RL/REG-98-21
Revision 0

Regulatory Unit Position on Implementing and Assuring Compliance With Integrated Safety Management

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Office of Radiological, Nuclear and Process Safety Regulation of TWRS Privatization Contractors

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PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the *TWRS Privatization Request for Proposal* (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-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 will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed 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 bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization 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 privatized contractors to treat 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 treat the tank waste. The Phase I effort consists of two parts: Part A and Part B.

Part A consists of a twenty-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS Privatization 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 will be used by the Contractors to develop the Part-A products and four months will be used by DOE to evaluate the products.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS Privatization Contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shelled tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I; and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS Privatization Contracts is DOE regulation of radiological, nuclear, and process safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors* (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, RL; the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of this regulation.

The authority of the RU to regulate the TWRS Privatization Contractors is derived solely from the terms of the TWRS Privatization Contracts. Its authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS Privatization Contracts, and the four documents (listed below), which are incorporated into the Contracts. This special 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 Contractors from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

The Policy, the MOA, the TWRS Privatization Contracts, and the four documents incorporated in the Contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. The four documents incorporated in the Contracts (and also incorporated in the MOA) are

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

In the execution of the regulatory program, the RU will consider not only the relevant approaches and practices of DOE but also those of the Nuclear Regulatory Commission (NRC). The Policy states that

> "It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Campus, 100 Sprout Road, Richland, Washington.

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1.0 PURPOSE AND SUMMARY

The purpose of this paper is to show how Integrated Safety Management (ISM) is central to the Tank Waste Remediation System (TWRS) Privatization regulatory concept. The paper shows that ISM flows through the regulatory process, finally becoming embodied in the contractor deliverables. This paper describes tools the Regulatory Unit (RU) has to assure contractor compliance with the concepts of ISM.

This paper concludes that the Contractor must perform work according to the process specified in their Integrated Safety Management Plan (ISMP) and implementing procedures. Where the Contractor fails to do so, that failure may be subject to action by the RU under the terms of the Contract. Where the Contractor fails to do so and that failure has nuclear safety significance, the Contractor may be subject to enforcement action by DOE under the Price Anderson Amendments Act (PAAA).

2.0 BACKGROUND

In pre-contract discussions with prospective TWRS Privatization bidders and with stakeholders, radiological and nuclear safety regulation was a significant concern. The stakeholders insisted that privatization not diminish safety. 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 established. The regulatory framework also had to recognize that specific processes for vitrifying the types of waste stored at Hanford did not currently exist. Therefore, the regulatory approach had to accommodate emerging technology.

The process established was "bottoms up," allowing the contractor to establish the set of standards they would meet to achieve safety. (The regulator would approve the Contractor's set of standards.) Although different than the "top down" programs used elsewhere by both DOE and NRC, this approach has the flexibility to accommodate emerging technology.

The contractor is constrained in selecting standards by a requirement that the standards:

1. Comply with applicable federal, state and local laws and regulations
2. Conform to the DOE top-level safety standards and principles specified in DOE/RL-96-0006, "Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors"
3. Follow the process specified in DOE/RL-96-0004, "Process for Establishing Safety Standards and Requirements."

Taken together, these three elements are referred to as the "safety triad" and form the basis for the RU making a determination that the contractor has achieved "adequate safety."[1] The RU cannot make an adequate safety determination in the absence of any of the three elements.

The third element of the safety triad, the process for selecting standards, is based on ISM. The goal of ISM is improved safety management. That is the theme of Defense Nuclear Facilities Safety Board (Board) recommendation 95-2, presented to the U.S. Department of Energy (DOE) on October 11, 1995. Specifically, the Board recommended:[2]

1. Institutionalize the process of incorporating into the planning and execution of every major defense nuclear activity involving hazardous materials those controls necessary to ensure that environment, safety and health objectives are achieved.

2. Require the conduct of all operations and activities within the defense nuclear complex or the former defense nuclear complex that involve radioactive and other substantially hazardous materials to be subject to Safety Management Plans that are graded according to the risk associated with the activity.

The DOE-wide goal to establish ISM as part of its initiative to achieve more contract accountability reflects many of the elements of Board recommendation 95-2. The DOE Safety Management System Policy states as its objective:[3]

> "The Department and Contractors must 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. This is to be accomplished through effective integration of safety management into all facets of work planning and execution. In other words, the overall management of safety functions and activities becomes an integral part of mission accomplishment."

The policy document for privatization contractor regulation, DOE/RL-95-25, establishes ISM as one of five basic regulatory elements. The Policy was signed by the Under Secretary, the Assistant Secretary for Environment, Safety and Health, the Assistant Secretary for Environmental Management, and the Manager, Richland Operations Office (RL). The Policy is the underlying document that describes the methods chosen for the RL Manager to discharge the safety regulation responsibility for TWRS Privatization. It states:[4]

> "The framework for radiological, nuclear and process safety regulation of TWRS Privatization contractors shall be as follows:

[1] Note that "adequate" does not mean "at the limit" or "just barely enough." Rather, solid requirements and a rigorous process the contractor must follow define adequate safety.
[2] "Defense Nuclear Facilities Safety Board Recommendation 95-2 to the Secretary of Energy," Pursuant to 42 U.S.C. Para. 2286a(a)(5) Atomic Energy Act of 1954, as amended, October 11, 1995.
[3] DOE P 450.4, "Safety Management System Policy," October 15, 1996.
[4] DOE/RL-95-25, "Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors," pg. 3, Section 5.0, "Implementing Framework."

