INSPECTION TECHNICAL PROCEDURE

I-131

DOCUMENT CONTROL AND RECORDS MANAGEMENT PROGRAM INSPECTION

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INSPECTION TECHNICAL PROCEDURE I-131, REV. 3
DOCUMENT CONTROL AND RECORDS MANAGEMENT PROGRAM INSPECTION

1.0 PURPOSE

This inspection procedure provides WTP Safety Regulation Division (OSR) guidance to assess the Contractor's document control and records management activities. This guidance is based on the requirements set forth in 10 CFR 830, Subpart A, "Quality Assurance Requirements," and in the Contractor's Quality Assurance Manual (QAM). Specifically, this procedure addresses assessment of the adequacy and effectiveness of the following:

- Procedures controlling document control and records management activities
- Distribution and use of documents
- Major document changes
- Minor document changes
- Incorporating changes
- Expedited document changes
- Document review
- Generation of records
- Authentication of records
- Classification of records
- Receipt control of records
- Storage of records
- Retention and disposition of records
- Retrieval of records
- Correcting information in records
- Replacement of records.

2.0 OBJECTIVES

The objective of this inspection procedure is for the OSR to verify the Contractor's processes for controlling documents and managing records are according to the QAM, policies, and procedures. The inspection should assess the Contractor's document control process to determine that it establishes requirements for preparing, reviewing, approving, revising, and controlling documents that specify or prescribe activities that affect quality, including changes, to ensure correct information is used in performing work activities. Further, it should assess whether the Contractor's records management process establishes requirements for collecting, storing, maintaining, and dispositioning documents, including providing sufficient evidence of the quality of activities performed.

This inspection procedure is one component of a complete construction inspection program. This inspection procedure and others will be used, as needed, to ensure that construction activities are being conducted as required by authorization basis commitments and Contractor

procedures. During the construction phase, a significant portion of this inspection procedure is expected to be accomplished at least once for the Contractor and each major subcontractor involved with the activities addressed by this procedure. However, the entire procedure is not expected to be completed during any one inspection or every time the inspection procedure is used.

3.0 INSPECTION REQUIREMENTS

3.1 Document Control Procedures

3.1.1 The inspectors should verify the preparation, issue, and change of documents that specify technical requirements, quality requirements, or prescribe activities affecting quality (i.e., instructions, procedures, and drawings) were controlled to ensure that correct documents were being employed. (QAM Policy Q-06.1, Section 3.1.1)

3.1.2 The inspectors should verify the documents that specify technical requirements, quality requirements, or prescribe activities affecting quality, including changes thereto, were reviewed for adequacy and approved for issue by authorized personnel. (QAM Policy Q-06.1, Section 3.1.2)

3.1.3 The inspectors should verify the organizations and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents were assigned. (QAM Policy Q-06.1, Section 3.1.3)

3.2 Distribution and Use of Documents

The inspectors should verify the distribution and use of documents, including changes and editorial corrections to documents, included the following controls: [Note: QAM Policy Q-06.1, Section 3.2 applies to all bullets.]

- The controlled documents were identified
- Controlled documents were reviewed for completeness and approved prior to distribution
- A method was established to ensure the correct controlled documents, either in hardcopy or electronic media, were distributed to, or made available to, and used at, the work location
- Effective dates were established for approved implementing documents
- A method was established to ensure the disposition of obsolete or superseded documents so they were controlled and not used to perform work

- A method was established to identify the current status of each document that was required to be controlled.

3.3 Major Document Changes

3.3.1 The inspectors should verify changes to documents, except minor changes, were reviewed and approved by those organizations or technical disciplines affected by the change. (QAM Policy Q-06.1, Section 3.3.1)

3.3.2 The inspectors should verify individuals reviewing document changes had access to pertinent document background data or information upon which to base their review and approval. (QAM Policy Q-6.1, Section 3.3.2)

3.4 Minor Document Changes

The inspectors should verify the following minor changes to documents were approved for release by the organizational position responsible: [Note: QAM Policy Q-06.1, Sections 3.4.1 and 3.4.2 apply to all bullets.]

