

The Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study

Maintaining and Recording Electronic Chain-of-Custody

Battelle
Columbus, OH 43201
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Standard Operating Procedure

CTEPP-SOP-4.11

Title: Maintaining and Recording Electronic Chain-of-Custody

Source: Battelle

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Exposure Measurements & Analysis Branch

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STANDARD OPERATING PROCEDURE (SOP) FOR MAINTAINING AND
RECORDING ELECTRONIC CHAIN-OF-CUSTODY

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1.0 Scope and Applicability

This standard operating procedure (SOP) describes the method for maintaining and recording electronic Chain-of-Custody (CoC) Records for CTEPP samples.

2.0 Summary of Method

The method for maintaining and recording electronic CoC events for CTEPP samples is summarized in this SOP. The CoC events that will be logged electronically include the creation of a sample's identification code, bar code labels, and hard copy CoC documentation; sample receipt at Battelle in Columbus Ohio (OH); transfer of samples to the extraction lab; import of analytical results into the CTEPP database; possible disqualification of samples for QA/QC reasons; and transfer of the samples to archival storage.

3.0 Definition

- 3.1 Magnetic Storage Media: any type of diskette, cartridge, tape, or fixed disk used to store computer data.
- 3.2 Microsoft Access 2000 (or later version): software used to create relational computer databases.
- 3.3 Database: a file or group of files containing records on related data, including ancillary index, report, and query files.
- 3.4 VirusScan for Windows 98 2nd Edition (or higher): a computer virus-scanning program used to detect computer viruses and disinfect PC hard drives and diskettes. Battelle has a site license with McAfee International Associates (www.mcafee.com) and regularly receives upgraded versions of VirusScan.

4.0 Cautions

Not applicable.

5.0 Responsibilities

- 5.1 The CTEPP Database Leader (DBL) and Task Order Leader (TOL) will oversee the maintaining and recording of electronic CoC operations and ensure the SOPs are followed by all project staff.
- 5.2 The CTEPP project staff will be responsible for conducting various tasks in the electronic CoC operation.

6.0 Apparatus and Materials

- 6.1 Microsoft Access 2000 (or later version)
- 6.2 Microsoft Excel 2000 (or later version)
- 6.3 IBM-compatible personal computer (PC), Pentium II processor (or better)
- 6.4 Pocket PC handheld computing device (Windows CE 3.1 or better) equipped with compact flash laser barcode reader.
- 6.5 100 MB or 250 MB Zip formatted diskettes, and/or CD R and/or CD RW compact discs for data backup, and archival.
- 6.6 Charge coupled device (CCD) decoded scanner
- 6.7 Remove'Em Laser Labels (Avery, 1 x 2 5/8")

7.0 Procedure

- 7.1 Creation of sample identification code, bar code labels, and bar code documentation
 - 7.1.1 To get to the CTEPP Database "Main Menu" screen, load the database by double-clicking on its PC desktop icon
 - 7.1.2 Click on the button labeled "Generate Sample ID Bar Code Labels"
 - 7.1.3 Enter the number of sample identification codes for each environmental sample matrix category to generate bar code labels and bar code documentation. Table 1 summarizes the list of the environmental sample matrices monitored for the CTEPP study, and their corresponding 3-digit sample identification prefix codes.
 - 7.1.4 Enter the 3-digit Staff ID code (first, middle, and last name initials).
 - 7.1.5 To create the Sample Identification Codes and print out their bar code labels and bar code documentation sheets, click on button labeled "Press Button to Generate Bar Codes".
 - 7.1.6 The labels with bar codes will print first. Feed the adhesive-backed label paper into the auxiliary tray of the laser printer one sheet at a time.

