

# **Regulatory Unit Position on Assessment of the Contractor's Integrated Safety Management Program as Described in the Integrated Safety Management Plan**



July 1, 1999

Office of Radiological, Nuclear, and Process  
Safety Regulation of the TWRS Privatization Contractor

U. S. Department of Energy  
Richland Operations Office  
P.O. Box 550, A4-70  
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Approved by: \_\_\_\_\_

Date: \_\_\_\_\_

# PREFACE

In February 1996, the U.S. Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal for privatized processing of waste as part of the Hanford River Protection Project (RPP). 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 radioactive and hazardous wastes.

Using the privatization concept, DOE is purchasing waste processing services from a contractor-owned, contractor-operated facility through a fixed-price contract. DOE plans to provide the waste feedstock to be processed but will 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 RPP Privatization (RPP-P) Program is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort the objectives of which are to: (a) demonstrate the technical and business viability of using a privatized contractor 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 was a twenty-month period from September 1996 to May 1998 that established technical, operational, regulatory, and financial elements necessary for privatized waste processing services. This included identification by the RPP-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 were for the contractors to develop the Part-A deliverables and four months were for DOE to evaluate the deliverables and determine whether to authorize one or both of the Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B.

Part B-1 is a twenty-four month period, starting August 24, 1998, 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 RPP-P Program is DOE's approach to safety regulation. DOE has specifically defined a regulatory approach and has specifically chartered a dedicated Office of Safety Regulation of the RPP-P Contractor (Regulatory Unit). The aim of DOE in proceeding with the safety regulation of the RPP-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. Since external regulation of safety may occur at some future date, DOE regulation should permit a seamless transition to external regulatory agencies. DOE is patterning its regulation of the RPP-P contractor to be consistent with that of the U.S. Nuclear Regulatory Commission (NRC) for radiological and nuclear safety. 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. The RL Manager has assigned safety regulatory authority to the RL Director of the RPP-P Regulatory Unit (the RPP-P Regulatory Official). The regulatory authority of the Regulatory Official is exclusive to the regulation of the RPP-P contractor. The Regulatory Official is the formal point of execution for safety regulation of the RPP-P contractor.

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

The relationship between DOE and the privatized contractor performing work under a fixed-priced contract is different than the relationship under traditional Management and Operations 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 RPP-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. The contractor is not relieved from any obligations to comply with such regulations and is subject to the enforcement practices contained therein.

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# Regulatory Unit Position on Assessment of the Contractor's Integrated Safety Management Program as Described in the Integrated Safety Management Plan

## 1.0 INTRODUCTION

The U.S. Department of Energy (DOE) issued a plan (*Department of Energy Plan for the Development and Implementation of Integrated Safety Management*) for the implementation of integrated safety management (ISM). The objective of ISM is for the DOE and its contractors to systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment.

Consistent with the ISM concept, the DOE initiated a type of contract reform called "privatization" to a portion of its River Protection Project (RPP)<sup>1</sup> at the Richland Operations Office (RL). A key element of the Tank Waste Remediation System Privatization (TWRS-P) contracts was the DOE's regulation of radiological, nuclear, and process safety through establishing a specifically chartered, dedicated Regulatory Unit (RU). Regulation by the RU was authorized in the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (Policy), DOE/RL-96-25, and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (MOA), DOE/RL-96-26. The nature and scope of this special regulation (in the sense that it was based on terms of a contract rather than formal regulations) was delineated in the MOA, the RPP-P Contract,<sup>2</sup> and the four documents (listed below), which were incorporated into the MOA and Contract:

*Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005*

*DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003*

*Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006*

*Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004.*

In pre-contract discussions with prospective RPP-P bidders and with stakeholders, radiological and nuclear safety regulation was a significant concern. Prospective bidders took the position that the top-down, order-based safety program specified by DOE was too uncertain and unpredictable to support fixed-price bidding. A new regulatory framework that could accommodate this situation had to be

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<sup>1</sup> River Protection Project (RPP) was formerly known as the Tank Waste Remediation System (TWRS). TWRS is still used in document titles that have not been revised to reflect the name change.

