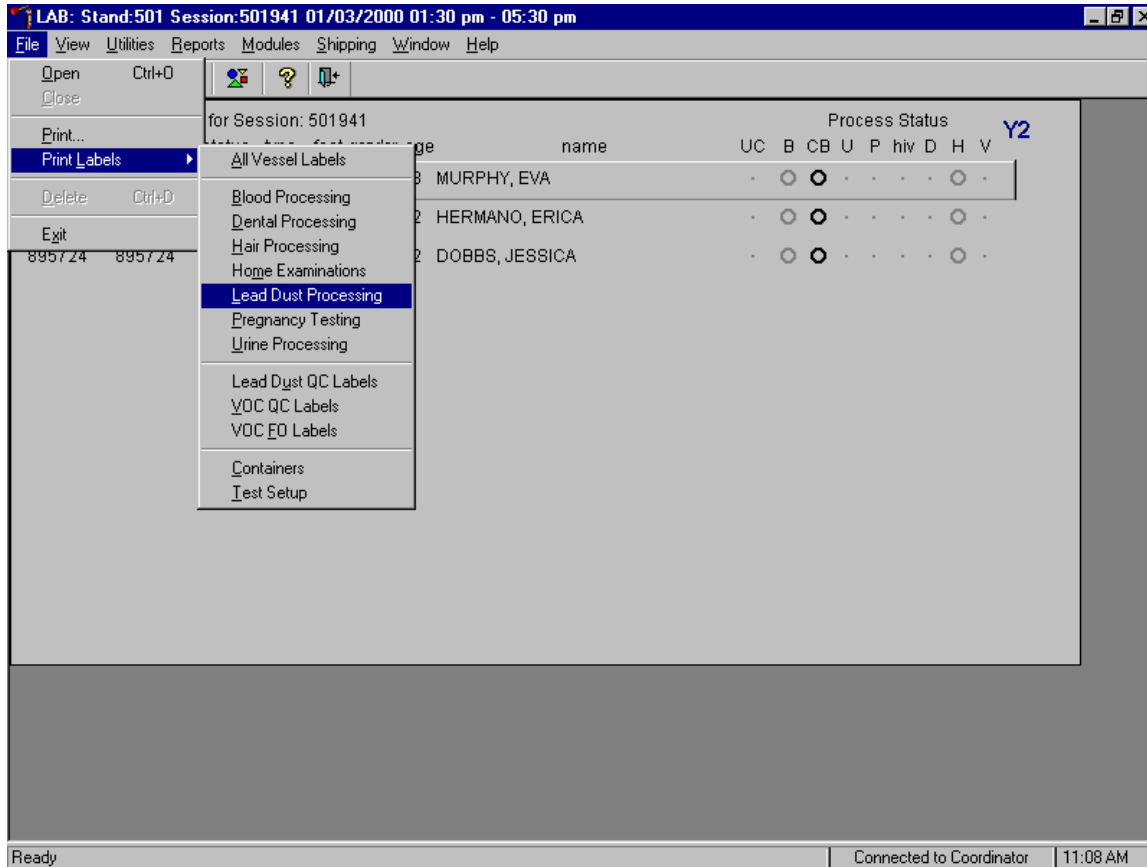
Exhibit C-1. Equipment and supplies

5.25 x 5.25 five inch tall box with 4 x 4 grid	Rubber bands
Small shipper	12 x 12 plastic bags

Exhibit C-2 Laboratory lead dust vessels

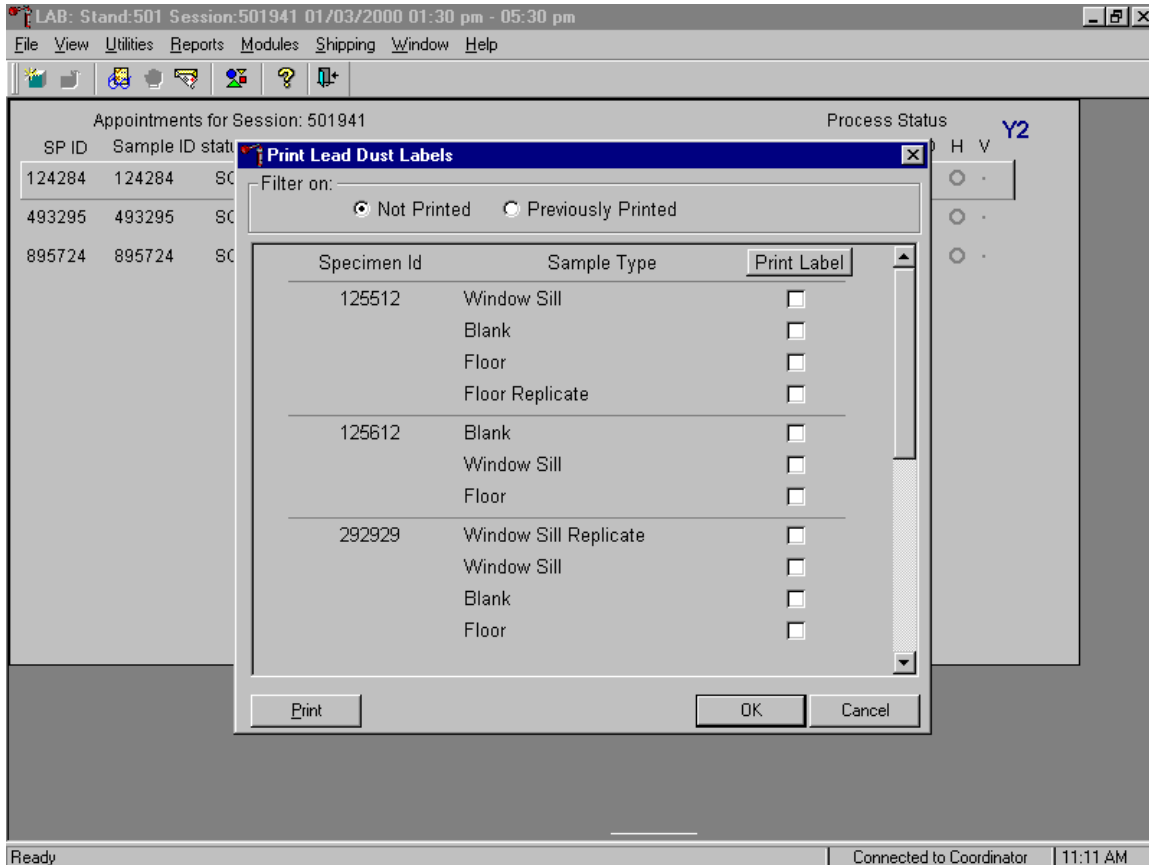
Vessel ID	Test Name	Sample Type	Vessel Type	Vessel Storage
60	Lead Dust Floor	Wipe	50-mL conical tube	4 x 4 five inch box
61	Lead Dust Windowsill	Wipe	50-mL conical tube	4 x 4 five inch box

Physically match the vessels listed on the Lead Dust Transmittal form to the actual lead dust samples. If there are discrepancies, contact the field office manager to reconcile the inconsistencies. Print laboratory labels for lead dust samples collected in the home. Access the Lead Dust Processing label module.



To access the Lead Dust Processing label module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, drag the arrow to {Print Labels}, then to {Lead Dust Processing}, and left click or type [Alt] [F/f], [L/l], [L/l].

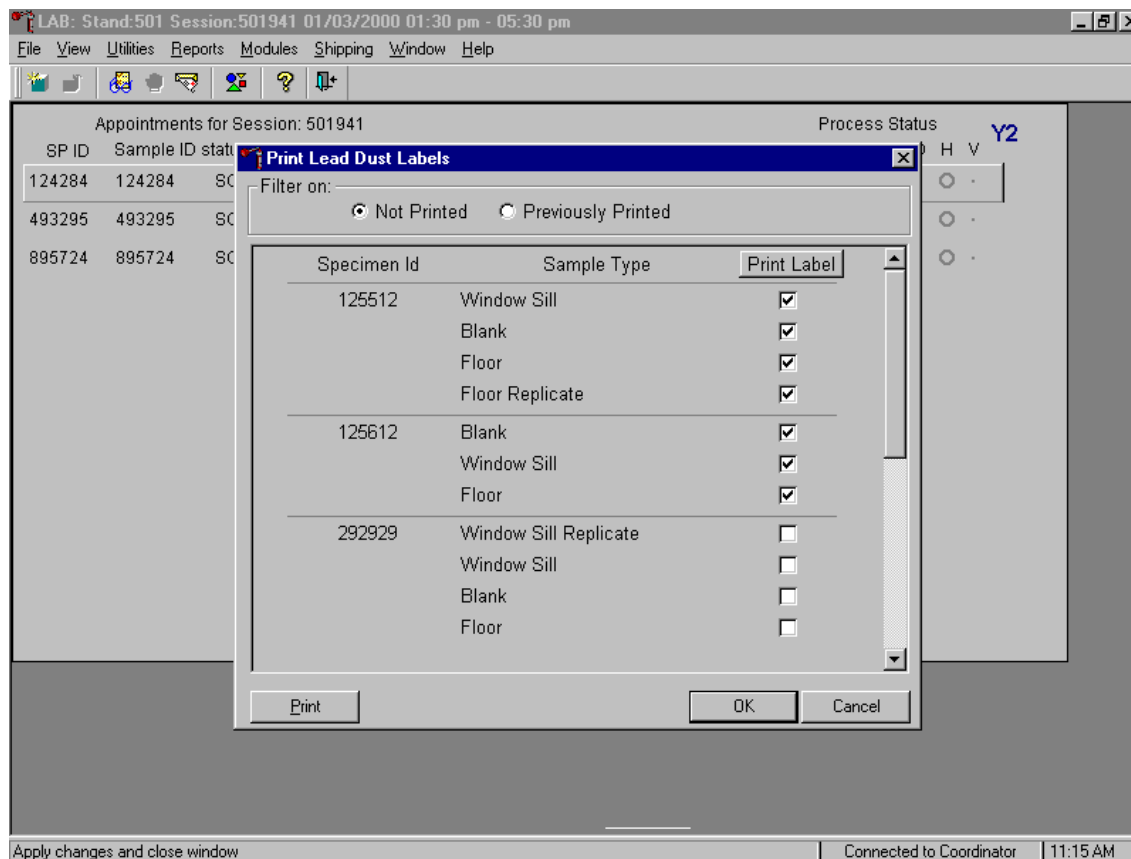
The Print Lead Dust Labels window displays.



The Print Lead Dust Labels window contains a filter that selects or displays samples for which labels have not been printed or samples for which labels have been previously printed, the Specimen ID for each set of samples, the sample types collected, and a check box to mark each sample as requiring a label. Generally, set the filter to Not Printed to view samples that require labels.

