

**Regulatory Unit Position on the
Tank Waste Remediation System–Privatization
Waste Treatment Plant (WTP) Regulatory Basis
(Including Authorization Agreements)**



September 10, 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
Richland, Washington 99352

**Regulatory Unit Position on the
Tank Waste Remediation System–Privatization
Waste Treatment Plant (WTP) Regulatory Basis
(Including Authorization Agreements)**



September 10, 1999

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

U.S. Department of Energy, Richland Operations Office
P.O. Box 550, A4-70
Richland, Washington 99352

Approved by: _____
Regulatory Official

Date: _____

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 Radiological, Nuclear and Process 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 Radiological, Nuclear, and Process Safety Regulation of TWRS-P Contractor are available to the public for review at DOE/RL Public Reading Room at the Combined Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.

This page intentionally left blank.

Table of Contents

1.0	INTRODUCTION.....	1
2.0	WTP REGULATORY BASIS.....	1
2.1	DOE Nuclear Safety Requirements	2
2.2	TWRS-P Contract (Contract No. DE-AC06-96RL13308)	2
2.3	WTP Authorization Agreements	3
2.4	Non-Radiological Safety and Health Requirements.....	4
2.5	WTP Authorization Basis.....	5
2.6	Commitments Not Yet Identified in the Defined Set of Authorization Basis Documents.....	5
3.0	WTP REGULATORY BASIS DOCUMENT CHANGE CONTROL.....	6
3.1	Contract Changes.....	6
3.2	Authorization Agreement Amendments	6
3.3	Contractor-Initiated Authorization Basis Changes and Authorization Basis Amendments.....	7
3.4	Commitments Not Yet Identified in the Defined Set of Authorization Basis Documents.....	7
4.0	REFERENCES.....	7
5.0	LIST OF TERMS.....	9

Attachments

Attachment 1, Definitions		11
Attachment 2, TWRS-P Contract Regulatory Requirements.....		13

This page intentionally left blank.

REGULATORY UNIT POSITION ON THE TANK WASTE REMEDIAATION SYSTEM-PRIVATIZATION WTP REGULATORY BASIS (INCLUDING AUTHORIZATION AGREEMENTS)

1.0 INTRODUCTION

This position paper describes the Office of Radiological, Nuclear, and Process Safety Regulation (Regulatory Unit) position on the regulatory interaction between the U.S. Department of Energy (DOE), Richland Operations Office (RL), the Regulatory Unit (RU), and the Tank Waste Remediation System Privatization (TWRS-P) Contractor regarding the TWRS-P Waste Treatment Plant (WTP) Regulatory Basis.

The WTP Regulatory Basis is the composite of information that is the basis for WTP safety regulation. This paper identifies the specific elements of the WTP Regulatory Basis, describes how these elements are related, and documents RU positions regarding the development and maintenance of those elements that are within joint jurisdiction of the RU and the TWRS-P Contractor. This paper also describes certain RU expectations concerning the content of authorization agreements established as a result of the construction, production operations, and deactivation authorization regulatory actions.

2.0 WTP REGULATORY BASIS

The following items make up the composition of information used for the radiological, nuclear, and process safety regulation of the WTP project and constitute the Regulatory Basis:

1. Applicable DOE nuclear safety requirements enforceable under 10 CFR 820.
2. TWRS-P Contract,¹ including documents relevant to regulation incorporated by reference in the Contract.
3. Authorization agreements established as a result of the construction, production operations, and deactivation authorization regulatory actions.
4. Non-Radiological safety and health requirements under the Occupational Safety and Health Act of 1970 (29USC657, 673) as promulgated in 29 CFR 1900, et. seq.
5. WTP Authorization Basis documents submitted by the Contractor and accepted by the RU in connection with construction, production operations, and deactivation authorization regulatory actions.
6. Commitments made by the Contractor subsequent to regulatory actions and not currently incorporated into the set of Authorization Basis documents.

¹ Contract No. DE-AC06-96RL13308 between BNFL Inc., and DOE dated August 24, 1998.

The following subsections provide additional details on the composition of the WTP Regulatory Basis.

