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DOE Regulatory Unit Assessment Report of BNFL Inc.'s Integrated Safety Management Plan (ISMP) Implementation

May 23, 2000

Office of Safety Regulation of the TWRS-P Contractor

U.S. Department of Energy
Richland Operations Office
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PREFACE

The U.S. Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal in February 1996 for privatized processing of waste as part of the Hanford Tank Waste Remediation System (TWRS) program which in 1999 came under the cognizance of the Office of River Protection (ORP). Offerors were requested to submit proposals for the initial processing of the tank waste at the Hanford Site. Some of this radioactive waste has been stored in large underground storage tanks at the Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 250,000 metric tons of processed chemicals and 215 million curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE intends to purchase waste processing services from a contractor-owned, contractor-operated facility through a fixed-price contract. DOE will provide the waste feedstock for processing but maintain ownership of the waste. The contractor must: (a) provide private financing; (b) design the equipment and facility; (c) apply for and receive required permits and licenses; (d) construct the facility and commission its operation; (e) operate the facility to process tank waste according to DOE specifications; and (f) deactivate the facility.

The TWRS Privatization (TWRS-P) Project is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort. The objectives of Phase I are to (a) demonstrate the technical and business viability of using privatized contractors to process Hanford tank waste; (b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; (c) maintain environmental protection and compliance; and (d) substantially reduce life-cycle costs and time required to process the tank waste. The Phase I effort consists of three parts: Part A, Part B-1, and Part B-2.

Part A, which concluded in August 1998, was a twenty-month period to establish technical, operational, regulatory, and financial elements necessary for privatized waste processing services at fixed-unit prices. This included identification by the TWRS-P Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months was for the Contractors to develop the Part A deliverables and four months was for DOE to evaluate the deliverables and determine whether to authorize Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B-1.

Part B-1 is a twenty-four month period to (a) further the waste processing system design introduced in Part A, (b) revise the technical, operational, regulatory, and financial elements established in Part A, (c) provide firm fixed-unit prices for the waste processing services, and (d) achieve financial closure.

Part B-2 is a sixteen-year period to complete design, construction, and permitting of the privatized facilities; provide waste processing services for representative tank wastes at firm fixed-unit prices; and deactivate the facilities. During Part B-2, approximately 10% by volume (25% by activity) of the total Hanford tank wastes will be processed.

Phase II will be a full-scale production effort. The objectives of Phase II are to implement the lessons learned from Phase I and to process all remaining tank waste into forms suitable for final disposal.

An essential element of the TWRS-P Project is DOE's approach to safety regulation. DOE has specifically defined a regulatory approach and chartered a dedicated Office of Safety Regulation of the TWRS-P Contractor (Regulatory Unit). The DOE aim in proceeding with the safety regulation of the TWRS-P contractor is to establish a regulatory environment that will permit privatization to occur on a timely, predictable, and stable basis. In addition, attention to safety must be consistent with that which would accrue from regulation by external agencies. DOE is patterning its radiological and nuclear safety regulation of the TWRS-P contractor to be consistent with that of the U.S. Nuclear Regulatory Commission (NRC). For industrial hygiene and safety (IH&S), regulation is consistent with that of the Occupational Safety and Health Administration (OSHA).

The RL Manager has responsibility and authority for safety regulation and has assigned this authority to the RL Director of the TWRS-P Regulatory Unit (the Regulatory Official). This regulatory authority is exclusive to the regulation of the TWRS-P contractor. The Regulatory Official is the formal point of execution for safety regulation of the TWRS-P contractor.

The DOE requires the contractor to integrate safety into all facets of work planning and execution. This Integrated Safety Management (ISM) process emphasizes that it is the contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. Like the approach taken by the NRC and OSHA, the privatized contractor has primary responsibility for safety. The DOE, through its program, is responsible for ensuring that the contractor establishes and complies with approved safety limits.

The relationship between DOE and the privatized contractor performing work under a fixed-price contract is different than the relationship under traditional Management and Operations (M&O) contracts. For fixed-price contracting to be successful, this different safety relationship with the contractor is accompanied by modified relationships among DOE's internal organizations. For example, the arrangement by which the RL Manager applies regulation to the TWRS-P contractor should be a surrogate for an external regulator (such as the NRC or OSHA) with strong emphasis on independence, reliability, and openness.

Regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

All documents issued by the Office of Safety Regulation of TWRS-P Contractor are available to the public through the DOE/RL Public Reading Room at the Consolidated Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.

