



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

99-RU-0406

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

Dear Mr. Lawrence:

**SELF-ASSESSMENT AND CORRECTIVE ACTION INSPECTION REPORT, IR-99-003**

On June 14 through June 18, 1999, the Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit) completed an inspection of the self-assessment and corrective action program at your facility.

The inspectors identified one Finding, documented in the Notice of Finding (Enclosure 1). The Finding resulted from the inspectors identifying that a self-assessment and corrective action related commitment in your Integrated Safety Management Plan (ISMP) was not being properly implemented. Specifically, the inspectors found that, contrary to ISMP Section 10.2, "Independent Assessments," you had not established or implemented methods for using performance indicators to determine the frequency of independent assessments. You are requested to provide a written response to this Finding within 30 days, in accordance with the instruction provided in the enclosed Notice of Finding.

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

The results of our inspection revealed that your have establishment and implementation of the self-identification portion of the program was considered a strength. In addition, the management self-assessment that resulted in Deficiency Report DR-W375-99-QA-00059 prior to our inspection was noteworthy and contributed to your state of readiness for the inspection by identifying many areas where management attention is needed to improve the effectiveness of this program. Accordingly, the tracking of this DR to resolution was identified as an Inspection Follow-up Item.

M. J. Lawrence  
99-RU-0406

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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:NKH

Enclosures

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) (a) of the Contract requires the contractor to develop and implement an integrated standards based safety management program. DOE/RL-96-0003, "DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors," which is incorporated by reference in the Contract, requires the integrated standards based safety management program to be documented in an Integrated Safety Management Plan (ISMP) which is reviewed and approved by the Regulatory Unit. Standard 4, Section (b), and DOE/RL-96-0003, Section 3.3.1, establish that the contractor during Part B of the contract shall implement the ISMP.

During the performance of an inspection of self-assessment and corrective action activities at the offices of the contractor's River Protection Project Privatization (RPP-P) program, the Regulatory Unit identified the following Finding.

Section 10.2 of the contractor's Integrated Safety Management Plan (ISMP) requires that the frequency of independent assessments will be based, in part, on performance indicators.

Contrary to this requirement, the inspectors found that the contractor had not established or implemented methods for using performance indicators to determine the frequency of independent assessments.

This is considered an inspection Finding.

The contractor is requested to provide to the Regulatory Unit within 30 days of the date of the cover letter that transmitted this Notice, a reply to the Finding described above. The reply should include: (1) agreement or disagreement with the Finding, (2) the reason for the Finding, if the contractor agrees with it, and if the contractor disagrees, 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.

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

INSPECTION: SELF-ASSESSMENT AND CORRECTIVE ACTION

REPORT NO: IR-99-003

FACILITY: BNFL Inc.

LOCATION: 3000 George Washington Way  
Richland, Washington 99352

DATES: June 14-18, 1999

INSPECTORS: N. Hunemuller (Lead), Senior Regulatory Technical Advisor  
R. Smoter, Regulatory Unit Consultant  
D. Kirsch, Regulatory Unit Consultant

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

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EXECUTIVE SUMMARY  
Self-Assessment and Corrective Action  
Inspection Report Number IR-99-003

## INTRODUCTION

This inspection of the BNFL Inc. (the contractor) Self-Assessment and Corrective Action Program covered the following specific areas:

- Effectiveness of Procedures for Self-Assessments (Section 1.2)
- Effectiveness of Procedures for Corrective Actions (Section 1.3)
- Frequency of Self-Assessments (Section 1.4)
- Timeliness of Corrective Actions (Section 1.5)
- Adequacy of Records (Section 1.6)
- Adequacy of Disposition of Issues Identified During Self-Assessments (Section 1.7)

## SIGNIFICANT OBSERVATIONS AND CONCLUSIONS

- Establishment and implementation of the self-identification portion of the program was considered a strength. (Section 1.1)
- Procedures were in place and being followed but were not clearly written. The lack of clarity in the quality improvement procedures was self-identified by the contractor in DR-W375-99-QA-00059. (Section 1.2)
- Employees did not understand the formal requirements for reporting quality deficiencies. (Section 1.2)
- Authorization basis requirements were not explicitly included in the procedures. (Section 1.2)
- The atmosphere of open communication within the project helped to mitigate weaknesses such as those that were documented in DR-W375-99-QA-00059. (Section 1.2)
- The tracking of DR-W375-99-QA-00059 to resolution was identified as an Inspection Follow-up Item. (Section 1.2)
- The contractor had established and effectively initiated implementation of procedures for taking corrective action and was meeting authorization basis commitments in a manner consistent with the early stage of the RPP-P program. (Section 1.3)
- There was no documentation of QA's significance determination evaluations, i.e., no documented rationale for significance determinations. (Section 1.3)