- Correcting grammar or spelling
- Re-numbering sections or attachments that do not affect the sequence of work
- Changing the title or number of the document
- Updating organizational titles. (Note: A change in organizational title accompanied by a change in responsibilities is not considered an editorial correction.)

3.5 Incorporating Changes

3.5.1 The inspectors should verify implementing documents defined the method used to incorporate changes. (QAM Policy Q-06.1, Section 3.5.1)

3.5.2 The inspectors should verify implementing documents required that a history of changes to quality-affecting documents, including the reasons for the changes, were documented and maintained, and the document history was reviewed each time additional changes to the document were proposed. (QAM Policy Q-06.1, Section 3.5.2)

3.5.3 The inspectors should verify implementing documents define the maximum number of changes permitted prior to requiring reissue of the entire controlled document if the defined method for incorporating change was other than reissue of the entire controlled document. (QAM Policy Q-06.1, Section 3.5.3)

3.6 Expedited Document Changes

3.6.1 The inspectors should verify expedited changes were made at the work location by responsible management if an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays. (QAM Policy Q-06.1, Section 3.6.1)

3.6.2 The inspectors should verify after expedited changes were authorized, the changes were processed through the normal change process, and the processing occurred in a timely manner consistent with the type and nature of the documents being changed. (QAM Policy Q-06.1, Section 3.6.2)

3.6.3 The inspectors should verify implementing documents describe the process to control expedited changes according to the following requirements: [Note: QAM Policy Q-06.1, Section 3.6.3 applies to all bullets.]

- The level of management with the authority to make expedited changes was identified
- The time limits for processing expedited changes through the normal change process was specified
- An evaluation of the work is performed if the normal review process resulted in a change that was different from the expedited change.

3.7 Document Review

3.7.1 The inspectors should verify implementing documents and other documents that specify technical or quality requirements, including changes, were reviewed to the following requirements: [Note: QAM Policy Q-06.1, Section 3.7 applies to bullets 1-5, and Section 4.1 applies to bullets 6-8.]

- Pertinent background information or data was made available to the reviewers
- The review was performed by those other than the preparer
- Reviewers were technically competent for the subject area of the document
- The scope of the review considered all aspects of the document
    - Each organization or technical discipline affected by the document reviewed the document including subsequent changes
    - The QA organization reviewed all documents that directly implemented the QAM requirements, including changes

- Mandatory comments resulting from the review were documented and resolved before approving the document.

- Review criteria, including applicability, correctness, technical adequacy, completeness, accuracy, and compliance with requirements, were established before performing the review

- The QA organization reviewed implementing documents and changes thereto that translated the QARD into work processes. The QA organization reviewed changes to other documents if they were required to review the previous version, unless the QA organization concurred that its review was no longer required

- Each organization or technical discipline affected by the document reviewed the document according to the established review criteria. Changes to the document were reviewed by those organizations or technical disciplines affected by the change.

3.7.2 The inspectors should verify implementing documents contained the following information as appropriate to the work to be performed: [Note: QAM Policy Q-05.1, Section 4.1.1 applies to bullet 1, and Section 3.4.1 applies to bullets 2-7. QAM Policy Q-17.1, Section 3.2.4 applies to bullets 8-9.]

- A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations

- Responsibilities and organizational interfaces of the organizations affected by the document

- Where work must be performed in a given sequence a description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations shall be established. The organization responsible for preparing the document shall determine the appropriate level of detail

- Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished, where necessary for work acceptance

- Prerequisites, limits, precautions, process parameters, and environmental conditions, for testing and operational activities

- Quality verification and hold points where appropriate

- Methods for demonstrating that the work was performed as required (such as provisions for recording inspections and test results, checkoff lists, or signoff blocks

- Identification of associated items and activities, where appropriate and applicable

- Identification of QA records generated by the implementing document
- Identification of the organization responsible for submitting the records to the records management system.