RECORD OF REVISION

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Executive Summary

This report documents the results of the Regulatory Unit's (RU's)[1] assessment of the implementation of BNFL Inc.'s (BNFL's) Integrated Safety Management Plan (ISMP), BNFL-5193-ISP-01. This report was prepared in anticipation of the readiness-to-proceed-with-B2 decision. This report reflects aggregation of information from six inspections, nine design review reports,[2] the Radiation Protection Program (RPP) evaluation report, the Quality Assurance Program and Implementation Plan (QAPIP) evaluation report, three safety evaluations for authorization basis amendments, and observation of Contractor Integrated Safety Management (ISM) Cycle II Reviews.[3] This report addresses the Guiding Principles and Core Safety Management Functions of Integrated Safety Management (ISM) from the Department of Energy (DOE) Safety Management System Policy, DOE P 450.4, dated October 15, 1996.

The RU found that, for the most part, the Contractor was adequately implementing its ISMP in a manner that was compatible with DOE P 450.4. However, in the area of authorization basis maintenance, the Contractor did not effectively allocate resources, clearly define the work, or perform the work within established controls. Furthermore, the lack of procedural adherence was a common problem, generally, for design-related work. The lack of adherence to the Contractor's hazard analysis procedures resulted in concern that the hazard analysis for the upcoming Construction Authorization Request (CAR) submittal may be unacceptable. Moreover, the Contractor's authorization basis maintenance procedures did not adequately identify and prioritize specific tasks, operations, or work items.

[1] The official organization title is Office of Safety Regulation of the Tank Waste Remediation System Privatization (TWRS-P) Contractor.

[2] Design Review Report Memoranda dated May 27, 1999 (99-RU-0309); June 10, 1999 (99-RU-0355); July 22, 1999 (99-RU-0437); August 27, 1999 (99-RU-0498); September 23, 1999 (99-RU-0551); October 22, 1999 (00-RU-0026); November 19, 1999 (00-RU-0074); December 15, 1999 (00-RU-0100); and January 14, 2000 (00-RU-0166)

[3] Letter 00-RU-0283, D. Clark Gibbs to M. J. Bullock, "BNFL Integrated Safety Management Program, Cycle II Reviews," dated March 30, 2000.

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DOE Regulatory Unit Assessment Report of BNFL Inc.'s Integrated Safety Management Plan (ISMP) Implementation

1.0 INTRODUCTION AND PURPOSE

This report was prepared in anticipation of the readiness-to-proceed with B-2 decision. The RU was scheduled to provide input for the B2 decision by May 24, 2000. This report reflects aggregation of information from six inspections, nine design review reports, the Radiation Protection Program (RPP) evaluation report, the Quality Assurance Program and Implementation Plan (QAPIP) evaluation report, three safety evaluations for authorization basis amendments, and observation of Contractor Integrated Safety Management (ISM) Cycle II Reviews.

The following sections were based on the input provided for each of the Guiding Principles and Core Safety Management Functions of ISM from the Department of Energy (DOE) Safety Management System Policy, DOE P 450.4, dated October 15, 1996. The conclusions stated at the end of each section were based solely upon the input derived from the specifically listed references to this assessment report.

2.0 GUIDING PRINCIPLES OF ISM

2.1 Line Management Responsibility for Safety

Objective: Line management was responsible for protection of the public, the workers, and the environment.

Assessment: Based on the Regulatory Unit's (RU) evaluation, *DOE Regulatory Unit Evaluation Report of BNFL Inc.'s Quality Assurance Program and Implementation Plan*, RL/REG-2000-5, the Contractor's QAPIP clearly made cognizant management and staff responsible for quality and for quality improvement. This was consistent with the principles of 10 CFR 830.120.

From the RU inspection of the Contractor's safety integration program, inspection report IR-99-008, the RU determined that the Contractor demonstrated an adequate commitment to safety integration during the design phase. This was evident in the project Health and Safety Policy, in the manner in which management and supervisors were communicating expectations, in the way the design program was structured, and in the way management and staff were implementing the design program.

The RU also determined from the safety integration inspection (IR-99-008) that the Contractor was implementing an effective Safety Committee Program to provide oversight of safety related activities during the design phase. The Project Safety Committee (PSC) was reviewing the results from the safety program via presentation by the Industrial Safety Committee Chair. The PSC was reviewing indicators and corrective actions from assessments and inspections as well as audit and assessment reports. From the observation of two PSC meetings, the inspectors found actual PSC meeting performance to be mixed. The first meeting was not well structured in that it

was difficult to determine what was being asked of the PSC or the purpose of the presentations. The second meeting was better. The PSC was observed to review project safety performance, including reviewing self-assessment and RU inspection issues to identify common problems, such as procedural compliance. The Contractor had self-identified that it had failed to implement an Executive Committee, as required by the Integrated Safety Management Plan (ISMP), to overview project safety activities.

From the reviews of the Contractor's authorization basis amendment requests (ABARs),[4] the RU determined that the ABARs reflected adequate management involvement in the regulatory process in that a dedicated staff was assigned to process ABARs in accordance with the Contractor's ISMP.

Conclusion: The Contractor adequately demonstrated that line management was responsible for safety.