- The procedures did not explicitly require review for effectiveness of completed corrective actions. (Section 1.3)
- There was no defined responsibility or process for evaluating the safety significance of issues identified in corporate assessments or tracking resulting corrective actions. (Section 1.3)
- The contractor had established comprehensive schedules for conducting management assessments and independent assessments. However, the inspectors noted that the basis for independent assessment schedules was not consistent with authorization basis commitments. The ISMP requires that the frequency of independent assessments will be based, in part, on performance indicators. The inspectors found that performance indicators had not been identified or used for this purpose. This was considered a Finding. (DR-W375-99-QA-00062 was initiated as a result of this Finding.) (Section 1.4)
- Safety significance was not explicitly or systematically addressed in the scheduling of independent assessments. (Section 1.4)
- The contractor's timeliness of corrective actions conformed to the QAPIP requirements. (Section 1.5)
- The Guidelines for Significance Review, provided by the Corrective Action procedure, did not contain any provision for escalating the significance of several common area issues, which by themselves may be of low significance, but, when considered in the aggregate, may identify broader organizational or functional area concerns. (Section 1.5)
- The quality assessment and corrective action records were adequate to meet the contractor's commitments in the authorization basis. However, the corrective action and self-assessment computerized tracking systems were not yet fully developed and no corrective action records had yet been completely finalized. (Section 1.6)
- The contractor's program for conducting management self-assessments and addressing resultant corrective actions was being acceptably implemented at this stage of the project and program. The management self-assessment program was in the early stages of implementation and was evolving. The contractor planned additional management attention to improve effectiveness of this program. (Section 1.7)

## SELF-ASSESSMENT AND CORRECTIVE ACTION INSPECTION

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## SELF-ASSESSMENT AND CORRECTIVE ACTION INSPECTION REPORT

### 1.0 REPORT DETAILS

#### 1.1 INTRODUCTION

The River Protection Project Privatization (RPP-P) (formerly the Tank Waste Remediation System Privatization (TWRS-P)) project was in the early design stages at the time of this inspection. The contractor (BNFL) was actively in the process of hiring the staff to continue progress on the early design phase of the project.

In accordance with the TWRS-P Contract (Contract, DE-AC06-96RL13308 between DOE and BNFL, dated August 24, 1998) and specifically 10 CFR 830.120, *Quality Assurance Requirements*, the contractor was required to assess work performance and identify and correct problems including identifying the causes of problems and working to prevent recurrence. This requirement was reflected in the contractor's authorization bases such as, the Quality Assurance Program and Implementing Plan ((QAPIP) BNFL-5193-QAP-01, Rev.4), Safety Requirements Document ((SRD) BNFL-5193-SRD-01, Rev. 2), and Integrated Safety Management Plan ((ISMP) BNFL-5193-ISP, Rev. 4).

The inspectors reviewed the contractor's Self-Assessment and Corrective Action implementing procedures to determine if they complied with the commitments in the QAPIP, SRD, and ISMP. In addition, the inspectors assessed the implementation of the contractor's Self-Assessment and Corrective Action program as it related to the design phase of the RPP-P Contract to ensure that the contractor was following its plan and procedures.

The inspectors considered the establishment and implementation of the self-identification portion of the program a strength. A large number of management self-assessments had been scheduled and completed. The Quality Assurance (QA) organization had provided effective support of the initiation and first implementation stages of the program.

#### 1.2 EFFECTIVENESS OF PROCEDURES FOR SELF-ASSESSMENTS (INSPECTION TECHNICAL PROCEDURE (ITP) I-103)

##### 1.2.1 Inspection Scope

The inspectors assessed the effectiveness of the contractor's procedures used to conduct management assessments and independent assessments. The inspectors reviewed the procedures against the contractor's commitments in the contractor's authorization bases.

##### 1.2.2 Observations and Assessments

The inspectors verified that procedures were in place and being followed for the conduct of management assessments and independent assessments. The specific procedures reviewed are

listed in Section 3.4, “Key Documents Reviewed.” The self-assessment and corrective action program procedures, referred to as quality improvement procedures by the contractor, were issued recently, and the contractor was still gathering the initial feedback on the use of the procedures during the inspection. Contractor management and Quality Assurance (QA) staff indicated that, based on the initial feedback being gathered, the contractor was in the process of adding more detail to the procedures to improve consistency and clarify management expectations. The inspectors reviewed the procedures and interviewed contractor staff who had used the procedures. Based upon interviews and records review, the inspectors determined that the procedures were followed, including the use of schedules, records, and checklists.

Notwithstanding the fact that the procedures had been issued and were being followed, the inspectors also observed the lack of clarity in the procedures that was being reflected in the contractor’s initial feedback on the use of the procedures. Several contractor employees, including managers, stated that they thought the procedures were not clear about when to write a deficiency report (DR). The procedure for management assessments did not clearly specify exactly who was required to do self-assessments. The interviewees indicated that the forms and checklists in the procedures were not clear to them. In the management assessment procedure there was no identified review chain. Employees, including managers, did not understand that it was not QA’s responsibility, by procedure or management direction, to review management self-assessments to generate DRs. From a review of the procedures, the inspectors observed that the procedures were inconsistent with respect to closure of DRs and corrective action reports (CARs). The lack of clarity in the quality improvement procedures was self-identified by the contractor in DR-W375-99-QA-00059. The tracking of this DR to resolution was identified as an Inspection Follow-up Item (IR-99-003-01-IFI).