1. …
2. …
3. …
4. Appropriate application of principles of standards-based integrated safety management…."

The Regulatory Plan, Policy Element (PE) 15, further discusses the appropriate application of the principles of standards-based ISM.[5]

Requirements

Within the TWRS Privatization, the Contract defines ISM requirements, notably in Standard 4,[6] which states:

> "The primary objectives of the Safety, Health, and Environmental Program are to:
>
> 1. …
> 2. …
> 3. Implement a cost-effective program that integrates safety, health, and environmental protection in all Contractor activities;"

And under "Radiological, Nuclear and Process Safety," which states:

> "The Contractor shall develop and implement an integrated standards-based safety management program to ensure that radiological, nuclear, and process safety requirements are defined, implemented, and maintained," and
>
> "The Contractor's integrated standards-based safety management program shall be developed to comply with the specific nuclear safety regulations defined under the 10 CFR 800 series of nuclear safety requirements and with the regulatory program established in [DOE/RL-96-0003, 4, 5, and 6]."

Table S4-1 of the Contract requires that the Contractor submit an ISMP. The ISMP content is defined, in part, in the Regulatory Process,[7] as:

> "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);" and

[5] RL/REG-97-10, "Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors Regulatory Plan," Rev. 2, July 1998.
[6] TWRS Privatization Contract No. DE-RP06-96RL13308, September 23, 1996.
[7] "DOE Regulatory Process for Radiological, Nuclear and Process Safety for TWRS Privatization Contractors," DOE/RL-96-0003, February 1996, Section 3.3.1, pg. 5.

> "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."

The requirement that safety management processes be "standards based" reflects the close tie between the Safety Requirements Document (SRD) and the ISMP. Both the Policy[8] and the Standards Process Description[9] are explicit in requiring the execution of a DOE-specified standards selection process that results in the SRD. The contractor is also required to certify "(t)hat this process was employed with integrity."[10] The ISMP contains an integrated view of all safety management processes, including the standards selection process.

3.0 IMPLEMENTING ISM

A clear, central concept of ISM is that the contractor should tailor the basic framework for ensuring protection of the public, workers and the environment to the specifics of the work proposed. This concept emphasizes the need to fit the safety measures to the specific hazards of the work. A preconfigured "one-size-fits-all" approach is inconsistent with the concept of ISM.

The Board suggested, and the DOE policy endorses, that "tailoring" may be structured according to the recurring safety functions, namely:[11]

- Identify Applicable Requirement(s),
- Define Work,
- Analyze Hazards,
- Develop and Implement Controls,
- Perform Work,
- Assess, Feedback, and Improve.

For TWRS Privatization, the Contract carries this concept forward in the Standards Process Description.[12] This document outlines steps covering the first four bullets of the Board recommendation as related to developing standards that are the technical basis for achieving ISM. It does not speak to the operations or "perform work" phase of ISM. Consistent with the requirement for integration over the life cycle of activities, noted above,[13] the Contractor will also be responsible for the "Perform Work" and "Assess, Feedback, and Improve" portions of ISM at the appropriate time.

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[8] DOE/RL-95-25, Section 5.0, "Implementing Framework."
[9] DOE/RL-96-0004, "Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization," DOE/RL-96-0004, February 1996.
[10] Ibid., Section 3.3, "Contractor's Recommendation and Certification."
[11] "Integrated Safety Management," DNFSB/TECH-16, June 1997.
[12] DOE/RL-96-0004, Figure 1, "Process Steps to Develop Recommended Set."
[13] "DOE Regulatory Process for Radiological, Nuclear and Process Safety for TWRS Privatization Contractors," DOE/RL-96-0003, February 1996, Section 3.3.1, pg. 5.

The purpose of the Standards Process Description is:[14]

> "…to describe the process that the TWRS Privatization Contractor shall use to develop and recommend a set of radiological, nuclear, and process safety standards and requirements. Employing this process will produce a standards set, to be recommended by the Contractor Representative for approval consideration by the Director of the DOE Regulatory Unit, that will serve as a basis for issuance of an approved Safety Requirements Document (SRD), as a condition of the contract."

The Standards Process Description also states:[15]

> "A key feature of this process is that these standards for performance of work link directly to specific radiological, nuclear and process hazards associated with that work."

