# INSPECTION TECHNICAL PROCEDURE

# I-102

# CONFIGURATION MANAGEMENT ASSESSMENT

April 17, 2002
Revision 3

Approved: _____ Date: _____
Verification and Confirmation Official

Concur: _____ Date: _____

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# INSPECTION TECHNICAL PROCEDURE I-102, REV. 3
# CONFIGURATION MANAGEMENT ASSESSMENT

## 1.0 PURPOSE

This inspection procedure verifies the Contractor's Configuration Management (CM) Program is being implemented to ensure objectives related to radiological, nuclear, and process safety are fully achieved.

## 2.0 OBJECTIVES

The objectives of this inspection procedure are as follows:

- Verify the Contractor is meeting its CM Program commitments in its Safety Requirements Document (SRD), Integrated Safety Management Plan (ISMP), and Quality Assurance Manual (QAM).
- Verify the Contractor's CM Program procedures appropriately reflect the CM commitments in the SRD, ISMP, and QAM.
- Obtain confidence the Contractor is adequately implementing its CM commitments and procedures.

## 3.0 INSPECTION REQUIREMENTS

### 3.1 CM Program

3.1.1 Verify the Contractor has a CM program in place; CM policies, activities, and conventions specific to the River Protection Project Waste Treatment Plant (RPP-WTP) are defined in a Configuration Management Plan (CMP); and appropriate CM procedures support Plan implementation have been prepared and implemented by the Contractor. (ISMP, Section 1.3.16; SRD, Safety Criterion 4.0-1;and ISO 10007:1995(E))

3.1.2 Verify the Contractor prepared written procedures to manage changes to process chemicals, technology, equipment (including installed software), and procedures, and changes to facilities which affect a covered process. (SRD, Safety Criterion 4.0-2; and ISO 10007:1995(E))

3.1.3 Verify Contractor's personnel who are responsible for design and construction are aware of the CM procedures, and are informed of changes to the CM process in advance of implementation of the changed process. (ISMP, Section 1.3.16; and SRD, Safety Criterion 4.0-2)

3.1.4 Verify the Contractor's architect-engineering group has individuals assigned to identify, evaluate, approve, and implement changes to the RPP-WTP facility design, and these individuals are aware of their CM responsibilities. (ISMP, Section 1.3.16)

3.1.5 Verify the Contractor's personnel involved in the CM process have received specific CM training. (ISMP, Section 1.3.16; QAM Policy Q-02.2; and SRD, Safety Criterion 4.0-2)

3.1.6 Verify the Contractor has performed management and independent assessments to determine if project requirements for CM are being met. (QAM Policies Q-18.1 and Q-18.3; and ISO 10007:1995(E))

3.1.7 Verify the CM Program includes, as a minimum, the following integrated activities: configuration identification; configuration control; configuration status tracking and reporting; and configuration auditing. (ISO 10007:1995(E))

## 3.2 Application of CM to Subcontractors and Vendors

3.2.1 Verify the Contractor included a provision for CM in its subcontracts and procurement documents for configured items and subcontractor and vendor CM programs are compatible with that of the Contractor. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.2.2 Verify the subcontractor personnel responsible for CM are qualified. (ISMP, Section 1.3.16)

## 3.3 Organization for Managing CM Program and Implementation

3.3.1 Verify the Contractor developed a CM organizational structure with appropriately assigned responsibilities for all CM activities with sufficient independence and authority to achieve the required CM objectives, and CM program implementation is consistent with these authorities and responsibilities. (ISO 10007:1995(E))

3.3.2 Verify the Contractor defined the relationships among activities directly involved in and related to the CM process, the organizational structure supports effective integration, and CM program implementation is consistent with the defined relationships. (ISO 10007:1995(E))

3.3.3 Verify the Contractor specified and assigned the authority to approve configuration baselines and any changes thereto, and CM program implementation is consistent with this approval authority. (ISO 10007:1995(E))

## 3.4 Identification and Documentation

3.4.1 Verify the Contractor developed and proceduralized criteria for selecting configured items for control under the RPP-WTP CM program, and the selection process used a "top

down" approach that breaks down the Project into manageable elements. (ISMP, Sections 1.3.16; and ISO 10007:1995(E))

3.4.2 Verify the configured item selection criteria include consideration of at least the following: (ISO 10007:1995(E))

- Performance parameters and physical characteristics of ITS SSC's for achieving design functions
- Criticality in terms of high risks, safety, mission success
- New or modified technology, design, or development
- Interfaces with other items
- Procurement conditions
- Logistic and maintenance aspects.