- 7.1.7 If the printer jams, cancel the print job, and print out any pages left in the printer's memory on plain paper. Click on the "Yes, printer got jammed" radio button, and scan in the bar code label of the last properly printed bar code.
- 7.1.8 If the printer does not jam, click on the "No, labels printed out correctly" radio button.
- 7.1.9 The CoC sheets will then automatically print out on plain 8½ x 11" paper.
- 7.1.10 Click on the button labeled "Exit the Database".
- 7.2 Preliminary Login of Sampling Materials from Field
 - 7.2.1 Preliminary Login Using a Bar Code Reader attached to a desktop PC on the Battelle Local Area Network (LAN)
 - 7.2.1.1 Within the databases's "Main Menu" screen, click on the button labeled "Enter Data into the Database".
 - 7.2.1.2 Within the "Data Entry" screen, click on the button labeled "Login Samples Received at Battelle".
 - 7.2.1.3 Within the "CTEPP Sample Receipt and Login" screen, click on the button labeled "Scan in Preliminary Sample Receipt Data into Desktop PC".
 - 7.2.1.4 Using the CCD, scan the bar code on the label of the sample being logged in. The "Date Received" field will automatically default to the current date.
 - 7.2.1.5 Hit the "Enter" key, and continue logging in all of the samples contained in the shipment.
 - 7.2.1.6 After all received samples have been scanned, click on the black "X" located at the top-right of the "Samples Received" screen to print out the Preliminary Sample Receipt Report.
 - 7.2.1.7 Review the Preliminary Sample Receipt Report to make sure all samples received are listed on the report.
 - 7.2.2 Preliminary Login Using a Bar Code Reader attached to a portable Pocket PC
 - 7.2.2.1 Remove the Pocket PC from its cradle. Place it back into the cradle in order to ensure that the database on the Pocket PC is synchronized with the CTEPP database. NOTE: If the CTEPP database is open and running on any networked PC, the Pocket PC synchronization will fail. Close the database and re-seat the Pocket PC in its cradle to repeat synchronization after any failure.

- 7.2.2.2 Press the top button in the lower-right corner of the Pocket PC (below the screen) – it has a small icon of a rocket ship blasting off on it – to see the main menu on the screen.
- 7.2.2.3 With your finger or the Pocket PC stylus, touch the on-screen button marked “Receipt”. *Be careful not to use excessive force* as this could damage the Pocket PC’s touch screen.
- 7.2.2.4 Scan the bar code label of the first sample into the new record of the Preliminary Sample Receipt database on the Pocket PC by pressing the button located on the left side under the thumbwheel button and above the infrared port.
- 7.2.2.5 With your finger or the Pocket PC stylus, touch the on-screen icon that looks like a new sheet of paper to create a new database record.
- 7.2.2.6 Repeat steps 7.2.2.4 and 7.2.2.5 to scan the bar code label of each sample received.
NOTE: the date received field is automatically set to the current date, so samples must be logged in the day they are received.
- 7.2.2.7 Put the Pocket PC back into its cradle to synchronize the Preliminary Sample Receipt data you just collected with the desktop PC CTEPP database. NOTE: If the CTEPP database is open and running on any networked PC, the Pocket PC synchronization will fail. Close the database and re-seat the Pocket PC in its cradle to repeat synchronization after any failure.
- 7.2.2.8 After the “Synchronization Complete” message appears on the Pocket PC screen, open the CTEPP database (on a desktop PC) and click on the “Enter Data into the Database”, “Login Samples Received at Battelle”, and “Synchronize Preliminary Receipt Data with Pocket PC” buttons to finish synchronizing data and print out the Preliminary Sample Receipt Report.
- 7.2.2.9 Review the Preliminary Sample Receipt Report to make sure all samples received are listed on the report.

7.3 Complete Sample Login Data Entry

- 7.3.1 To finish entering the rest of the Sample Login data for the Sample IDs you scanned in, click on the “Complete Sample Receipt Data Entry” button on the “CTEPP Sample Receipt and Login” screen.
- 7.3.2 Select the shipment receipt date from the pull-down menu.
- 7.3.3 Enter the missing data into the required and optional fields for all the samples shown on the form.