2.2 Clear Roles and Responsibilities

Objective: Clear and unambiguous lines of authority and responsibility for ensuring safety were established and maintained at all organizational levels.

Assessment: Based upon the RU's review, RL/REG-2000-5, the Contractor's QAPIP Rev. 5 clarified and strengthened the assignment of quality assurance (QA) program responsibilities, compared to previous versions. The Contractor created a separate section documenting roles and responsibilities in this revision.

From the design reviews, Design Review Report Memoranda 99-RU-0309, 99-RU-0355, 99-RU-0437, 99-RU-0498, 99-RU-0551, 00-RU-0026, 00-RU-0074, 00-RU-0100 and 00-RU-0166, the RU observed that the TWRS-P Project Management Plan stated the Technical Manager was accountable for the overall Contract technical approach. The project procedure, "Design Review," specified the responsibility of the Technical Manager to establish and select members for multi-discipline design reviews. The Technical Manager chaired the majority of multi-discipline design reviews to assess the overall technical approach, selected appropriate reviewers and staff to support reviews, and managed major technical baseline changes such as process selection for transuranic removal for waste Envelope C, sulfate removal, and high level waste melter breakdown cell deletion. The role of discipline Functional Managers was defined in the "Design Review" procedure. The procedure required Functional Managers to input expertise and experience of those not involved in the project and provide the design manager information needed to control the design. Functional Managers carried out their role by defining and chairing single discipline design reviews and occasionally brought in experts not involved in the project.

[4] Letter 00-RU-0020, D. Clark Gibbs to M. J. Lawrence, "Authorization Basis Amendment Request, ABAR-W375-99-00008, Revision 0, NPH Analysis and Design Approach," dated October 27, 1999.
Letter 00-RU-0036, D. Clark Gibbs to M. J. Lawrence, "Approval of Authorization Basis Amendment Request, ABAR-W375-00-00004, Miscellaneous Revisions to the SRD," dated October 27, 1999.
Letter 00-RU-0164, D. Clark Gibbs to M. J. Bullock, "Approval of Authorization Basis Amendment Request, ABAR-W375-99-0005," dated January 12, 2000.

Furthermore, based upon the safety integration inspection (IR-99-008), the RU determined that the design program was being implemented in a way that called upon technical disciplines to provide input to the design several times as it moved from conceptual to final form. Organizationally, the Contractor had implemented an integrated design team approach wherein each design organization was staffed with representatives of organizations and engineering disciplines that had a vested interest in the final design product. For example, design responsibility was organized by functional areas headed by Area Project Managers who had design staffs accomplishing aspects of design related to that particular area. Design groups were staffed with necessary engineering disciplines, including representatives of safety, regulatory conformance, operations, and maintenance.

Based upon the RU's inspection of the Contractor's Employee Concerns Program (ECP), inspection report IR-00-002, the RU determined that the Contractor had established an ECP that was adequate for the status of the project. As of the date of the inspection the Contractor had received no employee concerns. Therefore, the Contractor's ability to resolve employee concerns could not be assessed. The RU reviewed the ECP implementing procedures and found that lines of authority and responsibility for the ECP were well defined. The RU also found that there was demonstrated Senior Management support for the ECP. Senior Management had made specific endorsement of the process by recently distributing an all-employee memorandum reinforcing the ECP. Additionally, the mandatory training module reiterated senior management support.

Conclusion: The Contractor adequately established clear roles and responsibilities for ensuring safety.

2.3 Competence Commensurate with Responsibilities

Objective: Personnel possessed the experience, knowledge, skills, and abilities that were necessary to discharge their responsibilities.

Assessment: The RU determined based upon its evaluation, RL/REG-2000-5, that the Contractor's QAPIP (Section 2, "Personnel Training and Qualification") was consistent with the principle of competence commensurate with responsibilities.

From the design reviews (Design Review Report Memoranda) the RU observed that the Contractor's staff included personnel with significant experience from the DOE complex and Sellafield in the areas of facility design and operations. Discussion of experience regarding what worked and what did not work from West Valley Demonstration Project, Defense Waste Processing Facility, and Sellafield routinely occurred in design reviews. Designers appeared to possess the knowledge necessary for performing the design based on presentations of the design, responses to questions and review of design media. External expertise was obtained through subcontracts where the Contractor did not have the expertise or adequate resources.

From the safety integration inspection (IR-99-008), the RU determined that Contractor teams associated with multidisciplinary design reviews and hazards analysis reviews were staffed with the necessary engineering disciplines, including representatives of safety, regulatory

conformance, operations, and maintenance. Personnel involved in the design process were familiar with the program and procedures governing the design process and these procedures assured that an adequate level of safety integration was accomplished during the design process.

Conclusion: Contractor personnel possessed adequate competence commensurate with their responsibilities.