Four engineering staff employees were interviewed regarding their understanding of Procedures K10P004, “Improvement and Suggestions,” and K13P054, “Corrective Action.” All the employees had been with the project for less than six months, but all had completed their orientation training. Although all of the employees stated that they knew where to find the procedures on the computer, none of the employees knew of the specific procedures for, or understood, DRs or the Corrective Action Management System. They stated that they would bring quality issues to their management’s attention and resolve the issues through discussions with their management. None of the four employees had a good understanding of quality levels or how they related to criteria for triggering reporting and correction of deficiencies. While the openness between employees and management was considered a strength, the inspectors observed that the employees did not understand the formal requirements for reporting quality deficiencies. The need to improve clarity in the area of employee identification of deficiencies, including improving the associated computer-based training, was another issue contained in DR-W375-99-QA-00059.

The inspectors observed that authorization basis requirements were not explicitly included in the procedures. As self-identified in DR-W375-99-QA-00059, the inspectors independently observed that the coverage of management assessments did not explicitly address the requirements from the authorization basis, such as from the ISMP. The inspectors found that the applicable procedures did not address the ISMP requirement to use performance indicator results to determine the frequency of independent assessments (see Section 1.4 of this report for a discussion of the Finding). The procedure for corrective actions did not explicitly address the QAPIP requirement for an effectiveness review of completed corrective actions. The inspectors

noted that the lack of explicit procedural coverage of authorization basis requirements was similar to an observation from Inspection Report IR-99-001, “Personnel Training and Qualification,” that “it was not clear that the staff understood the importance and use of the authorization basis.”

### 1.2.3 Conclusions

The inspectors verified that procedures were in place and being followed. The inspectors also observed that the procedures were not clearly written. The lack of clarity in the quality improvement procedures was self-identified by the contractor in DR-W375-99-QA-00059. The inspectors observed that the employees did not understand the formal requirements for reporting quality deficiencies. The inspectors observed that authorization basis requirements were not explicitly included in the procedures. The inspectors noted that the atmosphere of open communication within the project helped to mitigate weaknesses such as those that were documented in DR-W375-99-QA-00059.

The tracking of DR-W375-99-QA-00059 to resolution was identified as an Inspection Follow-up Item.

## **1.3 EFFECTIVENESS OF PROCEDURES FOR CORRECTIVE ACTIONS (ITP I-103)**

### 1.3.1 Inspection Scope

The inspectors assessed the effectiveness of the contractor’s procedures used to address corrective actions resulting from management assessments, independent assessments, and other sources. The inspectors reviewed procedures, management meeting minutes, assessment and audit reports, deficiency reports (DRs), and corrective action reports (CARs) against commitments in the contractor’s authorization basis.

### 1.3.2 Observations and Assessments

The inspectors reviewed the contractor’s procedures K13P054, “Corrective Action,” and K13P055, “Corrective Action Management System,” that address documenting and assessing conditions requiring corrective action. The inspectors reviewed and discussed corrective actions associated with management assessments and independent assessments (i.e., surveillances and audits performed by the QA organization). The inspectors also reviewed and discussed several DRs and CARs with contractor personnel. Specifically, the following items were reviewed and discussed:

- SV-W375-QA00001, Surveillance Report, “TWRS Privatization Training and Qualifications”
- SV-W375-QA00002, Surveillance Report, “TWRS Privatization Project Management”
- AR-W375-QA-00002, Audit Report for the Savannah River Technology Center

- AR-W375-QA-00001, Audit Report for GTS Duratek, Columbia MD
- SA-W375-99-00001, Management Assessment, Management Procedures
- SA-W375-99-00002, Management Assessment, Work Processes
- SA-W375-99-00112, Management Assessment, Quality Improvement/Management Assessment Process
- SA-W375-99-00113, Management Assessment, Quality Improvement/Management Assessment Process Follow-up
- SA-W375-99-00043, Management Assessment, Flow-down of QA Requirements
- CAR-W375-99-QA00028/DR-W375-99-QA00032
- CAR-W375-99-QA00029/DR-W375-99-QA00042
- CAR-W375-99-QA00030/DR-W375-99-QA00029

In general, the inspectors observed that corrective actions were being effectively developed, documented, and tracked; however, the following observations were made.

The inspectors noted that corrective action procedures were confusing regarding the verification of corrective action completion prior to final closure of DRs. The procedure flowcharts did not specify any corrective action verification (by QA or others) for DRs and the procedure text regarding the specific process for verification of DR-related actions was ambiguous. The procedures clearly required verification of corrective actions prior to the closure of CARs. From a review of 15 DRs being processed for closure and discussions with QA personnel; it was clear that in practice, QA personnel verified completion of corrective actions associated with DRs.