- 7.3.3.1 Tab to enter the participant identification number (PID). Do not enter the “dashes”, the database code enters them automatically.
- 7.3.3.2 Tab to enter your Staff ID code. Click on the pull-down menu and click on the listed Staff ID.
- 7.3.3.3 Tab to enter the date the sample was collected in the field, using the format described in Section 7.3.4.
- 7.3.3.4 Tab to enter the QC Sample description. If the sample is a QC sample, click on the pull-down menu and select the QC sample type; otherwise “NA”, for “Not Applicable”, is entered into the database by default.
- 7.3.3.5 Tab to enter any comments about the sample, e.g., “sample container damaged”.
- 7.3.4 After all the data has been entered, click on the pink button located at the bottom-right of the desktop PC screen.
- 7.3.5 The database will prompt the user if it finds missing required data, until the user has entered all required data.
- 7.3.6 Once the data has all been successfully appended, print out a Sample Receipt Report by clicking on the “Print a Sample Receipt Report” button on the “CTEPP Sample Receipt and Login” screen.
- 7.3.7 Proofread the data listed on the report, making sure all Sample IDs are listed. Write in any necessary changes (missing data, typos, etc.) onto the report, sign and submit it to the DBL. If no changes are needed, sign the report as having received the samples, and place it in the CTEPP Sample Receipt notebook.
- 7.3.8 Compare the Sample Receipt Report with the CoC sheet(s) received from the field. Notify the field sample custodian of any missing samples.
- 7.3.9 File the field CoC sheet(s) in the “Field CoC Sheets” 3-ring binder.
- 7.4 Preliminary Login of Samples Transferred to the Extraction Lab
 - 7.4.1 Preliminary Login Using a Bar Code Reader attached to a desktop PC on the Battelle Local Area Network (LAN)
 - 7.4.1.1 Within the databases’s “Main Menu” screen, click on the button labeled “Enter Data into

the Database”.

7.4.1.2 Within the “Data Entry” screen, click on the button labeled “Transfer Samples to Extraction”.

7.4.1.3 Within the “CTEPP Sample Transferred to Extraction Lab” screen, click on the button labeled “Scan in Extraction Transfer Data using Desktop PC”.

7.4.1.4 Using the CCD, scan the bar code on the label of the sample being transferred. The “Date Received” field will automatically default to the current date.

7.4.1.5 Hit the “Enter” key, and continue logging in all of the samples that are being transferred to the extraction lab.

7.4.1.6 After all transferred samples have been scanned, click on the black “X” located at the top-right of the “Samples Received” screen to print out the Preliminary Sample Transferred to Extraction Report.

7.4.1.7 Review the Preliminary Sample Transferred to Extraction Report to make sure all samples received are listed on the report.

7.4.2 Preliminary Login Using a Bar Code Reader attached to a portable Pocket PC.

7.4.2.1 Remove the Pocket PC from its cradle. Place it back into the cradle in order to ensure that the database on the Pocket PC is synchronized with the CTEPP database. NOTE: If the CTEPP database is open and running on any networked PC, the Pocket PC synchronization will fail. Close the database and re-seat the Pocket PC in its cradle to repeat synchronization after any failure.

7.4.2.2 Press the top button in the lower-right corner of the Pocket PC (below the screen) – it has a small icon of a rocket ship blasting off on it – to see the main menu on the screen.

7.4.2.3 With your finger or the Pocket PC stylus, touch the on-screen button marked “Extract”.
Be careful not to use excessive force as this could damage the Pocket PC’s touch screen.

7.4.2.4 Scan the bar code label of the first sample into the new record of the Preliminary Transfer to Extraction database on the Pocket PC by pressing the button located on the left side under the thumbwheel button and above the infrared port.

7.4.2.5 With your finger or the Pocket PC stylus, touch the on-screen icon that looks like a new sheet of paper to create a new database record.

7.4.2.6 Repeat steps 7.4.2.4 and 7.4.2.5 to scan the bar code label of each sample transferred.
NOTE: The date received field is automatically set to the current date, so samples must be logged in the day they are transferred.

7.4.2.7 Put the Pocket PC back into its cradle to synchronize the Preliminary Transfer to Extraction data you just collected with the desktop PC CTEPP database. NOTE: If the CTEPP database is open and running on any networked PC, the Pocket PC synchronization will fail. Close the database and re-seat the Pocket PC in its cradle to repeat synchronization after any failure.