2.1 DOE Nuclear Safety Requirements

DOE nuclear safety requirements applicable to WTP derive their authority from the Atomic Energy Act and the Price-Anderson Amendments Act. Nuclear Safety Requirements enforceable under 10 CFR 820, “Nuclear Activity Procedural Rules,” include any DOE Nuclear Safety Requirements set forth in the Code of Federal Regulations, issued Compliance Orders, and any program, plan or other provision required to implement any DOE Nuclear Safety Requirement or Compliance Order.

DOE Nuclear Safety Requirements applicable to WTP include 10 CFR 708 “Contractor Employee Protection Program Criteria and Procedures,” 10 CFR 830.120 “Quality Assurance Requirements,” and 10 CFR 835 “Occupational Radiation Protection.”

2.2 TWRS-P Contract (Contract No. DE-AC06-96RL13308)

The TWRS-P Contract is the result of the DOE request for proposal issued in February 1996, for the privatized processing of waste as part of the Hanford Tank Waste Remediation System. The authority of the RU to regulate the TWRS-P Contractor is derived from the *Policy for Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors*, DOE/RL-96-25, and is embodied within the terms of the TWRS-P Contract. Also embodied within the terms of the Contract are the following documents:

- *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003
- *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004
- *Concept for the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005
- *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006
- *Regulatory Unit Position Paper on Contractor-Initiated Changes to the Authorization Basis*, RL/REG-97-13
- *Regulatory Unit Position on New Safety Information and Back-Fits*, RL/REG-98-14
- *Inspection Program Description for the Regulatory Oversight of TWRS Privatization Contractors*, RL/REG-98-05

- *Corrective Action Program Description, RL/REG-98-06*

The documents embodied within the terms of the Contract listed above can be revised subject to the mutual agreement of the RO and the Contractor. Change control requirements applicable to these documents are addressed in Section 3.1 of this paper. Revisions which impact cost and/or schedule are handled in accordance with Clause H.28 of the Contract.

Attachment 2 repeats the safety regulation requirements from the contract, such that the complete scope of the WTP Regulatory Basis is identified within this position paper. However, the TWRS-P Contract remains the definitive source and should be consulted for the complete and current set of safety regulatory requirements.

2.3 WTP Authorization Agreements

An authorization agreement is the document, mutually agreed upon by the Regulatory Official (RO) and Contractor management, that specifies authorization terms and conditions. The formal execution of an authorization agreement is intended to result in an enhanced level of protection (safety) for the workers, public, and environment, with reduced uncertainty. Specifically, the authorization agreement documents the following.

- The RU's conclusion that, through evaluation of the Contractor's authorization request, the authorized work can be conducted safely,
- The RU's authorization for the conduct of specific work activities subject to the terms and conditions specified in the agreement, and
- The TWRS-P Contractor's commitment to conduct the specified work activities in accordance with the terms and conditions specified in the agreement.

2.3.1 Authorization agreements will be drafted by the RU and require the signatures of both the Regulatory Official and the BNFL General Manager to become effective.

2.3.2 The authorization agreement will address BNFL's implementation of the specific safety management programs required to be developed by the Contract, Safety Requirements Document, and/or Integrated Safety Management Plan, and that the RU reviewed as part of the authorization request (i.e., as described within the Safety Analysis Report or the Technical Safety Requirement Administrative Controls).

2.3.3 The authorization agreement will identify the physical and programmatic boundaries of the authorized activities and/or operations based on the technical, managerial, and safety considerations provided in the authorization request.

2.3.4 The authorization agreement will identify the work scope for authorized activities or operations, which must be supported by the hazards analysis identified in the Authorization Basis.