3.8 Records Management Procedures

3.8.1 The inspectors should verify records were identified, generated, authenticated, and maintained, their final disposition specified, and requirements and responsibilities for these activities were documented. (QAM Policy Q-17.1, Section 3.1.2)

3.8.2 The inspectors should verify a project records system was maintained and enforced in accordance with written procedures, instructions, or other documentation. (QAM Policy Q-17.1, Section 3.1.3)

3.8.3 The inspectors should verify requirements and responsibilities for record transmittal, distribution, and retention were established and documented, and records were distributed, handled, and controlled in accordance with written procedures. (QAM Policy Q-17.1, Sections 3.1.4 and 3.1.5)

3.9 Generation of Records

3.9.1 The inspectors should verify records were legible and identifiable. (QAM Policy Q-17.1, Section 3.2.1)

3.9.2 The inspectors should verify records were traceable to associated items and activities and accurately reflect the work accomplished or information required. (QAM Policy Q-17.1, Section 3.2.2)

3.9.3 The inspectors should verify individuals handling records protected them from damage or loss until the records were submitted to the records management system. (QAM Policy Q-17.1, Section 3.2.3)

3.9.4 The inspectors should verify individuals creating records ensured the records were legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply. (QAM Policy Q-17.1, Section 3.2.5)

3.10 Authentication of Records

3.10.1 The inspectors should verify documents considered valid records were stamped, initialed, or signed and dated by authorized personnel (or otherwise authenticated). (QAM Policy Q-17.1, Section 3.3.1)

3.10.2 The inspectors should verify documents whose nature precludes stamping, initialing, or signing (i.e., magnetic or optical media) were identified as complete by authorized personnel. (QAM Policy Q-17.1, Section 3.3.2)

3.11 Classification of Records

3.11.1 The inspectors should verify records were classified as lifetime or nonpermanent. (QAM Policy Q-17.1, Section 3.4.1)

3.11.2 The inspectors should verify records classified as lifetime meet one or more of the following criteria: [Note: QAM Policy Q-17.1, Section 3.4.2, applies to bullets 1-5, and Section 4.1 applies to bullets 6-10.]

- Those which would be of significant value in demonstrating capability for safe operation.
- Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
- Those which would be of significant value in determining the cause of an accident or malfunction of an item.
- Those which would provide required baseline data for in-service inspections.
- Project personnel exposure records.
- Documents that provide evidence of the quality of items.
- Documents that provide evidence of the quality of activities related to items.
- Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.
- Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.
- Personnel training and qualification documents for individuals executing program requirements.

3.11.3 The inspectors should verify documents which are implementing documents as described in QAM Policy Q-05.1, *Instructions, Procedures and Drawings*, were classified as nonpermanent records. (QAM Policy Q-17.1, Section 3.4.2)

3.11.4 The inspectors should verify documents that do not meet the requirements for lifetime records, but provide evidence the QA program was properly executed, were classified as nonpermanent records. (QAM Policy Q-17.1, Section 3.4.3)

3.12 Receipt Control of Records

3.12.1 The inspectors should verify the organization responsible for the receipt of records designated a person or position responsible for receiving records. (QAM Policy Q-17.1, Section 3.5.1)

3.12.2 The inspectors should verify the designee organized and implemented a system of receipt control of records for temporary storage, including a method for verifying that the records were those designated. (QAM Policy Q-17.1, Section 3.5.2)

3.12.3 The inspectors should verify the records were protected from damage, deterioration, or loss when received. (QAM Policy Q-17.1, Section 3.5.3)

3.12.4 The inspectors should verify the Contractor's receipt control system includes the following, as a minimum: [Note: QAM Policy Q-17.1, Section 3.5.5 applies to all bullets.]

