Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

99-RU-0513

Mr. M. J. Lawrence, Executive Vice President
General Manager
BNFL Inc.
3000 George Washington Way
Richland, Washington 99352

Dear Mr. Lawrence:

CONFIGURATION MANAGEMENT PROGRAM INSPECTION REPORT, IR-99-005

On August 9-12, 1999, the Office of Radiological, Nuclear, and Process Safety Regulation of the TWRS-P Contractor (Regulatory Unit) completed an inspection of the configuration management program at the BNFL Inc. (BNFL) facility.

Details of the inspection are documented in the enclosed inspection report. No Findings were identified. However, one significant weakness was identified concerning BNFL's lack of an effective program to validate and verify computer software used to perform design of important to safety structures, systems, and components (SSCs). Although per the Quality Assurance Program and Implementation Plan (QAPIP), Section 6.2.3, the validation and verification process was not required until the software is used to prepare final design documents, current preliminary design activities could be impacted by software that may contain errors. In addition to the weakness, BNFL's efforts to link design input information to SSCs was just being developed and not implemented at the time of the inspection. These two areas are important elements of a good configuration management program and will be reviewed during a future inspection.

With the exception of the two areas described above, the inspection team found the BNFL configuration management program in place and functioning as required. The recently issued configuration management plan and related implementing procedures complied with the governing standard and authorization bases commitments. Staff was found well-trained and knowledgeable of configuration management requirements. The implementation of the newly developed configuration management database, planned to be functional in late 1999 or early 2000, should provide a useful tool to maintain the extensive design related information linked to SSCs for use during the life of the TWRS-P facility.

Nothing in this letter should be construed as changing the Contract (DE-AC06-96RL13308). If you have any questions regarding this inspection, please contact me or Pat Carier of my staff on (509) 376-3574.

Sincerely,

D. Clark Gibbs, Regulatory Official
Office of Radiological, Nuclear, and
Process Safety Regulation

RNP:JWM

Enclosure: Inspection Report IR-99-005

cc w/encl:
D. W. Edwards, BNFL

Enclosure
IR-99-005

U.S. DEPARTMENT OF ENERGY

Richland Operations Office
Office of Radiological, Nuclear, and Process Safety Regulation
of the TWRS-P Contractor

INSPECTION: CONFIGURATION MANAGEMENT PROGRAM

REPORT NO: IR-99-005

FACILITY: BNFL Inc.

LOCATION: 3000 George Washington Way
Richland, Washington 99352

DATES: August 9-12, 1999

INSPECTORS: J. McCormick-Barger (Lead), Senior Regulatory Technical Advisor
P. Carier, Verification and Confirmation Official
J. Adams, Senior Regulatory Technical Advisor

APPROVED BY: Pat Carier, Verification and Confirmation Official
Office of Radiological, Nuclear, and Process Safety Regulation

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EXECUTIVE SUMMARY
Configuration Management Program
Inspection Report Number IR-99-005

INTRODUCTION

This inspection of the BNFL Inc. (the contractor) Configuration Management (CM) Program covered the following specific areas:

- Configuration Management Program (Section 1.2)
- Application of CM to Subcontractors and Vendors (Section 1.3)
- Design Criteria (Section 1.4)
- Design Baseline (Section 1.5)
- Configuration Management Database (Section 1.6)
- Design Change Control (Section 1.7)
- Design Interfaces (Section 1.8)
- Staff Training (Section 1.9)
- Procurement Documents (Section 1.10)
- Self-Assessments of Configuration Management (Section 1.11)

SIGNIFICANT OBSERVATIONS AND CONCLUSIONS

- A CM plan was issued that followed the guidance provided in International Organization for Standards (ISO) Standard 10007 and addressed applicable requirements in the authorization basis. The appropriate procedures and codes of practice were in place from the onset of the design phase and continued to be used by the design staff to ensure configuration of the plant was maintained throughout the design phase. Interviewed staff were knowledgeable of the CM program and associated implementing procedures. (Section 1.2)

- One significant issue was self-identified by the contractor concerning the lack of a process to link design input information to SSCs. The contractor was developing a design input memorandum (DIM) process to address this requirement. Follow-up of the contractor's activities to resolve this issue will be tracked as an Inspection Follow-up Item. (Section 1.2)

- The issued CM plan and implementing procedures provided appropriate guidance concerning application of CM to subcontractors and vendors. (Section 1.3)

- The contractor was adequately controlling the design criteria used to design the TWRS-P facility. (Section 1.4)

- Technical baseline information was adequately defined and controlled. One significant weakness was identified concerning the lack of an adequate program for verifying and validating computer software used to perform "safety critical" calculations. (Section 1.5)

- The contractor had an adequate CM database in-place to control design information. However, the database did not relate SSCs to design inputs as required by Section 5.3 of the Integrated Safety Management Plan (ISMP). Action taken by the contractor to resolve this issue was comprehensive, and if properly implemented, should adequately address the ISMP requirement. (Section 1.6)

- The contractor's provisions for controlling the design change process were adequate and met the authorization basis requirements. Design change documents were appropriately reviewed and approved and adequately addressed safety. A weakness was identified in that the design change control procedure lacked flexibility to defer performing Detailed Impact Assessments when technical justification to do so existed, and provisions to ensure that approved DCAs were implemented in an accurate and timely manner. (Section 1.7)