The corrective action procedures did not explicitly require a review, in accordance with the QAPIP and ISMP, for effectiveness of the corrective actions that have been completed. The inspectors noted that at this stage of the project, there have been no corrective actions for which ultimate effectiveness could yet be verified by contractor personnel or evaluated by the inspectors. The inspectors observed that QA personnel understood and intended to meet the QAPIP requirement.

From interviews, the inspectors observed that employees did not understand the procedural requirements or circumstances that would require initiating a DR. This included staff-level employees, supervisors, and management. For example, some managers believed that if they did not write a DR for an issue identified in a self-assessment, then QA would write the DR if a DR was required. However, according to procedures and interviews with QA staff, QA only reviews identified DR's.

The corrective action procedures contained criteria for establishing the significance of conditions described in DRs and NCRs. The inspectors observed that the process and criteria for making these determinations did not consider the potential for the collective or aggregate significance of

several items to indicate a more significant problem. DRs and NCRs determined to be significant in accordance with the contractor's corrective action process are documented and tracked as CARs. These significance determinations are being performed and documented by QA personnel; however, there was no documentation of the rationale for these determinations.

The inspectors reviewed QA-99-019 which documents a corporate audit of RPP-P program QAPIP implementation. The report contained several findings requiring determination of safety significance and appropriate corrective action. The inspectors observed that there was no defined responsibility or process for evaluating the safety significance of issues identified in corporate assessments or tracking resulting corrective actions. Through discussions with QA personnel, it was determined that there was some confusion in the organization regarding the handling of these findings; however, several DRs (DR-W375-99-QA-00020 through 00028) were written to ensure appropriate evaluation and tracking of these findings.

The inspectors determined that corrective actions were being discussed at monthly "business committee" meetings chaired by the General Manager and at monthly "project management" meetings chaired by the Project Manager. The inspectors reviewed meeting minutes from the 1/28/99 and 2/17/99 business committee meetings and the 4/19/99 and 5/17/99 project management meetings. The minutes demonstrated that certain corrective actions were discussed at these meetings, however, it wasn't possible to ascertain why certain actions were discussed and others were not. In discussions with QA personnel on this issue, the inspectors determined that the QA Manager recently began to provide a "Corrective Action Management System Analysis" with periodic reports on corrective action status in order to highlight areas that need management attention. Also, the contractor was refining the management meeting minute formats to include more systematic documentation of corrective action reviews during management meetings.

### 1.3.3 Conclusions

The inspectors determined that that the contractor had established and effectively initiated implementation of procedures for taking corrective action. However, there was no documentation of QA's significance determination evaluations, i.e., no documented rationale for significance determinations. The inspectors also noted that the procedures were confusing and did not explicitly require review for effectiveness of completed corrective actions. The inspectors observed that there was no defined responsibility or process for evaluating the safety significance of issues identified in corporate assessments or tracking resulting corrective actions. Notwithstanding these issues, from a review of selected contractor assessment documentation, DRs, CARs, information in the CAMS database, and interviews with contractor personnel, the inspectors concluded the contractor was meeting relevant authorization basis commitments in a manner consistent with the early stage of the RPP-P program.

## **1.4 FREQUENCY OF SELF-ASSESSMENTS (ITP I-103)**

### 1.4.1 Inspection Scope

The inspectors assessed the frequency of the contractor's performance of management assessments and independent assessments (i.e., audits and surveillances performed by the quality

assurance organization). The inspectors also assessed the contractors use of performance indicators and trending results for determining independent assessment schedules.

#### 1.4.2 Observations and Assessments

The inspectors reviewed the contractor's procedures K10P008, "Management Assessment," K13C051, "Code of Practice for TWRS Privatization Quality Assurance Program Audit and Assessment," and K13P053, "Quality Assurance Surveillance" that address the scheduling and performance of assessments. The inspectors also reviewed and discussed management assessment and independent assessment schedules provided by the contractor. The inspectors made the following observations.

The contractor's schedules for management assessments were reviewed and discussed with contractor management and supervisory personnel. The ISMP stated that management assessments will be performed annually. The contractor's current set of management assessments and associated schedules were established in a hierarchical manner. Assessments and schedules were established by the General Manager and functional managers (direct reports to the General Manager) based on an annual schedule that reflects the RU inspection schedule as well as the functional manager's priorities. More specific areas for assessment and scheduling inputs supporting the functional manager's assessment was received from team leaders and supervisors. There was substantial flexibility in establishing and scheduling these supporting management assessments. This flexibility resulted in significant variation in assessment activities across the various functional areas. However, the contractor had performed an extensive number of assessments (122 completed as of the date of the inspection) and the established schedules should result in a comprehensive set of management assessments being completed within the ISMP specified annual periodicity.

