



CHANGE NOTICE

CN No.: 8.0-0-1

Affected Document: QP 8.0, Identification and Control of Items...Data Rev. 0

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Approved by: N/A

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Training Required:
Yes No

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Currently Read as Follows:

Section 8.0.4.1 as published.

Section 8.0.4.2 as published

Changed to Read:

Add a new paragraph to Section 8.0.4.1 as follows:

Items tested in accordance with procedures developed under QP 11.0 are identified, controlled, and ultimately dispositioned.

Add a new paragraph to Section 8.0.4.2 as follows:

When samples are no longer needed for scientific investigations, they are archived in accordance with a TIP prepared in accordance with 033-YMP-QP 13.0, Handling, Storage and Shipping, and 033-YMP-QP 17.0, QA Records.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0100

Subject: IDENTIFICATION AND CONTROL OF ITEMS,
SAMPLES, AND DATA

Approved:

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8.0.1 PURPOSE

The purpose of this procedure is to establish methods for the identification and control of items, samples, and data used in the Yucca Mountain Project (YMP). The establishment of controls and methods of identification will prevent the use of incorrect or defective materials, parts, and components.

8.0.2 SCOPE

This procedure applies to those items, samples, and data that must have their identity traceable to some point of origin and maintained to end-use. This procedure also applies to items or samples with a limited shelf or operating life.

8.0.3 RESPONSIBILITIES

The Task Leader (TL) whose activities warrant the use of this procedure is responsible for implementing the controls. The TL is also responsible for writing Technical Implementing Procedures (TIP's) required. TIP's are prepared, reviewed, and approved in accordance with the procedure 033-YMP-QP 5.0, "Technical Implementing Procedures." Procedures are issued in accordance with the procedure 033-YMP-QP 6.0, "Document Control".

The YMP Quality Assurance Manager (QA Manager) is responsible for monitoring the implementation of this procedure and for assuring the continued effectiveness of the applicable controls.

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8.0.4 IDENTIFICATION AND CONTROLS

This section describes the identification and controls necessary to be used for items (e.g. materials, parts, and components), samples, and data. Identification of items, samples, and data is verified prior to installation or use to assure traceability. This section is divided into three subsections: the first covers items; the second covers samples; and the third covers data.

8.0.4.1 Identification and Control of Items

Controls are developed and implemented to assure that items are identified and controlled in a manner consistent with their intended use. Items are identified to assure that only correct and acceptable items are used or installed. These controls may be in the form of a TIP or stated as part of the work planning document as described in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

Items are identified when they are received, fabricated, stored, worked on, or shipped. This identification relates the material, part, or component to applicable documentation such as drawings, design specifications, drilling logs, test records, inspection documents, or nonconformance reports. When it becomes necessary to transship items to other destinations, controls are established to assure that their identities are maintained throughout the handling, shipping, and storage activities.

8.0.4.1.1

Physical identification is used where practical. Where physical identification is either impossible or impractical, records or other methods are used, but traceability to the actual item is maintained.

8.0.4.1.2

Identification markings are applied using materials and methods that provide clear and legible identification and do not adversely affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided. Markings are not obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. Methods are described and implemented to assure that items are not inadvertently mixed with like items.

8.0.4.1.3

If codes, standards, or specifications include the requirement for unambiguous identification or traceability (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or inspection, test, or other records), measures are defined to provide identification and traceability control. Such identification and traceability control are intended to assure that materials, parts, and components are treated in a manner consistent with the intended use of the items and are traceable from receipt and fabrication of the items up to and including installation and use. The correct identification of materials, parts, and components is verified and documented prior to release for use.

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8.0.4.1.4

Items are handled and stored in a manner to prevent damage or deterioration due to aging or environmental exposure to the item identifier. Identifiers which are damaged or have deteriorated are replaced. A record is kept of all damaged or deteriorated identifiers. This record contains: the location and type of environment of the item identifier; describes the damage or deterioration; what is being done to prevent that from reoccurring; date of the occurrence; date the identifier is replaced; signature, initials or stamp of individual replacing the identifier. Traceability is maintained from the original item identifier through all subsequent replacement identifiers. Ways to protect items (materials, parts, and components) that might deteriorate from environmental exposure or that might be damaged during handling are defined and used. Additional detail for handling and storage on these procedures is found in procedure 033-YMP-QP 13.0, "Handling, Storage, and Shipping."