- Interface controls both internal and external were found to be adequate and appropriate for this level of project development. (Section 1.8)

- The staff was adequately trained and knowledgeable of the CM plan and associated implementing procedures and understood how to apply CM to their specific job assignments. The CM training provided was adequate. (Section 1.9)

- The contractors program for procuring goods and services included applicable elements of CM. The inspection was limited to a program review since few procurement activities were ongoing at the time of the inspection. (Section 1.10)

- The contractor's self and independent assessments of the CM program were thorough and effective, resulting in the identification of a large number of CM implementation issues that were addressed or being addressed at the time of the inspection. (Section 1.11)

CONFIGURATION MANAGEMENT PROGRAM

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CONFIGURATION MANAGEMENT PROGRAM INSPECTION REPORT

1.0 REPORT DETAILS

1.1 INTRODUCTION

In accordance with the Tank Waste Remediation System-Privatization (TWRS-P) Contract (Contract, DE-AC06-96RL13308 between DOE and BNFL (the contractor), dated August 24, 1998) and specifically the Safety Requirements Document (SRD), Safety Criterion (SC) 4.0-1, (required by Part 1, Section C, Standard 4, Section c.2) (d)) the contractor was required to apply formal configuration management to all TWRS-P activities through deactivation of the facility. This requirement was reflected in the contractor's Configuration Management (CM) plan, dated August 6, 1999.

The inspectors reviewed the contractor's CM plan and implementing procedures against the contractor's authorization bases (SRD, Quality Assurance Program and Implementation Plan [QAPIP], and Integrated Safety Management Plan [ISMP]), and the implementing standard (ISO 10007, Quality Management – Guidelines for Configuration Management). In addition, the inspectors reviewed records, interviewed staff, and observed related activities to determine if the contractor was adequately establishing and maintaining the configuration of the TWRS-P facility design in accordance with the CM plan and procedures.

1.2 CONFIGURATION MANAGEMENT PROGRAM (INSPECTION TECHNICAL PROCEDURE (ITP) I-102)

1.2.1 Inspection Scope

The inspectors reviewed the CM program and procedures, and interviewed selected design staff to assess the contractor's ability to properly incorporate CM principles into the facility design at the current stage of the design process. Particular attention was placed on verifying that appropriate CM program elements were in place from the outset of the design phase. This was accomplished by verifying that the contractor prepared and implemented appropriate CM implementing procedures and that the staff was knowledgeable of the CM principles and procedures. Additionally, the inspectors reviewed the recently issued CM plan for consistency with the authorization basis commitments.

1.2.2 Observations and Assessments

During the assessment of the CM program, the inspectors reviewed the documents listed in Section 3.4 of this report.

1.2.2.1 Configuration Management Program Review

Following the entrance meeting, the contractor provided the inspectors an overview of the CM program. The presentation provided the following information:

- The contractor's definition of CM
- A discussion of the CM implementing standard, ISO 10007, Quality Management, Guidelines for Configuration Management
- A listing of procedures that implement CM
- A discussion of the four elements of the CM program
    1. Identification
    2. Change Control
    3. Status Accounting
    4. Verification and Audit
- A description of how the contractor is currently implementing the identification portion of CM program
- A definition of the TWRS-P Technical Baseline
- A summary description of how the change control, status accounting, and verification and audit are being implemented.

This presentation was essentially the same presentation made to contractor employees as part of the CM training. Training is discussed in Section 1.9 of this report.

Shortly following the entrance meeting, the inspectors were provided a copy of the River Protection Project-Waste Treatment Plant (RPP-WTP) CM plan. The inspectors compared the CM plan against the implementing standard (ISO 10007). The CM plan followed the elements of the implementing standard with the exception of the Configuration Board (CB) discussed in Section 7.3 of the standard. The contractor chose not to implement the CB since the standard stated "(t)he project manager may establish a configuration board…" the contractor considered the "may" statement to be optional and stated that the board was not warranted at this phase of the project and that the functions of the board outlined in the standard were fulfilled by the line organization. The Regulatory Unit found the position taken by the contractor on this issue acceptable.

As part of the programmatic review, the inspectors interviewed a number of contractor personnel involved in the design effort. Personnel were questioned on their knowledge of the technical baseline, design criteria, basis of design, authorization basis, functional specification, and the Contract. Personnel interviewed were knowledgeable of the major elements of a configuration management program, understood the procedures that governed the CM program, and knew where to get the latest revision of these procedures.

Additionally, the inspectors reviewed the implementation of the CM commitments contained in the authorization basis. In particular, Sections 1.3.16, 5.3, and 11.1 of the ISMP and Section 6.2.1 and 6.2.5 of the QAPIP were reviewed against implementing procedures. With few exceptions, the inspectors found that implementing procedures addressed the commitments in the authorization basis.

One major exception concerned the requirements in Section 5.3 of the ISMP to link design input requirements to structures, systems, and components (SSCs). During the entrance meeting, the contractor described its plan to implement a design input memorandum (DIM) process that would require designers to list in a DIM, all design input information used to develop design documents at the time the documents are being approved. This process was being tested at the time of the inspection and a procedure controlling this activity had been prepared but not issued. The contractor informed the inspectors that the DIM process, once finalized, would be used during the development of all design documents including the development of draft documents (alpha revisions to draft documents). The contractor stated they had not fully developed the list of design inputs that would be required to be entered on DIMs.