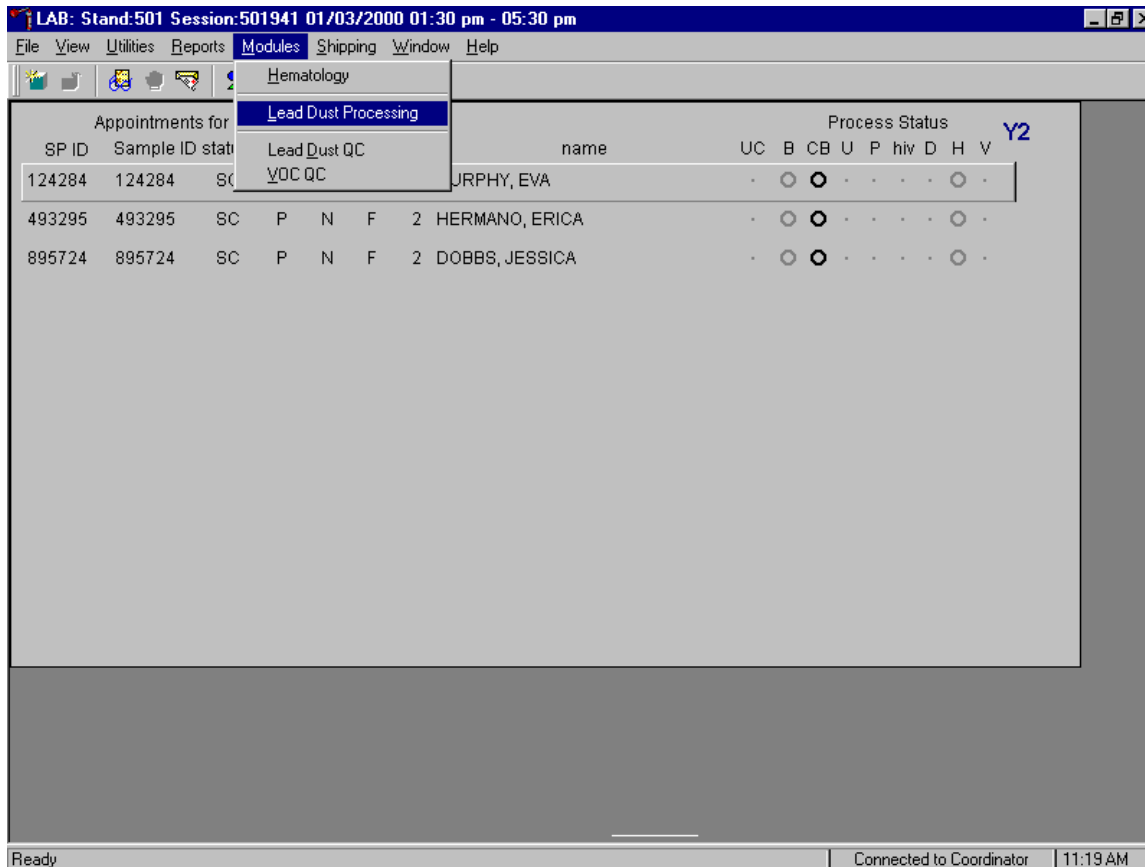
Physically match each sample's specimen ID and sample type to the data displayed in the window. Use the scroll bar to view all Specimen IDs and sample types.

Mark the checkbox for each Specimen ID and sample type.



To mark each sample type for each Specimen ID, use the mouse to direct the mouse arrow to each individual checkbox and left click. To mark all Sample Types for all Specimen IDs at one time, use the mouse to direct the mouse arrow to the **Print Label** box at the top of the checkbox column and left click. To remove all checkmarks, use the mouse to direct the mouse arrow to the **Print Label** box and left click a second time. After physically matching all the samples in the window to the samples from the field office and marking the corresponding checkbox, print the labels. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click. Labels print on the Datamax printer. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. Alternatively, to print the labels, use the mouse to direct the mouse arrow to the **OK** button and left click. The window deletes or removes the marked Specimen ID and Sample Types and refreshes to display only those Specimen IDs and Sample Types for which labels have not been printed. To close the window without saving any data in the database or printing any labels, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

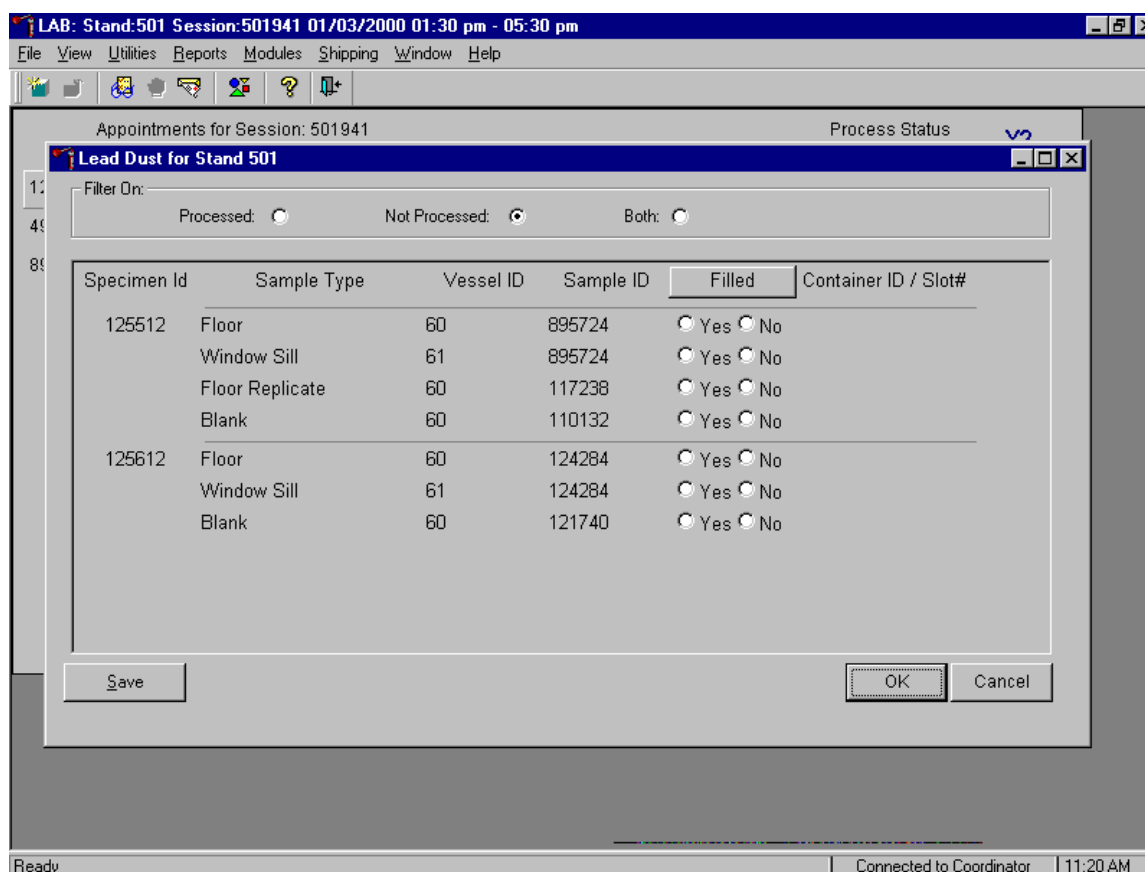
Process the lead dust samples.



To access the Lead Dust Processing module, use the mouse to direct the mouse arrow to {Modules} in the top menu bar, left click, drag the arrow to {Lead Dust Processing} and left click or type [Alt] [M/m], [L/l].



The Lead Dust processing window displays.

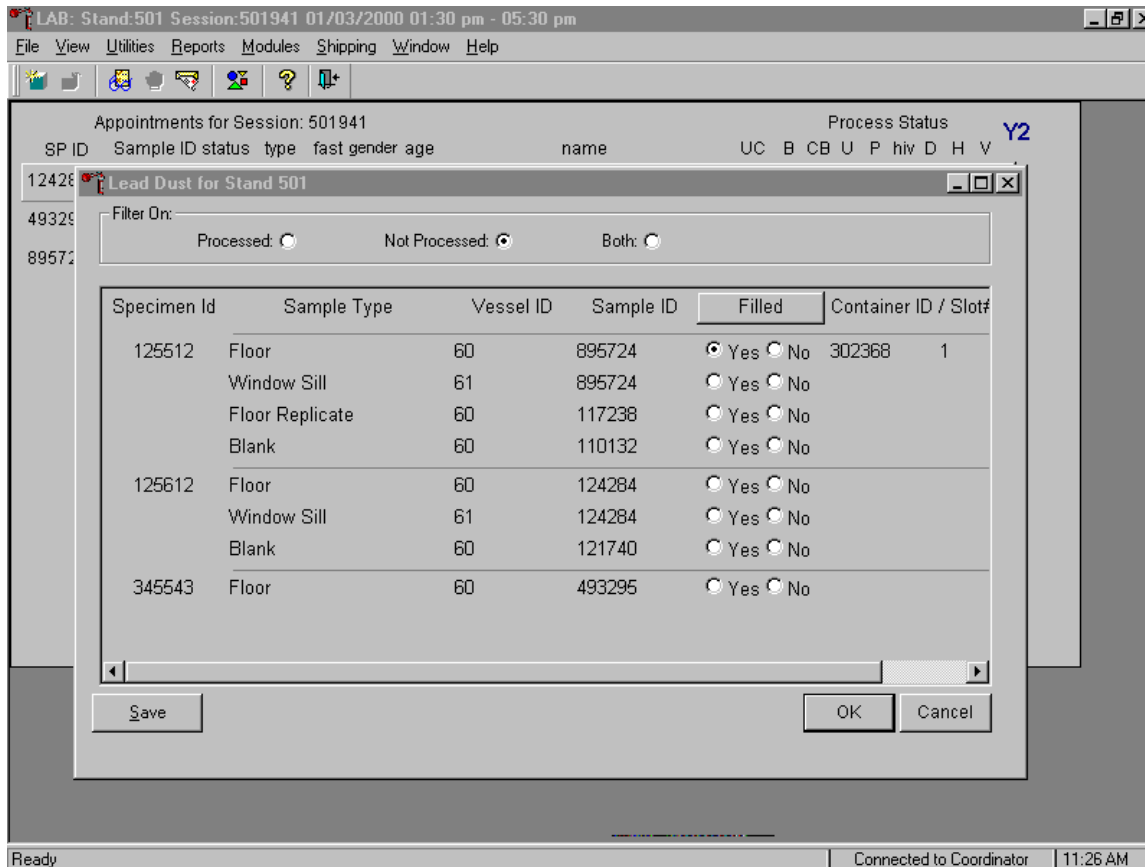


The Lead Dust for Stand XXX window contains a filter that selects or displays processed samples, not processed samples, or both previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing.

This window contains column titles for Specimen ID, Sample Types, Vessel ID (either 60 or 61), Sample ID, a Filled button, and Container ID/Slot # column.