2.4 Balanced Priorities

Objective: Resources were effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment was a priority whenever activities were planned and performed. There was evidence of a "safety culture" at all levels in the organization.

Assessment: The RU determined from the safety integration inspection (IR-99-008) that Contractor senior management had established an acceptable safety culture through the establishment of integrated design teams, an extensive set of programs and procedures assuring safety integration consideration, and frequent Design Manager communication and reinforcement of expectations for safety integration implementation. Contractor staff reflected an adequate integrated safety culture that was evident in the areas reviewed.

The RU observed that design reviews (Design Review Report Memoranda) conducted during the summer of 1999 included limited operations and safety representation. Later design reviews included safety and operations representatives. These representatives actively participated in design reviews and made contributions that should improve facility operability and safety.

The RU also observed from the design reviews (Design Review Report Memoranda) that the Contractor was making a significant investment in safety to protect the public, workers, and the environment. This was seen in their ISM Cycle 1 and 2 process. Contractor teams were taking work definition from system descriptions, process flow diagrams, and piping and instrumentation drawings, and identifying hazards using a hazard and operability (HAZOP) analysis process. Contractor teams performing this analysis included representatives from safety, operations, and design. However, the Contractor had not applied adequate resources to maintain their authorization basis (AB) current with the design.

From the reviews of the Contractor's ABARs, letters 00-RU-0020, 00-RU-0036 and 00-RU-0164, the RU determined that the ABAR process required effort commensurate with the safety significance of the task. The ABAR process provided latitude to input minimal or significant effort to justify the proposed change.

Conclusion: Although protecting the public, the workers, and the environment was a priority when activities were planned and performed, resources were not effectively allocated to maintain the AB.

2.5 Identification of Safety Standards and Requirements

Objective: Before work was performed, the associated hazards were evaluated and an agreed-upon set of safety standards and requirements was established which, if properly implemented, should provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.

Assessment: From inspection of the Contractor's standards selection process, inspection report IR-99-006, the RU determined that the team approach was evident and was considered a strength. The examples of identification of work, hazards evaluation, and development of control strategies were acceptable. During the inspection, the Contractor was in a stage of the standards selection process that was identified as "ISM Cycle I." The identification of standards step was not complete for ISM Cycle I for any system. Final results of the standards selection process including identification of standards through certification could not be effectively evaluated.

Also based on the standards selection process inspection (IR-99-006), the RU observed that the Process Management Team (PMT) performed some but not all aspects of oversight. The RU determined that the PMT performed such aspects of oversight as providing leadership, direction, guidance and support. However, the PMT did not review or approve the products from the steps of the standards selection process nor verify that the requirements for performing the steps were met. Furthermore, the RU found that there was not a clear separation of responsibilities between the PSC and the PMT such that the independence of the PSC was retained. This was considered an inspection Finding (IR-99-006-02-FIN).

Based on the review of the Contractor's ABAR for natural phenomena hazard (NPH) analysis and design approach, letter 00-RU-0020, the RU confirmed that seismic standards were initially proposed by the Contractor during the standards development process associated with Part A of the TWRS-P Contract. A detailed evaluation of seismic hazards and design requirements for the facility was initiated to support the topical meeting agenda that was associated with Part B1 of the Contract. The culmination of this effort was a refinement of the seismic and other NPH design criteria that were developed during Part A of the Contract. The amendment was initiated to reflect these changes in seismic and other NPH requirements.

The primary purpose of the NPH ABAR was to replace the initial *ad hoc* standards in the Contractor's ISMP with two appendices to the Contractor's Safety Requirements Document (SRD). The RU found that the two appendices were equivalent to the *ad hoc* standards and did not represent a decrease in commitment. The RU also found that the consolidation of requirements represented by this change simplified and clarified the safety standards and requirements.

A secondary purpose of the NPH ABAR was to propose certain safety criteria be considered stand-alone subordinate standards, especially as related to criticality safety. The RU accepted the proposed changes except one that left undefined the standards or guides the Contractor would adopt as an alternative to the SRD requirement that K-effective be equal to or less than 0.95. The RU determined that this standard was not appropriate for inclusion in the SRD. In general,

the Contractor's submittal identifying safety standards and requirements was logical, consistent and complete.

From the design reviews (Design Review Report Memoranda) the RU observed that the Contractor's stated design requirements were consolidated in the Design Criteria Database (DCD). The DCD included requirements from the Contract, Basis of Design, Functional Specification, and AB. Other key requirements were extracted from the Standards Identification Process Database (SIPD) and Interface Control Documents (ICDs). Some design reviews evaluated the design against the Contract and Basis of Design. However, evaluation against other requirements was limited, if performed.