The inspectors questioned the contractor concerning how the DIM would link SSCs to design inputs, since the plan was to link DIMs to design documents, not SSCs. The contractor initially stated that all SSCs would have unique design documents; however, later they stated that a review would be performed prior to finalizing the DIM process to ensure the process complied with the authorization basis requirements. The inspectors interviewed several design engineers to assess if previous design input information was retrievable. From discussions with the engineers, the inspectors concluded that design input information, used to develop preliminary design documents, was being maintained and readily available to be referenced in DIMs, once the process is formalized.

The lack of a formal method to link design input information to SSCs would normally be considered a Finding; however, the contractor had previously identified this issue in a Quality Assurance (QA) surveillance (Surveillance Report No: SV-W375-99-QA00009, Rev. 0, dated July 22, 1999) and a management self-assessment, dated July 30, 1999. If properly implemented, the development of the DIM process should address this issue. Follow-up of contractor efforts to develop and implement the DIM process will be tracked as an Inspection Follow-up Item (IR-99-005-01-IFI).

As stated above, the contractor performed a self-assessment of the CM program and documented this assessment in a report dated July 30, 1999 (Management Self-Assessment of RPP-WTP Configuration Management.) The contractor also reviewed the CM program and documented it in QA Surveillance Report No: SV-W375-99-QA00009. The inspectors' review of the CM program found no additional issues other than those identified in the surveillance and self-assessment reports.

1.2.2.2 Configuration Management Procedure Review

For some of the procedures listed in Section 3.4 of this report, the inspectors performed a more detailed review to ensure consistency with the CM plan and authorization basis commitments. The procedure review focussed on the four major elements of CM, as described in Section 1.2.2.1, above. With exception of the issue associated with the DIM process, identified above, the inspectors found that the CM implementing procedures were consistent with the CM plan. Additionally, the inspectors found that the CM related authorization basis commitments were properly addressed in the procedures.

1.2.3 Conclusions

The inspectors observed that a CM plan was issued that followed the guidance provide in ISO Standard 10007 and addressed applicable requirements in the authorization basis. The appropriate procedures and codes of practice were in place from the onset of the design phase and continued to be used by the design staff to ensure configuration of the plant was maintained throughout the design phase. The interviewed staff were knowledgeable of the CM program and associated implementing procedures. One significant issue was self-identified by the contractor concerning the lack of a process to link design input information to SSCs. The contractor was developing a DIM process to address this requirement. Follow-up of the contractor's activities to resolve this issue will be tracked as an Inspection Follow-up Item.

1.3 APPLICATION OF CM TO SUBCONTRACTORS AND VENDORS (ITP I-102)

1.3.1 Inspection Scope

The inspectors reviewed the contractors CM program to ensure that vendors and subcontractors were required to address the elements of the contractor's CM program and that the contractor ensured the effective implementation of the vendors' and subcontractors' CM programs.

1.3.2 Observations and Assessments

The inspectors found that the contractor had not yet written subcontracts or procurement documents that necessitated the delivery of configured items or require implementation of a CM program. However, Section 4.1.6, Subcontractor and Supplier Control, of the CM plan provided the appropriate guidance, and if properly implemented, should result in CM principles being applied by subcontractors and suppliers. The inspectors also reviewed Code of Practice K70C552_0, *Code of Practice for Preparation, Checking and Approval of Specifications, Data Sheets & Bill of Material*, dated November 1998, to ensure that the appropriate CM principles were required to be specified to subcontractors and suppliers. The inspectors found that design requirements were to be specified and documents required to be supplied by the subcontractors and vendors would include the appropriate certification, drawings, calculations and manuals. The inspectors reviewed a draft specification to determine conformance with the code of practice. The review found that the contractor was following the code of practice. Detailed inspection in this area, once significant procurement activities begin, will be the subject of a subsequent CM inspection.

1.3.3 Conclusions

The inspectors found limited information to review in the application of CM to subcontractors and vendors since the contractor had not yet finalized subcontracts which require implementation of a CM program. The issued CM plan and implementing procedures provided the appropriate guidance.

1.4 DESIGN CRITERIA (ITP I-102)

1.4.1 Inspection Scope

The inspectors reviewed the contractor's methods for documenting and controlling the design criteria used to design important to safety SSCs.

1.4.2 Observations and Assessments

In accordance with the inspection procedure, the inspectors intended to review the contractor's system descriptions and design criteria associated with important to safety SSCs. However, the contractor stated that contrary to Section 6.2.5, Configuration Management, of the QAPIP, the CM program did not begin with system descriptions. The contractor stated that a revision to the QAPIP to remove that statement had been submitted to the Regulatory Unit (RU) for approval. The revised statement would replace the system descriptions with functional requirements. The contractor stated that system descriptions would be developed but not until the design was better defined. No system descriptions had been generated to date. The inspectors verified that the latest QAPIP revision, submitted to the RU on August 5, 1999, removed the reference to system description when discussing configuration management baseline documents. Although the QAPIP revision had been submitted to the RU for approval, the revision had not been approved at the time this report was written. Follow-up of resolution of this authorization basis inconsistency will be tracked as an Inspection Follow-up Item (IR-99-005-02-IFI).