<sup>2</sup> Contract DE-AC06-96RL13308 between DOE and BNFL Inc., dated August 24, 1998.

established. The regulatory framework also had to recognize that specific processes for vitrifying the types of waste stored at the Hanford Site did not currently exist. Therefore, the regulatory approach had to accommodate this emerging technology.

A bottoms-up, standards-based regulatory approach was established, allowing the contractor to recommend a set of standards that would achieve adequate safety for its particular waste-processing endeavor. The regulator would approve the contractor's set of standards. Recognizing the need for integrating safety into all aspects of the RPP-P program, DOE required in the Contract that the contractor develop and implement an integrated program for radiological, nuclear, and process safety, and for environmental protection. The contractor's standards-based ISM program was documented in its Integrated Safety Management Plan (ISMP). The RU reviewed the BNFL ISMP for conformance to the Contract-stipulated requirements. The basis for approval of the ISMP was contained in DOE/RL-96-0003 (Section 3.3.1), and the review was conducted using the guidance for the Standards Approval Package (RL/REG-97-07, RL/REG-97-08).

Subsequent to the above described review, the DOE issued Department-wide guidance on approval of ISM programs. The Department-wide guidance focused on the seven guiding principles and the five core functions of ISM. As would be expected, the BNFL ISMP differed somewhat in form from that proposed by the Department-wide guidance. However, it acceptably addressed the guiding principles and core functions set forth in the DOE-wide guidance.

In a memorandum from J. D. Wagoner to T. J. O'Toole dated May 21, 1997, the Manager, RL, addressed the question as to whether the DOE-wide protocol for approval of ISM plans for defense nuclear facilities should be imposed on the TWRS-P contractors. The discussion paper attached to that memorandum concluded that, "From consideration of the features already present in the Regulatory Policy and Top Level Standards mandated for the TWRS-P privatization contractors, the provisions for approval of the contractors' ISM plans under the authority and means established by the Regulatory Official, meet the intent of the DNFSB 95-2 and the associated DOE recommendations. They are fully consistent with those being established under the proposed DEAR clause<sup>3</sup> and related DOE-wide protocol for ISM plan approval....For these reasons, changes to the privatization contracts to accommodate additional requirements resulting from this protocol are not necessary."

The DOE ISM program will continue to evolve as experience is gained in its implementation. Continued communication between the RU and other DOE offices regarding ISM is important to ensure that subsequent changes in the ISM program are evaluated relative to the uniqueness of the TWRS-P Contract.

The RU oversight of the RPP-P contractor's implementation of its ISMP occurs routinely over time as inspections are conducted or contractor submittals to the RU are reviewed. However, each such activity may address only a portion of the ISMP. To date, no steps have been taken to assess ISMP implementation in a more comprehensive manner.

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<sup>3</sup> The proposed DEAR clause referred to is the DOE Acquisition Regulation, DEAR 48 CFR 970.5204-2, which had two major components: (1) provision for a DOE approved Integrated Safety Management Plan, and (2) annual negotiation of Environment, Safety and Health related performance measures.

## 2.0 PURPOSE

The purpose of this paper is to describe the following: (1) the RU position for preparing comprehensive assessments of the RPP-P contractor's ISMP implementation, (2) how the RU's oversight of the RPP-P contractor's ISM system compares with the DOE-wide oversight of the contractor's ISM system, and (3) the RU's plans for evaluating the impact of DOE-wide changes in ISM implementation on the RPP-P ISM program.

## 3.0 BACKGROUND

### 3.1 DOE-WIDE ISM IMPLEMENTATION PLAN

The *Department of Energy Plan for the Development and Implementation of Integrated Safety Management* identifies six basic components of safety management. The first three components (objective, guiding principles, and core functions) should be used consistently in implementing safety management throughout the DOE complex. The discussion in this paper is limited to these three components, and describes how the regulatory approach to oversight of the RPP-P contractor has developed relative to the DOE-wide guidance. The remaining three components (mechanisms, responsibilities, and implementation) are needed to ensure safety management, and they will vary based on the specific nature and hazard of the work being performed. Because by design these latter three components vary based on the work being performed by each contractor, there is no need for purposes of this paper to address the DOE guidance or the RPP-P contractor's implementation of these components.