3.4.3 Verify the configured items which resulted from application of the selection process conform to the selection criteria, and the set of configured items for the RPP-WTP is complete, comprising those items necessary to ensure CM is maintained on the Project. (ISO 10007:1995(E); and ISMP, Section 1.3.16)

3.4.4 Verify numbering conventions were established and applied to the identification of configured items, as well as to parts and assemblies; identification numbers are unique to given items; and Project numbering conventions integrate, to the extent necessary, with corporate and supplier numbering systems. For plant installed software, a definition of the baseline elements of each software baseline shall be part of the labeling/numbering applied to the software. (ISO 10007:1995(E); and QAM, Policy Q-03.2)

3.4.5 Verify numbering conventions or other information management systems permit management of hierarchical or subordinate relationships between: (ISO 10007:1995(E))

- Configured items within the Project
- Components/assemblies within configured items
- Configured items and configuration documents
- Configuration documents and changes to those documents

3.4.6 Verify the Contractor established criteria for determining the necessary set of configuration documents for configured items, and the documentation includes configured item interfaces, changes, deviations, and waivers. (ISO 10007:1995(E))

3.4.7 Verify configuration documentation is uniquely identified in accordance with prescribed procedures. (ISO 10007:1995(E))

3.4.8 Verify designated configuration documents are maintained as part of the WTP Technical Baseline, and the Technical Baseline is controlled to ensure currency and accuracy. Verify a configuration baseline was defined for plant installed software at the completion of each major phase of software development. (ISO 10007:1995(E); and QAM, Policy Q-03.2)

3.4.9 Verify records including Authorization Basis (AB) documents; engineering and other source requirements documents; design documents; identification of SSC's; and links between design documents and requirements documents are maintained in an electronic database management system managed by Project Document Control. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.4.10 Verify CM database ownership is assigned and organizational/functional interfaces are designated and function effectively to ensure timely entry of CM information (new and revised configuration documents) into the CM database. (ISMP, Section 1.3.16)

## 3.5 Change Control

3.5.1 Verify the Contractor established a procedure , which describes the process for controlling changes to the design/configuration that includes identification, evaluation, approval, and implementation. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.5.2 Verify application of the change control process is graded, based on the type of change, its significance (extent to which the change impacts safety, environmental protection, the AB, scope, schedule, or cost), and whether the changed item/document is preliminary or final. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.5.3 Verify changes to the design/configuration were documented and include, as a minimum: (ISMP, Section 1.3.16; and ISO 10007:1995(E))

- Configured items and associated configuration documentation to be changed, by name and revision
- Description of the change
- Reason for the change
- Urgency/priority
- Name of individual preparing the proposal, organization, and date.

3.5.4 Verify the Contractor formally records and tracks the status of processing proposed changes, including related decisions and dispositions, and ongoing changes are formally

and timely communicated to responsible stakeholders to ensure consistent integration and configuration control. (ISO 10007:1995(E))

3.5.5 Verify the Contractor established criteria for evaluating changes to the design/configuration, which include: (ISMP, Section 1.3.16; and ISO 10007:1995(E))

- Compliance with regulations
- Compliance with the AB
- Compliance with applicable codes and standards
- Safety and environmental significance

3.5.6 Verify the Contractor documented its evaluation of the proposed change, including, as applicable, the technical merits of the change and the impact on: (ISO 10007:1995(E)); and QAM, Policy Q-03.2)

- Interchangeability, interfaces (for software, the affected software baselines), and the necessity for re-identification
- Contract, AB, schedule, and cost
- Manufacturing, test, and inspection methods
- Purchases and stocks
- Maintenance, user handbooks, spare parts, and spare parts manuals.

3.5.7 Verify the Contractors' CM procedures assigned review and approval responsibilities and authorities for CM design/configuration changes, the level of detail for review and responsibilities and authorities are commensurate with those required for approval of the original design/configuration, and review and approval of changes is in accordance with these procedures. (QAM, Policy Q-06.1; ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.5.8 Verify a proposed change evaluated as impacting the AB and/or Technical Safety Requirements (TSR's) in a manner which requires OSR approval, or results in the existence of an Unreviewed Safety Question (USQ), is submitted by the Contractor for review and approval by OSR prior to implementation of the change. (ISMP, Sections 1.3.16, 3.3.3, and 3.16.4)

3.5.9 Verify the adequacy of implementation of design/configuration changes by assuring that: (ISO 10007:1995(E)); and QAM, Policy Q-03.2)

- The change was formally approved.