The contractor defined its design criteria as the Part B Contract, the authorization basis, the basis of design, and the functional specification. The inspectors performed a cursory review of these documents and determined that they contained appropriate design criteria related information necessary to perform design activities at this stage in the TWRS-P design. The inspectors verified that these documents were readily available to staff and being adequately controlled by Project Document Control.

1.4.3 Conclusions

The contractor adequately controlled the criteria used to design the TWRS-P facility. Systems descriptions, originally intended to be baseline documents for design, were replaced with functional requirements. The functional requirements were contained in the Functional Specification and controlled by Project Document Control.

1.5 DESIGN BASELINE (ITP I-102)

1.5.1 Inspection Scope

The inspectors reviewed the CM program and procedures, and interviewed selected design and document control staff to assess the contractor's ability to properly define and control technical baseline (design baseline) information. In addition, the inspectors reviewed the contractor's

program for controlling computer software used to perform design work associated with important to safety SSCs.

1.5.2 Observations and Assessments

The contractor defined its technical baseline information as Contract Part A drawings and associated design change applications (DCAs), design criteria as defined in Section 1.4.2, above, and new design documents designated as revision 0 or above. With the exception of Part A drawings, revisions with letter designators (alpha designators) were considered draft documents and not part of the technical baseline. Beyond the Part A drawings, few new drawings had been approved as revision 0 or higher documents. From a review of the contractors document control system, the inspectors determined that technical baseline information was adequately controlled. Changes to technical baseline documents required DCAs and received distribution as discussed in Section 1.8, Design Interfaces, of this report. During the inspection, the inspectors determined that drawings, requested from Project Document Control (PDC) did not include a list of any DCAs that are expected to affect the drawings once the DCAs are implemented. The PDC manager stated that contractor staff were to access the technical baseline data files to determine if DCAs affect the drawings. Subsequently, the PDC manager stated that the contractor planned to provide requesters with a list of DCAs that have referenced the requested document as a document that could be affected by the DCAs. This notification process addressed the inspectors' concern that requesters of documents be notified of DCAs that might affect the documents requested.

The inspectors also reviewed the contractor's program for validating and verifying computer software used to perform design of important to safety SSCs. Code of practice K70C515_0, *Code of Practice for Computer Program Use,* dated November 1998, was written to provide guidance for the control of computer programs used in the design process to perform calculations and analyses that are considered "safety critical." The procedure did not provide specific requirements on how to verify and validate software. In addition, the contractor stated that a large number of design related software had been obtained from a subcontractor that had not been verified or validated by the contractor. At the time of the inspection, the contractor had been working to address this issue. Section 6.2.3, "Computer Software Control," of the QAPIP, required that "Software verification and validation testing shall occur prior to software use in preparation of final design documents and includes comparison of program results with benchmark solutions."

Since no final design documents had been prepared that relied on data obtained from software that had not been validated or verified, this issue was not considered a Finding. However, failure to address this area in a timely manner is considered a significant weakness that must be addressed before the software output can be used as input to final design efforts. Follow-up of contractor activities to address this concern will be tracked as an Inspection Follow-up Item (IR-99-005-03-IFI.)

1.5.3 Conclusions

Technical baseline information was found to be adequately defined and controlled. One significant weakness was identified concerning the lack of an adequate program for verifying and validating computer software used to perform "safety critical" calculations.

1.6 CONFIGURATION MANAGEMENT DATABASE (ITP I-102)

1.6.1 Inspection Scope

The inspectors reviewed the current and planned systems for maintaining a database of design related information. This review included interviewing Project Document Control staff and design engineers. In addition, the inspectors attended a demonstration of the contractor's proposed CM database program that was expected to have the capability to link SSCs (configured items) to all design inputs and other CM related information.

1.6.2 Observations and Assessments

As discussed in Section 1.2 of this report, the contractor was in the process of developing a design input memorandum (DIM) process that was intended to provide design input information for each design document issued. Project Document Control would then develop a database from these DIMs that would be used as part of the new CM database program in conjunction with other CM databases to provide computer terminal access to all design information linked to configured items (SSCs). This program was not expected to be in-place until late 1999 or early 2000.

The contractor's current CM database contained all controlled documents listed by document number. Although adequately controlled, this database did not link the design documents to SSCs. Since few design efforts had resulted in approved design documents, the contractor's schedule to implement the new CM database program and the DIM process had no safety impact. As discussed in Section 1.2 of this report, interviews with design engineers indicated that design input information was being informally maintained and should be easily captured once the DIM process is finalized and put in place.

1.6.3 Conclusions

The contractor had an adequate CM database in-place to control design information. However, the database did not relate SSCs to design inputs as required by Section 5.3 of the ISMP. Action being taken by the contractor to resolve this issue was comprehensive, and if properly implemented, should adequately address the ISMP requirement.

1.7 DESIGN CHANGE CONTROL (ITP I-102)

1.7.1 Inspection Scope

The inspectors reviewed the contractor's configuration management plan and implementing procedures related to design change control to determine if the program to control design changes complied with authorization basis requirements. In addition, the inspectors reviewed selected design change amendments (DCAs) to assess the implementation and effectiveness of the design change program.

