



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

99-RU-0360

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

Dear Mr. Lawrence:

QUALITY ASSURANCE INSPECTION REPORT, IR-99-002

On May 17 through May 20, 1999, the Office of Radiological, Nuclear, and Process Safety Regulation of the TWRS-P Contractor (Regulatory Unit) completed an inspection of the Quality Assurance (QA) program at the BNFL Inc. (BNFL) facility.

The inspection team identified two Findings (documented in the Notice of Finding (Enclosure 1)). The Findings resulted from BNFL not properly implementing two quality improvement related commitments in your Quality Assurance Program and Implementing Plan (QAPIP). Specifically BNFL's corrective action program did not require that cause and preventative actions be determined for all Deficiency Reports (DR) identified. In the second case, BNFL failed to convert one DR to a Corrective Action Request (CAR) after the Project QA Manager determined that the deficiency was significant. In addition to the Findings, the inspection team identified a weakness in that BNFL's quality related procedures tended to lack detail. These procedures were challenging the project, and may result in significant problems as quality related design activities move forward in the near future. This weakness is of particular concern because procedures that provide adequate detail and result in consistent and well-controlled activities are necessary to ensure acceptable quality and safety.

You are requested to provide a written response to the first Finding within 30 days, in accordance with the instruction provided in the enclosed Notice of Finding. No response is requested for the second Finding because the Project QA Manager corrected the Finding during the inspection. In addition, please provide a written description of the actions you plan to take to assess the adequacy of the level of detail of your quality related implementing procedures and the actions, if any, you plan to take to improve these procedures.

Details of the inspection, including the Findings, are documented in the enclosed inspection report (Enclosure 2).

Mr. M. J. Lawrence
99-RU-0360

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The results of our inspection revealed that BNFL's quality improvement efforts were effective in identifying and addressing issues related to implementation of BNFL's QAPIP. However, several of the areas that the team assessed had not been fully implemented because the vitrification facility is only in the conceptual design stage (developing flow diagrams and/or piping and instrumentation diagrams (P&IDs)). We encourage BNFL to continue this quality improvement effort as the River Protection Project-Privatization (RPP-P) (formerly the Tank Waste Remediation System-Privatization (TWRS-P)) effort moves forward.

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 Carrier of my staff on (509) 376-3574.

Sincerely,

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

RNP:JWM

Enclosures:

1. Notice of Findings
2. Inspection Report IR-99-002

cc w/encls:

D. W. Edwards, BNFL

NOTICE OF FINDING

Standard 4, "Safety, Health, and Environmental Program," of Contract DE-AC06-RL13308, dated August 24, 1998, between BNFL Inc. (the contractor) and the U.S. Department of Energy (DOE), defines the contractor's responsibilities under the Contract as they relate to conventional non-radiological worker safety and health; radiological, nuclear, and process safety; and environmental protection.

Standard 4, Section (c) (2) (b) of the Contract requires the contractor to comply with the specific nuclear regulations defined in the effective rules of the 10 CFR 800 series of nuclear requirements.

Title 10 of the Code of Federal Regulations Part 830, "Nuclear Safety Management," Section 120, "Quality Assurance (QA) Requirements," requires the contractor to conduct work in accordance with the requirements of the Section 120 and to develop a QA Program that reflects the requirements of Section 120.

Section (c) (1) (iii), "Quality Improvement," of 10 CFR 830.120, "Quality Assurance Requirements," requires that "processes to detect and prevent quality problems shall be established and implemented." This section further requires that "correction shall include identifying the causes of problems and working to prevent recurrence."

The contractor's QA Program is defined in BNFL-5193-QAP-01, Rev. 4, "Quality Assurance Program and Implementation Plan," dated May 1998.

1. Section 3.2.2, "Corrective Action" of the contractor's Quality Assurance Program and Implementation Plan (QAPIP) requires:

"Nonconformances and deficiencies that have a negative impact on quality shall be analyzed to determine the cause and preventive action that must be taken to eliminate the causes of nonconforming conditions to prevent recurrence."

Procedure K13P054_1, "Corrective Action," dated March 1999, requires that project personnel initiate Deficiency Reports (DR) for selected Conditions Adverse to Quality (CAQ).

Contrary to the above, on May 18, 1999, the inspectors found that Procedure K13P054_1 did not require that cause and preventive action be determined for all DRs. In addition, the inspectors identified a large number of DRs that did not specify cause or preventive actions.

This is considered an inspection Finding.

2. Section 3.3.2, "Corrective Action, of the QAPIP states that nonconformances and deficiencies that have a negative impact on quality shall be analyzed to determine the

cause and preventive action that must be taken to eliminated the causes of nonconforming conditions to prevent recurrence.” Procedure K13P054_1, "Corrective Action" dated March 1999, which implements Section 3.3.2 of the QAPIP, specifies that the Project QA Manager “Initiates Corrective Action Reports for CAQs which are considered to be significant.”

Contrary to the above, on May 18, 1999, the inspectors found that Deficiency Report DR-W375-99-QA00032 was evaluated by the Project QA Manager and determined to be “significant” without the follow-on preparation of a Corrective Action Report.

This is considered an inspection Finding.

For Finding Number 2, the Project QA Manager corrected the Finding during the inspection, the inspection team verified the correction, and no additional contractor action is required.

The Regulatory Unit requests that the contractor provide, within 30 days of the date of the cover letter that transmitted this Notice, a reply to the first Finding above. The reply should include for each Finding: (1) admission or denial of the alleged Finding, (2) the reason for the Finding, if admitted, and if denied, the reason why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further Findings, and (5) the date when full compliance with the applicable commitments in your authorization base will be achieved. Where good cause is shown, consideration will be given to extending the requested response time.

U.S. DEPARTMENT OF ENERGY
Richland Operations Office
Office of Radiological, Nuclear, and Process Safety Regulation
of the TWRS-P Contractor

INSPECTION: QUALITY ASSURANCE ASSESSMENT

REPORT NO: IR-99-002

FACILITY: BNFL Inc.