The stated objective of integrated safety management is "...for the Department and contractors to systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment. Stated simply, the objective is to: DO WORK SAFELY."

The guiding principles of ISM are as follows.

1. **Line Management Responsibility for Safety.** Line management is responsible for protection of the public, the workers, and the environment.
2. **Clear Roles and Responsibilities.** Clear and unambiguous lines of authority and responsibility for ensuring safety are established and maintained at all organizational levels within the Department and its contractors.
3. **Competence Commensurate with Responsibilities.** Personnel possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.
4. **Balanced Priorities.** Resources are effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment is a priority whenever activities are planned and performed.

5. **Identification of Safety Standards and Requirements.** Before work is performed, the associated hazards are evaluated and an agreed-upon set of safety standards and requirements is established which, if properly implemented, provides adequate assurance that the public, the workers, and the environment are protected from adverse consequences.
6. **Hazard Controls Tailored to Work Being Performed.** Administrative and engineering controls to prevent and mitigate hazards are tailored to the work and associated hazards being performed.
7. **Operations Authorization.** The conditions and requirements to be satisfied for operations to be initiated and conducted are clearly established and agreed upon.

The core safety management functions of ISM are as follows.

1. Define scope of work.
2. Identify and analyze hazards associated with the work.
3. Develop and implement hazards controls.
4. Perform work within controls.
5. Provide feedback on the adequacy of controls and continuous improvement in defining and planning work.

The DOE has also developed a policy (DOE P 450.4, *Safety Management System Policy*) and a guide (DOE G 450.4 –1, *Integrated Safety Management System Guide*)<sup>4</sup> and is developing a program for verification of contractors' ISM systems.<sup>5</sup> (These documents have not yet been incorporated into the TWRS-P Contract.) The draft verification program provides for a two-part evaluation of the adequacy of the ISM program with the first part addressing the contractor's program and the second part focusing on implementation of the program. The use of the seven guiding principals and five core functions are central to the policy, guidance, and verification documents.

### 3.2 RU PROGRAM FOR ISMP APPROVAL

The RU program for regulation of the RPP-P contractor was developed from Contract requirements and in advance of the issuance of the DOE-wide policies and guidance previously described. Contract documents described the manner in which the regulatory process was to work. One of these documents, DOE/RL-96-0003, described the regulatory process for radiological, nuclear, and process safety for RPP-P contractors. The first regulatory action described in that document was Standards Approval. Section 3.3.1 states, "The purpose of Standards Approval regulatory action is to approve the Contractor-recommended set of radiological, nuclear, and process safety standards and

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<sup>4</sup> DOE G 450.4-1, *Integrated Safety Management System Guide*, is to be used with DOE P 450.4, *Safety Management System Policy*, and DEAR Safety Management System Contract Clauses.

<sup>5</sup> Integrated Safety Management System Verification (ISMSV) Core Requirements (Draft)

requirements documented in a Safety Requirements Document (SRD) and to approve the Contractor's standards-based integrated safety management program documented in an Integrated Safety Management Plan (ISMP)."

As stated in the Introduction section of DOE/RL-96-0003, the ISMP proposed by the RPP-P contractor, and the RU evaluation of that proposed ISMP, were based on the requirements and approval criteria set forth in DOE/RL-96-0003. The approval criteria were as follows.