- The procedures and instructions used to implement the change were consistent with the approved design/configuration change documents. For software changes, a release and control process for baseline elements was specified and implemented.

- The results of activities specified to verify compliance of the change with design/configuration requirements (design verification, testing, vendor/supplier certification, etc.) demonstrated the change, as implemented, was acceptable.

### 3.6 Status Tracking and Reporting

3.6.1 Verify the CM database is consistent with the objective of generating records and reports for managing CM program development and implementation. (ISO 10007:1995(E))

3.6.2 Verify CM information is timely and accurately recorded, linked to related documents, and submitted in the prescribed form for record retention in accordance with the QAM. (QAM, Policy Q-06.1 and 17.1; and ISO 10007:1995(E))

3.6.3 Verify the Contractor established requirements for periodic development and distribution of CM program status reports to management, and management is using these reports and taking action when adverse performance trends are identified. (ISO 10007:1995(E); and QAM, Policy Q-16.1)

### 3.7 Configuration Audit

3.7.1 Verify the Contractor has established procedures for Configuration Auditing to confirm configured items conform to their configuration documents, and these include audits to confirm both functional and physical performance requirements. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.7.2 Verify the Contractor performed and documented Configuration Audits before acceptance of associated configuration baselines to assure that the configured items complied with their specific requirements and were accurately reflected in configuration documentation. Also, verify results were appropriately evaluated and dispositioned, or acceptable. (ISO 10007:1995(E))

3.7.3 Verify functional Configuration Audits confirm the adequacy of the required functions of configured items by evaluating records of applicable reviews, inspections, and tests against the functional and performance requirements for the configured items. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.7.4 Verify physical Configuration Audits confirm the adequacy of the as-built, tested configurations of the configured items by examining and comparing records of the physical, tested configurations against applicable configuration documentation. (ISMP, Section 1.3.16; and ISO 10007:1995(E))

3.7.5 Verify the Contractor scheduled and performed periodic Configuration Management System audits to verify the CM program is effective and meets applicable requirements. (QAM, Policy Q-18.1; and ISO 10007:1995(E))

# 4.0 INSPECTION GUIDANCE

## 4.1 CM Program

4.1.1 Obtain and review the Contractor's CM Plan and procedures for appropriate scope. The Plan and procedures should reflect the Contractor's CM program commitments in the SRD (including implementing standard ISO 10007:1995(E)), ISMP, and QAM. Ensure the CM Program includes, as a minimum, the elements of configuration identification, configuration control, status tracking and reporting, and configuration auditing. Determine whether emphasis is placed on integrating these elements during program implementation. Interview the Contractor stakeholders responsible for CM program implementation to verify the CM Plan is being consistently implemented, and the four program elements are well integrated.

When selecting individuals to discuss CM Plan implementation, select some from the Configuration Management Group, as well as some from the Design Engineering and Construction organizations.

4.1.2 Review the Contractor's procedures to ensure they address management of changes to process chemicals, technology, equipment (including installed software), procedures, and facilities that impact a changed process.

4.1.3 Select a random sample (a minimum of five staff individuals plus one manager) of the Contractor's staff responsible for design, and who should be aware of the CM procedures. Do the same for Contractor’s staff responsible for construction activities in the field, and who should be aware of the CM procedures. Also select two Configuration Management Engineers from the CM Group, as well as the Configuration Management Manager/Supervisor, with whom to discuss CM procedures. Meet with these individuals (ideally, on a one-on-one basis) and verify they are aware of the CM procedures and the requirements affecting their respective activities. Discuss any recent changes to the procedures and whether or not (and how) individuals were informed of the changes in advance of the effective implementation dates. Verify controlled copies of the CM procedures are disseminated and available to these individuals and their organizations, and the procedures in use are the current revisions.

4.1.4 See 4.1.3, above.

4.1.5 Obtain and review a sample of eight (8) of the Contractor's staff members' training records (3 of the individuals interviewed in the design organization; 3 of the individuals interviewed in the construction organization; and 2 of the Configuration Engineers from the CM Group) to ensure they have received required CM training. Interview the selected individuals to verify they have received the documented training. Determine if

procedures prescribe mechanisms to keep personnel training current relative to new or modified CM procedures and changes to the design/configured items.