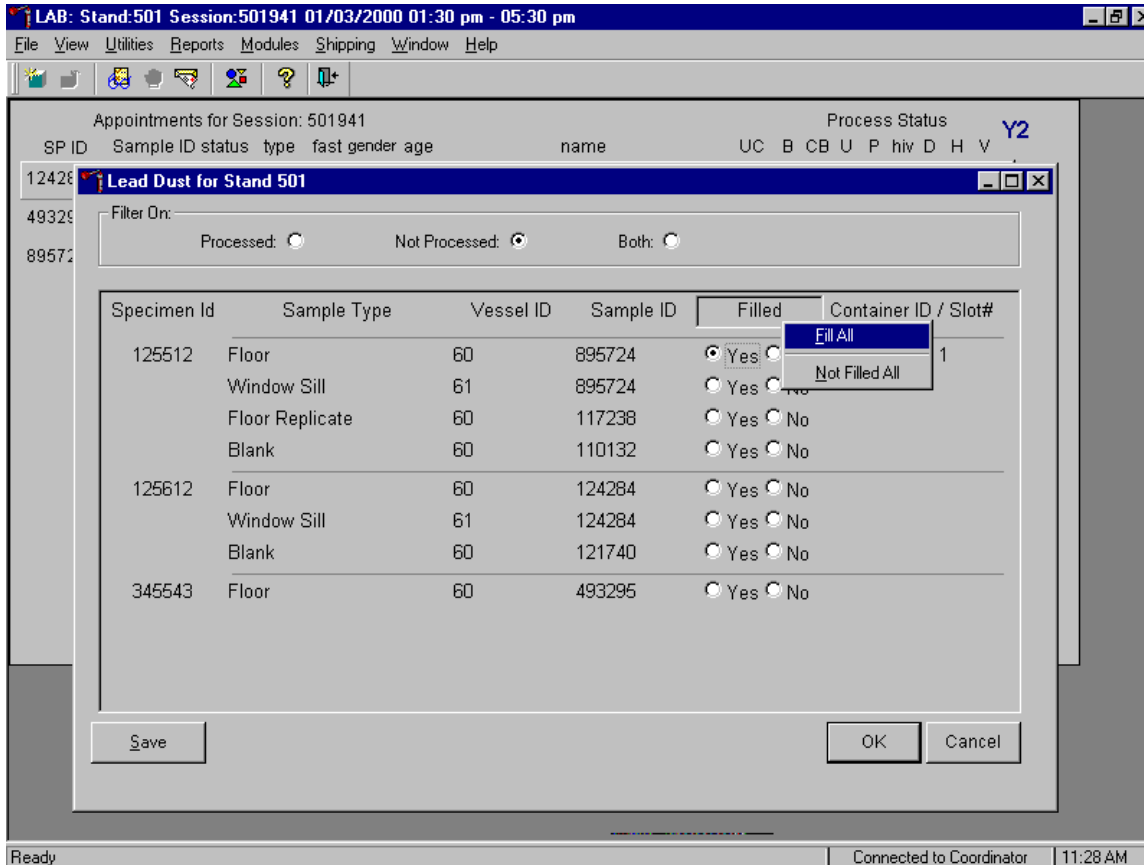
Match the samples to the Datamax laboratory labels. The laboratory label contains the Sample ID concatenated with the vessel ID and includes the text, “W Lead Dust” for windowsill samples or “F Lead Dust” for floor samples. Remove the field office label, relabel each sample with the laboratory label, and mark the vessel as collected or filled.

Individually mark each vessel as filled, yes or no.



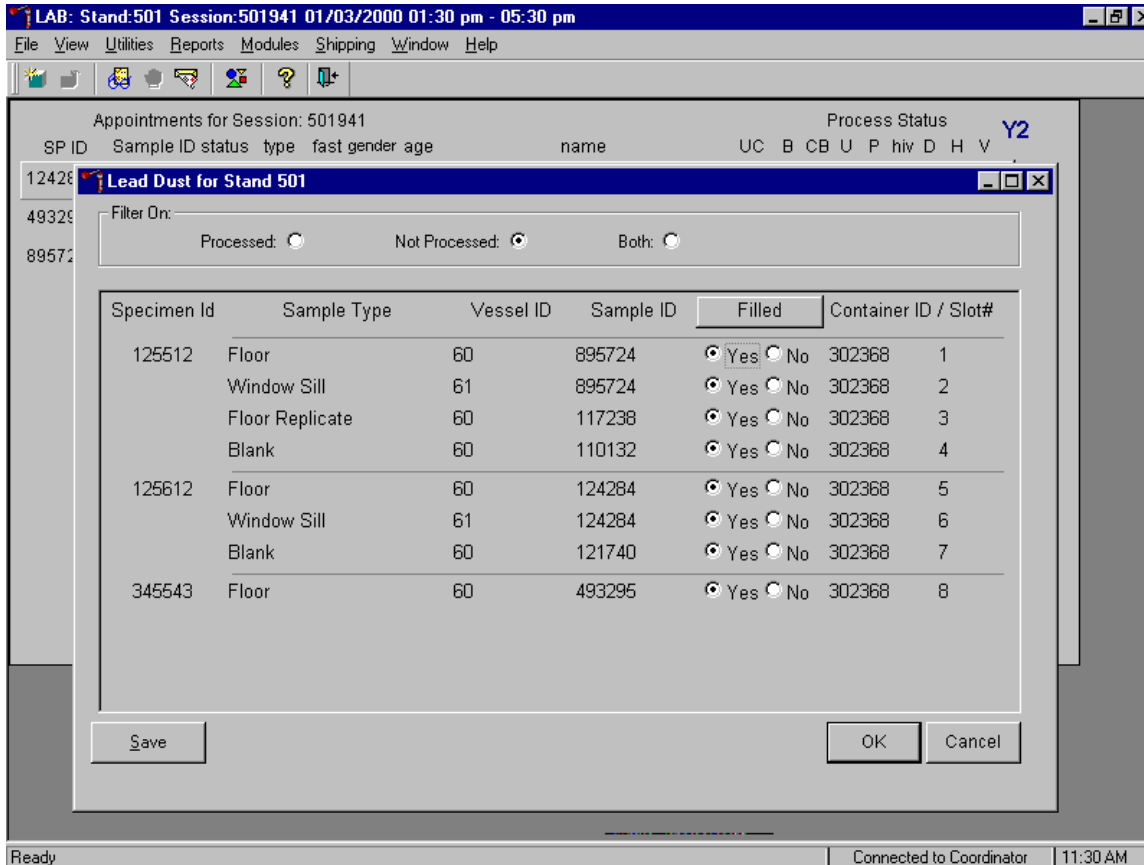
To mark individual lead dust vessel as collected or “filled,” use the mouse to direct the mouse arrow to the center of the Filled radio button and left click. As each vessel is marked as “Filled - yes,” it is automatically assigned to a slot in an existing (open) container.

Collectively mark all vessels as filled or not filled.



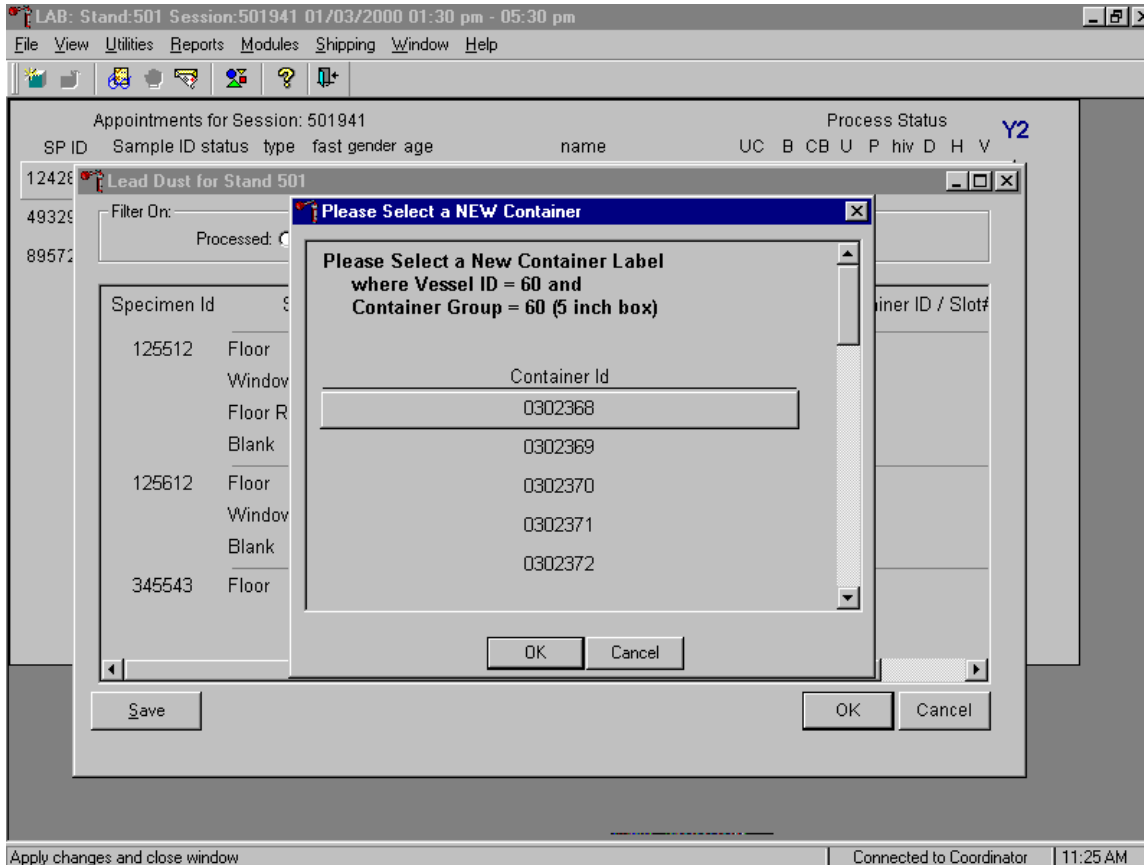
To collectively mark all vessels as filled, use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click and drag the arrow to {Fill All} or type [F]. To mark all vessels as Not Filled, use the mouse to direct the mouse arrow to the **Filled** box, left click and drag the arrow to {Not Filled All} or type [N/n].

Continue to process all lead dust vessels.



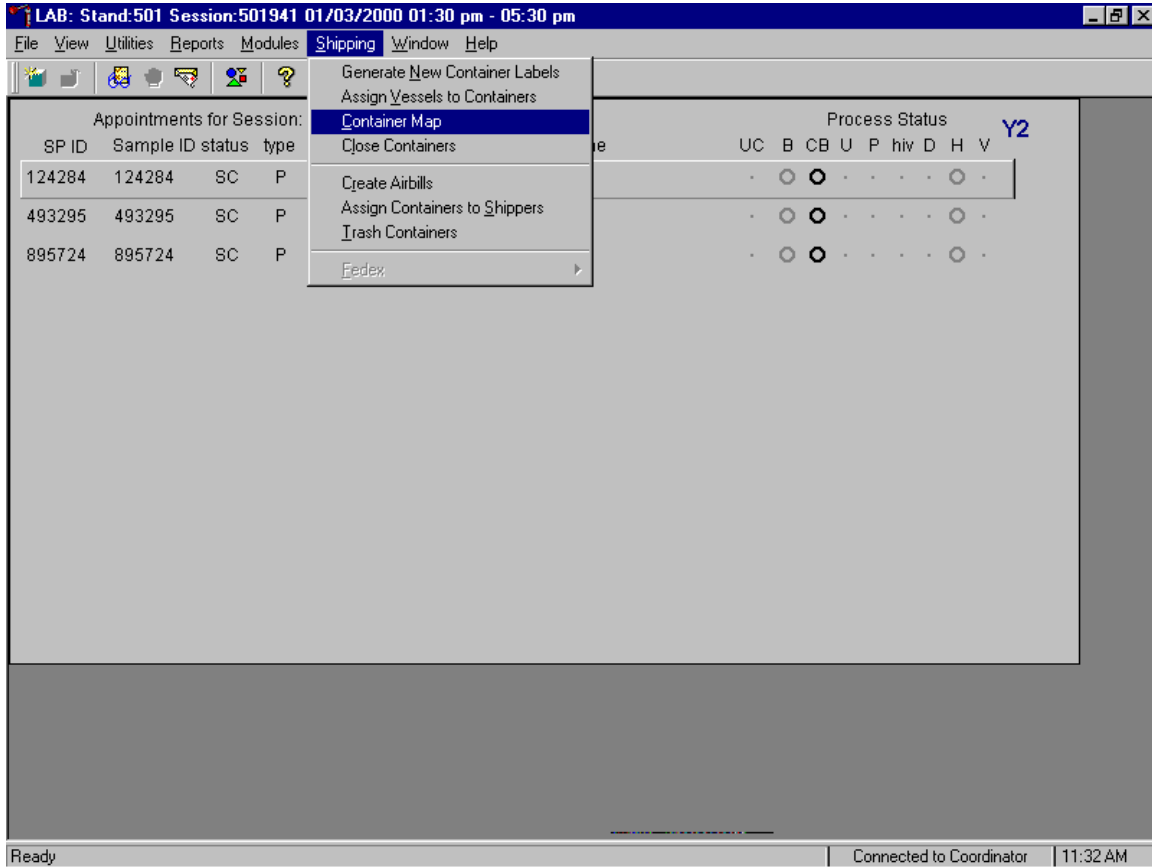
Store each filled vessel in the assigned slot in the designated container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the **Save** button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **OK** button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Open a new container when prompted.