1.7.2 Observations and Assessments

Design documents that had been issued and are part of the technical baseline could be changed by the use of the design change application process outlined in Procedure K70P030_2, Design *Change Control*, dated March 1999. The technical baseline included facility drawings, specifications, calculations, system descriptions and authorization basis documents. At the time of the inspection, approximately 1500 design documents had been issued, although not all of them were part of the technical baseline. Forty-seven DCAs had been issued pertaining to these documents. The initial DCAs were issued to revise the design, to support Part B activities, and to support the Part A Contract deliverables. Therefore, the technical baseline was formally established to contain the documents described above and the issued DCAs. Several DCAs were reviewed to determine if they were appropriately characterized and communicated throughout the design organization and if the contractor followed its process for analysis of the design changes. The results of these reviews are described in the sections that follow.

1.7.2.1 DCA-W375-99-00015 (DCA#15):

This DCA addressed adding separate stacks and monitoring rooms for the Pre-Treatment, Low Activity Waste (LAW) and High Level Waste (HLW) process buildings. This change affected the off gas systems and vessel ventilation systems. The DCA summary recommended multiple stacks over a single site stack based on design simplicity, lower process risk, phased construction, and lower cost.

In the checklist for the DCA, typical of all DCAs, the contractor posed a number of questions related to potential safety issues for the change and concluded that the assumptions for the stack used in the analysis with respect to air emissions documented in the Initial Safety Analyses Report (ISAR) and Hazards Analyses Report (HAR) did not change, and associated analyses were not invalidated for the project. One line of questions that were conspicuously absent from the DCA considerations had to do with seismic considerations and accident analysis. It was not clear if seismic or accident issues were different than originally presented in the HAR. In a memorandum contained in the DCA from the TWRS-P Pretreatment/Balance of Plant (PT/BOF) Hazard and Safety Analysis Lead, dated March 25, 1999, it was stated that there were no safety issues that would require resolution before the change could be implemented, but it was also stated that the upcoming Hazards and Operability Analyses (HAZOP-1) review may reveal safety issues whose resolution would impact the proposed change.

Procedure K70P030_2 stated that a Detailed Impact Assessment (DIA) was required before final disposition of the DCA, if the DCA contained SSC=s important to safety or if the initial DCA impact information was insufficient. (DIAs were required to be generally presented in the form of reports and comprise more detailed assessments of the impact of the changes covering SSCs, safety evaluations, cost benefit analysis, etc.) In this case the DCA contained both important to safety SSCs and insufficient initial impact information in the seismic area. Thus, a DIA should have been required for this DCA. In Section 5 of the DCA, it was indicated that no DIA was required. This was considered a weakness in implementation of Procedure K700P030_2 for this DCA. The contractor agreed that the procedure was not followed from the standpoint that the change included SSCs, but that while the seismic question had not been adequately resolved for the change, it would be addressed at a later date when more design information was available. The contractor agreed that the wording in this procedure lacked the flexibility to allow management to defer performing DIAs when technical justification to do so existed. The contractor stated that the procedure would be revised.

1.7.2.2 DCA-W375-99-0002 (DCA#2) & -00012 (DCA#12):

These DCAs were developed to support the addition of sugar to HLW and LAW melters. Sugar is a reducing agent which had been shown to have the effect of increasing melter throughput by as much as three times. Sugar reacts with nitrates and iron in the melter to reduce NO_x emissions and help prevent reboil and foaming of the glass.

Review of the DCAs indicated that Procedure K70P030_2 was followed, except that as in the case of DCA#15, no DIAs were required. This change involved SSCs and according to the procedure such changes required DIAs.

These DCAs were selected because, according to the contractor representatives, they were ones that were almost completed, as the necessary changes to documents had been made. The inspectors reviewed the documents that had been modified and determined that progress was being made toward making modifications in the documents identified in the DCA as being affected.

1.7.2.3 DCA-W375-99-00019 (DCA #19):

This particular DCA addressed the use of a solution of cerium-nitrate for decontamination of HLW canisters instead of the use of pressurized water. The canisters would be dipped in the cerium-nitrate solution instead of being sprayed with high pressure water. The design change originated from a meeting on January 28, 1999. The meeting minutes were referenced in the DCA.

The package was complete from the perspective of containing all of the appropriate signatures and attachments with the exception of the last signature which verifies completion of the DCA. The inspectors noted that there was no standard format specified for the DIAs that were required by K70P030_2, furthermore, the extent of the changes to the technical baseline documents were

not readily apparent. For the safety impact, in a one page summary, the functional lead made the determination that, since the potential hazards for this DCA were chemical in nature and the process was successfully implemented at West Valley Demonstration Project, the contractor could defer the hazard evaluation to the scheduled HAZOP I hazard evaluation. With the rationale provided in the safety impact discussion, the design manager determined that a DIA was not required for this DCA. The design change control procedure did not provide sufficient clarity on what is necessary in terms of understanding the safety impact of changes before they were allowed to go forward.

1.7.2.4 DCA-W375-99-00040 (DCA#40):

This DCA involved the addition of a dedicated pump maintenance facility to the pretreatment building. This DCA was classified as both a criteria change as well as a design improvement. The DCA involved numerous impacts to the technical baseline. These were captured primarily in the description of the change and in the impact assessment; however, the scope and depth of some of the impacts were hard to ascertain. For example, the mechanical impacts required the addition of utility connections to provide support to the remote facility as well as P& IDs to include features for transfer of components to the maintenance facility. The ventilation impacts involved increased supply air quantities and chilled water requirements to handle the additional heat load generated by the workshop equipment. Documents impacted by the change were not captured in the Project Document Control (PDC) database report provided to the inspectors. Furthermore, there were no actions that were documented as necessary to close the DCA. The issue concerning the erroneous database report was discussed with the PDC Manager who indicated that it was due to a computer programming problem. To resolve this issue, the contractor was reviewing the database program.