- 2.3.5 The authorization agreement shall include certification by the TWRS-P Contractor that implementation of the authorization agreement is sufficient to protect the public, workers, and the environment.
- 2.3.6 The following information shall be incorporated by reference into the terms and conditions of the authorization agreement:
- Safety Requirements Document (SRD)²
 - Technical Safety Requirements
- 2.3.7 The terms and conditions of the authorization agreement shall include, but not be limited to, the following additional items:
- Compliance with applicable DOE nuclear safety requirements (10 CFR 800 series) -- The authorization agreement shall identify the specific nuclear safety requirements applicable to the authorization action.
 - Compliance with commitments made in the process of WTP regulation, but not included within the set of Authorization Basis documents.
 - Conformance with the WTP Authorization Basis.
 - The process for reporting deviations -- The authorization agreement shall describe the process that the TWRS-P Contractor will follow if the terms or conditions of the authorization agreement cannot be or are not met. This may be accomplished by including appropriate portions of the ISMP by reference.
- 2.3.8 By signing an authorization agreement with the TWRS-P Contractor, the RU is demonstrating confidence that the terms and conditions identified in the authorization agreement can be met. The authorization agreement shall describe the Contractor's general technical and managerial capabilities for performing the authorized work scope.
- 2.3.9 The authorization agreement shall describe the Contractor's process for reporting operating or construction events. This may be accomplished by including appropriate provisions in the agreement or by incorporating the appropriate portions of the ISMP by reference.
- 2.3.10 The effective date of the authorization agreement and the duration of the agreement shall be specified. The duration of the agreement shall be established based on consideration of the WTP facility design basis and be compatible with the current state of the WTP project plan.

2.4 Non-Radiological Safety and Health Requirements

The TWRS-P Contract states:³

² BNFL-5193-SRD-01, Safety Requirements Document, Revision in Effect.

“The Contractor shall comply with all applicable Federal, State, and local safety and health regulations, including those of the Washington Industrial Safety and Health Administration (WISHA) and OSHA.”

The TWRS-P Contract also requires that:⁴

“The Contractor shall develop and implement an integrated standards based safety management program that: (1) defines policies and procedures for protecting employees from conventional workplace hazards, and (2) ensures compliance with all applicable Federal State, and Local safety and health codes, regulations and standards including regulations of the WISHA and the OSHA.”

Under the Contract, BNFL is responsible for “providing safe and healthful working conditions for employees, and all other persons under the Contractor’s control who work in the general vicinity of the Contractor site, including subcontractors.”⁵ BNFL can achieve adequate non-radiological safety and health by conforming to OSHA standards.

2.5 WTP Authorization Basis

The WTP Authorization Basis is the composite of information provided by the Contractor in response to safety requirements that is the basis on which the Regulatory Official (RO) grants permission to perform regulated activities.

2.5.1 The specific documents that constitute the Authorization Basis shall be identified in the Contractor’s Integrated Safety Management Plan (ISMP).

2.6 Commitments Not Yet Identified in the Defined Set of Authorization Basis Documents

Over the course of the WTP project, the Contractor may make commitments in correspondence or other documents in response to regulatory or safety issues which supplement the WTP Authorization Basis described in Section 2.5. These commitments are part of the WTP Regulatory Basis. The following apply to these commitments:

2.6.1 Fulfillment of commitments submitted on the TWRS-P docket which are part of the basis for any RU action or decision will be identified, tracked, and verified by the RU using a Commitment Management System (CMS).

2.6.2 The CMS will not become a permanent repository for unique commitments. Commitments that permanently impact the WTP facility or its activities shall be reflected in Authorization Basis documents which are updated in accordance with the positions

³ DE-AC06-96RL13308, Part I, Section C.3, Pg. C-7.

⁴ DE-AC06-96RL13308, Standard 4, “Safety, Health, and Environmental Program.”

⁵ DE-AC06-96RL13308, C.3, “Regulatory Environment.”

provided in RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis*. Operating Authorization Basis documents will be updated annually per DOE/RL-96-0003 (refer to Section 2.2), including the incorporation of appropriate commitments made by BNFL in response to regulatory or safety issues. The RU will ensure that such commitments are incorporated into Authorization Basis documents as part of the review process for updated or revised Authorization Basis documents.

3.0 WTP REGULATORY BASIS DOCUMENT CHANGE CONTROL

This section provides RU positions on the need and frequency for updates to Regulatory Basis documents that are within the joint jurisdiction of the RU and the TWRS-P Contractor.

3.1 Contract Changes

- 3.1.1 Changes to the TWRS-P Contract shall be processed in accordance with the contract modification requirements specified within the Contract.
- 3.1.2 There is no requirement for periodic updating of the TWRS-P Contract beyond the requirement for the Manager, RL, to keep the document current.
- 3.1.3 Changes to the TWRS-P Contract shall be assessed by the RU for impact to other Regulatory Basis documents, particularly the authorization agreement in effect.