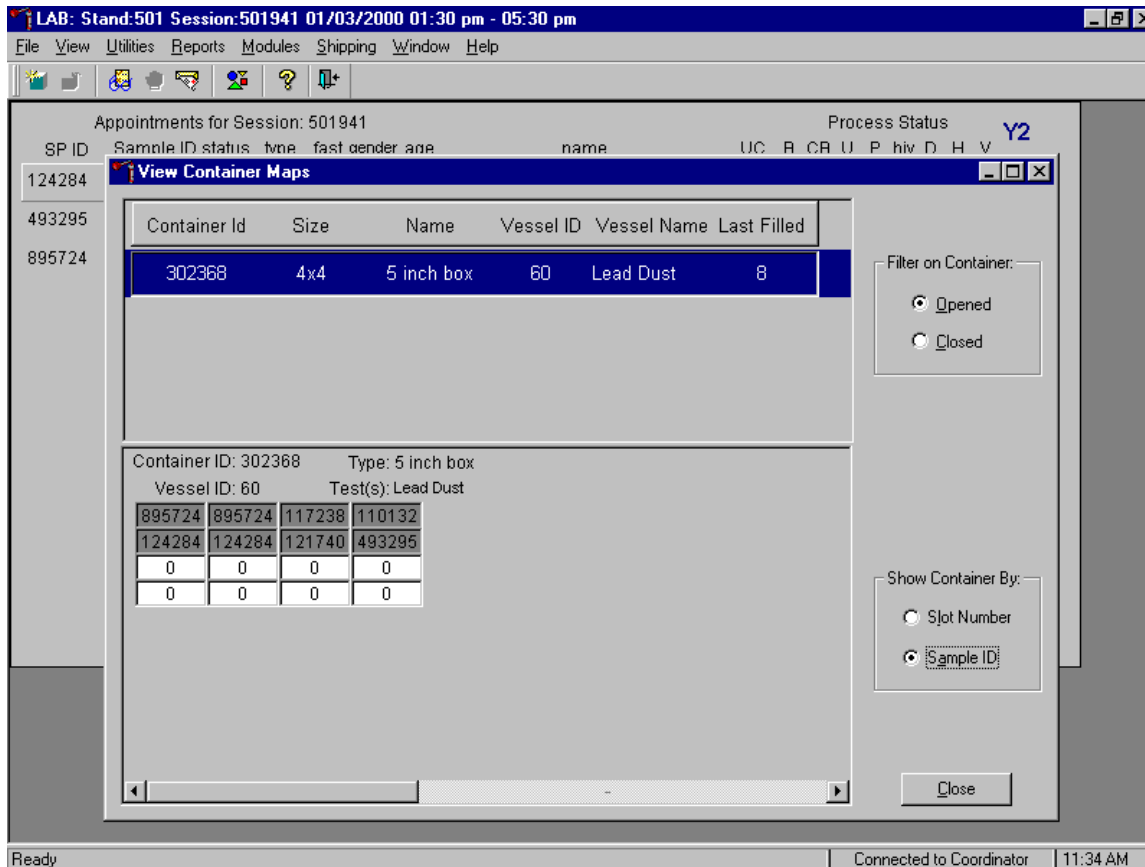
When a container is full, an opportunity to open a new container is automatically displayed on the “Please Select a NEW Container” window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the **OK** button and left click. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Check the slot assignment of the lead dust container at the end of each processing session.  
 Access the Container Map report.



To open the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping}, drag the arrow to {Container Map}, and left click or type [Alt] [S/c], [C/c].

Verify the contents of each container against the container map.

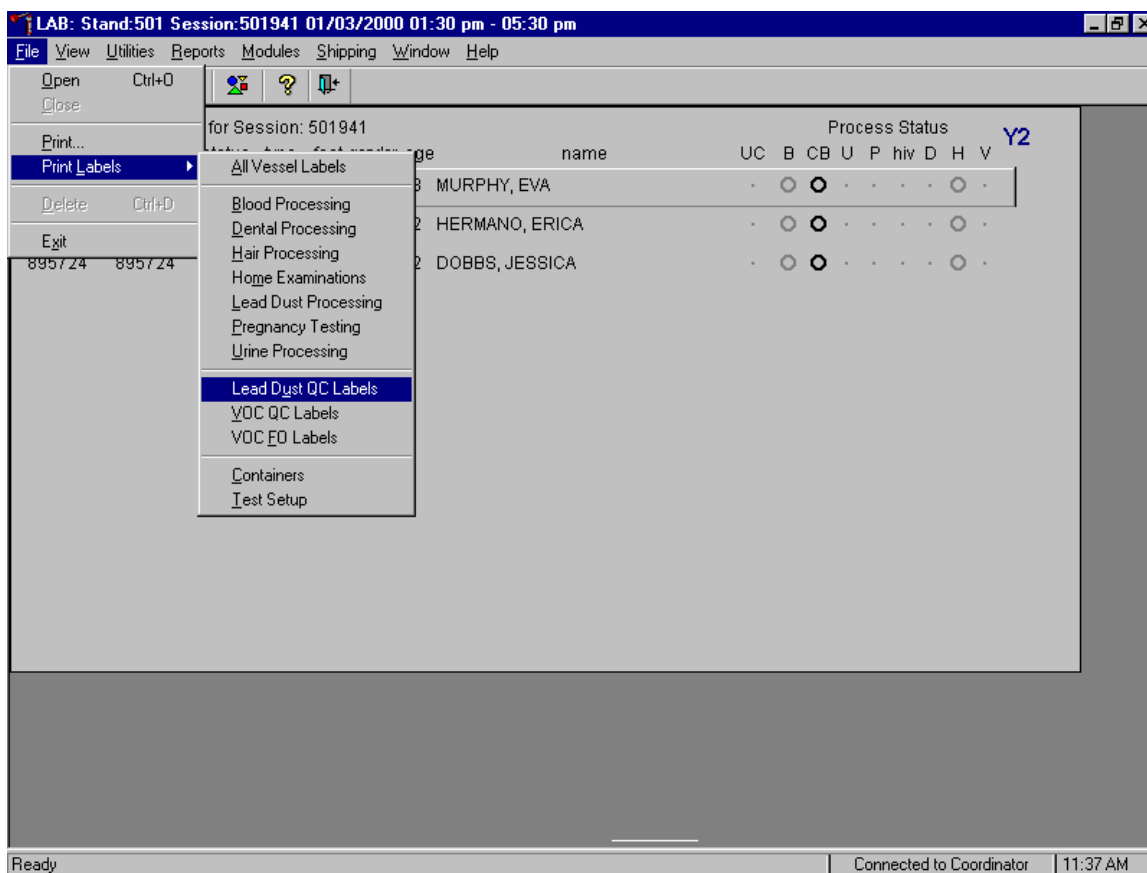


- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to the “Opened” radio button and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to the “Sample ID” radio button and left click.
- Highlight or select the first container ID for vessel 60 by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find Vessel ID 60.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining lead dust vessels.

- To exit the Container Map report, use the mouse to direct the mouse arrow to the **Close** button and left click.

### C.3 Lead Dust QC Processing

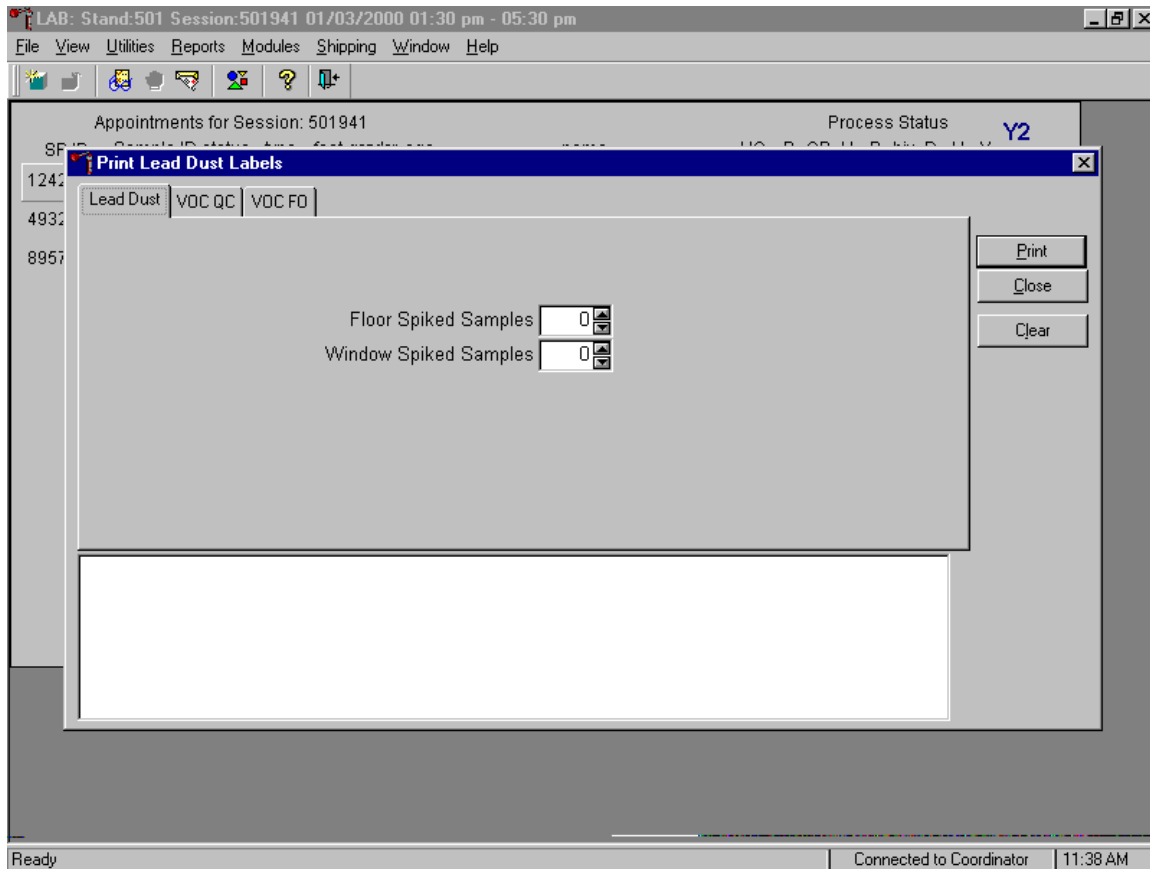
Print labels for the lead dust QC (positive control) samples. Access the Lead Dust QC Labels module.



To access the Lead Dust QC Label module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Print Labels}, then to {Lead Dust QC Labels}, and left click or type [Alt] [F/f], [L/l], [U/u].