4.1.6 Obtain and review the last four (4) management and/or Quality Assurance assessments/audits involving CM (if fewer then 4 since the last OSR CM inspection, then only review those) including the most recent one, to determine if they are periodically conducted and documented in accordance with prescribed procedures/schedules. Determine if the assessments/audits were sufficiently thorough, and if any deficiencies were found. Verify deficiencies affecting quality were timely entered into the Contractor's corrective action system and appropriately evaluated/dispositioned. Verify corrective actions for any deficiencies identified in the assessment/evaluation were implemented completely and in a timely manner.

4.1.7 See 4.1.1, above.

## 4.2 Application of CM to Subcontractors and Vendors

4.2.1 Identify the individuals (or a representative number of individuals) in the Contractor's organization responsible for monitoring compliance of subcontractors and vendors with the Contractor's CM program. Meet with these individuals to discuss the "flow down" of CM requirements to subcontractors and vendors. Determine the specific subcontracts for providing services and equipment to the Project that require "flow down" of CM requirements. Select a representative sampling (minimum 20%) of subcontracts with CM "flow down" requirements and verify the following:

- There are provisions in each subcontract covering CM. Subcontractors should be required to either follow the Contractor's CM procedures or develop in-house procedures, which are compatible with the Contractor's CM procedures and requirements. Contractor oversight personnel verified effective implementation of the vendors' and subcontractors' CM programs by reviewing the documentation associated with subcontracted services or component procurements, as well as for vendor manufactured/fabricated equipment, and performing "on site" surveillances of CM Program implementation at subcontractor/vendor facilities.

- Inquire whether there have been problems associated with subcontractor/vendor compliance with CM procedures and, if so, the actions being taken by the Contractor to correct the problems. If appropriate and applicable, the inspector may decide to assess the adequacy of the Contractor's actions to correct the problems.

4.2.2 For the subcontracts for which inspection activities were performed per section 4.2.1, above, discuss with the Contractor the results of its oversight activities for assuring subcontractors/vendors used CM-trained/qualified personnel to conduct activities associated with CM implementation.

## 4.3 Organization for Managing CM Program and Implementation

4.3.1 CM Program "ownership" should be assigned to a CM Group with responsibility to oversee and manage the CM process. Responsibilities of this group typically include:

- Act as CM point-of-contact and authority for the Project
- Prepare and maintain the CM Plan
- Review CM implementing procedures for consistency with the CM Plan
- Develop, maintain, and provide CM training
- Confirm CM is properly implemented.

CM program implementation is the responsibility of line organizations and personnel who have the capability to impact and/or change configured items and configuration documents (Design Engineering, Procurement, Construction, Operations, Document Control, etc.).

Verify roles and responsibilities have been identified and assigned to specific Contractor staff within the CM organization, including the CM Group and the overall Project/facility line organizations. Interview a representative sample of staff within the CM Group and in various Project/facility line organizations to verify whether or not these roles and responsibilities are being performed as specified in the CM Plan and implementing procedures.

4.3.2 Activities directly involved with the CM Program include those defined by the CM Plan and procedures. Activities which integrate with and support the CM Program include design control, document control, etc. Organizational responsibilities should be established which ensure effective integration of direct and support activities and processes for effective implementation of the CM Program. Interview key managers of organizations which provide CM Program support to determine the effectiveness of integration with the CM Program, as well as whether implementation is consistent with established processes and procedures.

4.3.3 No additional guidance provided.

## 4.4 Identification and Documentation

4.4.1 ISO 10007:1995(E) suggests selecting too many configured items hampers the ability to manage items and increases costs. Selecting too few, limits management visibility. A top-down process, with selection criteria, which breaks down the WTP into manageable elements should have been established in a procedure to ensure consistent application and results.

4.4.2 No additional guidance provided.

4.4.3 Results of the application of the process for selecting Configured Items should be documented and described in the approved CM Plan. Revision 0 of the approved WTP CM Plan identified 4 types of Configured Items for the WTP:

- Structures, Systems, and Components (SSC's), including their interfaces
- Plant installed software
- Configured interfaces (typically those identified in Interface Control Documents (ICD's))
- Authorization Basis (AB) documents.

Verify the set of Configured Items conforms to the selection criteria established in the selection process procedure, and this set of items is complete and sufficient to ensure the engineered configuration of the Project is controlled so that it meets design, performance, and acceptance requirements.