- A method for designing the required records.
- A method for identifying records received.
- Procedures for receipt and inspection of incoming records.

3.12.5 The inspectors should verify the receipt control system was structured to permit a current and accurate assessment of the status of records during the receiving process. (QAM Policy Q-17.1, Section 3.5.6)

3.13 Storage of Records

3.13.1 The inspectors should verify records were stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: [Note: QAM Policy Q-17.1, Section 3.6.1 applies to all bullets.]

- Natural disasters such as winds, floods, or fires.
- Environmental conditions such as high and low temperatures and humidity.
- Infestations of insects, mold, or rodents.

3.13.2 The inspectors should verify records storage arrangements provided adequate protection of special processed records (e.g., radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored. (QAM Policy Q-17.1, Section 3.6.2)

3.13.3 The inspectors should verify records storage areas were protected from unauthorized entry, larceny, and vandalism. (QAM Policy Q-17.1, Section 3.6.3)

3.13.4 The inspectors should verify records were stored in metal cabinets or on metal shelving and indexed for retrievability within a facility protected by fire alarm and/or fire suppression systems, or in an Underwriters Laboratory (UL) listed one-hour fire-rated cabinet. (QAM Policy Q-17.1, Section 3.6.4)

3.13.5 The inspectors should verify records were stored and preserved in predetermined storage facilities in accordance with an approved implementing procedure that provides the following: [Note: QAM Policy Q-17.1, Section 3.6.5 applies to all bullets.]

- A description of the storage facility.
- A description of the filing system used.
- A method for verifying that the records received were in agreement with the transmittal document.
- A description of controls governing record access, retrieval, and removal.
- A method for filing supplemental information.
- A method for disposition of superseded records.

3.14 Retention and Disposition of Records

3.14.1 The inspectors should verify the Contractor had documented QA record retention periods. (QAM Policy Q-17.1, Section 3.7.1)

3.14.2 The inspectors should verify records were maintained for their retention periods. (QAM Policy Q-17.1, Section 3.7.2)

3.14.3 The inspectors should verify lifetime records were maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. (QAM Policy Q-17.1, Section 3.7.3)

3.14.4 The inspectors should verify nonpermanent records were not disposed of until the following conditions were met: [Note: QAM Policy Q-17.1, Section 3.7.4 applies to all bullets.]

- Regulatory requirements were satisfied.
- Operational status permitted disposal of the records.

- Purchaser's requirements were satisfied, or a minimum of three years, whichever was longer.

3.15 Retrieval of Records

3.15.1 The inspectors should verify the Contractor's records are retrievable. (QAM Policy Q-17.1, Section 3.8.1)

3.15.2 The inspectors should verify the Contractor's records are indexed, and the indexing system includes the following: [Note: QAM Policy Q-17.1, Section 3.8.2 applies to all bullets.]

- Location of the records within the records management system.
- Identification of the item or related activity to which the records pertain.
- Classification of the record.

3.15.3 The inspectors should verify the Contractor's records were submitted to storage after processing was completed. (QAM Policy Q-17.1, Section 3.8.3)

3.15.4 The inspectors should verify access to the Contractor's records storage facilities was controlled. (QAM Policy Q-17.1, Section 3.8.4)

3.15.5 The inspectors should verify the Contractor maintained a list designating personnel who were permitted access to the records. (QAM Policy Q-17.1, Section 3.8.5)

3.15.6 The inspectors should verify the record management system provided for retrieval of records with planned retrieval times based on record type. (QAM Policy Q-17.1, Section 3.8.6)

3.16 Correcting Information in Records

3.16.1 The inspectors should verify corrections to records, including documents that will become records, included the initials or signature of the person authorized to make the correction and the date the correction was made. (QAM Policy Q-17.1, Section 3.9.1)

3.16.2 The inspectors should verify corrections to records were approved by the originating organization. The inspectors should verify if an organization that was originally responsible for approving a particular document was no longer responsible, the new responsible organization was identified. (QAM Policy Q-17.1, Sections 3.9.2 and 3.9.3)

3.16.3 The inspectors should verify corrections were made in the following manner: [Note: QAM Policy Q-17.l, Section 3.9.4 applies to all bullets.]