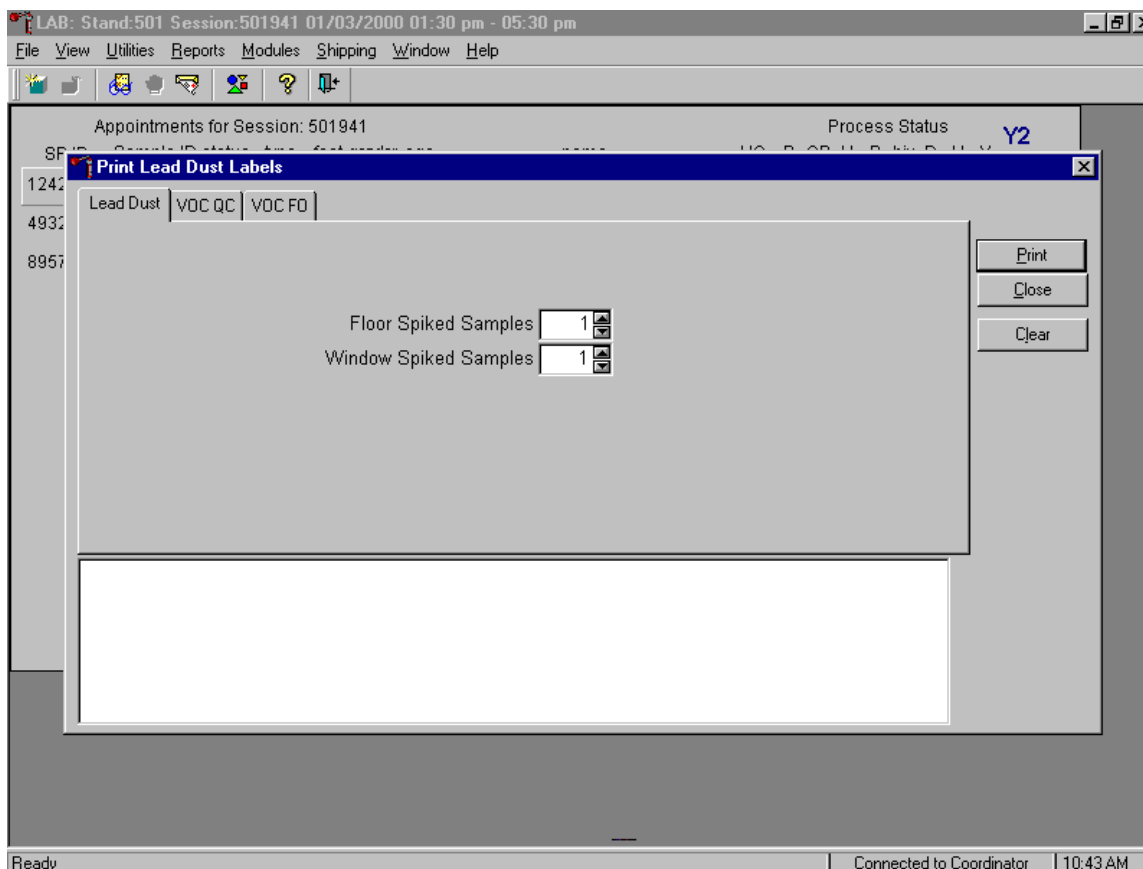


The Print Lead Dust Labels window displays.



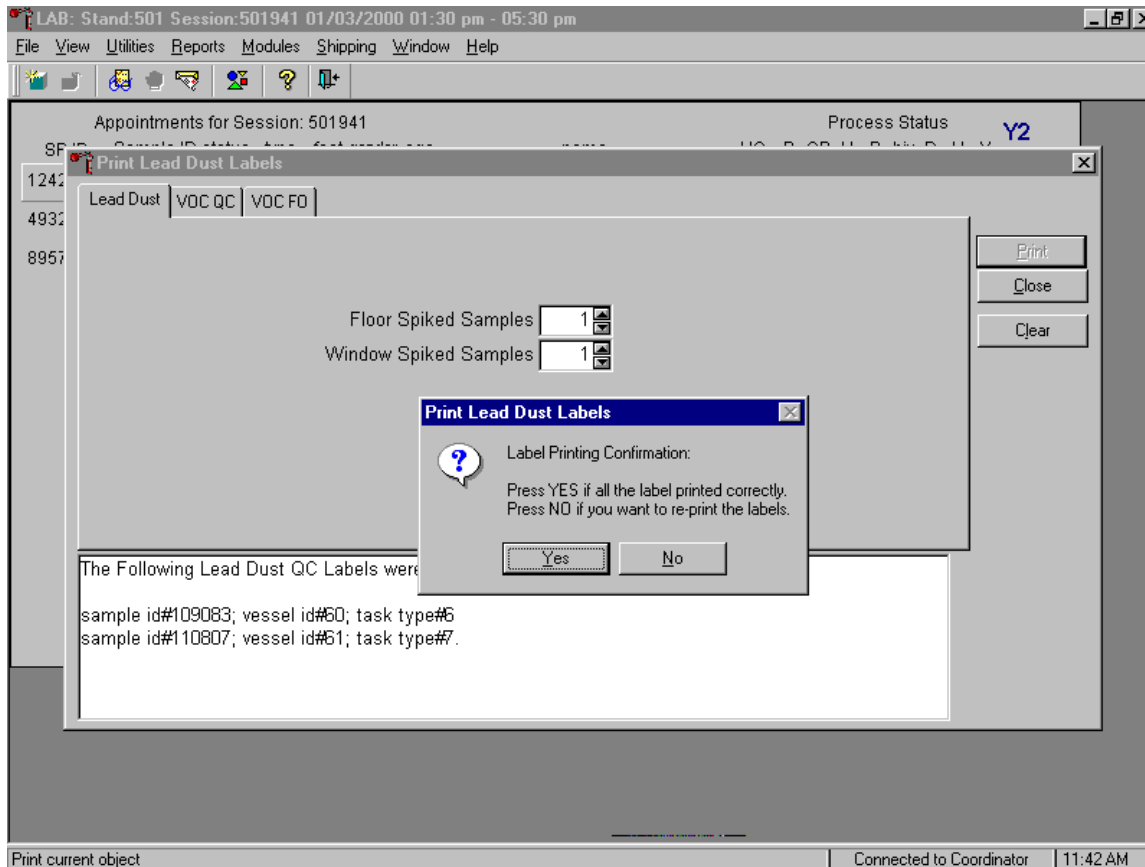
To select the Lead Dust file, use the mouse to direct the mouse arrow to the Lead Dust file header and left click. Use this module to print two types of lead dust QC labels – floor spiked samples and window spiked samples.

Continue the Print Lead Dust Labels process.



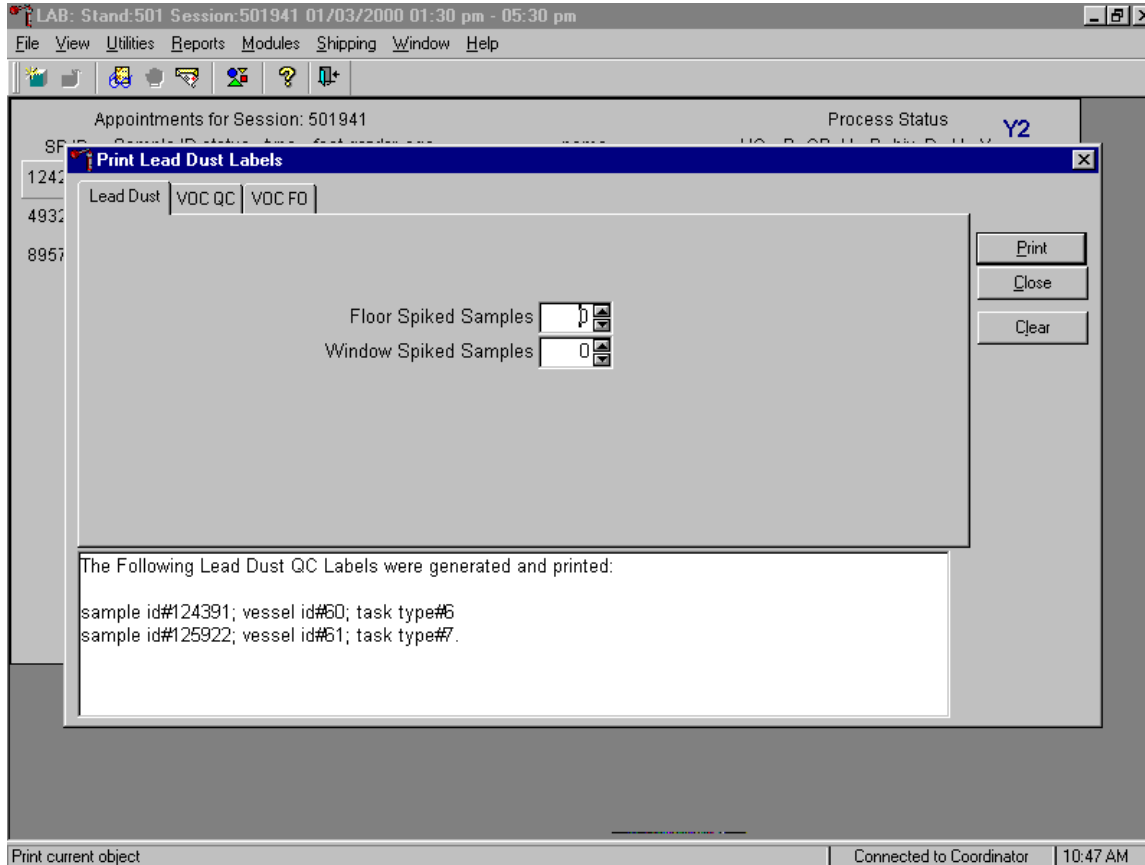
To select the number of floor and window spiked sample labels, use the mouse to direct the mouse arrow to the spin box and toggle the up-down controls until the number “1” is displayed in the text box. Alternatively, insert the cursor inside the Floor Spiked Samples text box, type the number one, and [Tab] to move to the Window Spiked Samples text box and type the number one. To print the labels, use the mouse to direct the mouse arrow to the **Print** button and left click or type [P/p]. Labels print on the Datamax printer. These labels are indistinguishable from routine vessel labels.

Confirm that the labels printed correctly before continuing.