3.2 Authorization Agreement Amendments

- 3.2.1 Revisions to approved authorization agreements shall be accomplished using authorization agreement amendments, as described within the regulatory oversight process requirements of DOE/RL-96-0003, Section 3.3.5.
- 3.2.2 WTP authorization agreements shall be assessed for impact whenever any Regulatory Basis document or commitment is revised. If an impact is identified, the RU will prepare the associated authorization agreement amendment. The amendment will be processed in parallel with the Regulatory Basis document or commitment change, including concurrent approvals.
- 3.2.3 The need for an authorization agreement amendment will normally result from a change made to a Regulatory Basis document or commitment. However, there may be instances when the TWRS-P Contractor desires to change only the authorization agreement. In those instances, the TWRS-P Contractor shall submit the desired change, along with appropriate justification, to the RU for consideration via formal correspondence. If the RU determines the change is necessary and defensible, the RU will process the authorization agreement amendment.

3.2.4 The RU shall determine the appropriate stakeholder involvement for each authorization agreement. The determination shall take into consideration the significance of the change, including the degree to which the basis for the original authorization is being altered. This determination shall be in conformance with the RU Openness Policy as set forth in RL/REG-97-04, *Policy for Openness and Openness Plan*.

3.3 Contractor-Initiated Authorization Basis Changes and Authorization Basis Amendments

3.3.1 Contractor-initiated changes to WTP Authorization Basis documents shall be accomplished in accordance with the approved process described in the ISMP. The process described in the ISMP shall be consistent with the positions provided in RU Position Paper RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis*. Contractor compliance with RL/REG-97-13 is required by Standard 4, Section c.2)(c) of the TWRS-P Contract.

3.3.2 Revisions to the TWRS-P Contractor's Quality Assurance Program and Implementation Plan (QAPIP) and periodic reviews and updates of the QAPIP shall maintain consistency with the provisions of 10 CFR 830.120, using the process described in the QAPIP.

3.3.3 Revisions to the TWRS-P Contractor's Radiation Protection Program (RPP) and periodic reviews and updates of the RPP shall maintain consistency with the provisions of 10 CFR 835, using the revision process described in the RPP.

3.3.4 Authorization agreement impacts due to revised WTP Authorization Basis documents shall be assessed (see Section 3.2) and, if necessary, a parallel authorization agreement amendment processed.

3.3.5 Revisions to the QAPIP or RPP, if specifically identified within the authorization agreement, will require an associated authorization agreement amendment, as addressed in Section 3.2.

3.4 Commitments Not Yet Identified in the Defined Set of Authorization Basis Documents

If the TWRS-P Contractor desires to change a commitment (as described in Section 2.6), the Contractor shall submit docketed correspondence, with adequate justification, to the RU requesting the change.

4.0 REFERENCES

10 CFR 708, "DOE Contractor Employee Protection Program," *Code of Federal Regulations*, as amended.

10 CFR 820, “Procedural Rules for DOE Nuclear Activities,” *Code of Federal Regulations*, as amended.

10 CFR 830.120, “Quality Assurance Requirements,” *Code of Federal Regulations*, as amended.

10 CFR 835, “Occupational Radiation Protection,” *Code of Federal Regulations*, as amended.

Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0005, Revision 1, July 1998.

Corrective Action/Enforcement Action Program Description, RL/REG-98-06, Revision 2, 1998.

DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors, DOE/RL-96-0003, Revision 1, July 1998.

Inspection Program Description for the Regulatory Oversight of TWRS Privatization Contractors, RL/REG-98-05.

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, 1996.

Policy for Openness and Openness Plan, RL/REG-97-04, Revision 2, 1998.

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

Quality Assurance Program and Implementation Plan, BNFL-5193-QAP-01, Revision 4, 1998.

Radiation Protection Program for Design, BNFL-5193-QAP-01, Revision 4, 1998.

Regulatory Unit Management Directives, RL/REG-97-05, Revision 1, 1998.

Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis, RL/REG-97-13, Revision 4, 1998.

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

Safety Requirements Document, BNFL-5193-SRD-01, Volumes I and II, Revision 2, 1998.

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors, DOE/RL-96-0006, Revision 1, July 1998.

TWRS Privatization Contract, Contract No. DE-AC06-96RL13308, between DOE and BNFL, Inc., dated September 25, 1996.