- A single line was drawn through the corrected information.

- The individual revising the information initialed and dated the revision adjacent to the drawn line.
- Erasers or correction fluid or tapes were not be used.
- Corrections, when required, were recorded adjacent to the corrected information or by recording the referenced location of the correction.
- Corrections to authenticated records were resubmitted to the originating organization (or designee) for authentication.
- The implementing records procedures addressed the editorial correction of records.

3.16.4 The inspectors should verify corrections to electronic records were in accordance with established procedures. (QAM Policy Q-17.1, Section 3.9.5)

3.17 Replacement of Records

3.17.1 The inspectors should verify organizations originating records developed implementing documents that identified means for replacement, restoration, or substitution of lost or damaged records. (QAM Policy Q-17.1, Section 3.10.1)

3.17.2 The inspectors should verify lost or damaged records were replaced or restored, or if not feasible, the owning organization conducted and documented an evaluation of the impact. (QAM Policy Q-17.1, Section 3.10.2)

4.0 INSPECTION GUIDANCE

For each area listed below, the inspector should review the Contractor's QAM, policies, and procedures for various document control and records management activities, review objective evidence that the QAM, policies, and procedures have been implemented, and interview personnel responsible for various document control and records management activities. In addition to reviewing 10 CFR 830, Subpart A, and applicable parts of the QAM, the inspector also should review G-830.120.

Suggested sample sizes are included in some of the inspection elements below. However, the inspector should use judgment in selecting a different sample size based on the status of the construction activities or on the initial observations in any area. The samples should be large enough to provide confidence: (1) the Contractor has approved procedures, (2) the procedures are being implemented, and (3) the personnel are properly qualified for the work they are performing. The intent is to establish a high level of assurance that the end product meets requirements.

4.1 Document Control Procedures

4.1.1 The inspectors should review the Contractor's procedures for preparation, issuance, and change of documents specifying technical requirements, quality requirements, or prescribe activities affecting quality to confirm they were controlled to ensure correct documents were being employed. The inspectors should select and review instructions, procedures, and drawings to confirm the latest revisions were in use. The inspectors should select two copyholders of two procedures from each organization and interview the copyholders to confirm the correct revision was in use in the workplace. The inspectors should select six drawings and visit the construction site to confirm the correct revision was in use.

4.1.2 The inspectors should review the Contractor's procedures selected in Section 4.1.1 above to confirm the procedures were reviewed for adequacy and approved for issuance by authorized personnel. The inspectors should review the drawings selected in Section 4.1.1 above to confirm the drawings were reviewed for adequacy and approved for issuance by authorized personnel.

4.1.3 The inspectors should review objective evidence organizations and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents were assigned. The inspectors should confirm by document reviews and interviews the organizations and individuals assigned were aware of the assignment, and were performing the above activities.

4.2 Distribution and Use of Documents

The inspectors should review a sample of three documents, three changes to documents, and three corrections to documents to confirm the distribution and use was in accordance with the items listed in Section 3.2. The inspectors also should travel to the construction site to confirm the correct versions of the documents were available for use there.

4.3 Major Document Changes

4.3.1 The inspectors should review a sample of three major document changes to confirm they were reviewed and approved by those organizations or technical disciplines affected by the change.

4.3.2 The inspectors should interview individuals responsible for reviewing document changes to confirm they were aware of the information on which to base their review and approval. The inspectors should interview those individuals to confirm they knew the location of, and had access to, pertinent document background data or information.

4.4 Minor Document Changes

The inspectors should review a sample of three minor document changes to confirm the purpose of the change was consistent with the items listed in Section 3.4. Documents containing minor changes, such as editorial corrections, do not receive the same review and approval as the original documents.