LOCATION: 3000 George Washington Way
Richland, Washington 99352

DATES: May 17-20, 1999

INSPECTORS: J. McCormick-Barger (Lead), Senior Regulatory Technical Advisor
 A. Hawkins, Senior Regulatory Technical Advisor
 S. English, Consultant
 C. Taylor, Consultant

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

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EXECUTIVE SUMMARY
Quality Assurance Assessment
Inspection Report Number IR-99-002

INTRODUCTION

This inspection of the BNFL Inc. (the contractor) Quality Assurance Program covered the following specific areas:

- Maintenance of the QAPIP (Section 1.2)
- Project Management of Procedures (Section 1.3)
- Quality Improvements and Assessments (Section 1.4)
- Documents and Records (Section 1.5)
- Work Processes (Section 1.6)
- Design (Section 1.7)
- Procurement (Section 1.8)
- Inspection and Acceptance Testing (Section 1.9)

SIGNIFICANT OBSERVATIONS AND CONCLUSIONS

- Changes to the contractor's Quality Assurance Program and Implementation Plan (QAPIP) were being adequately controlled. However, lack of a proceduralized process for making QAPIP changes that occur within the one-year mandatory review period was an example of the procedural weakness discussed in Section 1.3 of this report. (Section 1.2)
- Contractor procedures and codes of practice prescribed the appropriate QAPIP requirements; however, these procedures lacked adequate detail to ensure acceptable quality and safety. Lack of detailed implementing procedures was considered a project weakness. (Section 1.3)
- The contractor's efforts to ensure that subcontractors' Quality Assurance Programs (QAPs) met the requirements of the QAPIP were initially not well controlled. Following self-identification of this problem, the contractor took adequate action to address the issue and implement a program that appropriately specified the requirements. (Section 1.3)
- Two Findings were identified in the area of quality improvement and assessments. The first regarded the contractor not determining cause and preventive action for some deficiencies defined by the contractor's procedures as having a negative impact on quality. The second regarded where a deficiency was determined by the Project QA Manager to have a negative impact on quality, but a Corrective Action Report (CAR) was not written as required by procedures. (Section 1.4)

- With the exception of the two Findings described above, the contractor was meeting the 10 CFR 830.120 requirements for Quality Improvement and Assessments. The inspectors found that the contractor was meeting the requirements of their QAPIP and that skill of the contractor's staff was currently compensating for lack of adequate procedure detail in most cases. The processes used by the contractor for quality improvement and for conducting assessments were recently established and still evolving. The contractor was examining their QA processes for possible improvements. (Section 1.4)
- Notable good practices included management's commitment to (self) assessments which were extensive and resulted in significant improvements, and the Business Committee's efforts to review proposed changes to project-wide training requirements. (Section 1.4)
- Generally, document control and records management practices were controlled in accordance with the requirements of the QAPIP, project procedures, and codes of practice. A concern was identified regarding the manner in which copyholders maintained controlled documents. In addition, an inspection follow-up item was opened to track resolution of a DR documenting the manner in which documents and records are stored (dual storage requirements were not met). (Section 1.5)
- The design process is at a preliminary stage and could not be evaluated against the detailed requirements of the QAPIP. (Section 1.7)
- The contractor initially had not followed the QAPIP and/or its procedures for preparing, reviewing, and approving QL-1 and -2 procurement documents. The contractor had previously identified this deficiency in a Deficiency Report and had taken adequate actions to address the problem. Recent procurement activities were found to be well controlled. (Section 1.8)
- Qualification and monitoring of suppliers and subcontractors were performed in accordance with the QAPIP and associated implementing procedures. However, weaknesses were identified regarding the lack of procedural guidance related to the control of the Approved Suppliers List (ASL) and for generation of request for proposals, contracts, or other contract award documents. (Section 1.8)

QUALITY ASSURANCE ASSESSMENT

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QUALITY ASSURANCE INSPECTION REPORT

1.0 REPORT DETAILS

1.1 INTRODUCTION

The River Protection Project- Privatization (RPP-P) (formally the Tank Waste Remediation System-Privatization (TWRP-P)) effort was in the early design stages (about 5% complete) at the time of this inspection. The contractor, BNFL Inc., was actively in the process of developing flow diagrams and piping and instrumentation diagrams (P&IDs) to support the conceptual design of the facility. Many of the quality related design programs were in-place but not fully implemented because of the stage of design. The inspection reviewed the contractor's quality related design programs and when applicable, the implementation of the programs.

In accordance with the RPP-P Contract (Contract DE-AC06-96RL13308 between U.S. Department of Energy (DOE) and the contractor, dated August 24, 1998) and specifically 10 CFR 830.120, "Quality Assurance Requirements," the contractor was required to have a Quality Assurance Program and Implementation Plan (QAPIP) that assigned responsibilities and authorities, defined policies and requirements, and provided for the performance and assessment of work.

The inspectors reviewed the contractor's implementing procedures to determine if they complied with the commitments in the QAPIP and Safety Requirements Document (SRD). In addition, the inspectors assessed the implementation of the contractor's QAPIP program as it related to the current design phase of the RPP-P Contract to ensure that the contractor was following its program and procedures and that Quality Level (QL)-1 and QL-2 functions were being properly conducted.

1.2 MAINTENANCE OF THE QAPIP (INSPECTION TECHNICAL PROCEDURE (ITP) I-101)

1.2.1 Inspection Scope

The inspectors assessed the adequacy of the contractor's policies and procedures used to review and revise the QAPIP. The inspectors interviewed the Document/Records Certification Lead and the Environmental Lead to assess the process. The inspectors also reviewed the policy and procedures described below against the contractor's commitments in the authorization bases, and reviewed the rationale for the proposed changes to Revision 4 of the QAPIP.