4.4.4 Select 3 ITS SSC's (1 each representing safety design category (SDC), safety design significant (SDS), and Risk Reduction Class (RRC) ITS categories) for detailed evaluation. If software installed in the plant is designated as a Configured Item as part of an ITS SSC, ensure one of the 3 ITS SSC's selected for review includes this installed software. Review the numbering assigned to determine if it is consistent with Project procedures, and to evaluate the adequacy of assigning unique numbers to procedurally-required "sub-levels" (e.g., system, component, assembly, part, etc.).

Select 2 components provided by a supplier and determine whether these are uniquely identified in accordance with procurement documents, and the numbering conventions integrate with those of the Project, as required.

Determine whether SSC's which are Configured Items have been procured and received on the Project, and/or installed/constructed in the field. Select 2 procured items, and 2 installed/constructed items and verify their physical numbering/identification is consistent with those assigned via application of the required numbering convention.

Select 3 interface control documents (ICD's) and 3 AB documents and verify their numbering/identification is consistent with those assigned via application of the required numbering convention.

4.4.5 For 3 of the Configured Items in the SSC category selected for detailed review in 4.4.4, above, and starting at the "system level," verify the numbering conventions used are consistent with:

- Related Configured Items

- Sub-level components, assemblies, and parts
- Associated Configuration Documentation
- Changes to the Configuration Documentation.

In addition, select one example of plant installed software designated as a Configured Item and verify the numbering conventions used are consistent with the above attributes.

4.4.6 Revision 0 of the approved WTP CM Plan states Configuration Document types include:

- System Descriptions, drawings, and specifications for SSC's
- Software requirements documents, Verification & Validation (V&V) reports, installation documents, user manuals, access control documents, and operations and maintenance manuals
- Interface Control Documents
- AB documents.

The above set of documents collectively represents the WTP Project design requirements, design configuration, verification, and acceptance. Verify these established types of Configuration Documents are sufficient to describe all physical and functional characteristics of WTP Configured Items, and the requirements, design, verification, and acceptance of these items, and they were categorized in accordance with criteria in applicable procedures. In performing this evaluation, consider the population of design-related documents that are <u>not</u> considered to be Configuration Documentation and whether the Contractor's categorization of these is correct.

4.4.7 See 4.4.5, above.

4.4.8 For the Configuration Documentation selected for review in 4.4.5, above, verify the subject documents are contained within the Technical Baseline and they are the most current, approved revisions of those documents.

- If Configured Items are being installed/constructed in the field, review the Configuration Documentation in use by construction personnel to ensure it is current and matches those referenced in the Technical Baseline.
- If Configured Items are being procured under Specifications, review the Specifications to determine if they are current and match those referenced in the Technical Baseline.

Plant installed software should be maintained as a Configured Item only after it has been installed, tested, and approved for use in the Plant for commissioning and operations. Prior to that point, software life cycle activities such as requirements identification,

design, implementation, testing, etc. are controlled in accordance with QAM, Policy Q-03.2, and inspected under the Design Process Assessment.

For the two activities above, interview involved personnel to determine their understanding of the importance of using the correct revisions of Configuration Documentation to effective CM Program implementation.

Request a demonstration by responsible Contractor/subcontractor staff of how the Technical Baseline information is kept current, accurate, and traceable, and how the process ensures current revisions are being used. Ask how changes to the Technical Baseline are communicated to the appropriate Contractor and subcontractor staff.

4.4.9 This inspection activity is concerned with records of activities performed under the control of the CM Program. For the installation/construction, procurement, and design/modification activities for which Configuration Documentation was reviewed in 4.4.8, above, review the completed records in the electronic database maintained by Project Document Control (PDC) to ensure they are accurate and current. Interview PDC personnel responsible for maintaining the electronic database to discuss problems they have had with maintaining records and controlling the database, and the timeliness and effectiveness of solutions implemented to address them.

4.4.10 Review the procedures governing establishment and management of the CM database. Identify the Contractor staff member(s) responsible for the CM database, and request an explanation of how the database integrates with other non-CM databases. Have the staff member demonstrate how the CM database is maintained/updated and how it functions. Ask if the database is functioning as planned. If it is not functioning as planned, ask what corrective actions are in progress or planned.