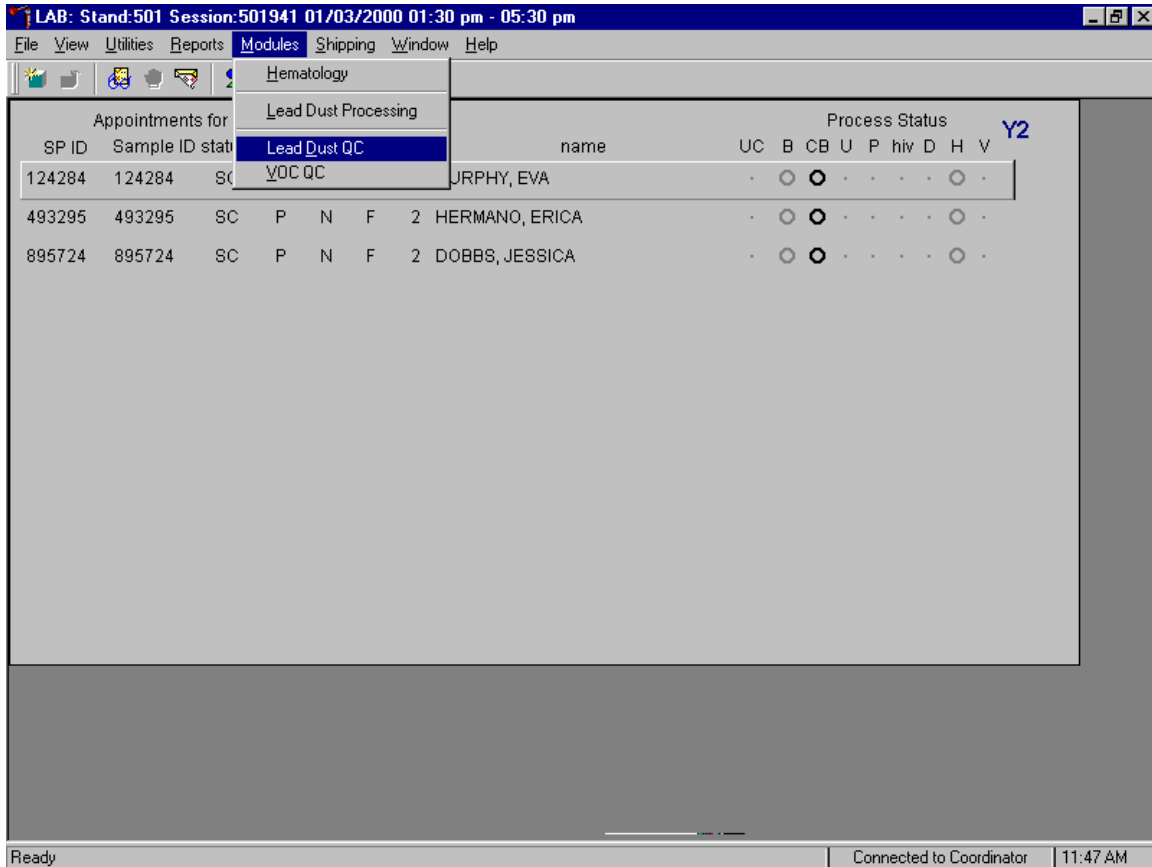
The Print Lead Dust Labels message box displays. If all the labels printed correctly, use the mouse to direct the mouse arrow to the **Yes** button and left click. If any of the labels did not print correctly and/or to re-print the labels, use the mouse to direct the mouse arrow to the **No** button and left click.

Verify the information contained in the lower white section of the Print Lead Dust Labels window.



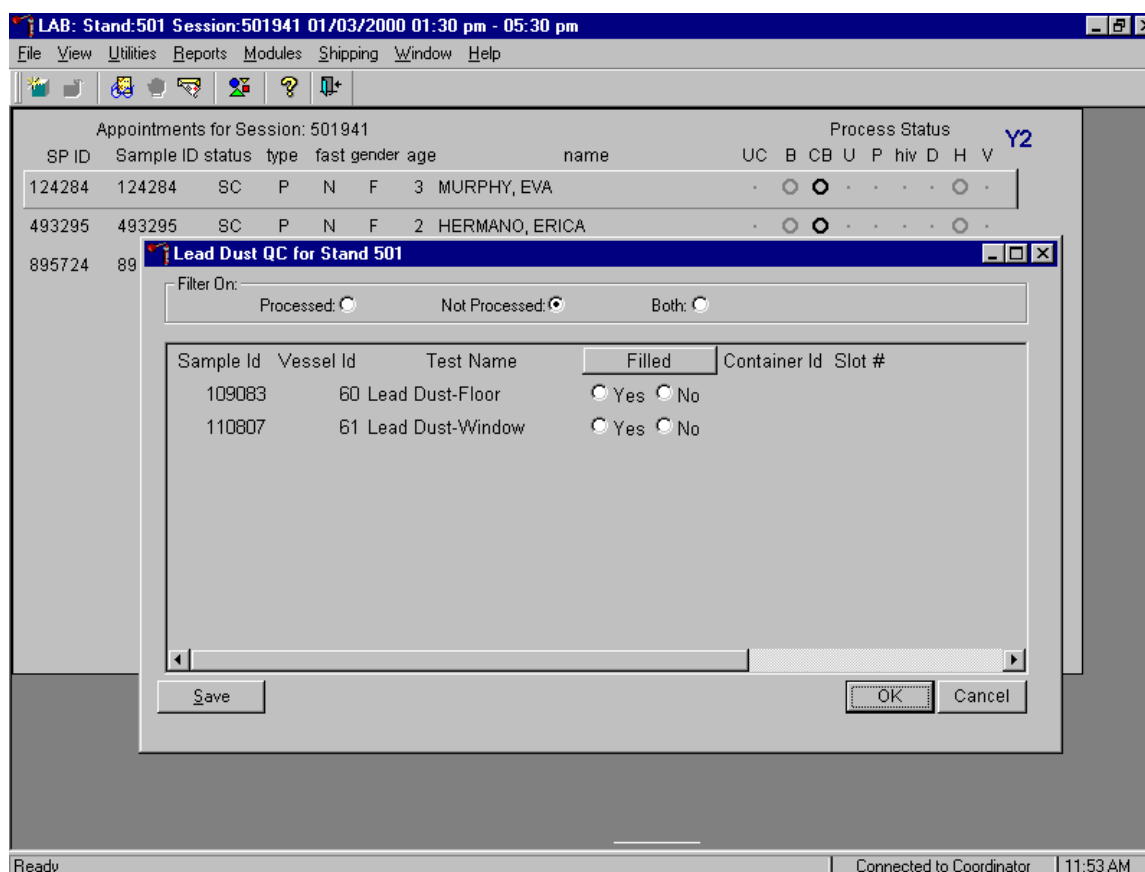
The lower white section of the Print Lead Dust QC Labels window displays the virtual sample ID #, vessel ID # and sample type #. To close the window, use the mouse to direct the mouse arrow to the **Clear** button and left click or type [Shift] [C/c].

Access the Lead Dust QC module to process the QC specimens.



To access the Lead Dust QC processing module, use the mouse to direct the mouse arrow to {Modules} in the menu bar, right click, drag the arrow to {Lead Dust QC}, and left click or type [Alt] [M/m], [U/u].

The Lead Dust QC processing screen displays.

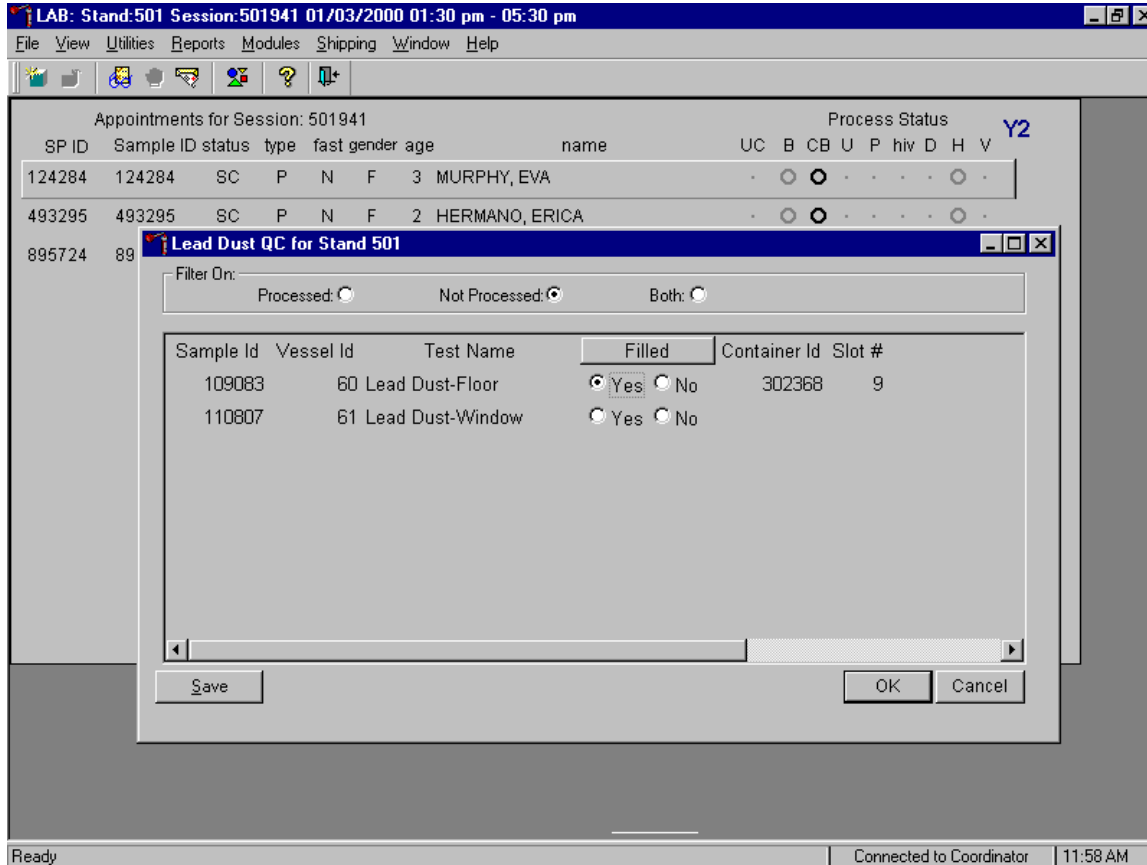


The Lead Dust for Stand XXX window contains a filter that selects or displays processed samples, and not processed samples; or both previously processed and not processed samples. Generally, set the filter to Not Processed to view samples that require processing.

This window contains columns for the Sample ID, Vessel ID (either 60 or 61), Test Name (either Lead Dust-Floor or Lead Dust-Window), a Filled box (radio buttons for Yes and No), and Container ID/Slot # column.

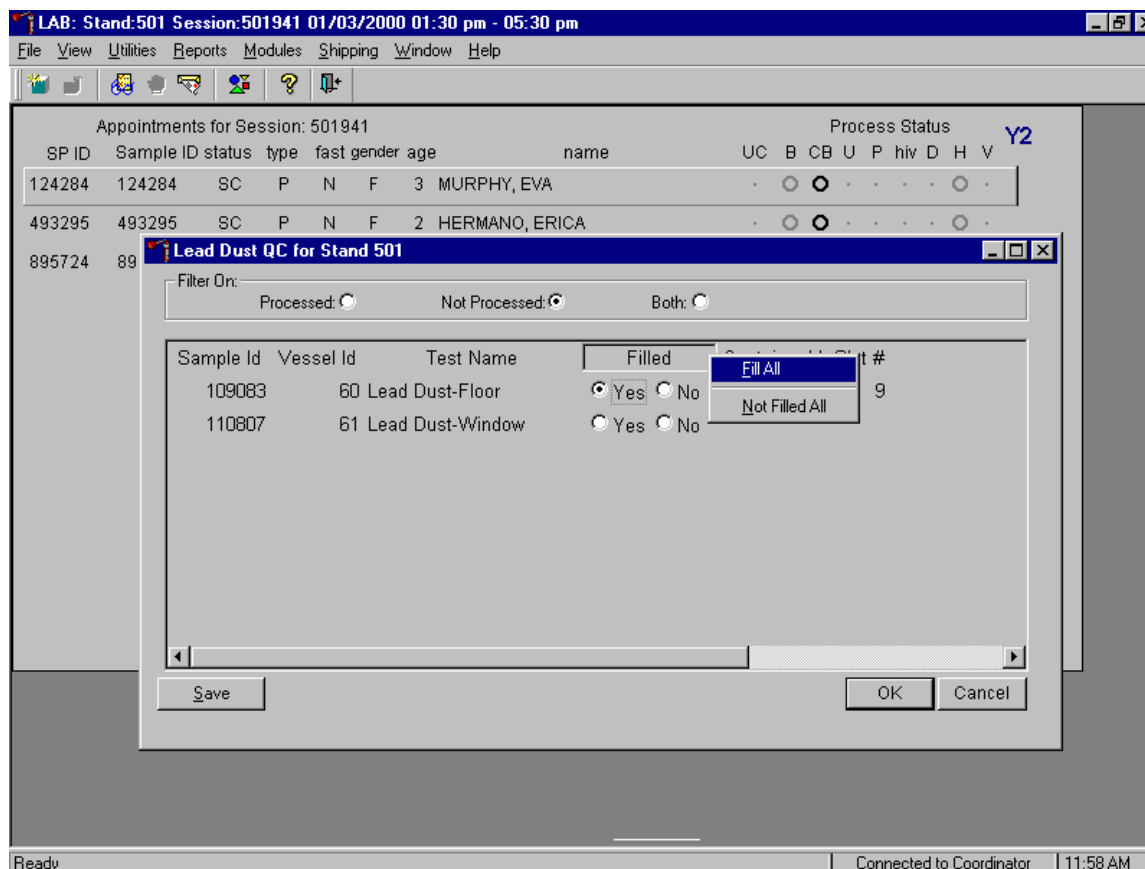
Match the samples to the Datamax labels. Remove the original QC label from the vessel and discard. Place the new laboratory label on the vessel lengthwise.