7.4.2.8 After the "Synchronization Complete" message appears on the Pocket PC screen, open the CTEPP database (on a desktop PC) and click on the "Enter Data into the Database", "Transfer Samples to Extraction", and "Synchronize Extraction Transfer Data with Pocket PC" buttons to finish synchronizing data and print out the Preliminary Sample Transfer to Extraction Report.

7.4.2.9 Review the Preliminary Sample Transfer to Extraction Report to make sure all samples transferred are listed on the report.

7.5 Complete Sample Transfer to Extraction Data Entry

7.5.1 To finish entering the rest of the Sample Transfer to Extraction data for the Sample Ids you scanned in, click on the "Complete Transfer to Extraction Data Entry" button on the "CTEPP Sample Transferred to Extraction Lab" screen.

7.5.2 Select the transfer date from the pull-down menu.

7.5.3 Enter the missing data into the required and optional fields for all the samples shown on the form.

7.5.3.1 Tab to enter Staff ID

7.5.3.2 Tab to enter any comments you have about the sample.

7.5.4 After all the data has been entered, click on the pink button located at the bottom-right of the desktop PC screen.

7.5.5 The database will prompt the user if it finds missing required data, until the user has entered all required data.

7.5.6 Once the data has all been successfully appended, print out a Samples Transferred to Extraction Report by clicking on the "Print a Transfer to Extraction Report" button on the

“CTEPP Sample Transferred to Extraction Lab” screen.

- 7.5.7 Proofread the data listed on the report, making sure all Sample IDs are listed. Write in any necessary changes (missing data, typos, etc.) onto the report, sign and submit it to the DBL. If no changes are needed, sign the report as having released the samples, have the person receiving the samples sign as having received them, and place it in the CTEPP Samples Transferred to Extraction” notebook.
- 7.6 The procedures for importing of analytical samples results will follow the CTEPP-SOP-4.12 entitled Procedures for Entering or Importing Electronic Data into the Database.
- 7.7 Login of Disqualified Samples
 - 7.7.1 Within the database’s “Main Menu” screen, click on the button labeled “Enter Data into the Database”.
 - 7.7.2 Within the “Data Entry” screen, click on the button labeled “Disqualify Samples”.
 - 7.7.3 Within the “Disqualify Samples” screen, scan the bar code on the CoC sheet belonging to the sample being disqualified.
 - 7.7.4 Tab to enter the date disqualified, using the format described in Section 7.3.4.
 - 7.7.5 Tab to enter your Staff ID.
 - 7.7.6 Tab to enter the reason why the sample was disqualified.
 - 7.7.7 Hit the “Enter” key to continue logging samples. After all disqualified samples have been logged, click on the black “X” located at the top-right of the “Disqualify Samples” screen.
 - 7.7.8 Within the “Data Entry” screen, click on the button labeled “Return to Main Screen”.
 - 7.7.9 Within the “Main Menu” screen, click on the button labeled “Print Out a Report”.
 - 7.7.10 Within the “Report” screen, click on the button labeled “Disqualified Sample Summary”.
 - 7.7.11 Review this report for accuracy and keep a copy of it in the study files.
 - 7.7.12 Staff who notes the sample’s disqualification should sign and date the CoC sheets.
- 7.8 Login of Samples Transferred to Archive Storage