The RU also observed from the design reviews (Design Review Report Memoranda) that the design of a few areas of the facility was proceeding without definitive requirements. One key example was the analytical laboratory. The planned laboratory design was to be based on an assessment of sample collection system design, analysis needs including data quality, numbers of samples, and turnaround time. As of January 2000, very little project specific information had been assembled to provide the design basis for the analytical laboratory.

Conclusion: The Contractor was refining its identification of safety standards and requirements. The hazards associated with the work to be performed were being evaluated and the agreed-upon, refined, set of safety standards and requirements, if properly implemented, should provide adequate assurance that the public, the workers, and the environment will be protected from adverse consequences.

2.6 Hazard Controls Tailored to Work Being Performed

Objective: Administrative and engineering controls to prevent and mitigate hazards were tailored to the work being performed.

Assessment: From the RU inspection of the Contractor's safety integration program (IR-99-008), the RU determined that the Contractor was identifying tailored hazards controls during the conduct of hazards analysis reviews. In addition, during the preliminary design phase, the Contractor was conducting an adequate and effective safety improvement program. This program focused on office related industrial hygiene and safety activities and included a sub-committee of the Safety Committee comprised of representatives of various Contractor organizations that reviewed and assessed worker activities and made recommendations concerning worker safety.

Conclusion: The Contractor was tailoring administrative and engineering controls to prevent and mitigate hazards associated with the work to be performed.

2.7 Operations Authorization

Objective: The conditions and requirements to be satisfied for operations to be initiated and conducted were clearly established and agreed-upon.

Assessment: From the review of the ABARs, letters 00-RU-0020, 00-RU-0036 and 00-RU-0164, the RU observed that a process was in place for ABARs and this process, if properly implemented, should be adequate for supporting safe operations when the time comes.

In connection with the RU evaluation of the Contractor's RPP, *Regulatory Unit Evaluation of the BNFL Inc. Radiation Protection Program for Design Revision 2*, RL/REG-00-01, it should be noted that the TWRS-P Contract required compliance with 10 CFR 835 and submittal of a RPP to the RU. The RPP was to describe the Contractor's occupational radiological protection program and ensure compliance with 10 CFR 835. An amendment was made to 10 CFR 835 that became effective on December 4, 1998. To update the RPP, as required by 10 CFR 835, the Contractor submitted a revised RPP on June 2, 1999. The RU performed a detailed evaluation of the revised RPP from June 3, 1999 - October 22, 1999.

Changes to the regulation substantively affected the Contractor's RPP for design. The Contractor appropriately changed the RPP to incorporate the changes to the requirements. Although the RU observed minor difficulties during the RPP review process, the Contractor provided acceptable responses to reviewer questions when clarification was needed. The RU reviewers found that the RPP measures for achieving compliance with 10 CFR 835 met the established review criteria. As such, the reviewers concluded that the RPP, when properly implemented, would achieve compliance with the regulations. The RU reviewers recommended approval and the Regulatory Official (RO) approved the RPP.

Conclusion: The Contractor adequately established the conditions and requirements to be satisfied for the Radiation Protection Program for design. The Contractor had also established a process for ABARs that, if properly implemented, should be adequate for supporting safe operations when required.

3.0 CORE SAFETY MANAGEMENT FUNCTIONS OF ISM

3.1 Define Workscope

Objective: At each organizational level, work was clearly defined into discrete tasks or processes that facility personnel understood and could adequately control. Specific tasks, operations, or work items were identified and prioritized.

Assessment: According to the TWRS-P Contract, the Contractor's ISMP was required to conform with RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis.* This requirement was reflected in Section 3.3, "Authorization Basis," of the ISMP. Related to the above requirements and commitments, the RU's inspection of the Contractor's AB management program, inspection report IR-99-007, assessed the Contractor's procedures for developing and approving design and administrative documents (e.g., plans, procedures, and codes of practice) to determine if they included features that would ensure consistency between the documents and the description of the facility and administrative processes contained in the AB.

The AB management inspection (IR-99-007) found that the Contractor's procedures, relating to

the review and approval process of the AB assessment, to be complex and confusing. AB management processes were not well integrated with other processes that related to developing, reviewing, or approving the facility design or administrative controls associated with the Contractor's activities.

Several AB management Findings (IR-99-007) were identified which indicated that the Contractor had not yet established and implemented an effective work process for managing changes to the AB. As a result, Contractor personnel did not completely understand the required tasks and controls. For example, the inspection found that untrained Contractor personnel were performing screening reviews and safety evaluations and in some instances Contractor personnel were not following procedures.

From the design reviews (Design Review Report Memoranda), the RU observed that the scope of work was defined in the Contract, Functional Specification, Basis of Design, and AB. Requirements from these documents were further developed into system descriptions, data sheets, drawings, and other design media. The process for performing work was documented in the Project Management Plan, Engineering Execution Plan, Integrated Management Plan, and A-7 Design Process. At this early stage of design the Contractor had focussed significant resources on work scope definition through facility and system optimization studies. Although these studies and associated changes slowed design progress, objectives of system optimization studies included: establishing an efficient viable process; developing a functional and efficient layout; selecting mechanical handling concepts; and optimizing design to reduce cost.