4.4.11 Select 4 approved design changes for ITS SSC's (if possible, one in each discipline area (e.g., mechanical, electrical, civil, and instrumentation and control) which are designated as Configured Items and under the control of the CM Program. Also, one of the four changes selected for review should involve plant installed software. Ask the database administrator how the CM database responded to these design changes. Request an explanation of how the Contractor's staff assured themselves that all design elements potentially affected by each change were properly and sufficiently accounted for before the proposed design change was approved. If possible, independently assess whether the database response was adequate and sufficient. Verify design requirements for each selected SSC were included in the CM database. Ask the Contractor's staff to distinguish between design requirements and design criteria.

## 4.5 Change Control

4.5.1 Revision 0 of the approved WTP CM Plan identified 4 types of Configured Items for the WTP – SSC's, plant installed software, ICD's, and AB documents. Sections 4.0 through 7.0 describe the change control processes used for each type of Configured Item and the WTP procedures which implement the processes. Verify each change control

process/procedure includes the required elements of identification, evaluation, approval, and implementation.

4.5.2 Revision 0 of the approved WTP CM Plan notes changes to preliminary and final design documents are processed in accordance with the procedure for Design Change control, and identification, evaluation, approval, and implementation is graded based on the type of change and whether the design document is preliminary or final. Preliminary (alpha revision) design documents are subject to revision control (increase in the alpha revision designator) with change history described in drawing revision boxes and specification history sheets. No formal change identification or evaluation is documented. Minor changes to final design documents that do not impact the AB, safety, environment, schedule, scope, or cost are processed using a Design Change Notice (DCN). Significant changes to final design documents are processed using a Design Change Application (DCA) which requires documented identification and justification of the change; evaluation of impact on plant capacity, impact assessments by disciplines involved, and regulatory impact; approval, and implementation documentation. Verify procedures governing the change control process reflect the graded approach described in the approved CM Plan.

QAM, Policy Q-03.2 states the software defect reporting and resolution system shall be integrated with the software configuration management system. In this context, changes to plant installed software may be required as a result of defect reporting. Verify procedures governing reporting, processing, and resolving software defects appropriately integrate with the change control process under the software configuration management system.

Select 3 design changes to ITS SSC's, 3 changes to ICD's, 3 changes to plant installed software, and 3 changes to AB documents made since the last CM inspection and review the associated change documentation to ensure the appropriate processes were used and performed in accordance with applicable procedures. Ensure that the changes selected (which affected ITS SSC's), include a representative sample of Design Change Notices (DCN's), Design Change Applications (DCA's), Field Change Requests (FCR's), Field Change Notices (FCN's), Drawing Change Notices (DCN's), Nonconformance Reports (NCR's), and Supplier Deviation Disposition Requests (SDDR's). Note that Interface Change Forms (ICF's) are used to change ICD's.

4.5.3 ISMP, Section 1.3.16 requires changes to be documented, except if they are "insignificant" (those with no effect on safety, environmental protection, the AB, Project scope, schedule, or cost.) In discussions with Project staff and managers, during the inspection, determine if any changes were made since the last CM inspection which were not documented because they were considered "insignificant," and discuss the specifics of these changes to ascertain whether they were appropriately processed (e.g., they did or did not need to be documented). In addition, review of items in the Corrective Action database and the Work Control database, that constituted or resulted in changes to Configured Items, may also be a source of information relating to whether they were "insignificant" and not further documented for evaluation, approval, and implementation under CM change control.

Using the same change documents selected for review under 4.5.2, above, verify , the change documentation includes, as a minimum, the attributes noted in Section 3.5.3 of this inspection procedure.

4.5.4 Using the same change documents selected for review under 4.5.2, above, ensure , formal status of each change was communicated throughout the Project to responsible stakeholders (Design Engineering, Construction, Procurement, Facility line management, Maintenance, etc.), and to applicable subcontractors. Ask to see appropriate documentation to verify , such communications were made. Select a sample of stakeholders from various organizations who were informed of the changes, and through interviews, verify , they are knowledgeable of the status and , they received timely change notification.

