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Standard Guide for Sample Chain-of-Custody Procedures[1]

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1. Scope

1.1 This guide contains a comprehensive discussion of potential requirements for a sample chain-of-custody program and describes the procedures involved in sample chain-of-custody. The purpose of these procedures is to provide accountability for and documentation of sample integrity from the time samples are collected until sample disposal.

1.2 These procedures are intended to document sample possession during each stage of a sample's life cycle, that is, during collection, shipment, storage, and the process of analysis.

1.3 Sample chain-of-custody is just one aspect of the larger issue of data defensibility (see 3.2.2 and Appendix X1).

1.4 A sufficient chain-of-custody process, that is, one that provides sufficient evidence of sample integrity in a legal or regulatory setting, is situationally dependent. The procedures presented in this guide are generally considered sufficient to assure legal defensibility of sample integrity. In a given situation, less stringent measures may be adequate. It is the responsibility of the users of this guide to determine their exact needs. Legal counsel may be needed to make this determination.

1.5 Because there is no definitive program that guarantees legal defensibility of data integrity in any given situation, this guide provides a description and discussion of a comprehensive list of possible elements of a chain-of-custody program, all of which have been employed in actual programs but are given as options for the development of a specific chain-of-custody program. In addition, within particular chain-of-custody elements, this guide proscribes certain activities to assure that if these options are chosen, they will be implemented properly.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1129 Terminology Relating to Water
D3325 Practice for Preservation of Waterborne Oil Samples
D3370 Practices for Sampling Water from Closed Conduits
D3694 Practices for Preparation of Sample Containers and for Preservation of Organic Constituents
D3856 Guide for Management Systems in Laboratories Engaged in Analysis of Water
D4210 Practice for Intralaboratory Quality Control Procedures and a Discussion on Reporting Low-Level Data (Withdrawn 2002)[3]
D4841 Practice for Estimation of Holding Time for Water Samples Containing Organic and Inorganic Constituents

2.2 *U.S. EPA Standard:*

U.S. EPA Good Automated Laboratory Practices [4]

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology D1129.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *custody*—physical possession or control. A sample is under custody if it is in possession or under control so as to prevent tampering or alteration of its characteristics.

3.2.2 *data defensibility*—a process that provides sufficient assurance, both legal and technical, that assertions made about a sample and its measurable characteristics can be supported to

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

an acceptable level of certainty. See Appendix X1 for a discussion of the elements of a data defensibility process.

3.2.3 *sample*—a portion of an environmental or source matrix that is collected and used to determine the characteristics of that matrix.

3.2.4 *sample chain-of-custody*—a process whereby a sample is maintained under physical possession or control during its entire life cycle, that is, from collection to disposal.

3.2.5 *sample chain-of-custody record*— documentation providing evidence that physical possession or control was maintained during sample chain-of-custody.

4. Summary of Guide

4.1 This guide addresses chain-of-custody procedures as they relate to field practices, shipping methods, and laboratory handling of samples.

5. Significance and Use

5.1 Chain-of-custody procedures are a necessary element in a program to assure one's ability to support data and conclusions adequately in a legal or regulatory situation, but custody documentation alone is not sufficient. A complete data defensibility scheme should be followed.

5.2 In applying the sample chain-of-custody procedures in this guide, it is assumed that all of the other elements of data defensibility have been applied, if applicable.

6. Procedure

6.1 *Facility Chain-of-Custody Standard Operating Procedure*—Each organization should have a chain-of-custody procedure document. This document should spell out in detail the specific procedures utilized at this facility to achieve sample chain-of-custody. It should contain copies of all the forms used in the chain-of-custody process and detailed instructions for their use. It should be kept current and revisions tracked. This guide may serve as a template for the chain-of-custody procedure document.

6.2 *Sample Collection Phase:*

6.2.1 *Custody Assignment*—A single field sampling person should be assigned responsibility for custody of samples. An alternate custodian should also be assigned to cover the prime custodian's absence. As few people as possible should handle samples. The assigned field sampler should be personally responsible for the care and custody of the samples collected until they are properly transferred. While samples are in their custody, field personnel should be able to testify that no one was able to tamper with the samples without their knowledge.