1.7.2.5 Design Change Control Summary:

The main emphasis of the design change control procedure was that of identification of design changes, identification of individuals who had responsibility associated with evaluations for the DCA, and recording approval signatures. These aspects of the procedure were considered strengths, particularly in the way they were being handled in the issued DCAs. On the other hand, the procedure has very little guidance on implementation of changes. For example, the procedure was silent on who had responsibility for approving the accuracy of document modifications associated with changes. An important purpose of design change control is to effect appropriate modifications to safety related documents. The procedure provided no guidance for tracking and handling needed document modifications, this was considered a weakness in the procedure. Notwithstanding, in several cases adequate modifications to affected documents had been made.

To date forty-seven DCAs had been issued and none had been completed. The inspectors concluded that this was partly due to the lack of implementation guidance for tracking and handling affected documents. Another contributing factor was that no target dates were established for closeout of DCAs. This was also viewed as a procedure weakness (the contractor revised this aspect of the procedure by the end of the inspection). In addition, the contractor

stated that a revision of the procedure would provide more formality to the DCA form, specifically adding a cover sheet which would highlight affected documents and provide a standard format for the impact assessments. The inspectors considered such a revision to potentially correct this weakness. The effectiveness of the revised procedure will be reviewed in a subsequent inspection.

1.7.3 Conclusions

The contractor's provisions for controlling the design change process were adequate and met the authorization basis requirements. Design change documents were appropriately reviewed and approved, and adequately addressed safety. A weakness was identified in that the design change control procedure lacked flexibility to defer performing Detailed Impact Assessments when technical justification to do so existed, and provisions to ensure that approved DCAs were implemented in an accurate and timely manner.

1.8 DESIGN INTERFACES (ITP I-102)

1.8.1 Inspection Scope

The inspectors assessed the controls of design interfaces between various internal and external organizations relative to design and design changes to ensure proper notification and coordination of facility activities. The inspectors reviewed procedures K70P554_1B, *Interface Control,* dated 8/99, and K12C023C_1, *Code of Practice for the Internal Review of Documents*, dated 05/99, against the authorization basis requirements including ISO Standard 10007. The inspectors also reviewed, *Management Self-Assessments of RPP-WTP Configuration Management*, dated July 30, 1999, and QA surveillance SV-W375-99-QA00009, Rev. 0, dated July 22, 1999. In addition, an interview with the CM, the Document Control, and Engineering Managers was conducted to discuss responsibilities of the various interfaces.

1.8.2 Observations and Assessments

From the inspectors' review of the contractor's CM implementing procedures described in Section 1.8.1, above, the inspectors determined that an administrative program was established to ensure that internal organizations were being kept informed of design and design change activities. This effort was accomplished through a design document distribution system that was directed by design management during the development of design documents and document changes. Project Document Control was required to use the distribution sheet, prepared by design management, to issue approved design documents and to provide the recipients with revisions or design change forms associated with the design documents. This process ensured the contractor that appropriated organizations and individuals were kept informed of design activities in their area of responsibility.

Based on a review of the draft revision (K70P554_1B) of the Interface Control procedure, the inspectors concluded that the procedure, when implemented, should adequately implement the

CM requirements associated with interface controls as described in the authorization basis and ISO Standard 10007.

The contractor's interface controls were focused on design activities at the current early stages of design. Additional interfaces (for example, startup, operations, and maintenance) were not required at this stage in design, but will be reviewed by the inspectors during future inspections when the interfaces are required.

1.8.3 Conclusions

Interface controls both internal and external were adequate and appropriate for this level of project development.

1.9 STAFF TRAINING (ITP I-102)

1.9.1 Inspection Scope

The inspectors assessed the implementation of CM training. To perform this assessment, the inspectors reviewed the contractor's procedures associated with training, the training profiles of selected individuals, and the training material that was developed. The inspectors also interviewed selected staff to determine their understanding of CM and how it applies to their individual positions.

1.9.2 Observations and Assessments

The inspectors reviewed the training module used to conduct CM training. The module was scheduled as a 45-minute training class. It consisted of a lesson plan with 3 stated objectives, and 20 overhead/handouts oriented toward giving the student an understanding of the 4 major elements of CM (identification, change control, status accounting, and verification and audit) as stated in the CM plan. The training included the Department of Energy's position on CM as described in DOE/RL-96-0006, *Top-Level Radiological, Nuclear and Process Safety Standards and Principles for TWRS Privatization Contractors.* The training also related the CM program to ISO Standard 10007, listed the procedures involved or affected by CM, and explained the four elements of CM with some amount of detail. The training did not cover the specifics of the design input memorandum (DIM) process, which had not yet been fully developed at the time of the assessment. The inspectors interviewed five individuals from the contractor's staff to ascertain their knowledge of CM and found that the they had a good understanding of the elements of CM and how it applied to their jobs.