The inspectors also reviewed procedure K13P002\_0, "Internal Management Systems Assessment," which required assessments of company and project management systems to be performed at least annually. The inspectors examined the contractor's plans for implementing this procedure by reviewing and discussing the self-assessment schedules for the General Manager, Project Manager, and QA Manager. The inspectors determined that the contractor intended to complete the Project Manager's and QA Manager's assessments in August 1999, and then use those assessments as input to complete the General Manager's assessment in September 1999. The inspectors concluded that the contractor's plans appeared to provide for acceptable implementation of the procedure requirements.

The contractor's schedules for independent assessments were reviewed and discussed with contractor Quality Assurance (QA) staff. There were two types of independent assessments performed to date; QA audits and QA surveillances. Audits and surveillances vary in level-of-detail, process formality, and documentation, but do not necessarily address different areas of assessment. The inspectors noted that the QA surveillance schedule provided by the contractor closely paralleled the RU inspection program schedule. From discussion with the QA Manager and QA staff, the inspectors determined that the audit and surveillance schedule was developed based on the RU inspection schedule and factors such as sequence and progress of work activities, opportunities for conducting inspections, and judgement of the QA organization.

The QAPIP states that the scheduling of independent assessments be based in part on the relative importance to safety of the activity being assessed. From a review of relevant procedures and discussions with QA staff, the inspectors observed that safety significance was not explicitly or systematically considered as a factor in developing the schedule for independent assessments. However, because the scheduling of independent assessments was based on the work status at this stage of the project, including consideration of known upcoming external assessments such as RU inspections, safety significant activities appeared to be covered and safety significance was likely an implicit consideration in scheduling independent assessments.

The ISMP Section 10.2 requires, among other things, that the frequency of independent assessments for various functional areas be based on performance indicators results. The inspectors found that the applicable procedures did not address the use of performance indicator results to determine the frequency of independent assessments, nor, according to interviews, had performance indicators been identified or used for this purpose. This was considered a Finding (IR-99-003-02-FIN). Following the identification of this Finding by the inspectors, DR-W375-99-QA-00062 was written by the contractor to address this issue.

### 1.4.3 Conclusions

The inspectors determined that the contractor had established comprehensive schedules for conducting management assessments and independent assessments. However, the inspectors noted that the basis for independent assessment schedules was not entirely consistent with relevant authorization basis commitments. The inspectors identified one Finding in this area. The ISMP requires that the frequency of independent assessments will be based, in part, on performance indicators. However, the inspectors found that performance indicators had not been identified or used for this purpose. The inspectors also noted that safety significance was not explicitly or systematically addressed in the scheduling of independent assessments.

## **1.5 TIMELINESS OF CORRECTIVE ACTIONS (ITP I-103)**

### 1.5.1 Inspection Scope

The inspectors assessed the timeliness of the contractor's corrective actions. The inspectors evaluated the contractor's tracking system, means for taking corrective actions in a timely manner commensurate with the significance of the identified problems, and line management response.

### 1.5.2 Observations and Assessments

In the area of independent assessments, the inspectors examined two supplier audits and two surveillances performed by the Quality Assurance organization, including the issues identified, corrective actions assigned, the significance assigned to the issues, and the timeliness of the corrective actions.

The supplier audits were planned, scoped, and conducted in accordance with procedure requirements, although the audits were conducted prior to the issue date of the Code of Practice for TWRS Privatization Quality Assurance Program Audit and Assessment (K13C051\_0). The

surveillances were also planned, scoped, and conducted in accordance with procedure requirements. The surveillances appeared to be substantial assessments of, in one case, the training and qualification program and, in the another case, the project management system documentation implementation of the commitments made in the QAPIP. The surveillances and audits identified several substantial issues, which were properly documented in DRs and CARs, in accordance with Corrective Action procedure requirements.

The inspectors examined the procedure detailing the Corrective Action Management System (CAMS) requirements and determined that the system only required that all Deficiency Reports (DR), Nonconformance Reports (NCR), and Corrective Action Reports (CAR) be entered into the CAMS database. To date, the contractor had not issued any NCRs because no hardware had been procured. Issues that do not have the DR/CAR level of significance are not classified as any of these report types and, therefore, were not entered into the database. For example, the inspectors observed that management assessments predominantly identify issues that did not reach the level of significance of DR, CAR, or NCR type issues and, accordingly, these were not entered into the CAMS system.