Based on the design process inspection (IR-00-001), the RU observed that one element of defining work concerned the project's ability to communicate design information across organizational units. Design information, transmitted across interfaces, was found to be identified and controlled. However, this information was documented by varying methods across the project. Methods included the use of meeting minutes, memoranda, sample schedules, system descriptions, drawings, internal interface descriptions, and external interface control documents. Failure to have a consistent method to identify and control internal design interface information across the project was considered a design program weakness.

Also from the design process inspection (IR-00-001), the RU determined that although work scope (conduct of design reviews) was defined, the Contractor was not following the design review procedures. For example, the Contractor was not using design control checklists to document review and approval of design media. In addition, some actions identified during design reviews were not actively statused and action closure was not consistently documented in Project Document Control. The procedural issues discussed above were considered examples of a Finding against the Contractor's QAPIP for failure to follow procedures.

Conclusion: The Contractor did not always clearly define work into discrete tasks or processes that Contractor personnel understood and adequately controlled, particularly in the areas of AB maintenance and adherence to procedures. Moreover, specific tasks, operations, or work items related to AB maintenance were not adequately identified and prioritized in the Contractor's procedures.

3.2 Identify and Analyze Hazards Associated with the Work

Objective: At each organizational level, the full spectrum of hazards associated with work or a task was identified, analyzed and categorized. The hazards analyzed should have included nuclear, chemical and common industrial hazards. Personnel responsible for determining environmental, safety, and health impacts of the process worked closely with individuals responsible for the process.

Assessment: The RU observed that design reviews (Design Review Report Memoranda) identified numerous hazards that required assessment and control. Examples of these hazards included, flammable gasses in offgas systems, potential evaporator steam tube failures, and erosion of equipment. The process for analyzing hazards was underway with active participation from members of the disciplines performing the design work. The majority of work to identify hazards, identify control strategies, and select control strategies was performed in ISM meetings conducted in accordance with the "Design Guide for Integrated Safety Cycles 1 and 2." Examples of hazard analyses, control strategy selection, and incorporation into the design were observed. An example of this was the addition of active ventilation of the process vessel vent system to address hydrogen accumulation in the pretreatment facility.

Based on the safety integration inspection (IR-99-008), the RU observed that safety integration was being implemented in the design. Hazards associated with the designs being reviewed were being identified, analyzed, and categorized by the Contractor's review teams. Both design reviews and ISM Cycle 1 meetings included adequate representation from key organizations responsible for delivery of a plant embodying the principles of safety integration.

Based on the design process inspection (IR-00-001), the RU observed that the Contractor had an ISM program and design process in place that was adequate to analyze and implement into the design, the hazards, and hazardous situations associated with normal operations, anticipated operational occurrences, maintenance, testing, external events, natural phenomena hazards, and postulated accidents. Implementation of the program was limited during the inspection. However, the Contractor was in the process of implementing most elements of the ISM program in the ISM Cycle II reviews.

Also from the design process inspection (IR-00-001), the RU observed that the Contractor had a process in place to establish target reliabilities for important-to-safety systems, structures, and components used to implement control strategies for preventing or mitigating hazards and hazardous situations. The Contractor was aware of the need and was planning to account for system unavailability as part of the risk and reliability modeling. Furthermore, human factor considerations had been included in the design of the facility, although not in all areas. Human factor input by the operations and engineering staff and the use of Sellafield designs compensated for the absence of task analysis and human factor reviews. However, task analyses and human factor reviews were planned and the Contractor was taking action to procure a human factors specialist to address human factors considerations prior to detailed design of areas requiring operator-facility interfaces. Finally, a Finding was identified during the design process inspection for failure of the Contractor to develop procedures and implement the ISMP requirement to consider testability and inspectability in the evolving facility design.

Based upon observation of Contractor ISM Cycle II reviews, letter 00-RU-0283, the RU identified a concern that the HAZOP process was not consistently employed with integrity, potentially resulting in an unacceptable Construction Authorization Request (CAR) submittal. The RU observed a lack of appropriate attendance of relevant specialists at some of the Contractor's ISM Cycle II meetings, resulting in hazards or control strategies being inadequately evaluated in the meetings and generating a large number of action items for follow-up and resolution outside of the meetings. The Contractor's hazard identification activities were not performed using the design confirmation level of detail required by the Contractor's procedures, potentially resulting in a CAR hazard analysis based on insufficient information. Some of the Contractor's ISM teams used a "what if" approach to hazard identification instead of the systematic application of the HAZOP Cycle II guidewords required by the Contractor's procedures. In some instances during hazard identification meetings, the Contractor's design engineers were reluctant to both consider unmitigated event scenarios and disregard control strategy features they had planned to incorporate into the design. In at least one instance, a Contractor ISM team postponed the consideration of operability issues until ISM Cycle III (i.e., during facility construction). As a result of the above observations, the RU was concerned that the hazard analysis for the upcoming CAR submittal may be unacceptable.