1.9.3 Conclusions

The staff was adequately trained and knowledgeable of the CM plan and associated implementing procedures and understood how to apply CM to their specific job assignments. The CM training provided was adequate.

1.10 PROCUREMENT DOCUMENTS (ITP I-102)

1.10.1 Inspection Scope

The inspectors assessed the application of the principles of CM to the procurement process and reviewed the applicable engineering, procurement, and quality procedures in this area. In addition, the inspectors reviewed a procurement package and interviewed engineering, quality assurance, and procurement staff to ascertain their understanding of procurement related CM.

1.10.2 Observations and Assessments

The inspectors reviewed procedure K70C552_0, *Code of Practice for Preparation, Checking and Approval of Specifications, Data Sheets & Bill of Material*, dated November 1998, which was the governing procedure for engineering to prepare and approve specifications for procurement. The procedure required the procurement specification to address the requirements for manuals and related documentation. From interviews with the engineering staff, the inspectors determined that engineering was responsible for requiring the necessary CM documentation for procurement, including such things as as-built drawings, technical documents showing the design or conformance to the design, vendor manuals, etc. The contractor stated that they had the obligation to notify the vendor of any design changes that might occur after the procurement was received from the vendor. Notification to vendors would occur by either sending upgraded documents to the vendor or writing another procurement specification for the vendor to use. One procurement package was reviewed, SP-W375HV-M0001, Rev A, dated July 8, 1999, *Procurement Specification-HLW Canisters for Drop Test*. The contractor required reports for a number of requested quality tests, along with as-built specifications of the canister. The inspectors judged the procurement document to have contained adequate and appropriate level of detail.

The inspectors reviewed the QA procedures for document reviews, which included procedure K13C050_0, *Code of Practice for QA Document Reviews*, dated 4/99. The inspectors noted that the procedure provided a procurement evaluation checklist (Appendix 3 of the procedure), which required the QA reviewer to check procurement documents to ensure that design engineering was specifying, among other things, CM related vendor information.

1.10.3 Conclusions

The contractor's program for procuring goods and services included applicable elements of CM. The inspection was limited to a program review since limited procurement activities were ongoing at the time of the inspection.

1.11 SELF-ASSESSMENTS OF CONFIGURATION MANAGEMENT (ITP I-102)

1.11.1 Inspection Scope

The inspectors reviewed the contractor's self and independent assessments of CM. This effort included reviewing the recent management self-assessment and QA surveillance.

1.11.2 Observations and Assessments

The most recent management self-assessment was conduct in late July 1999. The self-assessment was performed by the CM Manager and covered 23 assessment attributes, which were commitments from the authorization basis. The assessment report made statements of satisfactory or unsatisfactory performance based on the CM Manager's assessment of the contractor's fulfillment of the attributes. A number of issues were identified in the self-assessment involving incomplete or inadequate procedures. The QA surveillance of CM, performed in July 1999, noted this same problem and resulted in the issuance of a deficiency report on this matter. The lack of an approved CM plan, which was noted in the self and QA assessments, was later escalated to a Corrective Action Request (CAR). The QA surveillance report noted that some portions of the CM program were not fully implemented as committed in the authorization basis, including a major element of CM, which linked the design criteria and other important design basis information to the design drawings.

The contractor's self and independent assessments resulted in the identification of a large number of implementation issues that had been or were being addressed at the time of the inspection. Improvements in CM implementation procedures and the action to implement a DIM process occurred because of these assessments, and resulted in a CM program that addressed the requirements stated in the Contract and authorization basis.

1.11.3 Conclusions

The contractor's self and independent assessments of the CM program were thorough and effective, resulting in the identification of a number of CM implementation issues that were addressed or being addressed at the time of the inspections.

2.0 EXIT MEETING SUMMARY

The inspectors presented the inspection results to members of contractor management at an exit meeting on August 12, 1999. The contractor acknowledged the observations and conclusions presented.

The inspectors asked the contractor whether any materials examined during the inspection should be considered proprietary information. No proprietary information was identified.

3.0 REPORT BACKGROUND INFORMATION

3.1 PARTIAL LIST OF PERSONS CONTACTED

Mark Platt, Safety Program Lead
Dennis Kline, Safety and Regulatory Manager
Don Edwards, Safety and Regulatory Programs Manager
Joel Hebdon, Environmental Safety and Health Manager
Ed Hughes, Engineering Manager
Andy Elsden, Technical Manager
D. O'Connor, Safety and Regulatory Programs
Mike Fish, Configuration Manager
Gail Voyles, QA Manager
Steve Lynch, Project Management Support
G. A. Blunt, Project Document Control Manager
Jim Isherwood, Design Manager (Pretreatment)
John Isherwood, Design Manager, (HLW)
Garth Duncan, Design Manager, (LAW)

3.2 LIST OF INSPECTION PROCEDURES USED

Inspection Technical Procedure I-102, "Configuration Management Assessment"

3.3 LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

IR-99-005-01-IFI	Follow-up Item	Follow-up on contractor's efforts to develop and implement the DIM process
IR-99-005-02-IFI	Follow-up Item	Follow-up on the contractor's efforts to address inconsistency between QAPIP and current practice concerning use of system descriptions
IR-99-005-03-IFI	Follow-up Item	Follow-up on the contractor's actions to address computer software verification and validation