"The approval of the Contractor's proposed ISMP will be issued upon determination by the Director of the Regulatory Unit that:

1. The program documented in the ISMP complies with all applicable law and regulations.
2. The program documented in the ISMP conforms to the top-level radiological, nuclear, and process standards and principles contained in DOE/RL-96-0006.
3. The selected safety management processes documented in the ISMP are standards based and are appropriately tailored to the hazards associated with the Contractor's proposed facility, its operation, and its deactivation.
4. The selected safety management processes documented in the ISMP properly and adequately address management of process hazards.
5. The program documented in the ISMP contains appropriate features of integrated safety management (i.e., integration among safety, design, and operations interests; integration over the life cycle of the activities; and integration into work planning and performance).
6. The interfaces among regulatory regimes are appropriately addressed to ensure that adequate protection is fully achieved.
7. Safety documentation processes delineated in the ISMP provide for appropriate document control and maintenance.
8. Scheduling of the safety-related activities as described in the ISMP, including generation of regulatory submittals, is consistent with Figure 2 of this document.
9. Self assessment elements documented in the ISMP are appropriate.
10. Safety definition, implementation, and maintenance roles, responsibilities and authorities defined in the ISMP are clear and appropriate."

These criteria did not explicitly address the seven guiding principles and five core functions on ISM that were subsequently described in the *Department of Energy Plan for the Development and Implementation of Integrated Safety Management*. However, the ISMP reviewers were aware of these principles and core functions which were addressed in their review consistent with the ISMP review guidance (RL/REG-97-07, *Guidance for the Review of TWRS Privatization Contractor Integrated*

*Safety Management Plan Submittal Package*). The RU evaluation determined that the ISMP was consistent with DOE's guiding principles and core safety management functions of ISM. Section 3.5 of the *DOE Regulatory Unit Evaluation Report of the BNFL Integrated Safety Management Plan* (RL/REG-98-03) identified specific sections of the ISMP that addressed each of the principles and functions. This section of the evaluation also noted that the SRD review identified specific sections of that document which also addressed DOE's seven guiding principles of ISM.

As stated above, the SRD is also a key document in the implementation of RPP-P ISM. It documents the results of the standards selection process. In practice, the SRD and ISMP are closely linked. The SRD and ISMP are based on common information (the work, the hazards, and selected controls), and are used together to address overall conformance to top-level safety standards and principles, compliance with applicable laws and regulations, and to demonstrate that adequate safety will be achieved. The ISMP (Revision 4) submitted by BNFL incorporates the SRD into its description of ISM, so while the ISMP is the document commonly addressed in this paper, the SRD is included in ISM by the privatization contractor.

#### **4.0 RU ASSESSMENT OF ISMP IMPLEMENTATION**

The verification process used by the RU to assess the contractor's ISM program involves a two-part process consistent with the DOE draft verification process description.<sup>6</sup> That is, the first part involves an initial review and approval of the ISMP, and the second part involves verification of its implementation. The initial review of the ISMP was described in Section 3.2 above. The verification of ISMP implementation by the RU is accomplished through a series of actions involving inspections, document reviews, and other oversight activities.

The RU inspection program developed for the design phase of the RPP-P project includes several separate inspection areas: quality assurance program and implementation, configuration management, self-assessments and corrective actions, design process, standards selection process, training and qualification of personnel, authorization basis management, employee concerns program, safety integration, SRD design standards implementation, and radiological as low as reasonably achievable (ALARA) design. Each of these areas is a part of the contractor's ISMP, and collectively, the inspection program contains elements that address the five core functions and seven guiding principles described in the DOE ISM program. The findings from these inspections will address the contractor's success in integrating safety management into its various work activities. In addition, actual work performance may show the extent to which safety is being incorporated into all aspects of work activities. Unplanned events or failure to meet certain standards may be indicators that safety integration is not as effective as it might be. Substantial information regarding the contractor's integration of safety management is also obtained during the RU staff review of contract deliverables, or other oversight activities, such as facility design review. Therefore, to assure that the RU assessment of the contractor's performance relative to the ISMP is comprehensive, the results of oversight activities other than the inspection program are also considered.

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<sup>6</sup> Integrated Safety Management System Verification (ISMSV) Core Requirements (Draft).