4.5 Incorporating Changes

4.5.1 The inspectors should review the Contractor’s procedures to confirm a method was defined to incorporate changes.

4.5.2 The inspectors should confirm the Contractor's procedure defining the method used to incorporate changes required a history of changes to quality-affecting documents was documented and maintained. The inspectors should review the procedures selected in Section 4.1.1 above to confirm the history of changes contained the reasons for the changes. [Note: If the procedures selected in Section 4.1.1 above had not been changed, the inspectors should select two other procedures from each organization.] The inspectors should interview the Contractor's personnel who were responsible for changing the procedures to confirm they reviewed the revision history prior to making the change. The inspectors should follow this same guidance for other quality-affecting documents, such as specifications, plans, calculations, and drawings.

4.5.3 The inspectors should confirm the Contractor's procedures define the maximum number of changes permitted prior to requiring reissuance of the entire controlled document. The procedures should identify this number for procedures, specifications, plans, calculations, and drawings.

4.6 Expedited Document Changes

4.6.1 The inspectors should select and review a sample of three expedited changes made at the construction site to confirm the expedited change process was used at the work location if an activity could not be performed as listed in the document. The inspectors should confirm responsible management made the expedited changes, and the expedited changes were required because the normal document change process would cause unreasonable delays. The inspectors should follow the above guidance for expedited changes to procedures, calculations, and drawings.

4.6.2 The inspectors should review the expedited changes selected in Section 4.6.1 above to confirm the changes were authorized. The inspectors should follow each of the expedited changes to confirm each was processed through the normal change process, and the processing occurred in a timely manner.

4.6.3 The inspectors should interview the Contractor's personnel responsible for developing the expedited change process for procedures, calculations, and drawings to determine the individual responsible for authorizing the expedited changes had been identified and the

time limits for processing expedited changes through the normal change process was specified. The inspectors should confirm the level of management with the authority to make expedited changes was identified and the time limits for processing expedited changes through the normal change process was specified within the Contractor's procedures. The inspectors should follow the above guidance for expedited changes to procedures, calculations, and drawings. The inspectors should confirm an evaluation of the work was performed if the normal review process resulted in a change that was different from the expedited change.

4.7 Document Review

4.7.1 The inspectors should review the implementing documents selected in Section 4.1.1 to confirm the review requirements specified in 3.7 were employed. The inspectors should confirm the Contractor had established review criteria, including applicability, correctness, technical adequacy, completeness, accuracy, and compliance with requirements, prior to review of the document.

The inspectors should interview the Contractor's QA personnel to determine which implementing documents translate the QARD into work processes. The inspectors should select six implementing documents that translate the QARD into work processes to confirm the QA organization reviewed the documents. The inspectors should select six other documents confirm the QA organization reviewed other documents if they were required to review the previous version. [Note: The QA organization may concur that its review is no longer required.]

The inspectors should review the implementing documents selected above to confirm each organization or technical discipline affected by the document reviewed the document according to the established review criteria. The inspectors should select six changes to documents to confirm changes to the documents were reviewed by those organizations or technical disciplines affected by the change.

4.7.2 The inspectors should review the implementing documents selected in Section 4.1.1 to confirm they contained the information specified in Section 3.7.2.

4.8 Records Management Procedures

4.8.1 The inspectors should review the Contractor’s implementing documents to confirm records were identified, their final disposition was specified, and requirements and responsibilities for these activities were documented. The inspectors should review a sample of six records to confirm they were authenticated and maintained as specified in the implementing documents.

4.8.2 The inspectors should confirm the Contractor's project records system was maintained and enforced in accordance with the applicable procedures or instructions. The inspectors should obtain the procedure(s) used by the Project Document Control (PDC) personnel to confirm compliant implementation.

4.8.3 The inspectors should confirm the Contractor's PDC personnel complied with the procedure(s) for distribution, handling, and control of records. The inspectors should review the Contractor's procedure(s) for control of records to confirm requirements and responsibilities for record transmittal, distribution, and retention were established and documented.