Mark the lead dust floor and lead dust window QC vessels as collected or filled – “Yes” or “No.”



To mark the individual lead dust QC vessel as collected or “filled,” use the mouse to direct the mouse arrow to each 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. To mark the individual lead dust QC vessel as not collected or “Filled – No,” use the mouse to direct the mouse arrow to each “No” radio button and left click.

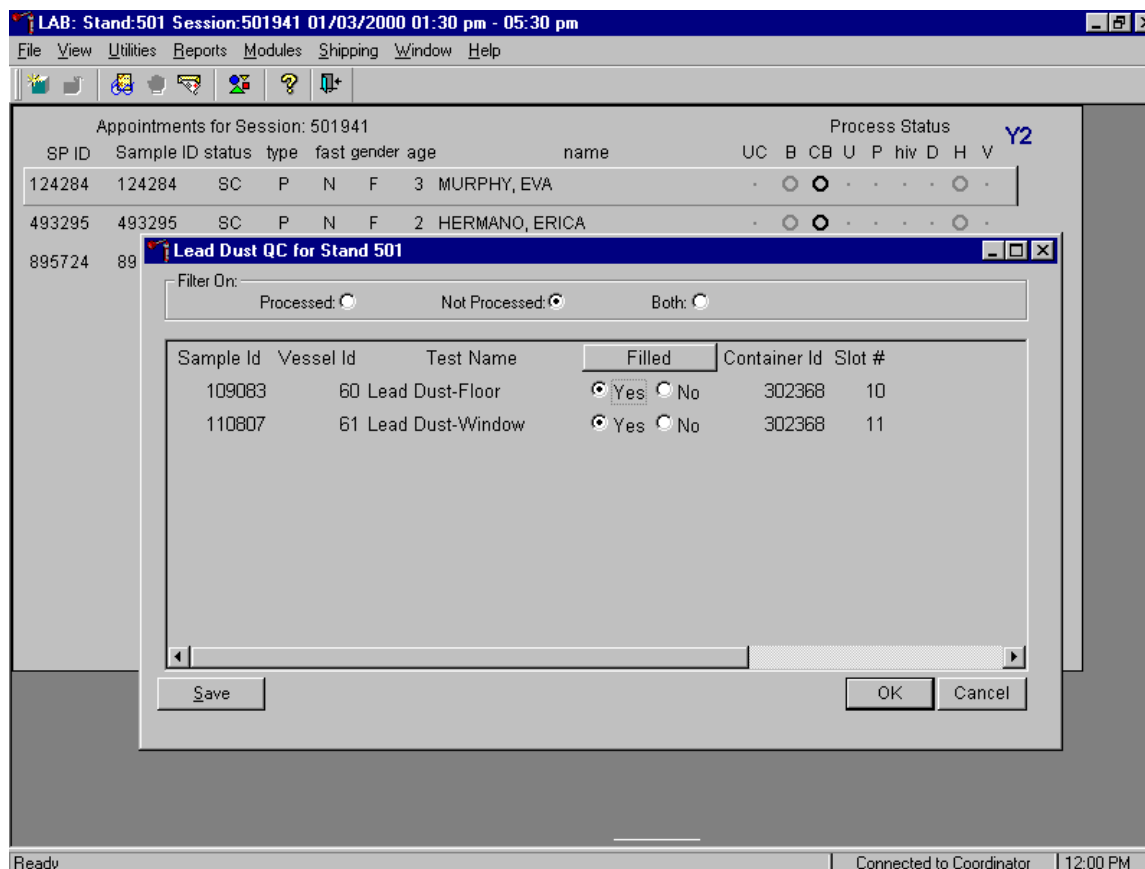
Collectively mark both vessels as filled or not filled.



To collectively mark both vessels as filled, use the mouse to direct the mouse arrow to the **Filled** button on the top of the radio buttons, left click and drag the arrow to {Fill All} or type [F/f]. To mark both vessels as Not Filled, use the mouse to direct the mouse arrow to the **Filled** box, left click and drag the arrow to {Not Filled All} or type [N/n].

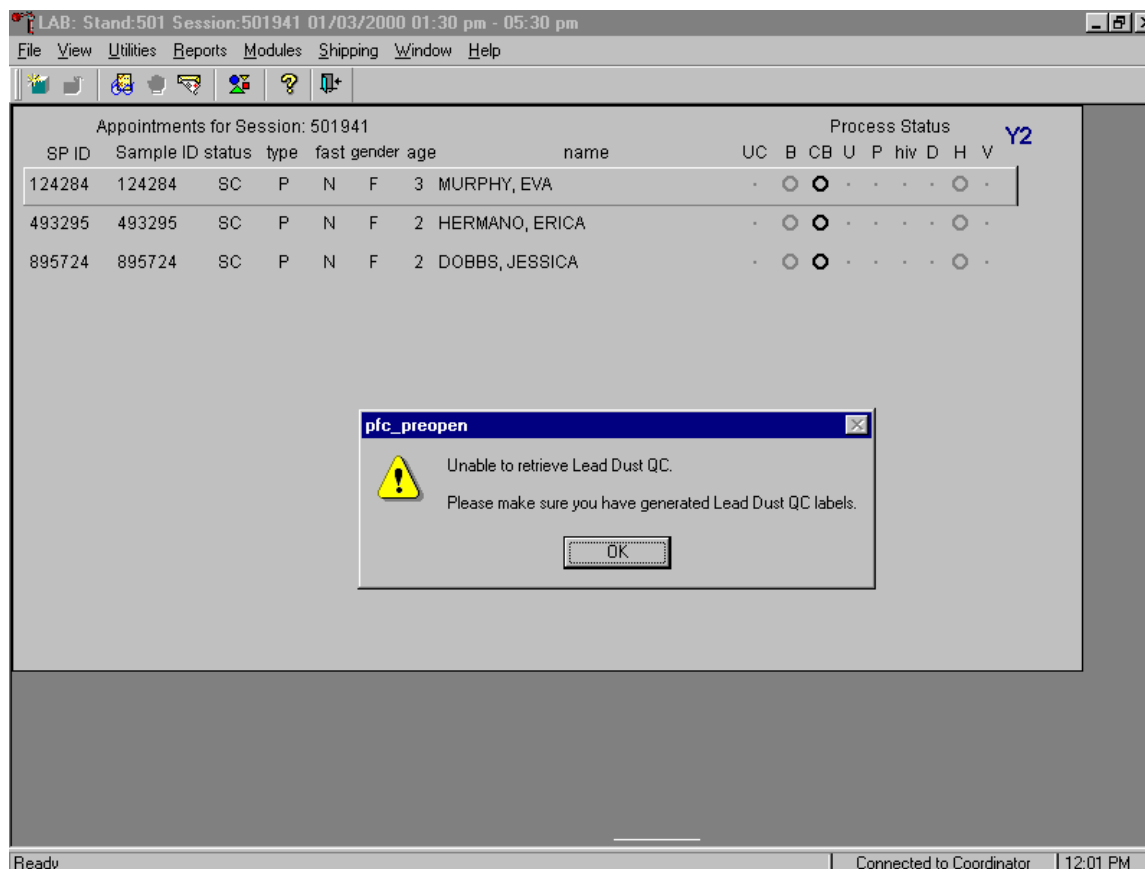


Store each filled vessel in the assigned slot in the assigned container.



To record this action or to save this data to the database and remove the information from the screen, use the mouse to direct the mouse arrow to the **S**ave button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the **O**K button and left click. To close the window without recording any data in the database, use the mouse to direct the mouse arrow to the **C**ancel button and left click.

Only vessels for which labels have been printed are capable of being processed.



If the Lead Dust QC module is accessed and labels have not been printed, a message text box displays. To remove the text box, use the mouse to direct the mouse arrow to the **OK** button and left click. Access the Lead Dust QC Label module to print the QC labels and then proceed to process the QC samples.

#### C.4 Packing and Shipping Procedure

Ship lead dust specimens to the University of Cincinnati in a double-sided Styrofoam and corrugated cardboard shipper at room temperature. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information. Include a preprinted FedEx return airbill label with the current field office address for the first 3 or 4 weeks of the stand.

Include a preprinted FedEx return airbill label with the Westat warehouse address for the last 2 weeks of the stand

Laboratory	Test	Temperature	Container	Frequency
University of Cincinnati	Lead Dust	Room temperature	4 x 4 five inch box	Weekly

### **Pack a Medium or Small Shipper for Ambient Temperature Shipment**

Ship lead dust specimens at ambient temperature.

- Pack the bottom of the Styrofoam shipper with crumbled newsprint.
- Place the sealed boxes on top of the newsprint.
- Pack the sides with crumbled newsprint.
- Place more crumpled newsprint on top so that the shipper is filled to 1/4" below the rim.
- Place a plastic envelope containing the appropriate shipping manifest and the preprinted FedEx airbill 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 envelope (10 pounds) on the appropriate FedEx label.
- Seal the container with several tape strips.

### **Label Shippers**

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:

- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- 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.
- Place one additional tape strip across the FedEx pouch.

Appendix D  
International Air Transport Association (IATA)  
Dangerous Goods Regulations

## APPENDIX D

### INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS REGULATIONS

#### D.1 General Provisions

IATA is the International Air Transport Association. It publishes dangerous goods regulations. NHANES falls under these regulations because specimens are packed in dry ice, which is classified as dangerous goods, and shipped via FedEx, which uses air transport.

Dangerous goods are articles or substances, which are capable of posing a significant risk to health, safety, or to property, when transported by air and which are classified as to the type of hazard. The IATA Dangerous Goods Regulations are applicable to all shippers and agents that offer consignments of dangerous goods to airlines. A shipper must comply fully with these regulations when offering a consignment of dangerous goods to IATA member airlines, and to airlines participating in IATA interline agreements for cargo. Before offering any package for air transport, the shipper must comply with the following responsibilities.

- A shipper must provide such information to his employees as will enable them to carry out their responsibilities with regard to the transport of dangerous goods by air.
- The shipper must ensure that the articles or substances are not prohibited for transport by air.
- The articles or substances must be properly identified, classified, packed, marked, labeled, and documented in accordance with IATA regulations.
- Before a consignment of dangerous goods is offered for air transport, all relevant persons involved in its preparation must have received training to enable them to carry out their responsibilities.

Training requirements must include:

- General familiarization aimed at providing familiarity with IATA general provisions.
- Function specific training in the requirements applicable to the function for which that person is responsible.

- Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.

Training must be provided or verified upon the employment of a person in a position involving the transport of dangerous goods by air. Recurrent training must take place within 24 months of previous training to ensure knowledge is current.

A record of training must be maintained, which must include:

- The individual's name;
- The most recent training completion date;
- A description, copy, or reference to training materials used to meet the training requirement;
- The name and address of the organization providing the training; and
- A copy of the certification issued when the individual was trained, which shows a test has been completed satisfactorily.

## **D.2 Classifications**

Dangerous goods are defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of the three UN packing groups according to provisions of IATA regulations. The nine classes relate to the type of hazard, whereas the packing groups relate to the degree of danger within the class.

### **D.2.1 Class 9 – Miscellaneous Dangerous Goods**

Class 9 defines miscellaneous dangerous goods as substances and articles, which, during air transport present a danger not covered by other classes. Included in this class is solid carbon dioxide, or dry ice. Dry ice is regulated by packing instruction 904.

## **D.2.2 List of Dangerous Goods**

Dry ice is classified as UN number 1845 and is classified as a Class 9 dangerous good. Shipping packaging must be labeled with a Miscellaneous Class 9 label.

Dry ice is included within Packing Group 3, which is classified as a minor danger. A maximum net quantity per package is 200 kg or 441 lb. A special provision directs that packing tests are not considered necessary.

## **D.3 General Packing Provisions**

Packing group III indicates a minor degree of danger. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and "snow" in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns to skin because of direct contact due to its very low temperature (about  $-79^{\circ}\text{C}$ ). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.

Packing materials must be free of any indication that their integrity has been compromised. Packages must be constructed, closed, and prepared for transport to prevent any leakage during air transport, which might be caused by temperature, pressure, or by vibration normally occurring in air transport.

Packaging used for solids, which may become liquid at temperatures likely to be encountered during air transport must also be capable of containing that substance in the liquid state.

Inner packaging – cushioning material: Inner packaging must be packed, secured, or cushioned so as to prevent their breakage or leakage, and so as to control their movement within the outer packing during normal conditions of transport. Cushioning material must not react dangerously with the contents of the inner packaging.

### **D.3.1 Packing Instruction 904 (Dry Ice)**

Carbon dioxide, solid (dry ice) when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

The net weight of dry ice must be marked on the outside of the package.

Arrangements between the shipper and operator(s) must be made for each shipment; to ensure ventilation, safety procedures are followed. The "Nature and Quantity of Dangerous Goods" box on the Shipper's Declaration must show in sequence:

1. Proper shipping name (**Dry Ice**);
2. Class or division number (**9**);
3. UN number (**UN 1845**); and
4. Net quantity per package (**kg**).

### **D.3.2 Packing Instruction 605 (Diagnostic Specimens)**

Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations. The shipper must also ensure that shipments are prepared in such a manner that they arrive at their destination in good condition and that they present no hazard to persons or animals during shipment. The packaging must include:

#### **650(a) inner packaging comprising:**

- A leak proof primary receptacle(s) – for diagnostic specimens the maximum quantity must not exceed 500-mL
- A watertight secondary packaging – the maximum quantity per outer packaging for diagnostic specimens must not exceed 4L



- An absorbent material – must be placed between the primary and the secondary packaging

If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually and the absorbing material must be sufficient to absorb the entire contents of all primary receptacles.

**650(b) outer packaging comprising:**

- An outer packaging of adequate strength for its capacity, weight, and intended use.
- The primary receptacle or the secondary packaging used for diagnostic specimens must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- Packages consigned as freight must be at least 100mm (4 inches) in the smallest overall external dimension.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

Each package and the "Nature and Quantity of Goods" box of the air waybill must show the text "DIAGNOSTIC SPECIMENS" – "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650."

The majority of diagnostic specimens can and must be packaged according to the following guidelines.

- Substances shipped at ambient temperature or higher.
- Primary receptacles include those of glass, metal, or plastic. Positive means of ensuring a leak-proof seal, such as heat seal, skirted stopper, or metal crimp seal must be provided. If screw caps are used these must be reinforced with adhesive tape.
- Substances shipped refrigerated or frozen (wet ice, prefrozen packs, carbon dioxide, solid [dry ice]):
- Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of

the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

#### **D.4 Labeling and Marking**

All markings must be readily visible, legible, and so placed that they are not covered or obscured by any part of or attachment to the packaging or any other label or marking.

Each package must be marked with each of the following:

- The proper shipping name of the contents and the corresponding UN numbers;
- The name and address of the shipper and the consignee;
- The net weight of dry ice within the package; and
- "Diagnostic Specimens" and "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650."

The hazard label to be used on packages and overpacks is specified for each substance. All packages must bear the appropriate hazard label. The label identifying the primary hazard of the dangerous goods must bear the class number in the bottom corner of the label. For Class 9 goods (dry ice), the package is required to bear the Class 9 "Miscellaneous" dangerous goods label.

All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. Each label must be affixed on a background of contrasting color or must have a dotted or solid line outer border. The label must not be folded or affixed in such a manner that different parts of the label appear on different faces of the package.

#### **D.5 Documentation**

An air waybill must be completed for each consignment of dangerous goods. For each shipment containing dangerous goods the shipper must:

- Use only the correct form in the correct manner;

- Complete the form accurately and legibly;
- Ensure that the form is properly signed when the shipment is presented to the operator for shipment; and
- Ensure that the shipment has been prepared in accordance with IATA regulations.

Each form must include:

- Full name and address of the shipper;
- Full name and address of the consignee;
- Deletion of "radioactive";
- Proper shipping name (Dry Ice);
- Class or division number (9);
- UN number (UN 1845);
- Net quantity per package (kg);
- Response telephone number;
- Name and title of signatory;
- Place and date; and
- Signature.

Reference: IATA Dangerous Goods regulations, 38<sup>th</sup> Edition, effective January 1, 1997,  
ISBN 92-9035-863-7

**D.6 IATA Regulations Examination**

Name \_\_\_\_\_

Date \_\_\_\_\_

1. IATA stands for \_\_\_\_\_
2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard.  
(T or F)
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
4. What are the three training requirements?
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
5. How many UN hazard classes are there? \_\_\_\_\_
6. To what UN hazard class does dry ice belong? \_\_\_\_\_
7. What is the dry ice UN number? \_\_\_\_\_
8. To what packing group does dry ice belong? \_\_\_\_\_
9. Dry ice is used primarily for cooling and can cause severe burns to skin because of direct contact due to its very low temperature (about -79° C). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.  
(T or F)

10. Is the weight of dry ice required on the outside of the packaging?  
(T or F)
11. Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations.  
What packing instruction regulates diagnostic specimens? \_\_\_\_\_
12. List the three inner packaging requirements.
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
13. What special requirement does the absorbing material have?  
\_\_\_\_\_
14. Outer packaging material must be of adequate \_\_\_\_\_ for its capacity, weight, and intended use.
15. Where is an itemized list of contents is placed?  
\_\_\_\_\_
16. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?  
\_\_\_\_\_
17. Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.  
(T or F)
18. All markings must be readily \_\_\_\_\_, \_\_\_\_\_ and so placed that they are not obscured by any part or attachment to the packaging or any other label or marking.
19. Each package must be marked with each of the following:
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_

20. What hazard label is required for Class 9? \_\_\_\_\_

21. The shipper is responsible for completing any air waybill for each consignment of dangerous goods. List the four requirements.

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

22. Each form must include:

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

## D.7 IATA Regulations Examination (Answer Key)

Name \_\_\_\_\_

Date \_\_\_\_\_

1. IATA stands for the International Air Transport Association
2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard.  
(T or F) True
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
  - Information to employees as will enable them to carry out their responsibilities.
  - Ensure that articles or substances are not prohibited for transport by air.
  - Articles must be properly identified, classified, packed, marked, labeled, and documented.
  - All persons involved in preparing consignment must have received training.
4. What are the three training requirements?
  - General familiarization aimed at providing familiarity with IATA general provisions;
  - Function specific training in the requirements applicable to the function for which that person is responsible; and
  - Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.
5. How many UN hazard classes are there? 9 (nine)
6. To what UN hazard class does dry ice belong? Class 9
7. What is the dry ice UN number? UN 1845
8. To what packing group does dry ice belong? Packing group 3
9. Dry ice is used primarily for cooling and can cause severe burns to skin because of direct contact due to its very low temperature (about -79° C). When carbon dioxide solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent build-up of pressure due to release of carbon dioxide gas.  
(T or F) True

10. Is the weight of dry ice required on the outside of the packaging?  
(T or F) True
11. Shippers of diagnostic specimens where a low probability that infectious substances are present (diagnostic specimens being transported to undergo routine screening tests or for purpose of initial diagnosis may be considered to fall under this category) must comply with these regulations.
12. What packing instruction regulates diagnostic specimens? Packing instruction 650 (Dry Ice)
13. List the three inner packaging requirements.
- A leak proof primary receptacle(s) - for diagnostic specimens the maximum quantity must not exceed 500-mL.
  - A watertight secondary packaging - the maximum quantity per outer packaging for diagnostic specimens must not exceed 4L.
  - An absorbent material - must be placed between the primary and the secondary packaging.
14. What special requirement does the absorbing material have?  
The absorbing material must be sufficient to absorb the entire contents of all primary receptacles.
15. Outer packaging material must be of adequate strength for its capacity, weight, and intended use.
16. Where is an itemized list of contents is placed?  
An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
17. What three primary receptacles are included in the guidelines for substances shipped at ambient temperature?  
glass, metal, or plastic
18. Ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or dry ice has been dissipated. If ice is used the packaging must be leak-proof. If dry ice is used the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperature and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.  
(T or F) True
19. All markings must be readily visible, legible and so placed that they are not obscured by any part or attachment to the packaging or any other label or marking.
20. Each package must be marked with each of the following:
- The proper shipping name of the contents and the corresponding UN numbers;
  - The name and address of the shipper and the consignee;



- The net weight of dry ice within the package; and
  - "Diagnostic Specimens" and "PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650."
21. What hazard label is required for Class 9? Class 9 "Miscellaneous"
22. The shipper is responsible for completing any air waybill for each consignment of dangerous goods. List the four requirements.
- Use only the correct form in the correct manner;
  - Complete the form accurately and legibly;
  - Ensure that the form is properly signed when the shipment is presented to the operator for shipment; and
  - Ensure that the shipment has been prepared in accordance with IATA regulations.
23. Each form must include:
- Full name and address of the shipper;
  - Full name and address of the consignee;
  - Deletion of "radioactive";
  - Proper shipping name (Dry Ice);
  - Class or division number (9);
  - UN number (UN 1845);
  - Net quantity per package (kg);
  - Response telephone number;
  - Name and title of signatory;
  - Place and date; and
  - Signature.

WESTAT

# Certificate of Test Completion

International Air Transport Association (IATA) Dangerous Goods Regulations

Name \_\_\_\_\_

Date of Successful Exam \_\_\_\_\_

Examiner \_\_\_\_\_

Appendix E  
Glossary of Terms

## **APPENDIX E GLOSSARY OF TERMS**

**Vessel:** These are the primary sample receptacles. Examples are cryovials, zip-closable bags, jars, Vacutainer® tubes, canisters.

**Container:** This is the unit that holds the vessels. Examples are 2-, 3-, and 5-inch tall boxes with various dividers, zip-closable bags, and Styrofoam mailers.

**Shippers:** This is the unit that holds the containers. Examples are insulated Bio-Shippers such as Styrofoam containers inside corrugated outside packaging, hard-sided coolers, and padded envelopes.