4.5.5 No additional guidance provided.

4.5.6 Using the same change documents selected for review under 4.5.2, above, review the documented evaluations of the changes to ensure , they address the attributes specified in applicable procedures. Changes to preliminary and final design documents (via DCN's and DCA's) are processed in accordance with EDPI-24590-WTP-3DP-G04T-00901, *Design Change Control*. Approved changes to design documents are made in accordance with EDPI-24590-WTP-3DP-G04B-00046, *Engineering Drawings,* and EDPI-24590-WTP-3DP-G04B-00049, *Engineering Specifications.* Changes involving SDDR's are processed via EDPI-24590-WTP-3DP-G04B-0063, *Supplier Deviation Disposition Requests.* Changes involving FCN's and FCR's are processed via EDPI-24590-WTP-3DP-G04B-00962, *Disposition of Field Change Request/Field Change Notice.* Changes involving NCR's are processed via EDPI-24590-WTP-3DP-G04B-00061, *Disposition of Nonconformance Reports.* Changes involving ICF's are processed via 24590-WTP-GPP-PADC-003, *Internal Review and Approval of Documents.*

4.5.7 Using the same change documents selected for review under 4.5.2, above, verify , the changes were evaluated and approved by persons, disciplines, and organizations specified in the procedures governing the type of changes being processed. Review several of the evaluations and independently assess the technical adequacy of the bases for the conclusions reached by Contractor personnel. Discuss insights from this review with responsible Contractor personnel, if necessary.

4.5.8 Review the population of changes made to Configured Items since the last CM inspection. From the description of the changes, select several which may have had the potential to impact the safety analysis and/or the AB (and the Technical Safety Requirements, if after the start of Hot Commissioning). For each of the changes selected, interview the person responsible for the change to discuss whether it impacted the safety analysis and/or the AB (and whether an Unreviewed Safety Question existed, if after the start of Hot Commissioning), whether the impact was such that OSR approval would be required prior to implementation, and how these determinations were made. Review documented safety evaluations which were completed to ensure they were adequately performed and arrived at correct, defensible conclusions. Verify OSR approval was obtained before implementation of any proposed change that would impact the safety

analysis or the AB (or that resulted in an Unreviewed Safety Question, if after the start of Hot Commissioning).

4.5.9 For the changes selected for review under 4.5.2, above, verify implementation was in accordance with approved change documents, procedures, and instructions. If implementation is ongoing (e.g., installation/construction in the field), observe field activities as part of implementation verification. Review design verification, test data, and vendor/supplier certifications to determine if these met the design/configuration requirements.

## 4.6 Status Tracking and Reporting

4.6.1 Determine what, if any, databases are maintained and reports generated which depict current status of processing changes to Configured Items and related Configuration Documentation. If databases used for status tracking are different from the CM database, examine whether such databases are adequately integrated with each other. Identify the person or organization assigned ownership of the tracking function and discuss the effectiveness of implementation. Review the database and reports for problem areas, and interview responsible managers to determine the extent of their knowledge of the problems and actions they have planned, or have implemented, to address them.

4.6.2 Review the status tracking database and reports for the changes selected for review under 4.5.2, above, to ensure status reflected in the tracking documents is accurate. Also, determine if these changes affect any related Configured Items and Configuration Documentation; ensure linkage through the tracking database reflects the need to change the related items, and the status of performing these changes is accurate and consistent with the change documents.

Discuss with the database administrator the timeliness of communication of change information from Configured Item and Configuration Documentation stakeholders to ensure tracking data is maintained current and accurate.

Examine records of completed CM-related changes to ensure they are properly retained in the prescribed format by the responsible organization.

4.6.3 Based on Revision 0 of the approved WTP CM Plan, the Configuration Management Group is responsible for "confirming that configuration management is properly and adequately implemented." To efficiently and effectively accomplish this, the Configuration Management Group will need to acquire current and accurate information about the effectiveness of CM Program implementation. One way of doing this is to generate periodic or "on demand" reports from the status tracking database. Discuss with the Manager of the CM Group what recurring reports are periodically produced and distributed to Project management for their use in monitoring the effectiveness of CM Program implementation. If no recurring reports are generated by the CM Group, determine whether they generate reports "on demand," how often, for what use, and to whom these are distributed. Discuss insights about CM Program implementation that the CM Group has derived from its review and evaluation of these reports, and if problems or

adverse trends have been observed, determine what actions they have taken to inform responsible managers and how (or whether) they track the effectiveness of corrective actions taken.

If time permits, interview some of the Project/line organization managers who implement the CM Program to determine what CM Program status tracking/performance information they receive, how this is communicated, at what periodicity, and the effectiveness/usefulness of the information to them. Discuss performance insights they have identified from the information provided and if problematic, the actions they are planning, or have taken, to address these issues.