1.2.2 Related Contractor Commitments

Section (c) (1) (i), "Management," 10 CFR 830.120, "Quality Assurance Requirements," required the following:

- “The QAP [Quality Assurance Program] shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.”
- “The QAP shall describe management processes, including planning, scheduling, and resource considerations.”

Section 1.5 of the contractor’s QAPIP stated that:

- “The TWRS-P Project Manager and TWRS-P Project QA Manager shall perform an annual review of the TWRS-P Project QAP, project quality policies, and implementing project procedures for conformance with applicable regulatory and quality requirements. Changes resulting from the review shall be documented and controlled.”
- “Changes to the QAP and Implementation Plan that affect commitments specified in the previously approved QAP and Implementation Plan shall be submitted to the RU for review and approval 30 days before the implementation of subject changes. These changes submitted for approval to the DOE shall be regarded as approved 30 days after submittal unless approved or rejected by the DOE at an earlier date.”

1.2.3 Observations and Assessments

The inspectors interviewed contractor QA personnel to determine the process for developing, reviewing, approving, and issuing revisions to the QAPIP. The inspectors were informed that K13P005_0, “Quality Assurance Program: Preparation, Review, Approval, and Distribution,” dated March 1999, was the procedure used to control the revision process for the QAPIP.

The inspectors reviewed K13P005_0 and examined objective evidence of the contractor’s activities associated with revising the QAPIP. For example, the inspectors examined the change process of Revisions 0, 1, and 2 of the QAPIP and the approval letter from the Regulatory Unit (RU), dated February 12, 1997. The inspectors also examined Revision 3, issued March 25, 1998, and Revision 4, issued May 8, 1998, as well as the approval letter from the RU, dated June 2, 1998. The inspectors also examined objective evidence that following approval by the RU, the QAPIP revisions were distributed to controlled copyholders and mandatory classroom training was required.

Contractor QA personnel told the inspectors that they did not have an Interim Change Notice (ICN) process to allow for changes that occur within the one-year mandatory review period. The review and revision process was initiated a couple of months before the annual deadline. The inspectors were told that any proposed changes identified during the year were documented in e-mail messages and recorded on a marked-up copy of the document. However, documentation of proposed changes to the QAPIP were not available for review.

Revision 4 of the QAPIP contained current upper management organizational structures, functional responsibilities, levels of authority, and interfaces. Although the contractor had no ICN process, when questioned, contractor staff confirmed that major upper management organizational changes would result in the initiation of a mid-year QAPIP revision. No major

organizational changes to upper management had occurred to date. Lack of a proceduralized process for making QAPIP changes that occur within the one-year mandatory review period was an example of the procedural weakness discussed in Section 1.3 of this report.

The inspectors examined activities associated with issuing the upcoming Revision 5 of the QAPIP. Since the QAPIP is part of the authorization basis, the contractor had prepared an Authorization Basis Change Notice and attached it to a table entitled, "Rationale for Proposed Changes to Revision 4 of the QAPIP." This table included the following information:

- Item number;
- Page number of the change;
- Description of the proposed change;
- Reason for the proposed change; and
- The question "Affects the Authorization Basis? (Yes/No)"

The inspectors determined that the change process being followed for Revision 5 to the QAPIP was in accordance with contractor procedures and well controlled.

1.2.4 Conclusions

The inspectors determined that changes to the QAPIP were being adequately controlled. However, lack of a proceduralized process for making QAPIP changes that occur within the one-year mandatory review period was an example of the procedural weakness discussed in Section 1.3 of this report.

1.3 PROJECT MANAGEMENT OF PROCEDURES

1.3.1 Inspection Scope

The inspectors assessed the adequacy of the contractor's policies and procedures against the commitments in the QAPIP. The inspectors interviewed the Project QA Manager, and received a presentation by the contractor during the inspection entrance meeting related to the hierarchy of procedures and codes of practice. In addition, the inspectors reviewed procurement documents to verify that subcontractors' were required to either follow the contractor's QAPIP or have a QAP that met applicable requirements of the contractor's QAPIP.

1.3.2 Related Contractor Commitments

Section 1.2.3 of the contractor's QAPIP stated that:

- "The development and implementation of clear and concise implementing procedures that accurately address the management controls and work processes are key to the effectiveness of the TWRS-P QAP. The procedures and management controls necessary to execute work shall address all phases of the project as defined by the Contract."

- “The QAP shall be implemented through project management documents using a tiered approach that includes the following:
 - project management plans;
 - project management procedures;
 - implementing procedures and work instructions.”

Section 1.2.3.1 of the contractor’s QAPIP stated that “Subcontractors performing work for the project are required to work to the QAP.”

Section 5.2 of the contractor’s QAPIP stated that “All activities affecting quality shall be prescribed by, and performed in accordance with, documented, management-approved procedures, instructions, and design documents.”

1.3.3 Observations and Assessments

1.3.3.1 Procedure Adequacy

During the course of the inspection, the inspectors reviewed several procedures and codes of practice. In general, these documents provided a flow chart that defined the position titles for staff and the activities for which these staff members were responsible. However, procedures and codes of practice did not provide details of how the specific activities were performed. Although interviews with staff members generally indicated that personnel understood and performed the activities specified in the procedures, examples of minor problems associated with procedure implementation were identified in Section 1.4 of this report.

Examples of activities or functions that were not contained in contractor procedures include the following.

- Specifying the control of a list designating personnel with access to the project records files
- Specifying a process for retrieving records files without undue delay
- Specifying the frequency for auditing suppliers and subcontractors on the Approved Suppliers List
- Specifying the process for removing a supplier or subcontractor from the Approved Suppliers List
- Providing specific instruction for converting a purchase requisition into a purchase order or contract
- Specifying a technique to document audits of contractors

- Specifying a process to allow for QAPIP changes that occur within the one-year mandatory review period.

The inspectors expressed concern to the contractor over the lack of detail in procedures. With many of the important to safety design functions yet to begin, lack of detail in procedures may result in quality related problems as the project progresses. Lack of detail in procedures was considered a project weakness. The resolution to this weakness will be tracked as an inspection follow-up item (IR-99-002-01-IFI).