- 7.8.1 Within the database's "Main Menu" screen, click on the button labeled "Enter Data into the Database".
- 7.8.2 Within the "Data Entry" screen, click on the button labeled "Archive Samples".
- 7.8.3 Within the "Archive Samples" screen, scan the bar code on the CoC sheet belonging to the sample being archived.
- 7.8.4 Tab to enter the date archived, using the format described in Section 7.3.4.
- 7.8.5 Tab to enter your Staff ID.
- 7.8.6 Tab to enter any comments on the sample.
- 7.8.7 Hit the "Enter" key to continue logging samples. After all archived samples have been logged, click on the black "X" located at the top-right of the "Archive Samples" screen.
- 7.8.8 Within the "Data Entry" screen, click on the button labeled "Return to Main Screen".
- 7.8.9 Within the "Main Menu" screen, click on the button labeled "Print Out a Report".
- 7.8.10 Within the "Report" screen, click on the button labeled "Archived Sample Summary".
- 7.8.11 Review this report for accuracy and keep a copy of it in the study files.
- 7.8.12 Sign and date the CoC sheets.
- 7.9 Data Archival Data to Magnetic Storage Media
 - 7.9.1 Backup the CTEPP Database onto a compact CD disc, or Zip, or floppy diskette once a week.
 - 7.9.2 Clearly label the archive as "CTEPP Database Backup", and indicate the date the backup was performed.

8.0 Records

The original records will be stored in a secured file room. All hard copy CoC documents will be stored in the CTEPP Data folders and archived in a secured file room for three years after completion of the study. All electronic files will be backed up on a ZIP or CD ROM diskette after the project is completed and stored in the secured file room. All electronic files will be protected by passwords. Only authorized project personnel will be allowed to access the files.

9.0 Quality Control and Quality Assurance

Upon completion of entering electronic CoC information into the database, all data will be printed out by the staff and checked for accuracy. Upon transfer of the custody of any sample, the hard copy CoC sheet must be signed and dated by the person receiving custody of the sample. All magnetic storage media will be scanned for virus infection, using the most current version of VirusScan for Windows 98 2nd Edition (or higher) prior to shipment. All magnetic storage media will be shipped in anti-static, rigid diskette mailers. Detailed documentation will be maintained for all data processing work performed. The QA Officer or designee, DBL, and TOL will oversee the CoC operation and ensure the SOPs are followed by all project staff.

10.0 Reference

- 10.1 Mastering Microsoft Access 2000 Development, Alison Balter, Sams Publishing, 1999.
- 10.2 Access 97 Programming, Scott Billings, Joe Rhemann, et al., Sams Publishing, 1997.
- 10.3 Using Excel Visual Basic for Applications, 2nd Edition Jeff Webb, QUE Corporation, 1996.
- 10.4 Microsoft Access for Windows 95 Power Toolkit: Cutting-Edge Tools & Techniques for Programmers, Michael Groh, Ventana, 1996.
- 10.5 Office 97 Bible, Edward Jones and Derek Sutton II, IDG Books Worldwide, 1997.
- 10.6 Running Microsoft Access 2 for Windows, John L. Viescas, Microsoft Press, 1994.
- 10.7 Microsoft Excel Version 5.0 User's Guide, Microsoft Corporation, 1993-94.
- 10.8 Implementation of EPA Order 2180.2 Standard Format for Media and Record Formats for the National Human Exposure Assessment Survey Pilot Studies, L.J. Barlion; Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, Cincinnati, OH, April 5, 1995.
- 10.9 Requirements for Delivering NHEXAS Data, EPA Draft, August 27, 1999.

Table 1. CTEPP Sample Matrices and 3-Digit Sample ID Prefix Codes

Sample Matrix	Sample ID Prefix
Indoor Air XAD-Neutrals ^(a)	IAN

Indoor Air XAD-Acids ^(b)	IAA
Outdoor Air XAD-Neutrals	OAN
Outdoor Air XAD-Acids	OAA
Solid Food Child	SFC
Liquid Food Child	LFC
Solid Food Adult	SFA
Liquid Food Adult	LFA
Drinking Water	DRW
Urine Child	URC
Urine Adult	URA
Dermal Wipe Child	DCH, DCD, DCN, DCA
Dermal Wipe Adult	DAH, DAN, DAA
Indoor Floor Dust	IFD
Soil	SOL
Hard Floor Surface Wipe	FSW
Food Preparation Surface Wipe	FPW
Transferable Residues (PUF Roller)	PUF

(a) Neutrals denotes that the sample extracts will be analyzed by GC/MS without any derivatization step and Acids denotes that the sample extracts will be derivatized to acid esters before GC/MS analysis.