5.0 LIST OF TERMS

BNFL	British Nuclear Fuels Limited, Inc.
CMS	Commitment Management System
DOE	U.S. Department of Energy
ISMP	Integrated Safety Management Plan
QAP	Quality Assurance Program
RO	Regulatory Official
RPP	Radiation Protection Program
RU	Regulatory Unit
SRD	Safety Requirements Document
TSR	Technical Safety Requirement
TWRS-P	Tank Waste Remediation System Privatization
WTP	Waste Treatment Plant

This page intentionally left blank.

Attachment 1, Definitions

Definitions

Authorization Agreement: The document mutually agreed upon by the Director of the Regulatory Unit and a regulated Contractor that specifies authorization terms and conditions. Any changes to these terms and conditions require DOE approval.

Authorization Basis: The composite of information provided by a Contractor in response to radiological, nuclear, and process safety requirements that is the basis on which the Director of the Regulatory Unit grants permission to perform regulated activities. The Authorization Basis includes that information requested by the Contractor for inclusion in the Authorization Basis and subsequently accepted by the RU. Examples of such information include:

1. The information submitted in connection with a request for Standards Approval, a request for Construction Authorization, a request for Operations Authorization, or an Initial Safety Analysis. This includes the information associated with the requests as described in DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, and any other information submitted by the Contractor in connection with the requests.
2. Amendments to the information described above that are on the Contractor docket. Such amendments may be in the form of revisions to previously submitted documents, or new information that supplements previously submitted information.

An Authorization Basis begins at the Standards Approval regulatory action and continues throughout the design, construction, operation, and decommissioning of a TWRS-P Contractor facility.

Quality Assurance Program (QAP): The Quality Assurance Program as required by 10 CFR 830.120, "Quality Assurance Requirements."

Radiation Protection Program (RPP): The Radiation Protection Program as required by 10 CFR 835, "Occupational Radiation Protection."

Regulatory Basis: The composite of information that is the basis for WTP project radiological, nuclear, and process safety regulation. This information includes:

- Applicable DOE nuclear safety requirements enforceable under 10 CFR 820,
- Radiological, nuclear and process safety regulatory requirements in the TWRS-P Contract (No. DE-AC06-96RL-13308), including documents relevant to regulation incorporated by reference in the Contract,
- Authorization agreements established as a result of the construction, production operations, and deactivation authorization regulatory actions,

- Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (DOE/RL-96-26),
- Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (DOE/RL-96-25),
- WTP Authorization Basis documents submitted by the TWRS-P Contractor and accepted by the Regulatory Unit in connection with construction, production operations, and deactivation authorization regulatory actions, and
- Commitments made by the TWRS-P Contractor subsequent to regulatory actions and not currently incorporated into the set of Authorization Basis documents.

Safety Requirements Document (SRD): A document that contains the approved and mandated set of radiological, nuclear, and process safety standards and requirements which, if implemented, provides adequate protection of workers, the public, and the environment against the hazards associated with the operation of the Contractor's facilities. The SRD is approved as part of the Standards Approval regulatory action.

Technical Safety Requirement (TSR): Those requirements that define the conditions, the safe boundaries, and the management or administrative controls necessary to ensure the safe operation of the facility, reduce the potential risk to the public and facility workers from uncontrolled releases of radioactive materials, and from radiation exposures due to inadvertent criticality. The TSRs are approved as part of the Production Operations Authorization regulatory action.

Top-Level Safety Standards: Any of the safety standards or principles established in DOE/RL-96-0006, *Top-level Radiological, Nuclear, And Process Safety Standards and Principles for TWRS Privatization Contractors*.

Attachment 2, TWRS-P Contract Regulatory Requirements**TWRS Privatization Contract Regulatory Requirements**

(Note: This tabulation of TWRS-P Contract regulatory requirements is provided as an aid to the understanding of the complete set of regulatory expectations included within the WTP Regulatory Basis. It is not intended to be the definitive source or set of contractual regulatory requirements. The TWRS-P Contract remains the definitive source and should be consulted for the complete and current set of radiological, nuclear, and process safety regulatory requirements.)