1.3.3.2 Pass-down of QAPIP Requirements to Sub-contractors

As stated in Section 1.9 of this report, procurement had been limited to services, initially procured with the use of “letter contracts” which had not received QA review. As a result, the initial procurement activities did not specify the requirement to follow the contractor’s QAPIP. The contractor identified this problem and issued a deficiency report, DR-W375-QA00001, on December 28, 1998. During the inspection, the contractor was in the process of converting the letter contracts to definitive contracts. In addition, the contractor had issued procurement procedures that, among other things, contained the requirements in the QAPIP related to subcontractors having a QAP that met the requirements of the contractor’s QAPIP. The inspectors reviewed copies of several subcontractors’ definitive contracts (e.g., GTS-Duratek, PNNL, and SRTC), and determined that they contained appropriate QA requirements and had been reviewed by the QA organization. In addition, the contractor sent copies of the QAPIP to the subcontractors and the contractor’s formal review of the subcontractors QAP were a condition of the definitive contracts.

Although the letter contracts were not issued in accordance with the QAPIP, the contractor had records that indicated that the QA staff had performed on site surveillance of the subcontractors before awarding the letter contracts. The QA surveillance reports indicated that the subcontractors’ QA programs met the requirements of the contractor’s QAPIP. Based on the contractor’s self-identification of the problems associated with the use of the letter contracts, the QA surveillance of the subcontractors prior to contract award, the actions to convert the letter contracts to definitive contracts, and the actions to develop procurement procedures that incorporate QAPIP requirements, the inspectors had no concerns with the contractor’s program for assuring that subcontractor QAPs met the requirements of the contractor’s QAPIP.

1.3.4 Conclusions

The inspectors determined that contractor procedures and codes of practice prescribed the appropriate QAPIP requirements; however, these procedures lacked adequate detail to ensure acceptable quality and safety. Lack of detailed implementing procedures was considered a project weakness. The contractor’s efforts to ensure that subcontractor QAPs met the requirements of the QAPIP were initially not well controlled. Following self-identification of this problem, the contractor took adequate action to address the issue and implement a program that appropriately specified the requirements.

1.4 QUALITY IMPROVEMENT AND ASSESSMENTS (ITP I-101)

1.4.1 Inspection Scope

During this review, the inspectors examined the contractor processes associated with: surveillance, independent assessments, management (self) assessments, trending, identification of deficiency reports and corrective action reports, corrective action tracking, employee suggestions and the use of the corrective action management system (CAMS).

In addition to personnel interviews, the inspectors reviewed the following written material:

- 3 auditor qualification files
- 1 Corrective Action Report (CAR)
- 1 in process training file
- The independent assessment (audit) of GTS Duratek conducted December 8 - 11, 1998
- Management assessments from the Procurement, Configuration Management, and the Pre-Operations Managers
- 6 closed Deficiency Reports (DRs) and verification forms
- Reports from the CAMS database
- K13P055_1, "Corrective Action Management System," dated March 1999
- K10P008_0, "Management Assessment," dated March 1999
- K13C053_0, "Code of Practice for TWRS Privatization Quality Assurance Audit and Assessment Personnel Qualification," dated March 1999
- K13C051_0, "Code of Practice for TWRS Privatization Quality Assurance Program Audit and Assessment," dated March 1999
- K13P002_0, "Internal Management Systems Assessment," dated December 1998
- K13P054_1, "Corrective Action," dated March 1999
- K13P051_1, "Authority to Stop Work," dated March 1999
- K13P059_0, "Identification, Tracking, and Reporting of Price Anderson Amendment Act Noncompliance," dated October 1998
- K13P062_0, "Quality Trending," dated February 1999.

1.4.2 Related Contractor Commitments

The contractor addressed quality improvement in Section 3, management assessments in Section 9, and independent assessments in Section 10 of the QAPIP.

- Section 3.0, "Quality Improvement," of the QAPIP, stated:

"Processes are established and implemented to detect and prevent quality problems, prevent recurrence, and to provide for quality improvement."
- Section 3.2.2, "Corrective Action," defined the requirements of corrective action as:

"Nonconformances and deficiencies that have a negative impact on quality shall be analyzed to determine the cause and preventive action that must be taken to eliminate the causes of nonconforming conditions to prevent recurrence."

1.4.3 Observations and Assessments

1.4.3.1 Surveillance Program

The surveillance program was being implemented but less frequently than identified in the January 1999 assessment schedule. The contractor previously identified this as a Finding during the contractor's corporate audit. The contractor was working to a new assessment schedule (identified as May 15, 1999) that was not officially issued. The schedule had a high correlation between the planned RU inspections and the contractor's planned assessments. However, the schedule did not reflect a balanced approach to looking at activities in all 10 areas of the QAPIP. For example, the assessment schedule did not address Documents and Records (Section (c) (1) (iv) of 10 CFR 830.120 and Chapter 4 of the QAPIP.)

1.4.3.2 Corrective Action

The inspectors interviewed selected contractor staff concerning the quality improvement program. The inspectors determined that not all staff understood the relationships among management assessments, independent assessments, improvement suggestions, deficiency reporting, and procedure/work revisions. The inspectors observed that several managers did not know how to document the results of management assessments. Most staff interviewed by the inspectors could not accurately describe the difference between a DR and a CAR. The inspectors noted that the contractor was providing additional training on the Quality Improvement Process at the time of the assessment.