6.2.2 *Documentation/Field Custody Forms:*

6.2.2.1 Standard forms should be designed and available for recording custody information related to field sample handling. The forms may be designed to handle one sample or multiple samples. A single sample form may allow room for laboratory chain-of-custody.

6.2.2.2 In any sampling effort, there is field information related to sample collection and field measurements that are recorded. This information is not specifically part of chain-of-custody, but part of the larger aspect of data defensibility. This information may be recorded on chain-of-custody forms or other forms specific for the purpose. Record keeping may be simplified if separate forms are used.

6.2.2.3 It may be useful to print field forms on polyethylene or other plastic coated paper to keep them from being affected by water or chemicals. An indelible ink, paint, or crayon should be used to enter information on the forms.

6.2.2.4 Spaces for the following information should be on the form:

(a) Sample identifying name.

(b) Sampling location ID, sampling point ID, date, and sampling time interval.

(c) Signatures of sampling personnel and signatures of all personnel handling and receiving the samples.

(d) Project identification code (if applicable).

(e) Preservation (to alert lab personnel): amount and type.

(f) Number of containers (where field sub-sampling occurs). Indicate number of replicates if there are multiple containers of the same sample.

(g) Field notes.

(h) Analyses desired (may be required in some situations).

(i) Sample type: grab, composite, etc.

Example forms are shown in Appendix X2.

6.2.2.5 Freight bills, post office receipts, and bills of lading should be retained as part of the permanent custody documentation.

6.2.3 *Sample Labeling:*

6.2.3.1 Sample labels may be in the form of adhesive labels or tags, or both. Tags have the advantage of being removable to become part of the record keeping process, although their inadvertent loss or inappropriate removal may leave the sample without documentation. Labels should be made of waterproof paper and indelible ink should be used to make entries. Alternatively, sample information may be written directly on the sample container, as long as the writing can be done indelibly. Containers should be free from other labels and other writing to prevent any confusion. If both tags and labels are used, care should be taken to ensure that the information on both is identical.

6.2.3.2 Labels or tags should be filled out just before or immediately after sample collection. Labels should contain spaces for the following information:

(a) Project identification code (if applicable).

(b) Sample identifying name (exactly as it appears on the chain-of-custody record).

(c) Sampling location ID, sampling point ID, and sampling time interval.

(d) Safety considerations (if applicable).

(e) Analysis schedule or schedule code (if applicable).

(f) Company or agency name.

An example label is shown in Appendix X2.

6.2.4 *Sample Sealing:*

6.2.4.1 Sample custody seals of waterproof adhesive paper may be used to detect unauthorized tampering with samples prior to receipt by the lab. When seals are used, they shall be applied so that it is necessary to break them in order to open the sample container.

6.2.4.2 Electrical (vinyl) tape may be used to prevent bottle closures from loosening in transit. Tape should be applied before any custody seals are applied.

NOTE 1—Electrical tape should not be used to seal vials used for volatile organic analyses due to the potential for sample contamination.

6.2.5 *Field Transfer of Custody and Shipment:*

6.2.5.1 Package samples properly for shipment and transport them to the laboratory for analysis. Special care should be taken when packaging in glass. It is important that all laws and regulations related to the transport of materials have been adequately addressed before shipping samples.

6.2.5.2 When employing a common carrier, the use of padlocks or custody seals on shipping containers should be considered. If padlocks are employed, the keys shall be shipped separately from the samples. Alternatively, padlocks may be sent unfastened to the field and the keys can be retained by the laboratory sample custodian (see 6.3.2.1). A separate custody record should accompany each shipment. Enter the method of shipment, courier name(s), and other pertinent information in the "remarks" section on the custody record.