The procedure described and required the issuance of monthly and quarterly status reports to management and for the QA Manager's review of monthly status reports for trending information. The inspectors examined the information contained in the CAMS database and interviewed the individual responsible for maintaining the system. The inspectors observed that CAMS was in the early stages of development. Corrective actions were tracked by the database and completion was verified. Although the procedure did not describe the fields of information in detail, or the establishment of cause codes, the inspectors determined that these omissions were not critical because of the high level of familiarity the CAMS Coordinator, and his backup, had with the system. The contractor had issued a procedure for Quality Trending (K13P062\_0) which established a detailed listing of cause codes, and had recently established a field for cause codes in the CAMS database, although the QAPIP did not require root cause analysis for preliminary design. Information available in the system included the deficient condition, assigned cause, corrective actions to correct the condition and prevent recurrence, date the condition was documented, QA program area, the first level functional manager responsible for the problem and correction, and dates that corrective action response and completion were required. This information enabled the CAMS Coordinator to obtain trending information for use in the performance of trending analyses. The system had all of the information required by Section 3.2.1 of the contractor's QAPIP and appeared to conform to the requirements of the QAPIP.

Regarding the issues and problems which did not rise to the significance level of a DR, CAR or NCR (for example, those predominantly identified by management self-assessments), the contractor was in the process of developing a database to track these issues to completion. This issue had been identified in a contractor's deficiency report (DR-W375-99-QA-00059) for correction.

The inspectors examined the Guidelines for Significance Review, provided by the Corrective Action procedure, K13P054\_1, and determined that these appeared to provide an acceptable basis for determining the significance of issues and problems. The inspectors examined several of the significance assignments to problems documented in the CAMS database and observed that the contractor appeared to have correctly applied the guidance. Further, the corrective

actions assigned appeared to be commensurate with the significance of the findings. Accordingly, the inspectors concluded that the contractor had appropriately implemented the requirements of the QAPIP, Section 3.2.2, regarding the assessment of finding significance. Notwithstanding, the inspectors also observed that the Guidelines for Significance Review and the procedure for Corrective Action did not provide for escalating the significance of several common area issues, which by themselves may be of low significance, but, when considered in the aggregate, may identify broader organizational or functional area concerns.

The CAMS was used to track and report whether managers had responded, within the 30 day requirement of the QAPIP, to identify corrective action and the projected date of completion. The CAMS Coordinator stated that if corrective action response was not received within 30 days, QA followed up by either personally discussing the situation with the delinquent manager, or notifying the delinquent manager and Project Document Control by e-mail. The projected date of completion was tracked and used to assure that closure documentation had been received by the agreed upon completion date and to schedule when QA would perform their required verifications of corrective action completion and effectiveness. The inspectors' examination of the CAMS database verified that all of the entries had been responded to in a timely manner in accordance with procedure and QAPIP, Section 10.2.5, requirements.

The contractor had initiated processes and tracking systems to assure that QA would verify the completion and effectiveness of corrective actions to resolve issues documented in the CAMS system. The inspectors examined the corrective action verifications that had been conducted and concluded that these had concentrated on verifying corrective action completion. However, this was acceptable for the present stage of the project because the corrective actions verified were directed toward improving or fixing program, documentation, and procedural issues, and not implementation issues. The QA staff, responsible for implementing the requirements, was knowledgeable of the QAPIP requirements to verify corrective action effectiveness and planned to accomplish the required effectiveness verifications. The inspectors concluded that the contractor had acceptably commenced implementing the requirements of the QAPIP, Section 3.2.2, regarding the tracking and verification of corrective actions.

The inspectors examined evidence demonstrating that meetings between project, quality assurance, and functional area management were held on a monthly and quarterly basis wherein the information in CAMS was assessed and discussed, including corrective actions and the timeliness of response or corrective action completion. Overdue items were a topic of discussion at the meetings. Accordingly, evidence existed to demonstrate that the Project Manager exercised responsibility for reviewing surveillance, assessment, and audit reports, investigating findings, and assuring that appropriate and timely corrective actions were taken, as required by the QAPIP, Sections 9.3 and 10.3.

### 1.5.3 Conclusions

The inspectors concluded that the contractor conformed to the QAPIP requirements except for the tracking of issues which did not reach the level of significance to be classified as either a Deficiency Report, Nonconformance Report, or Corrective Action Report. That exception was self-identified by the contractor in DR-W375-99-QA-00059.

Although the inspectors concluded that the contractor had appropriately implemented the requirements of the QAPIP, Section 3.2.2, regarding the assessment of finding significance, the inspectors also observed that the Guidelines for Significance Review, provided by the Corrective Action procedure, did not contain any provision for escalating the significance of several common area issues, which by themselves may be of low significance, but, when considered in the aggregate, may identify broader organizational or functional area concerns.

## **1.6 ADEQUACY OF RECORDS (ITP I-103)**

### 1.6.1 Inspection Scope

The inspectors reviewed the contractor's records of quality assessments and corrective actions.