Aspects of the contractor's corrective action assessment system required clarification. The inspectors observed that corrective actions for Findings in management assessments were procedurally outside the CAMS (e.g. - root cause and Price-Anderson Amendment Act review not required). Procedures did not clearly specify how managers should report cross-functional issues or who was responsible for identifying and preparing DRs from management assessments. (The QA organization was reviewing management assessment results individually to determine if corrective action was required.) The following definition of when the person doing a management assessment should write a DR may not be clear to most managers:

“Deficiency Reports (DR) shall be initiated to identify and correct discrepancies associated with implementing procedures and document(s) which affect QL-1, QL-2 and IHLW [Immobilized High Level Waste] affecting activities or SSCs.” (Procedure K13P054_1)

The process for tracking corrective actions was resource intensive. The inspectors observed that the CAMS input process required significant intervention by a knowledgeable QA representative to go from the input forms to the database. In addition, as noted previously, QA was responsible for screening input from all quality improvement sources to determine if a CAR should be

written. This was working for the limited number of documents currently received, but may not work as the number of documents increase.

During review of selected DRs, the inspectors found that the contractor was not determining cause and preventive action for deficiencies defined by the contractor's procedures as having a negative impact on quality. This was contrary to Section 3.2.2, "Corrective Action" of the QAPIP. This was considered a Finding (IR-99-002-02-FIN).

The inspectors also found one instance where a deficiency was determined by the Project QA Manager to have a negative impact on quality, but a Corrective Action Report (CAR) was not written. This was contrary to Procedure K13P054_1, which implemented Section 3.3.2 of the QAPIP, and required the Project QA Manager to initiate Corrective Action Reports for conditions adverse to quality which were considered to be significant. This was considered a Finding (IR-99-002-03-FIN). The Project QA Manager took action during the inspection to have a CAR written to address the condition described in the DR.

1.4.3.3 Procedures

From a review of contractor procedures, the inspectors determined that the procedures lacked detail. This was also identified by the Contracts and Procurement organization in their management assessment as the cause of a lack of common understanding regarding expectations. Lack of detail in procedures had caused implementation problems. For example, the inspectors observed that two experienced auditors used two acceptable, but distinctly different, techniques to document the GTS Duratek audit because the contractor's audit procedure did not describe a specific technique. In addition, the inspectors noted several problems with traceability among the documents that form the contractor's CAMS. This occurred where procedures did not specify numbering or tracking requirements. This issue was further discussed in Section 1.3, "Project Management of Procedures" of this report.

1.4.4 Conclusions

Two Findings were identified. The first regarded the contractor not determining cause and preventive action for deficiencies defined by the contractor's procedures as having a negative impact on quality. The second regarded where a deficiency was determined by the Project QA Manager to have a negative impact on quality, but a CAR was not written as required by procedures. With the exception of the two Findings, the inspectors found that the contractor met the 10 CFR 830.120 requirements for Quality Improvement and Assessments. The inspectors found that the contractor met the requirements of their QAPIP and that skill of the staff was currently compensating for lack of adequate procedure detail in most cases.

The processes used by the contractor for quality improvement and for conducting assessments were recently established and still evolving. The inspectors noted that the contractor was examining their QA processes for possible improvements.

The inspectors observed two notable good practices:

1. Management commitment to management (self) assessment was extensive. Management assessments conducted to date resulted in significant improvements.
2. The process of having the contractor's Business Committee review proposed changes to project-wide training requirements.

1.5 DOCUMENTS AND RECORDS (ITP I-101)

1.5.1 Inspection Scope

The inspectors assessed the plan and procedures described below that established the contractor's program for controlling documents and records. The inspectors also interviewed staff responsible for the control of documents and records and examined selected documents and records to ensure that they were properly controlled in accordance with the authorization bases requirements and contractor procedures.

Specifically, the inspectors assessed the following procedures and documents:

- K13C020B_1, "Code of Practice for Project Records Management," dated May 1999
- K13C022A_0, "Code of Practice for Project Records Inventory and Disposition," dated May 1999
- K13C023A_1, "Code of Practice for the Internal Review of Documents," dated April 8, 1999
- K70C528D_0, "Code of Practice for Managing Changes to Control the Authorization Basis," dated April 1999.

1.5.2 Related Contractor Commitments

Section (c) (1) (iv), "Documents and Records," of 10 CFR 830.120, "Quality Assurance Requirements," required the following:

- "Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design."
- "Records shall be specified, prepared, reviewed, approved, and maintained."

Section 4 of the QAPIP provided specific requirements for the control of Documents and Records.

1.5.3 Observations and Assessments

Controlled documents were maintained on-line, and were available to contractor personnel through desktop computers via "Read Only" Local Area Network (LAN) access files. When the contractor updated these controlled documents, a notice was sent to personnel to notify them of this update.

Some managers had elected to maintain their own hard copies of selected documents. The inspectors reviewed a sample of seven copyholders of various controlled documents to verify that they had the most current revision of the documents. Of this sample, one copyholder possessed the most recent version of the Standards Requirement Document (SRD), but had a copy number that was different than the number that Project Document Control had provided to the inspectors. Two other copyholders had copies of the SRD that did not contain change notice 2a and 2b. After discussing this deficiency with the copyholders, one of the copyholders found the change notices on his desk; the other was not able to find the notices. All other documents reviewed were the correct revision. The inspectors expressed to management the concern that hard copy control of quality related documents was not being well maintained by copyholders.

The inspectors verified that changes to contractor procedures and codes of practice were reviewed and approved by the originating organization. The sample of procedures verified included the following: K13C003D_0, "Code of Practice for Process Based Procedures," dated April 20, 1999, K70P011A_0, "Control and Verification of Contractor Work," dated November 21, 1998, K70P001_1, "Use of the Design Process," dated February 1999, K70C530B_0, "Code of Practice for ALARA in Design," dated March 12, 1999, and K70C003A_0, "Code of Practice for Design Change Control, dated March 1, 1999.

In addition, the inspectors verified changes to controlled documents were reviewed and approved by the originating organization, such as the Integrated Safety Management Plan (ISMP), the SRD, and the Radiation Protection Program for Design (RPP). No approval signatures could be located for Revision 3 of the ISMP, dated July 7, 1998, and Revision 0 of the SRD, dated June 10, 1998 (prior to signing the current RPP-P Contract). However, Revisions 4 of the ISMP and Revision 1 of the SRD (both dated December 2, 1998) were signed by appropriate levels of management. Both Revision 0 (dated October 9, 1998) and Revision 1 (dated December 2, 1998) of the Radiation Protection Plan (RPP) were appropriately signed.