Conclusion: The Contractor was identifying and analyzing hazards associated with the work to be done. Contractor personnel responsible for determining environmental, safety, and health impacts of the process worked closely with individuals responsible for the process. However, there was a lack of adherence to the Contractor's hazard analysis procedures resulting in concern that the hazard analysis for the upcoming CAR submittal may be unacceptable.

3.3 Develop and Implement Hazard Controls

Objective: Controls were developed and used which provided adequate protection of the public, the worker, and the environment for the hazards which had been analyzed. These controls may have included programmatic, administrative, and engineering requirements. Mechanisms were established for implementing the set of safety requirements agreed upon with the RU. Controls merged together at the workplace to prevent or mitigate the hazards that had been identified.

Assessment: Based on design reviews (Design Review Report Memoranda), the RU observed that it was too early in the design process to establish that adequate controls were fully developed, but some of the reviews identified features of the design that were providing hazard control. Examples included seismically qualifying cranes, active ventilation of process vessels, redundant instrumentation, and multiple steps in dilution of 12.2 M nitric acid.

From the safety integration inspection (IR-99-008), the RU determined that results of the hazards analysis were being communicated to designers and hazard control strategies and related performance requirements were being accommodated by the design.

Conclusion: The Contractor was developing hazard controls in the design which, if properly implemented, should provide adequate protection of the public, the worker, and the environment for the hazards which had been analyzed.

3.4 Perform Work Within Controls

Objective: Personnel who were assigned responsibility for completing this work were instructed on the hazards and the engineered and administrative controls that were to be used to control the hazards. Personnel performing the work were provided with instructions that effectively integrated the necessary controls. Appropriate mechanisms were in place to authorize the performance of the work, including a process that confirmed the readiness to perform the work before it was started.

Assessment: From the RU inspection of the Contractor's safety integration program (IR-99-008), the RU determined that the Contractor had established the program and procedures that assured that an adequate level of safety integration was accomplished during the design process. The inspectors reviewed a sample of the design program procedures and concluded that these provided for a substantial level of safety integration.

From the RU's evaluation of the Contractor's QAPIP, RL/REG-2000-5, the RU found that the proposed revision complied programmatically with applicable quality assurance regulations, related guidance, and met the requirements imposed by the Contract for design activities. However, the annual review was extended significantly and went through three complete or partial review cycles because of problems with the first two Contractor submittals. These problems included failure to follow prescribed procedures and 10 CFR 830.120 requirements for changes to the document. The final Contractor document, as noted above, was programmatically adequate, and at no time did the Contractor operate under a less-than-adequate QA program definition. Nonetheless, the Contractor repeatedly failed to follow requirements for documenting changes to the QAPIP.

The RU observed during design reviews (Design Review Report Memoranda) that the Contractor had not maintained the AB current with the design. Or conversely, the design work was not being performed within the controls established in the AB. Secondly, although the Contractor had procedures for performance of design and design review, the Contractor was not in compliance with these procedures. Specifically, the Contractor was not using design control checklists in single-discipline design reviews to document approval of design media and identify portions of the design that required further review. Furthermore, per the procedure for design review, the Contractor was required to track action items and document closure with the meeting record in Project Document Control (PDC). However, not all action items were actively tracked, some were obsolete, and closure was not always documented in PDC.

Conclusion: Contractor personnel did not always perform work within established administrative controls, particularly in the areas of AB maintenance and adherence to procedures.

3.5 Provide Feedback on Adequacy of Controls and Continuous Improvement in Defining and Planning Work

Objective: A process was established to measure performance and identify opportunities for improvement. Opportunities were provided for improvement even in those cases where the

current level of performance had been demonstrated to meet current expectations or safety goals. Recommended improvements were appropriately evaluated and implemented when proven to be cost effective. Safety performance was measured by line management and periodically validated by independent parties.

Assessment: From the RU's evaluation of the Contractor's QAPIP, RL/REG-2000-5, the RU found that the Contractor's QAPIP (Section 3, "Quality Improvement") was consistent with this core safety management function of ISM. However, the annual review was extended significantly and went through three complete or partial review cycles because of problems with the first two Contractor submittals. These problems included lack of lessons learned from previous submittals. The final Contractor document, as noted above, was programmatically adequate, and at no time did the Contractor operate under a less-than-adequate QA program definition. Nonetheless, the Contractor repeated errors made in the previous annual submittal of the QAPIP.