6.2.5.3 If sent by mail, register the package with return receipt requested.

6.2.5.4 When transferring the possession of samples, the individuals relinquishing and the individuals receiving the samples should sign, date, and note the time on the custody record. Document any opening and closing of the sample containers on the custody record. Provisions should be made for receipt of samples at nonstandard hours, such as nights and weekends by nonlaboratory personnel. Shipping documents, with noted time of receipt and receipt by whom, should be made part of the custody record.

6.3 *Laboratory Handling and Analysis Phase:*

6.3.1 *Documentation—Laboratory Custody Forms:*

6.3.1.1 The sample chain-of-custody record in the laboratory is traditionally maintained on paper forms. Based on the data defensibility needs of the organization, it may be possible to maintain the laboratory record in an electronic format. Various computer systems, such as a laboratory information management systems (LIMS) or other electronic data management systems, may meet the data integrity needs. It is the responsibility of each organization to assure that an electronic record system meets these needs. Users of such systems are encouraged to assure compliance of their electronic data system with the U.S. EPA Good Automated Laboratory Practices. All references to laboratory custody record forms in this guide should be understood to refer to either paper or electronic documents.

6.3.1.2 Design a form for the recording of chain-of-custody information related to sample possession in the laboratory. If samples are to be split and distributed to multiple analysts, multiple forms will be needed to accompany the sample splits. Transfer sample identification information to the forms accompanying the splits exactly as it appears on the primary receipt laboratory chain-of-custody form. If an LIMS label is used for the sample splits, a duplicate should be placed on the chain-of-custody form that accompanies them. Example forms are shown in Appendix X2.

6.3.2 *Laboratory Sample Receipt and Handling:*

6.3.2.1 In the laboratory, assign a sample custodian(s) to receive the samples. It is preferable to assign one person the primary responsibility to receive samples as the sample custodian for the laboratory. A second person should serve only as an alternate.

6.3.2.2 Upon receipt of a sample, the custodian should inspect the condition of the sample and the custody sample seal, if used. If sample seals are used, record condition on chain-of-custody record. Reconcile the information on the sample label against that on the chain-of-custody record. The temperature of the samples should be recorded on the chain-of-custody record. If samples are not delivered in a cooler, indicate on record. If pH adjustment to preserve the sample was done in the field, the pH of the samples should be checked and recorded on the chain-of-custody record.

6.3.2.3 If a sample container is leaking, note it on the custody record. The custodian, along with the supervisor responsible for the analytical work, should decide whether the leaky sample is valid. If seals are used, the custodian should examine whether the sample seal is intact or broken, since a broken seal may mean sample tampering and may make analytical results inadmissible as evidence in court. Any discrepancies between the information on the sample label and seal and the information on the chain-of-custody record should be resolved before the sample is assigned for analysis. This effort might require communication with the sample collector. Record the results of any such investigation.

6.3.2.4 After processing the sample, (splitting, logging, preserving) record all sample splits on the laboratory chain-of-custody form. When the sample is logged, the sample identifying information should be transcribed exactly as it appears on the field chain-of-custody form. If custody transfer to analytical staff will not occur immediately or if sample processing is delayed, the samples should be transferred to the custody lockup (see 6.3.3). Record all transfers to and from a lockup on the chain-of-custody form. The custody form should remain with the sample.

6.3.3 *Laboratory Security:*

6.3.3.1 In some situations, legally defensible custody in the laboratory has been achieved without regulating possession within the laboratory but rather by assuring controlled and restricted access to the laboratory facility through keying, guarding access points, and other measures. Sufficiency of security measures for legal defensibility can only be assessed on a case by case basis and should involve legal counsel.

6.3.3.2 Within the laboratory, a secure, locked location (a refrigerator or freezer), if appropriate, should be available. Multiple locations may be necessary to provide access to analysts after they receive their portions of the sample.

6.3.3.3 Limit the number of keys to locked locations and maintain control over them. Limiting keys to laboratory supervisors or providing multiple lockups assigned to specific analysts are appropriate options. Limiting access to samples provides greater security against accidental mishandling of samples.

6.3.3.4 As an alternative to secure lockups, tamperproof seals may also be used in the laboratory. Note any application of seals and their removal on the chain-of-custody forms.