The inspectors learned that earlier versions of the controlled documents were maintained in the files permanently. These documents were maintained in the same file as the current versions, and were not marked in any way. Contractor staff informed the inspectors that personnel needed to look in the computer to learn which was the most recent version of a specific document. The computer program labeled previous document versions with an "I" for inactive and an "A" for active. Previous versions of procedures were marked "superseded."

The inspectors were told that no project records retention and turnover plan had been developed to date; however, the project was under a moratorium on getting rid of records until a plan is developed. The inspectors were told that this plan would be completed prior to the due date of April 2000 (stipulated in the Deactivation Plan required by the Contract). In addition, retention times were not included on the record indices. The inspectors were told that retention times would be included in the new Data and Acquisition Sharing (DASH) system.

The inspectors verified that records were legible, dated, paginated, identifiable to the project or service involved, and maintained in an orderly manner. One anomaly was identified by the inspectors: the copy of DR-W375-QA00004 (dated December 11, 1998) that was maintained in the Deficiency Report file, had not been approved and dated by the Project QA Manager;

however, the copy attached to Audit Report AR-W375-QA00001 (dated January 12, 1999) was dated and approved.

The inspectors verified that corrections to documents were generally initialed and dated by the person making the change. In one instance, a correction to a calculation cover sheet (corrected the calculation identifier number) was made by the Project Administration Lead under verbal authorization by the author of the calculation. There was no documented evidence of the authorization to make the corrections; however, the correction was administrative in nature.

The inspectors learned that the contractor did not maintain and store records in remote, duplicate locations. The Project Administration Manager had identified this condition and documented it in Deficiency Report DR-W375-99-QA00029, Revision 0, dated April 26, 1999. Instead of dual storage, the contractor stored and maintained records in one-hour fire-rated file cabinets. The inspectors verified the one-hour fire-rated file cabinets. Resolution of the DR will require either changing the QAPIP to reflect the current storage arrangement, or change the arrangement to comply with the requirements in the QAPIP. This issue will be tracked as an inspection follow-up item (IR-99-002-04-IF1).

The inspectors verified that the contractor had developed a procedure that contained the records storage and maintenance requirements listed in QAPIP Section 4.2.3. With the exception of the dual storage requirements issue discussed above, only the following two items were not included in the procedure (i.e., K13C020B_1):

- list designating personnel with access to the files; and
- retrieval of information without undue delay.

Within the last month, the contractor had developed a list designating personnel with unescorted access to the files. Although it was not documented, the inspectors were told that retrieval of information without undue delay is accomplished by staggering lunch hours so that an authorized person was available to escort personnel into the files at all times during regular working hours.

1.5.4 Conclusions

Generally, document control and records management practices were controlled in accordance with the requirements of the QAPIP, project procedures, and codes of practice. A concern was identified regarding the manner in which copyholders maintain controlled documents. In addition, an inspection follow-up item was opened to track resolution of a DR documenting the manner in which documents and records were stored (dual storage requirements not met).

1.6 WORK PROCESSES (ITP I-106)

Section 5.0 of the QAPIP specified requirements and responsibilities associated with control of work processes, equipment, and conditions that affect the quality of services and products. During the current phase of the RPP-P Contract, work was limited to preliminary design. Consequently, the inspectors limited the inspection in this area to reviewing for adequacy the

procedures associated with the activities specified in the other sections of this inspection report. Section 1.3, "Project Management of Procedures" of this report, provided this assessment. During future inspections, as the contractor's activities progress, the inspectors will focus on the adequacy of work control programs related to performing special processes, using and controlling measuring and test equipment, handling and shipping quality related materials, and other quality related work activities.

1.7 DESIGN (ITP I-106)

1.7.1 Inspection Scope

The inspectors expected to review design activities that were under configuration control. However, due to the state of the design process, calculations and drawings were at a preliminary stage and not approved or put under revision control. Therefore, the inspectors limited activities to a review of the planning underway to address the QA aspects of design. This was done through a series of personnel interviews conducted in a vertical slice through a selected portion of the design organization.

In preparing for the assessment, the inspectors reviewed several of the design-related procedures (codes of practice) and identified several apparent inconsistencies. These inconsistencies were pursued during the inspection.

1.7.2 Related Contractor Commitments

The contractor addressed Design in Section 6 of the QAPIP.

- Section 6.2, "Requirements," of the QAPIP stated:

"The TWRS-P design process shall be established and implemented for design using sound engineering and scientific principles and appropriate standards."

This was consistent with Section (c)(2)(ii), "Design," of 10 CFR 830.120, "Quality Assurance Requirements," which requires that "items and processes shall be designed using sound engineering/scientific principles and appropriate standards".

1.7.3 Observations and Assessments

Most observations resulting from interviews with contractor staff were integrated into Section 1.4, "Quality Improvements and Assessments," of this inspection report. Procedural inconsistencies that were not resolved in discussions with contractor staff, resulted in the one observation, as follows.

Some procedures were internally inconsistent. The inspectors reviewed several procedures where text and flow diagrams were not clearly related. For example, K70P529_0, "Engineering Calculations: Preparation, Checking, and Approval," dated March 1999, page 8, called for the originator to submit results to the Project Database; however, this was not reflected on the flow

diagram. The text referred to a Project Database and an Updated Project File Log and the flow diagram referred to a Discipline Calibration Log. There were multiple logs and databases and from interviews with contractor staff, they were unfamiliar with the titles. For example, K13P053_0, “Code of Practice for TWRS Privatization Quality Assurance Audit and Assessment Personnel Qualification,” dated November 1998, page 4, called for a Surveillance Status Log. However, contractor staff did not know of this log – but they had equivalent data available from the CAMS. The inspectors had a question concerning the Standards Identification Database called out in K70C529_0. The individual being interviewed indicated that he was only familiar with the Safety Standards Database.