8.0.4.1.5

Items having limited shelf or operating life are identified and controlled to preclude use of items whose shelf life or operating life has expired.

8.0.4.2 Identification and Control of Samples

Controls are developed and implemented to assure that samples are identified and controlled in a manner consistent with their intended use. These controls define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation and records generation. These controls may be in the form of a TIP or stated as part of the work planning document as described in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

8.0.4.2.1

Physical identification is used to the maximum extent possible. Where physical identification cannot be placed on the sample, appropriate alternative identification methods or records are described and used. Identification methods provide a means by which the sample(s) can be traced to the appropriate documentation such as drawing's, specifications, drilling logs, test records, inspection documents, and nonconformance reports.

8.0.4.2.2

Samples are identified by placing the identification directly on the sample, on the sample container, and on the records. If it is impractical to place the identification on the sample or sample container, alternate methods for identification are described and used to assure that samples are not mixed with like samples and that the correct identification of samples is verified and documented prior to release for use.

8.0.4.2.3

Controls are developed and implemented to assure that collection methods, techniques, and related equipment produce the intended sample. Sample identification and handling methods are developed, required, and utilized to assure that all samples meet the technical objectives dictated by the scientific investigation for which the samples are collected.

8.0.4.2.4

Storage methods are developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long-term storage receive appropriate treatment to assure that they do not degrade during storage. (Long-term is not defined here and is defined by the responsible TL depending on the sensitivity of the sample to storage conditions.) Additional detail for storage is found in procedure 033-YMP-QP 13.0, "Handling, Storage, and Shipping."

8.0.4.2.5

Transportation methods are developed and implemented to assure that samples are handled in an approved manner. Samples are transported in appropriate container which preclude damage due to environmental exposure or any unsafe conditions. When samples are transported, the use of, multiple organizations the responsibilities and the documentation requirements are described. Controls are developed and implemented to assure that sample identification is verified and maintained when samples are transported or transferred from one organization's responsibility to another.

8.0.4.2.6

Measures are developed and implemented to maintain sample identification while in storage. These measures are consistent with the planned duration and conditions of storage. Samples are handled and stored in a manner to prevent damage or deterioration due to environmental exposure or aging to the sample identifier. Identifiers which are damaged or have deteriorated are replaced. A record is kept of all location and type of environment of the sample identifier; describes the damaged or deterioration; what is being done to prevent that from reoccurring; date of the occurrence; date identifier is replaced; signature, initials or stamp of individual replacing the identifier. Traceability is maintained from the original sample identifier through all subsequent replacement identifiers. When samples are handled their identification is verified.

8.0.4.2.7

Actions to be taken where samples may have a maximum life expectancy while in storage are described. Controls are developed and implemented to assure that the identifiers for these samples specify the maximum life expectancy. A record of the identifiers is kept. This record contains: the sample name; sample type; sample identifiers; maximum life expectancy; and disposition of sample after maximum life expectancy is met. Controls are developed and implemented for the handling of samples after their maximum life expectancy has been exceeded.

8.0.4.2.8

Methods are developed and implemented to assure that like samples are not mixed. Physical segregation of samples is used to the maximum degree practical.

8.0.4.2.9

Controls are developed and implemented for samples that are controlled by multiple organizations. These controls include organizational responsibilities and documentation requirements.

8.0.4.3 Identification and Control of Data

Controls are developed and implemented to assure that data generated from scientific investigation is identified to assist in the determination of its correct use. Identification of such data is provided in all documents, information systems, or both, in which the data appear. Additional detail is found in procedure 033-YMP-QP 3.0, "Scientific Investigation Control."

8.0.4.3.1

Identification of data includes a reference to the origin of the data (e.g. task, test, experiment, report, or publication) and the Quality Assurance Level assignment to the activity which produced the data.

8.0.4.3.2

Control measures are established and implemented to assure that data are properly identified. These measures include verification of the identification of the data prior to release for use.

8.0.4.3.3

Where data are the results of the efforts of more than one organization, TIP's describing the organizational responsibilities for that data are developed and implemented. The data resulting from the scientific investigation involving more than one organization are annotated to show which organization produced what portion of the data.

8.0.5 RETAINED DOCUMENTATION

Quality assurance records are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records."

Quality assurance records include the following:

- o records establishing item, sample, and data identification;
- o sample collection records;