### 1.6.2 Observations and Assessments

The contractor provided a demonstration of the Corrective Action Management System (CAMS). The CAMS was used for conditions adverse to quality (CAQs), which were those items that were reported in DRs, CARs, and NCRs (the inspectors were informed that there were no NCRs yet). During the demonstration the inspectors noted that the CAR number and DR number fields in the database records were blank. The contractor's preliminary investigation of this matter indicated that the information had not been lost but was not properly transferred during some recent computer development work. The contractor also provided a preview demonstration of the Self-Assessment Management System (SAMS) that was under development. In addition to observing the demonstrations, the inspectors interviewed the CAMS coordinator. The inspectors determined that the CAMS was a project-wide system used for identifying, prioritizing, tracking, analyzing, resolving and trending of CAQs. The inspectors observed that not all CAMS records identified the specific original source document of the CAQ. However, the CAMS coordinator demonstrated that this issue was being addressed and showed the inspectors several more recent records that included references to the source documents. The inspectors were also informed that the contractor was still in the process of determining access and security requirements for the CAMS. This may have been a contributing factor to the inspectors' observation that employees were not familiar with the CAMS.

The inspectors also interviewed the Project Administration Manager in Project Document Control (PDC) who was responsible for document control, records management, and technical publications. The inspectors did not review PDC administration in detail. In Inspection Report IR-99-002, "Quality Assurance Assessment," it was observed that "document control and records management practices were controlled in accordance with the requirements of the QAPIP, project procedures, and codes of practice." The inspectors did determine that PDC kept and could retrieve the final and complete documentation of such items as self-assessment schedules, records, and checklists. Based upon the interviews, the inspectors also observed that contractor employees knew that they could obtain final controlled documents from PDC. However, with respect to final documentation for corrective actions, the inspectors determined that no corrective actions had yet been fully completed to the point of having PDC-approved final documentation.

### 1.6.3 Conclusions

The inspectors determined that the quality assessment and corrective action records were adequate to meet the contractor's commitments in the authorization basis. The inspectors also observed that the corrective action and self-assessment computerized tracking systems were not yet fully developed and that no corrective action records had yet been completely finalized.

## **1.7 ADEQUACY OF DISPOSITION OF ISSUES IDENTIFIED DURING SELF-ASSESSMENTS (ITP I-103)**

### 1.7.1 Inspection Scope

The inspectors assessed the resolution of issues identified in management assessments with respect to systematic and cultural aspects, safety significance, and root cause.

### 1.7.2 Observations and Assessments

The inspectors verified that criteria for determining the importance or significance of problems and the extent of cause analysis were developed so that actions could be taken that were commensurate with the importance of the fault or nonconformance, as required by the QAPIP, Section 3.2.2. The discussion of the inspectors' assessments and findings to support this conclusion are contained in Section 1.5.2 of this report.

The inspectors examined contractor procedure K10P008\_0, "Management Assessment," interviewed several managers regarding their implementation of the procedure requirements, examined management assessment schedules and compared those schedules to contractor organization charts to verify that managers were implementing procedure requirements, and examined documentation of completed assessments and the resolution of findings.

As a result of these examinations, the inspectors observed that it was not clear that management assessments focused on both systematic and cultural issues as required by Section 9.2, of the contractor's QAPIP. The focus on systematic issues was evident, but the consideration of cultural issues was not so clear. However, the inspectors considered that this was most probably due to the fact that the contractor's management assessment program was in the early stages of implementation and was evolving. The inspectors observed that the procedure had only recently been issued and that the first round of assessments was still in progress. Consequently, the inspectors concluded that management assessments have, at the current stage of project and program status, appropriately begun to identify and resolve management issues and problems.

The inspectors determined that the management assessment procedure was not clear in a number of areas and contained several omissions. For example, managers had prepared schedules for the performance of management assessments; however, because the procedure did not clearly identify the levels of management intended to be subject to the procedure, it was not clear to the inspectors whether all of the managers who should perform self-assessments had provided schedules. The contractor, in Deficiency Report DR-W375-99-QA-00059, had identified this issue among others. In addition, the inspectors observed that the managers who conduct assessments were also responsible for specification and completion of corrective actions. The procedure did not provide guidance for review or concurrence with finding significance or

corrective actions. The inspectors considered that a lack of review might establish a potential conflict of interest in the exercise of problem significance assessment, notification of Quality Assurance and Project Management, or corrective action assignment. Based on the review of DR-W375-99-QA-0059, the inspectors concluded that the clarification of Quality-Improvement-related procedures required to resolve the DR would likely include establishing guidance for reviews and concurrences. The tracking of this DR to resolution was identified as an Inspection Follow-up Item (IR-99-003-01-IFI).

The inspectors examined three completed management self-assessments, including the assigned corrective actions and scheduled completion dates. The inspectors determined that the assessments used checklists to establish the attributes to be assessed, as required by procedure. The corrective actions assigned to specific findings were commensurate with the significance of the findings, and the findings were described in sufficient detail to establish whether they were isolated problems or contained broader organizational concerns. The scheduled corrective action completion dates appeared to be commensurate with the significance of the issues. The management responses included an acceptable implementation of the guidance for assessment of the significance of the problem, corrective action to correct the identified condition, and action to prevent recurrence. Accordingly, the inspectors concluded that actions to meet the requirements of the contractor's QAPIP, Section 10.2.5, had been acceptably initiated at the current stage of the project. Although the procedure did not require notification of QA, the managers generally forwarded the results of their assessment to QA, and based on the interviews, believed that QA exercised some oversight or would validate their assessment in some way. However, interviews with QA indicated that they did not review the assessments in any detail sufficient to independently assess the adequacy of corrective actions or the assigned significance.