In addition, position titles and roles described in some procedures did not match the current organization chart and staff was not able to clearly identify the positions described. For example, the individual interviewed concerning piping calculations did not recognize if he was the “Discipline Lead” who had the responsibility to approve calculations per K70P529.

The inspectors observed that the contractor was reviewing and modifying procedures as they were put into use to correct such problems.

1.7.4 Conclusions

The inspectors found that the design process is at a preliminary stage and could not be evaluated against the detailed requirements of the QAPIP.

1.8 PROCUREMENT (ITP I-106)

1.8.1 Inspection Scope

In order to assess the contractor’s implementation of its process for procuring QL-1 and QL-2 items and services, the inspectors interviewed the Commercial Manager, the Materials Manager, the Procurement Manager, and the Document/Records Certification Lead within the contractor’s Quality Assurance (QA) Department. The inspectors reviewed various documents such as the Approved Suppliers List (ASL), procurement documents for selected suppliers, copies of pre-award desk surveys, and audits of suppliers and subcontractors during the inspection.

1.8.2 Related Contractor Commitments

Section (c) (2) (iii), “Procurement”, of 10 CFR 830.120, “Quality Assurance,” required that:

- “Procured items and services shall meet established requirements and perform as specified.”
- “Prospective suppliers shall be evaluated and selected on the basis of specified criteria.”
- “Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.”

Section 7.0, "Procurement," of the QAPIP, provided the contractor's quality related requirements for procurement activities.

1.8.3 Observations and Assessments

1.8.3.1 Review of Procurement Documents

The contractor informed the inspectors that QL-1 and -2 procurement activities had been limited to procuring services; no materials had been procured. The inspectors were also informed that when the Contract was signed (August 24, 1998) procurement procedures and staff were not available onsite. Some QL-1 and -2 services, however, were needed immediately to support the preliminary design of the facility. To expedite the procurement process, the contractor's corporate office issued several "letter contracts." The inspectors reviewed the letter contracts for the following subcontractors:

- GTS-Duratek;
- Pacific Northwest National Laboratory (PNNL); and
- Savannah River Technology Center (SRTC).

The inspectors determined that these letter contracts did not contain evidence of Quality Level designation or Project QA Manager review. In addition, these contracts did not contain quality assurance requirements specified in Section 7.2.1, "Technical Requirements," of the QAPIP. When brought to the Project QA Manager's attention, he informed the inspectors that this problem had been identified by his QA auditors in December 1998. Deficiency Report DR-W375-QA00001 was written to document this concern on December 28, 1998.

To resolve the issues identified in the DR, the contractor revised its procurement procedures and was taking action to replace the letter contracts with definitive contracts. The inspectors reviewed a sample of these definitive contracts and determined that they contained the necessary QA requirements and were being reviewed by the QA organization.

The inspectors also reviewed the first procurement document begun in Phase 1 - Part B of the RPP-P Contract, the Request for Proposal (RFP) for the geotechnical field investigation and laboratory analysis. The QA Department had designated the procurement as QL-1, and there was evidence of review and approval by the Project QA Manager. The RFP was issued in May 1999, and contained the following technical and quality assurance requirements:

- SP-W375-C00001, Technical Specification for Geotechnical Field Investigation;
- SP-W375-C00002, Technical Specification for Laboratory Testing of Soil and Rock Samples;
- SP-W375-C00003, Technical Specification for Geotechnical Engineering Analysis and Reporting; and

- SP-W375-C00004, Technical Specification for Quality Assurance Requirements for Geotechnical Investigation and Geotechnical Engineering.

The inspectors concluded that the contractor's QA activities associated with the RFP were consistent with regulatory requirements.

1.8.3.2 Procurement Pre and Post Award Surveys

During interviews, the inspectors learned that the contractor's QA Department conducted pre-award surveys on the GTS-Duratek and SRTC QA Programs, and the sub-contractors were placed on the TWRS-P Approved Suppliers List (ASL) in August 1996. A pre-award survey was performed on PNNL's QA Program on August 13, 1998, and PNNL was placed on the ASL at that time.

The inspectors reviewed the TWRS Comment Review Record Sheet, dated October 13, 1998, which documented the pre-award desk survey conducted for SRTC. The review resulted in seven minor editorial comments by the QA reviewer. These comments were resolved by SRTC, and their QA Program was approved by the contractor on November 4, 1998.

The contractor's pre-award survey on PNNL concluded that PNNL's QAP met the requirements of 10 CFR 830.120.

The inspectors reviewed the results of post-award desk surveys that were conducted by the contractor. These surveys were performed by comparing the subcontractor's QA Program to the requirements specified in the QAPIP. The inspectors reviewed surveys for the following subcontractors:

- GTS-Duratek, and;
- SRTC.

The inspectors learned that on-site post-award surveys were performed at GTS-Duratek on March 11-13, 1997, July 9-11, 1997, and December 8-11, 1998. The inspectors reviewed the December 1998 GTS-Duratek audit report (i.e., AR-W375-QA-00001) and checklists. In addition, the inspectors reviewed the February 1999 post-award audit of SRTC (audit report, AR-W375-QA-00002). The contractor had conducted two post-award audits on SRTC: April 29 through May 1, 1997 and February 24, 1999. The reports reviewed indicated that the audits were detailed and adequate for the activities specified in the contracts. The contractor had scheduled a PNNL post award survey for the summer of 1999.

1.8.3.4 Review of the Approved Suppliers List (ASL)

The inspectors obtained a copy of the contractor's ASL maintained by the Project QA organization. This List was relatively small, reflecting the lack of significant procurement activities to date. The inspectors verified that the QL-1 and -2 suppliers discussed above were on the ASL and that the QA staff had evaluated the listed suppliers and determined that they met the applicable RPP-P quality requirements and commitments.