While different aspects of these assessments are carried out periodically, the RPP-P regulatory program provides for specific times in the life of the project when the ISMP (and the SRD) are revised to address the needs of the next phase of the project (specifically during authorization requests for construction, operation, and deactivation). The RU in its evaluation of these authorization requests must address the proposed revision to the ISMP to determine its relevance to the planned activities, and the contractor's conduct of safety-related activities during the prior project phase in accordance with the approved ISMP. This latter aspect--evaluation of the contractor's performance relative to the ISMP during the prior phase lends itself to comprehensive assessments of ISMP implementation which consider the numerous RU oversight activities which occur during the time period of interest. Recognizing the importance of integrating safety into the work activities through implementation of the ISMP on an ongoing basis, and the extended time between the different authorization requests, the RU believes that comprehensive assessments at more frequent intervals will also be beneficial. These assessments will normally be conducted every two years. This frequency may be reduced to one year or extended to three years based on the following considerations:

- Significance of any concerns identified in the previous assessment
- Evidence of progress in correcting previously identified concerns
- Stability of key management in the contractor's program
- The anticipated schedule of requested changes in the authorization basis.

As stated above, the RPP-P ISM approach as described in the contractor's ISMP was found to be consistent with the DOE-wide guidance in effect at that time. It should be recognized, however, that the DOE program for ISM continues to evolve while the RU program is "fixed" by the terms of the RPP-P Contract (although with provisions for adjustment throughout the project life). As such, the RU maintains an awareness of the DOE program regarding ISM. Should changes in the contractor's program be desirable as a result of DOE's broader experience with ISM implementation, these changes would be evaluated as potential safety enhancement in accordance with appropriate procedures (RL/REG-98-14, *Regulatory Unit Position on New Safety Information and Back-fits*).

In summary, the RU program for assessment of the contractor's implementation of its ISMP will have the following elements.

- Input regarding assessment of the ISMP implementation will be derived from RU inspections and other RU oversight activities.
- Periodically, comprehensive reports will be issued which assess the contractor's implementation of integration of safety management as described in the ISMP.
- The RU intends to maintain an ongoing awareness of the DOE ISM program.

## **5.0 REFERENCES**

*Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005, Revision 0, 1996.

*Department of Energy Plan for the Development and Implementation of Integrated Safety Management, Implementation Plan for Board Recommendation 95-2, U. S Department of Energy, Washington, D.C., April 1996.*

*DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003, Revision 0, 1996.*

*DOE Regulatory Unit Evaluation Report of the BNFL Integrated Safety Management Plan, RL/REG-98-03, Revision 0, March 1998.*

*Guidance for the Review of TWRS Privatization Contractor Integrated Safety Management Plan Submittal Package, RL/REG-97-07, Revision 0, June 1997.*

*Guidance for the Review of TWRS Privatization Contractor Safety Requirements Document Submittal Package, RL/REG-97-08, Revision 0, June 1997.*

*Integrated Safety Management Plan, BNFL-5193-ISP-01, Revision 4, 1998.*

*Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors, DOE/RL-96-26, Revision 0, July 3, 1996.*

*Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors, DOE/RL-96-25, Revision 0, July 3, 1996.*

*Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization, DOE/RL-96-0004, Revision 0, 1996.*

*Regulatory Unit Position on New Safety Information and Back-fits, RL/REG-98-14, Revision 1, 1998.*

*Safety Management System for Tank Waste Remediation System (TWRS) Privatization Contractors, memorandum from J. D. Wagoner to T. J. O'Toole, U.S. Department of Energy, Richland Operations Office, Richland, Washington, May 21, 1997.*

*Safety Management System Policy, DOE P 450.4, U.S. Department of Energy, Washington, D.C., 1996.*

*Safety Requirements Document, BNFL-5193-SRD-01, Revision 0, September 26, 1997.*

*Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, Revision 0, 1996.*

## **6.0 LIST OF TERMS**

ALARA	as low as reasonably achievable
DEAR	DOE Acquisition Regulation

DOE	U.S. Department of Energy
ISM	integrated safety management
ISMP	Integrated Safety Management Plan
ISMSV	Integrated Safety Management System Verification
MOA	Memorandum of Agreement
RL	U.S. Department of Energy, Richland Operations Office
RPP	River Protection Project
RPP-P	River Protection Project-Privatization
RU	Regulatory Unit
SRD	Safety Requirements Document
TWRS	Tank Waste Remediation System
TWRS-P	Tank Waste Remediation System-Privatization

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