4.9 Generation of Records

4.9.1 The inspectors should select six record generators (i.e., individuals who develop documents that will later become records). The inspectors should interview the record generators to determine the methods they used to confirm documents generated by them were legible and traceable. The inspectors should observe three documents from each record generator to confirm they were legible and traceable.

4.9.2 The inspectors should review the documents selected in Section 4.9.1 above to confirm documents with several pages, sections, or attachments included all pages, sections, and attachments, and were traceable to associated items and activities.

4.9.3 The inspectors should interview the record generators selected in Section 4.9.1 above to confirm the individuals handling documents which will be submitted as records protected them from damage or loss prior to submitting the documents to PDC.

4.9.4 The inspectors should review the documents selected in Section 4.9.1 above to confirm they were legible, accurate, and complete. The inspectors should specifically look for the use of whiteout, obliterations to information, and missing pages.

4.10 Authentication of Records

4.10.1 The inspectors should interview the Contractor's PDC personnel to determine what is meant by “authentication of records.” The inspectors should obtain and review a listing of personnel authorized to authenticate records. The inspectors should review the records selected in Section 4.9.1 above to confirm authentication by stamping, initialing or signing, and dating by authorized personnel.

4.10.2 The inspectors should interview the Contractor's PDC personnel to determine whether or not the records management system contains any documents whose nature precludes stamping, initialing, or signing (e.g., magnetic or optical media). If so, the inspectors should confirm the documents were identified as complete by authorized personnel.

4.11 Classification of Records

4.11.1 The inspectors should review the Contractor’s procedure or interview personnel to determine where/how records were classified as lifetime or nonpermanent. The inspectors should review a sample of six records or record types to determine their classification.

4.11.2 The inspectors should review the Contractor's records classified as lifetime to confirm the types of documents listed in Section 3.11.2 were included.

4.11.3 The inspectors should confirm procedures or work instructions were classified by the Contractor as nonpermanent records.

4.11.4 The inspectors should confirm documents that do not meet the requirements for lifetime records specified in Section 3.11.2, but provide evidence the QA program was properly executed, were classified as nonpermanent records. The inspectors should select six records classified as nonpermanent to confirm they did not meet the criteria specified in Section 3.11.2.

4.12 Receipt Control of Records

4.12.1 The inspectors should review the Contractor’s procedures or interview personnel to confirm a person or position was designated to be responsible for receiving records.

4.12.2 The inspectors should interview the Contractor's personnel responsible for receipt of records to confirm the individual(s) had a method for determining the records were the ones designated by the person submitting the document(s) to the records management system. The inspectors should review objective evidence the method was followed.

4.12.3 The inspectors should confirm the individual(s) handling documents submitted as records protected them from damage or loss prior to entering the documents into the records management system. The inspectors should observe six documents submitted to the Contractor's PDC for incorporation into the records management system to determine the records were safe from damage or loss.

4.12.4 The inspectors should interview the Contractor's PDC personnel and review the PDC procedure(s) to confirm the Contractor's receipt control system included the following, as a minimum:

- A method for designing the required records
- A method for identifying records received
- Procedures for receipt and inspection of incoming records

The inspectors should review objective evidence each of these methods was completely implemented.

4.12.5 The inspectors should review objective evidence the Contractor's receipt control system allowed a current and accurate assessment of the status of records during the receiving process. The inspectors should select six documents in the receipt control system to confirm they could be located.

4.13 Storage of Records

4.13.1 The inspectors should review the Contractor’s records storage facilities, containers, or combination thereof, to confirm they were constructed and maintained in a manner which minimized the risk of damage and destruction from the things listed in Section 3.13.1 above.

4.13.2 The inspectors should interview the Contractor's personnel who work in the PDC to confirm records storage arrangements provide adequate protection of special processed records. The inspectors should observe the special storage arrangements.