During interviews with procurement staff, the inspectors were provided a copy of the contractor's corporate ASL. From discussions with the Project QA Manager, the inspectors learned that the corporate ASL was used as a reference document. Suppliers on that List could not be used by the contractor until a review of the corporate supplier surveys were made by QA to determine if the supplies met applicable RPP-P requirements. Once the review was successfully completed, the suppliers would be added to the contractor's ASL.

Based on the above, the inspectors determined that the contractor's control of the ASL for QL-1 and QL-2 suppliers was adequate.

1.8.3.5 Procurement Procedures Review

Because of the DR described in Section 1.8.3.1 above, the contractor revised the purchase requisition procedures to include requirements and controls applicable to QL-1 and -2 items and services. The majority of procurement quality assurance requirements specified in QAPIP Section 7.2.1, were delegated to an appendix in procedure K40P001_0, "Procurement Process," dated February 1999, and K40C001_0, "Code of Practice for Preparing Purchase Requisitions," also dated February 1999.

However, in the body of the two procedures, a note indicated that the subject appendix should not be interpreted as requirements. This problem had earlier been identified by DOE, RPP-P staff during its review of the QAPIP and selected implementation procedures. Consequently, the contractor was able to show that actions were being taken to address the inappropriate note in the two procurement procedures. Since the two procedures described above had not yet been revised to remove the note, the inspectors will track this item as an inspection follow-up item (IR-99-002-05-IFI).

The inspectors identified that the contractor's procedures for procurement of goods and services covered quality related activities through the generation of purchase requisitions, but did not address requirements for generating requests for proposals, contracts, or other contract award documents. The Procurement Manager informed the inspectors that a detailed procedure was being prepared to address those activities. In addition, the inspectors determined through interviews with QA staff, that there were no procedures for describing the process for deleting a supplier or subcontractor from the ASL, or describing the frequency for performing re-qualification audits for suppliers and subcontractors on the ASL. The lack of procedural guidance is also discussed in Section 1.3, "Project Management of Procedures," of this inspection report and these issues were considered examples of the weakness identified in that section.

1.8.4 Conclusions

The inspectors determined that the contractor initially had not followed the QAPIP and/or its procedures for preparing, reviewing, and approving QL-1 and -2 procurement documents. The contractor had previously identified this deficiency in a Deficiency Report and had taken adequate actions to address the problem. Recent procurement activities were well controlled.

The inspectors determined that qualification and monitoring of suppliers and subcontractors were performed in accordance with the QAPIP and implementing procedures. However, examples of the weakness identified in Section 1.3, were identified in this section for the lack of procedural guidance related to the control of the ASL and for generation of requests for proposals, contracts, or other contract award documents.

1.9 INSPECTION AND ACCEPTANCE TESTING (ITP I-101)

In accordance with Table A-1, "Quality Assurance Program Implementation Matrix," of the QAPIP, the Inspection and Acceptance Testing program defined in the QAPIP is not required during preliminary and detailed design. However, it is required during procurement. The inspectors reviewed this area to determine if procurement activities had progressed to where inspection and acceptance testing would be required. As discussed in Section 1.8 of this report, procurement was limited to services. Consequently, neither the contractor had nor needed an inspection and acceptance-testing program.

When contractor activities progress to where QL-1 and QL-2 items are procured, the contractor will need this program. The inspectors will review this area at that time.

2.0 EXIT MEETING SUMMARY

The inspectors presented the inspection results to members of contractor management at an exit meeting on May 20, 1999. The contractor acknowledged the observations, conclusions, and Findings 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

M. J. Lawrence, Executive Vice Present and General Manager
Gale Voyles, Quality Assurance Manager
Dennis Kline, Safety and Regulatory Manager
Marsha Eades, Inspection Liaison
Maurice Gilmore, Environmental Lead
Nigel Lockwood, Technical Manager (VIT)
Tino Maciuca, Lead Documents Certification
Steve Morgan, Commercial Manager
Ed Higginbotham, Materials Manager
Gene McCaffrey, Procurement Manager
Mark VonWeber, Senior QA Specialist (Surveillance)
George Blunt, Project Administration Manager

Dana Trethewey, Project Administration Lead
 Chris Burrows, Project Manager
 Ed Hughes, Engineering Manager
 Al Boos, Area Project Manager
 Steve Lynch, Safety Deliverables Project Manager
 Phil Bailey, Area Project Manager LAW/HLW

3.2 LIST OF INSPECTION PROCEDURES USED

Inspection Technical Procedure I-101, "Quality Assurance Assessment"

3.3 LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

IR-99-002-01-IFI	Follow-up Item	Quality related procedures lacked detail
IR-99-002-02-FIN	Finding	Some DRs are not analyzed to determine cause and preventative actions
IR-99-002-04-IFI	Follow-up Item	Track to resolution DR-W375-99-QA00029 concerning lack of dual storage of Documents and Records
IR-99-002-05-IFI	Follow-up Item	Removal of an in appropriate note in K40P001_0 concerning appendix (QA requirements) not being interpreted as requirements

Closed

IR-99-002-03-FIN	Finding	CAR was not written for DR that was designated by QA manager as significant
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3.4 LIST OF ACRONYMS

BNFL	BNFL Inc.
CAM	Corrective Action Management System
CAQ	Condition Adverse to Quality
CAR	Corrective Action Report
CFR	Code of Federal Regulations
DASH	Data and Acquisition Sharing
DOE	U.S. Department of Energy
DR	Deficiency Report
INC	Interim Change Notice

ISMP	Integrated Safety Management Plan
ITP	Inspection Technical Procedure
LAN	Local Area Network
P&IDs	Piping and Instrumentation Diagrams
QA	Quality Assurance
QAP	Quality Assurance Program
QAPIP	Quality Assurance Program and Implementation Plan
QL	Quality Level
RPP	Radiation Protection Plan
RPP-P	River Protection Project-Privatization
RU	Regulatory Unit
SRD	Safety Requirements Document
SRTC	Savannah River Technology Center
TWRS-P	Tank Waste Remediation System Privatization

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