6.3.4 *Analyst Sample Receipt and Handling:*

6.3.4.1 When analytical staff take possession of their samples or sample aliquots, they should acknowledge receipt on the primary laboratory chain-of-custody form.

6.3.4.2 When an analyst takes possession of a sample split, he or she should also receive the accompanying chain-of-custody form. At that time, the analyst should inspect the condition of the sample and the sample seal, if used, and reconcile the information on the sample label against that on the chain-of-custody form.

6.3.4.3 While a sample is in their custody, analysts should be able to testify that no one tampered with the sample without their knowledge. If the sample, a portion of the sample, or processed sample such as a digestate will be held for an extended period of time, the analyst should store it in a security lockup and record all such transfers on the chain-of-custody form.

6.3.4.4 At such time as there is no further need for the sample, it should be disposed of properly and the disposal recorded. If the sample or processed sample is to be retained, it may be transferred to appropriate personnel. This transfer should be recorded on both the analyst custody form and the primary laboratory custody form. The primary custody form then accompanies the sample until its disposal.

6.3.5 *Interlaboratory Transfer:*

6.3.5.1 On some occasions, another laboratory will be performing analytical work that is not directly a part of the project plan, that is, data from this laboratory is not planned to be part of the data defensibility scheme. An example might be when a facility discharge is being monitored and the facility laboratory wishes a split of the sample. Under these circumstances, the chain-of-custody record remains with the owner. Prepare a receipt (an example receipt is shown in Appendix X2) for these samples and mark to indicate with whom the samples are being split. The person relinquishing the samples to the other laboratory should request the signature of a representative of the appropriate party acknowledging receipt of the samples. If a representative is unavailable or refuses to sign, note this in the“ received by” section. Complete this form and give a copy to the owner, operator, or agent in charge. The original is retained by the project supervisor. When appropriate, as in the case where the representative is unavailable, the custody record should contain a statement that the sample splits were delivered to the designated location at a designated time.

6.3.5.2 On some occasions, the sample may have to be split with another laboratory in order to obtain all of the necessary analytical information required in the study plan. In this case, identical chain-of-custody procedures should be employed at the alternate laboratory. Transfer of custody of the split should be handled in like fashion to that used to an intralaboratory transfer (see 6.3.4).

7. Keywords

7.1 chain of custody; custody; data defensibility; validation

APPENDIXES

(Nonmandatory Information)

X1. DISCUSSION OF THE ELEMENTS OF DATA DEFENSIBILITY

X1.1 Data defensibility can be thought of as “proof” that a sample represents the material from which it was taken; that the sample integrity was maintained; that the measurements made on the sample produced valid results; and, that the documentation of the “proof” (custody records, data sheets, etc.) is a factual record. Data defensibility involves the following:

X1.1.1 The use of proper procedures (for sample collection, preservation, analysis, etc.),

X1.1.2 Protection of samples from inappropriate alteration (from tampering, loss, mishandling, etc.), that is, chain-of-custody,

X1.1.3 The use of proper record collection, record handling, and record security procedures, and

X1.1.4 Accurate documentation of all sample related information.

X1.2 There are six principal elements of data defensibility besides chain-of-custody. For a discussion of many of these elements, see Data Validation in Guide D3856.

X1.2.1 *Project Setup and Preparation*—The production of data on environmental and source samples for the purpose of drawing valid conclusions requires good experimental design. Aspects of the project from sample collection to data interpretation shall be designed from a valid model.

X1.2.2 *Measurement Methods*—Measurements, both field determinations and lab analyses, shall be made using validated techniques with known levels of uncertainty. Use of methods such as those produced by ASTM Committee D19 can provide assurance that the procedures used will produce useful information.

X1.2.3 *Sample Collection Methods*—Sample results can only be as good as the sample analyzed. It is vital that the sample analyzed be representative of the designated variables in the environmental matrix of concern. It should not be inferred that the experimental design is appropriate or representative for any other environmental variables than those