The DNFSB considers defining requirements and standards as the framework for adequate safety management. They state:[16]

> "The determination of applicable requirements is an important prerequisite for the tailoring concept built into Integrated Safety Management. Once requirements have been identified, methods of compliance can then be tailored to suit the hazards of specific activities…These standards are to serve as a basic framework that it is incumbent on all managers of specific activities on site to use in planning work. The specific control measures resulting from these planning exercises, augmented by industry consensus standards, if appropriate, and adapted to the specifics of the hazards, are then to become the conditions, or "safety envelope," within which the work is to be performed. This concept of a requirements-based infrastructure is the ideal towards which DOE is striving for long-term operational missions that include the design, construction, operation, and decommissioning of nuclear facilities…."

The process for implementing ISM supports "bottoms up" standard selection. Its iterative nature also accommodates emerging technologies.

4.0 ASSURING COMPLIANCE

Requiring conformance with the authorization basis as a feature of the TWRS Privatization contract assures that safety requirements have the same enforceability as other components of the contract. The RU primarily assures compliance through its

[14] Ibid., Section 1.0, "Purpose."
[15] Ibid., Section 3.0, "Standards Process Description."
[16] "Integrated Safety Management," DNFSB/TECH-16, pg. 4-2, Section 4.1, "Identifying Applicable Requirements."

inspection function using authority established by the Contract.[17] However, the law establishes the extent of the DOE's authority to enforce the authorization basis.

Provisions of the Atomic Energy Act[18] authorize the DOE to:

> "Establish by rule, regulation or order such standards and instructions to govern the possession and use of special nuclear material and by-product material as the Commission may deem necessary or desirable to promote the common defense and security or to protect or to minimize danger to life or property."

The Department of Energy Organization Act[19] and the Atomic Energy Act require DOE to protect the public health and safety, as well as the safety of workers at DOE facilities. The Acts grant DOE broad authority to achieve this goal.

The DOE's statutory authority to take enforcement action stems from Section 17 of the PAAA.[20] This section makes most contractors covered by the Price-Anderson indemnification system subject to civil penalties for violations of applicable nuclear safety requirements. Section 18 of the PAAA subjects employees of DOE contractors to criminal penalties for knowing and willful violations of applicable DOE nuclear safety rules. (The DOE's enforcement authority applies only to civil penalties, as decisions on criminal violations are the responsibility of the Department of Justice.)

The Memorandum of Agreement gives the TWRS Regulatory Official the authority to "…require corrective actions by the contractors, including…

> Communication of regulatory noncompliances to the DOE Enforcement and Investigations staff."[21]

The Enforcement and Investigations staff provides PAAA enforcement for nuclear safety requirements promulgated in rules, such as 10 CFR 820, 830 and 835. 10 CFR 830, in particular, is applicable to ensuring compliance with the requirements of ISM. Two essential sections of 10 CFR 830 are:[22]

Section 830.4, "General Rule," which states:

> "(b) With respect to a particular DOE nuclear facility, the contractor responsible for the design, construction, operation, or decommissioning of that facility shall be responsible for implementation of, and compliance with, the requirements of this part."

[17] This is discussed in detail in Section 4, "Authority" of RL/REG-98-05, "Inspection Program Description for the Regulatory Oversight of TWRS Privatization Contractors," January 1998.
[18] Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011.
[19] Department of Energy Organization Act, 42 U.S.C. 7101.
[20] Price Anderson Amendments Act of 1988, 42 U.S.C. Sec. 2273.
[21] DOE/RL-96-26, "Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors," July 1996.
[22] 10 CFR 830, "Nuclear Safety Management," revised January 1, 1998.

Section 830.5, "Enforcement," which states:

> "The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of part 820 of this title."

Section 830.120, "Quality Assurance Requirements" falls under the provisions of these two sections. The DOE therefore uses section 830.120 as the applicable QA standard, because other standards are not enforceable.

The General Rule of 830.120 states:

> "A contractor responsible for a DOE nuclear facility shall:
>
> (i) conduct its work in accordance with the criteria of paragraph c of this section [c defines the QA criteria]
> (ii) develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work; and
> (iii) implement the QAP, as approved and modified by DOE."

Contractor compliance with the QA requirements, as implemented by the Contractor's QA Plan, becomes a primary basis for assuring compliance with the regulatory concepts of the Privatization effort, including ISM. Specifically, 830.120 states:

> "Work Processes. Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means."

BNFL, in their QAP, commits, as follows:[23]

> "The QAP shall be implemented though project management documents using a tiered approach that includes the following:
>
> > Project Management plans that define the management policies, goals, criteria and responsibilities to perform the work: Integrated Safety Management Plan, …"
>
> "Work activities shall be performed in accordance with established regulatory requirements, technical standards, and administrative controls. All activities affecting quality shall be prescribed by, and performed in accordance with, documented, management approved procedures, instructions, and design documents."

[23] BNFL-5193-QAP-01, "Quality Assurance Program and Implementation Plan," Rev. 4, May 1998.

The Contractor's processes necessary to implement ISM are therefore subject to, and the RU will evaluate them against, the requirements of the QA rule. Specifically, the Contractor must perform work according to the process specified in their ISMP and implementing procedures. Where the Contractor fails to do so, that failure may be subject to action by the RU under the terms of the Contract. Where the Contractor fails to do so and that failure has nuclear safety significance, the Contractor may be subject to enforcement action by DOE under the PAAA.