Implementation of this inspection procedure may result in OSR identifying CM-related problems not yet known to the Contractor. This will provide an opportunity to determine the effectiveness of status tracking and reporting, as follows:

- OSR should determine whether status tracking information and reports relate to OSR-identified, CM-related problems, and if they do, request the Contractor to generate reports that, upon close scrutiny, may highlight the problems. If this is the case, determine why the Contractor has not previously identified the problems. Also, independently assess whether the reports and the information therein are consistent with the known extent and significance of the problems.

- On the other hand, if no recurring or "on demand" reports generated by the status tracking database could facilitate identification of the CM-related problems, discuss with the Contractor whether the status tracking database and report generation capabilities are adequate.

## 4.7 Configuration Audit

4.7.1 Revision 0 of the approved WTP CM Plan notes that Functional and Physical Configuration Audits pertain only to SSC's and plant installed software designated as Configured Items, and not to ICD's and AB documents.

4.7.2 For the Configured Items (SSC's and related plant installed software) selected for review in Section 4.4.4, above, verify Configuration Audits (e.g., Functional and Physical Configuration Audits) were performed for each Configured Item before acceptance of its configuration baseline. Independently evaluate the results of the Functional and Physical Configuration Audits on these Configured Items and determine whether conclusions reached were supportable with sound technical bases.

4.7.3 See 4.7.2, above.

4.7.4 See 4.7.2, above.

4.7.5 Review the Contractor's Quality Assurance (QA) audit and Management Assessment schedules to identify the last CM Program audit and/or management assessment performed. Verify the periodicity of such audits/assessments meets the requirements of

the QAM and its implementing procedures. Review the results of the audit/assessment and compare them to:

- CM Group performance/effectiveness insights
- OSR-identified problems and adverse trends related to CM Program implementation
- CM-related problems and trends documented in the Contractor's Corrective Action Program database
- QA surveillances relating to the CM Program and its implementation

Note the above comparisons are most valid if the audits/assessments were performed within 3-6 months of the CM Group's development of performance insights, OSR's identification of problems, the Contractor's entry of problems and trends into its Corrective Action Program database, and completion of CM-related QA surveillances. If the inspectors determine there are significant differences between the results/findings of the audit/management assessment and the "performance picture" developed from the other information sources, these differences should be discussed with those responsible for the audit/management assessment to determine which performance conclusions are correct, as well as attempt to determine why the differences exist. In addition, significant differences should be highlighted in the inspection report so the Contractor can evaluate the reasons for their existence and take action to prevent recurrence.

## 5.0 REFERENCES

10 CFR 830, "Nuclear Safety Management," *Code of Federal Regulations*, as amended.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

*Integrated Safety Management Plan*, 24590-WTP-ISMP-ESH-01-001, Rev. 0.

*Quality Assurance Manual,* QAM-24590-01-00001, Rev. B.

RL/REG-97-05, *Office of Safety Regulation Management Directives*, Rev.1, U.S. Department of Energy, Richland Operations Office, 1998.

RL/REG-98-17, *Regulatory Unit Position on Tailoring for Safety*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

*Safety Requirements Document*, 24590-WTP-SRD-ESH-01-001-02, Rev. 0.

*Quality Management – Guidelines for Configuration Management,* International Organization for Standardization (ISO) 10007:1995(E).

*WTP Configuration Management Plan, Approved,* 24590-WTP-PL-MG-01-002, Rev. 0.

## 6.0 LIST OF TERMS

| | |
|---|---|
| AB | authorization basis |
| CM | Configuration Management |
| CMP | Configuration Management Plan |
| DCA | Design Change Application |
| DCN | Design Change Notice/Drawing Change Notice |
| DCR | Design Change Request |
| FCN | Field Change Notice |
| FCR | Field Change Request |
| ICD | Interface Control Document |
| ICF | Interface Change Form |
| ISMP | Integrated Safety Management Plan |
| ITP | Inspection Technical Procedure |
| NCR | Nonconformance Report |
| OSR | Office of Safety Regulation |
| PDC | Project Document Control |
| PSAR | Preliminary Safety Analysis Report |
| QAM | Quality Assurance Manual |
| RRC | Risk Reduction Class |
| RPP-WTP | River Protection Project - Waste Treatment Plant |
| SAR | Safety Analysis Report |
| SC | Safety Criterion |
| SDC | Safety Design Class |
| SDDR | Supplier Deviation Disposition Request |
| SDS | Safety Design Significant |
| SSC | Structures, Systems, and Components |
| SRD | Safety Requirements Document |
| TSR | Technical Safety Requirement |
| USQ | Unreviewed Safety Question |
| V&V | Verification and Validation |