4.13.3 The inspectors should interview the Contractor's personnel who work in the PDC to confirm records storage areas were protected from unauthorized entry, larceny, and vandalism. The inspectors should observe the methods used for protection of records.

4.13.4 The inspectors should visit the Contractor's PDC to observe the records storage areas to confirm the records were stored in metal cabinets or on metal shelving and indexed for retrievability. The inspectors should confirm the records storage facility was protected by a fire alarm and/or fire suppression systems or the records were stored in Underwriter's Laboratory listed one-hour fire-rated cabinets.

The inspectors should review the Contractor's implementing procedure for records storage was approved and contained the items listed in Section 3.13.5 above.

4.14 Retention and Disposition of Records

4.14.1 The inspectors should review the Contractor’s objective evidence to verify QA record retention periods had been documented.

4.14.2 The inspectors should select six records to confirm the Contractor had maintained the records for their retention periods.

4.14.3 The inspectors should select six records classified as lifetime records to confirm the Contractor had maintained them for the life of the particular item.

4.14.4 The inspectors should select six records classified as nonpermanent records to confirm the Contractor had maintained them until each of the conditions discussed in Section 3.14.4 above were satisfied.

4.15 Retrieval of Records

4.15.1 The inspectors should obtain a listing of the Contractor’s records and select a sample of six records to determine they were retrievable. The inspectors should try to retrieve the selected records.

4.15.2 The inspectors should review the Contractor's records indexing system to confirm it included the information described in Section 4.15.2 above.

4.15.3 The inspectors should select six record types to observe a record from each type to observe through the records receipt process to confirm the records were submitted to storage after processing was completed.

4.15.4 The inspectors should observe the Contractor's methods for access control to confirm access to the records storage facilities was controlled.

4.15.5 The inspectors should review the Contractor's list designating personnel who are permitted access to the records. The inspectors should enter the records storage area to determine the personnel within the area were included on the list.

4.15.6 The inspectors should review the Contractor's listing of record retrieval times to confirm the record management system provided for retrieval of records with planned retrieval times based on record type.

4.16 Correcting Information in Records

4.16.1 The inspectors should obtain a sample of six corrected records to confirm the corrections included the initials or signature of the person authorized to make the correction and the date the correction was made.

4.16.2 The inspectors should review the records obtained in Section 4.16.1 above to confirm corrections to the records were approved by the originating organization. If the organization originally responsible for approving a particular document was no longer responsible, the inspectors should verify the new responsible organization was identified.

4.16.3 The inspectors should review the corrected records selected in Section 4.16.1 above to verify the corrections were made in the manner described in Section 3.16.3 above.

4.16.4 The inspectors should interview the Contractor's personnel who work in PDC to determine if corrections had been made to electronic records. If so, the inspectors should review the corrections to confirm they were made in accordance with established procedures.

4.17 Replacement of Records

4.17.1 The inspectors should review procedures to confirm processes have been established for replacement, restoration, or substitution of lost or damaged records.

4.17.2 The inspectors should interview the Contractor's personnel who work in the PDC to determine if any records had been lost or damaged. If so, the inspectors should confirm the lost or damaged records were replaced or restored. If replacement or restoration was not feasible, the inspectors should confirm the Contractor conducted and documented an

evaluation of the impact of the loss or destruction of the record. The inspector should review the objective evidence of the evaluations.

5.0 REFERENCES

10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

DOE Implementation Guide for Use with 10 CFR 830.120, "Quality Assurance," G-830.120-REV. 0, 1994.

Quality Assurance Requirements and Description, DOE/RW-0333P, Revision 10.

Quality Assurance Manual, 24590-WTP-QAM-QA-01-001, Revision 4, Bechtel National, Inc., 2003.

6.0 LIST OF TERMS

OSR	WTP Safety Regulation Division
QAM	Quality Assurance Manual
QARD	Quality Assurance Requirements and Description