Based on the RU's inspection of the Contractor's self-assessment and corrective action program, inspection report IR-99-003, the RU determined that the Contractor had established a system of self-assessments and corrective actions that were adequate for the status of the project. The establishment and implementation of the self-identification portion of the program was considered a strength. While procedural weaknesses were identified during the inspection, the lack of clarity in the quality improvement procedures was self-identified by the Contractor and resolution was being tracked in its corrective action system. The Contractor had established comprehensive schedules for conducting management assessments and independent assessments. However, the RU noted that the basis for independent assessment schedules was not consistent with the AB commitments. The ISMP required that the frequency of independent assessments be based, in part, on performance indicators. The RU found that performance indicators had not been identified or used for that purpose. This was considered a Finding.

Conclusion: The Contractor had established a process to measure performance and identify opportunities for improvement. However, the effectiveness of this program was yet to be demonstrated, as evidenced by repeated errors in the QAPIP submittals and the lack of performance indicators for scheduling independent assessments as required by the AB.

4.0 SUMMARY

The Contractor adequately demonstrated that line management was responsible for safety. The Contractor had established clear roles and responsibilities for ensuring safety. Contractor personnel possessed competence commensurate their responsibilities. The Contractor was refining its identification of safety standards and requirements. The hazards associated with the work to be performed were being evaluated and the agreed-upon, refined, set of safety standards and requirements, if properly implemented, should provide adequate assurance that the public, the workers, and the environment will be protected from adverse consequences. The Contractor was tailoring administrative and engineering controls to prevent and mitigate hazards associated with the work to be performed. The Contractor had established the conditions and requirements to be satisfied for the radiation protection program for design. The Contractor had also established a process for ABARs that, if properly implemented, should be adequate for

supporting safe operations when required. The Contractor was identifying and analyzing hazards associated with the work to be done. Contractor personnel responsible for determining environmental, safety, and health impacts of the process worked closely with individuals responsible for the process. The Contractor was developing hazard controls in the design, which, if properly implemented, should provide adequate protection of the public, the worker, and the environment for the hazards that had been analyzed.

Although protecting the public, the workers, and the environment was a priority when activities were planned and performed, resources were not effectively allocated to maintain the AB. The Contractor did not always clearly define work into discrete tasks or processes that Contractor personnel understood and adequately controlled, particularly in the areas of AB maintenance and adherence to procedures. The lack of adherence to the Contractor's hazard analysis procedures resulted in concern that the hazard analysis for the upcoming CAR submittal may be unacceptable. Contractor personnel did not always perform work within established administrative controls, particularly in the areas of AB maintenance and adherence to procedures. Moreover, specific tasks, operations, or work items related to AB maintenance were not adequately identified and prioritized in the Contractor's procedures. The Contractor had established a process to measure performance and identify opportunities for improvement. However, the effectiveness of this program was yet to be demonstrated, as evidenced by repeated errors in the QAPIP submittals and the lack of performance indicators for scheduling independent assessments as required by the AB.

5.0 REFERENCES

IR-00-001, *Design Process Inspection Report*, , U.S. Department of Energy, Richland Operations Office, 2000.

IR-00-002, *Employee Concerns Program Inspection Report*, U.S. Department of Energy, Richland Operations Office, 2000.

IR-99-003, *Self-Assessment and Corrective Action Inspection Report*, U.S. Department of Energy, Richland Operations Office, 1999.

IR-99-007, *Authorization Basis Management Inspection Report*, U.S. Department of Energy, Richland Operations Office, 1999.

IR-99-007, *Standards Selection Process Report*, U.S. Department of Energy, Richland Operations Office, 1999.

IR-99-008, *Safety Integration Inspection Report*, U.S. Department of Energy, Richland Operations Office, 1999.

RL/REG-2000-01, *Regulatory Unit Evaluation of the BNFL Inc. Radiation Protection Program for Design Revision 2*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999

RL/REG-2000-05, *DOE Regulatory Unit Evaluation Report of BNFL Inc.'s Quality Assurance Program and Implementation Plan*, Rev. 0, 2000.

6.0 LIST OF TERMS

AB	authorization basis
ABAR	authorization basis amendment request
BNFL	BNFL Inc.
CAR	Construction Authorization Request
DCD	Design Criteria Database
DOE	U.S. Department of Energy
ECP	Employee Concerns Program
HAZOP	Hazard and Operability Study
ICD	Interface Control Documents
ISM	Integrated Safety Management
ISMP	Integrated Safety Management Plan
NPH	natural phenomena hazard
PDC	Project Document Control
PMT	Process Management Team
PSC	Project Safety Committee
QA	quality assurance
QAPIP	Quality Assurance Program and Implementation Plan
RO	Regulatory Official
RPP	Radiation Protection Program
RU	Regulatory Unit
SIPD	Standards Identification Process Database
SRD	Safety Requirement Documents