Closed

None

3.4 LIST OF DOCUMENTS REVIEWED DURING THE INSPECTION

Code of Practice K13C003D_0, "*Code of Practice for Production of Process Based Procedures*," April 1999

Code of Practice K13C005B_1, "*Code of Practice for the Numbering of Company Integrated Management System (IMS) Documents*," May 1999

Code of Practice K13C020B_1, "*Code of Practice for Project Records Management*," May 1999

Code of Practice K13C022A_0, "*Code of Practice for Project Records Inventory and Disposition*," May 1999

Code of Practice K13C023C_1, "*Code of Practice for the Internal Review of Documents*," May 1999

Code of Practice K13C050_0, "*Code of Practice for QA Document Reviews*," April 1999

Code of Practice K13C051_0, "*Code of Practice for TWRS Privatization Quality Assurance Program Audit and Assessment*," March 1999

Code of Practice K70C013_0, "*Code of Practice for Design Review Meetings*," November 1998

Code of Practice K70C551C_0, "*Code of Practice for Preparation, Checking and Approval of Drawings & Sketches*," February 1999

Code of Practice K70C552_0, "*Code of Practice for Preparation, Checking and Approval of Specifications, Data Sheets & Bill of Material*," November 1998

Code of Practice K70C553_0, "*Code of Practice for Plant Item Naming Conventions*," March 1999

Code of Practice K70C554_0, "*Code of Practice for TWRS Pipeline and Valve Naming Conventions*," March 1999

Code of Practice K71C502_0, "*Code of Practice for Revisions to the Safety Requirements Document*," November 1998

Code of Practice K71C504_0, "*Code of Practice for Revisions to the Integrated Safety Management Plan*," November 1998

Code of Practice K71C515_0, "*Code of Practice for Computer Program Use*," November 1998

Deficiency Report DR-W375-99-QA00070 (Rev. 0)

Deficiency Report DR-W375-99-QA00071 (Rev. 0)

Management Self-Assessment of RPP-WTP Configuration Management, conducted by M. Fish, July 30, 1999

Procedure K10P008_0, "*Management Assessment*," March 1999

Procedure K13P007A_0, "*Project Records Management*," May 1999

Procedure K13P052_1, "*Quality Levels of Systems, Structures, and Components*," March 1999

Procedure K13P053_0, "*Quality Assurance Surveillance*," November 1998

Procedure K13P054_1, "*Corrective Action*," March 1999

Procedure K13P055_1, "*Corrective Action Management System*," March 1999

Procedure K13P056_1, "*Identification of Nonconforming Conditions*," March 1999

Procedure K13P058A_1, "*Supplier Monitoring and Assessments*," July 1999

Procedure K60P016A_0, "*Change Control*," January 1999

Procedure K70P003_0, "*Design Review*," November 1998

Procedure K70P008_1, "*Review and Approval of Documents*," March 1999

Procedure K70P012_0, "*Contractor's Defect Notices*," November 1998

Procedure K70P030_2, "*Design Change Control*," March 1999

Procedure K70P033_1, "*Design Change Note*," March 1999

Procedure K70P528_B, "*Managing Changes to Control the Authorization Basis*," February 1999

Procedure K70P529B_0, "*Engineering Calculations: Preparation, Checking, and Approval*," March 1999

Procedure K70P551A_0, "*Preparation, Checking and Approval of Drawings & Sketches*," November 1998

Procedure K70P554_0, "*Interface Control*," November 1998

Procedure K70P555_0, "*Design Verification*," November 1998

Procedure K70P557_1B, "*Design Inputs*," August 1999

Procedure K71P0501_0, "*Revisions to the Safety Requirements Document*," November 1998

Procedure K71P504_0, "*Revisions to the Integrated Safety Management Plan*," November 1998

Procedure K71P505A_0, "*Safety Standards and Requirements Identification*," May 1999

Quality Management – Guidelines for Configuration Management, ISO 10007, 1995, 1st edition

RPP-WTP Configuration Management Plan, PL-W375-MG0002, Rev 0, dated August 6, 1999

Surveillance Report SV-W375-99-QA, Rev. 0, *Configuration Management Program*, dated July 22, 1999

3.5 LIST OF ACRONYMS

BNFL	BNFL Inc.
BOF	Balance of Facility
CAR	Corrective Action Request
CB	Configuration Board
CFR	Code of Federal Regulations
CM	Configuration Management
DCA	Design Change Application
DIA	Detailed Impact Assessment
DIM	Design Input Memorandum
DOE	U.S. Department of Energy
HAR	Hazards Analyses Report
HAZOP	Hazards and Operability Analyses
HLW	High Level Waste
ISAR	Initial Safety Analyses Report
ISMP	Integrated Safety Management Plan
ISO	International Organization for Standardization
ITP	Inspection Technical Procedure
LAW	Low Activity Waste
NO_x	Mixture of Nitrogen Oxide Compounds
PDC	Project Document Control
PT	Pretreatment
QA	Quality Assurance
QAPIP	Quality Assurance Program and Implementation Plan
RPP-P	River Protection Project-Privatization
RU	Regulatory Unit
SC	Safety Criterion
SRD	Safety Requirements Document
SSC	Structures, Systems, and Components
TWRS-P	Tank Waste Remediation System-Privatization
WTP	Waste Treatment Plant

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