### 1.7.3 Conclusions

The inspectors determined that the contractor's program for management self-assessments and corrective actions was being acceptably implemented at this stage of the project and program. The management self-assessment program was in the early stages of implementation and was evolving. The contractor planned additional management attention to improve effectiveness. The inspectors concluded that the contractor had acceptably implemented the requirements of the QAPIP at the current stage of the project.

## **2.0 EXIT MEETING SUMMARY**

The inspectors presented the inspection results to members of contractor management at an exit meeting on June 18, 1999. The contractor acknowledged the observations, conclusions, and Finding presented.

The inspectors asked the contractor whether any materials examined during the inspection should be considered proprietary information. The contractor stated that none of the materials were considered proprietary.

## **3.0 REPORT BACKGROUND INFORMATION**

### **3.1 PARTIAL LIST OF PERSONS CONTACTED**

G. Blunt, Project Document Control Manager  
 M. Eades, Safety Engineer (Inspection liaison)  
 A. Elsdon, Technical Manager  
 E. Hughes, Engineering Manager  
 S. Lynch, Special Projects Manager  
 M. VonWeber, Quality Assurance Audit & Surveillance Engineer  
 G. Voyles, QA Manager  
 S. Wallace, Project Controls Staff Lead

### 3.2 LIST OF INSPECTION PROCEDURES USED

Inspection Technical Procedure I-103, “Self-Assessment and Corrective Action Assessment”

### 3.3 LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

#### Opened

IR-99-003-01-IFI	Follow-up Item	Track to resolution DR-W375-99-QA-00059 concerning the need for clarification of certain Quality Improvement-related procedures.
IR-99-003-02-FIN	Finding	The contractor had not established or implemented methods for using performance indicators to determine the frequency of independent assessments.

#### Closed

None

### 3.0 KEY DOCUMENTS REVIEWED

#### Contractor Procedures

- K10P002\_0: “Internal Management Systems Assessment,” dated December 1998
- K10P003\_0: “Management Review,” dated December 1998
- K10P004\_0: “Improvement and Suggestions,” dated December 1998
- K10P008\_0: “Management Assessment,” dated March 1999
- K13P002\_0: “Internal Management Systems Assessment,” dated December 1998
- K13C003D\_0: “Code of Practice for the Production of Process Based Procedures,” dated April 1999
- K13C051\_0: “Code of Practice for TWRS Privatization Quality Assurance Program Audit and Assessment,” dated March 1999
- K13P053\_0: “Quality Assurance Surveillance,” dated November 1998

- K13P054\_1: “Corrective Action,” dated March 1999
- K13P055\_1: “Corrective Action Management System,” dated March 1999
- K13P056\_1: “Identification of Nonconforming Conditions,” dated March 1999
- K13P062\_0: “Quality Trending,” dated February 1999

#### Management Self-Assessments

- SA-W375-99-00037: “Preparation, Checking and Approval of Drawings and Sketches,” dated May 11, 1999
- SA-W375-99-00047: “Engineering Calculations; Preparation, Checking and Approval,” dated May 11, 1999
- SA-W375-99-00093: “Compliance with QA Requirements,” dated May 19, 1999

#### Audit Reports

- AR-W375-QA-00001: “Supplier Audit of GTS Duratek,” dated December 1998
- AR-W375-QA-00002: “Supplier Audit of Savannah River Technology Center,” dated February 1999

#### Surveillance Reports

- SV-W375-QA-00001: “Training and Qualification Surveillance Report,” dated February 1999
- SV-W375-QA-00002: “Verify Project Management System Documentation Implementation of Commitments made in the QAP and QAPIP,” dated March 1999

#### Other

- Deficiency Report DR-W375-99-QA-00059: “The need for clarification of certain Quality Improvement-related procedures is indicated by initial experience.”

### 3.4 LIST OF ACRONYMS

BNFL	BNFL Inc.
CAMS	Corrective Action Management System
CAR	Corrective Action Report
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DR	Deficiency Report
HR	Human Resources
ISAR	Initial Safety Analysis Report
ISMP	Integrated Safety Management Plan
ITP	Inspection Technical Procedure
NCR	Nonconformance Report
PD	Position Description
QA	Quality Assurance
QAO	Quality Assurance Orientation

QAP	Quality Assurance Program
QAPIP	Quality Assurance Program and Implementation Plan
QL	Quality Level
RL	Richland Operations Office
RPP-P	River Protection Project Privatization (formerly TWRS-P)
RU	Regulatory Unit
SRD	Safety Requirements Document
TWRS-P	Tank Waste Remediation System Privatization (now RPP-P)

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