1. As the Regulator, DOE, through the DOE Office of Radiological, Nuclear, and Process Safety (Regulatory Unit), will regulate radiological and nuclear safety to ensure that the Contractor provides for and operates within the required levels of public and worker protection. The Director of the Regulatory Unit will also provide oversight of process safety but will not engage in enforcement actions for process safety. (Part I, Section C, item C.2.a.3)
2. The Contractor will process DOE-owned highly radioactive and dangerous waste in privatized facilities. In order to operate its facilities within the appropriate and prudent level of controls consistent with the chemical and operational hazards and potential consequences, the Contractor shall establish and maintain a safety, health, and environmental program that reflects the principles and practices of: effective radiological, nuclear, and process safety controls; effective industrial safety controls; and effective environmental protection.

The Contractor shall be responsible for the protection of: human health and the environment from radioactive chemicals, hazardous materials, and dangerous waste contamination; and non-radiological worker safety and health from conventional industrial and occupational hazards. The Contractor is responsible for providing safe and healthful working conditions for employees, subcontractors and all other persons under the Contractor's control who work in the general vicinity of the Contractor site.

The Contractor shall comply with all applicable Federal, State, and local requirements for:

- a. Non-radiological worker safety and health;
- b. Radiological, nuclear, and process safety; and
- c. Environmental protection.

Except where regulatory authority is specifically reserved for DOE by law or regulation, or where regulatory compliance responsibility is established for DOE in the TWRS-P Contract, DOE will not serve as a regulator or enforce regulatory compliance requirements. Where joint responsibility for regulatory compliance is assigned by an external regulator to DOE and the Contractor, the Contractor has primary responsibility and accountability to the external regulator. Where joint responsibility does not exist, the

Contractor has full responsibility and accountability to the external regulator. (Part I, Section C, item C.3.a)

3. The Contractor shall comply with all applicable Federal, State, and local safety and health regulations, including those of the Washington Industrial Safety and Health Administration (WISHA) and Occupational Safety and Health Act of 1970 (OSHA). (Part I, Section C, item C.3.b.1)
4. DOE will regulate radiological and nuclear safety through a specifically chartered, dedicated Regulatory Unit. The Regulatory Official serves as the formal point of contact for radiological, nuclear, and process safety regulation. The Regulatory Official will provide oversight of process safety but will not engage in enforcement actions. (Part I, Section C, item C.3.b.2)
5. The Contractor is responsible for providing safe and healthful working conditions for employees and all other persons under the Contractor's control who work in the general vicinity of the Contractor site, including subcontractors. The Contractor shall develop and implement an integrated program for conventional non-radiological worker safety and health and radiological, nuclear, and process safety. During Parts B-1 and B-2, the Contractor shall implement its program, and submit the Part B deliverables described in paragraph c of Standard 4 of the TWRS-P Contract. The deliverables shall reflect the current degree of design and project maturity. (Part I, Section C, Standard 4, items b and c)
6. The Contractor shall develop and implement an integrated standards-based safety management program that: (1) defines policies and procedures for protecting employees from conventional workplace hazards, and (2) ensures compliance with all applicable Federal, State, and local safety and health codes, regulations and standards including regulations of the WISHA and the OSHA.

The Contractor's safety management program shall reflect proven principles of safety management and work planning that promote accident prevention, employee involvement, and sound hazard analysis and control. (Part I, Section C, Standard 4, item c.1)(a))

7. 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. Radiological, nuclear, and process safety requirements shall be adapted to the specific hazards that are identified with the Contractor's waste treatment services. (Part I, Section C, Standard 4, item c.2)(a))
8. The Contractor's integrated standards-based safety management program shall be developed to comply with the specific nuclear safety regulations defined in the effective rules of the 10 CFR 800 series of nuclear safety requirements and with the regulatory program established in the following four documents:

- a. *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003
- b. *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL-96-0004
- c. *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005
- d. *Top-Level DOE Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006.

Revisions to the above four documents are acceptable if the changes are mutually agreed to by the Contractor and the Regulatory Official, do not impact project cost or schedule, and are approved by the parties to the Memorandum of Understanding.

The Contractor's integrated standards-based safety management program shall integrate the appropriate planning and practices elements specified in 29 CFR 1910.119, "OSHA Process Safety Management of Highly Hazardous Chemicals." (Part I, Section C, Standard 4, item c.2)(b))

9. The Contractor's Integrated Safety Management Plan shall conform with both RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated changes to the Authorization Basis*, and RL/REG-98-14, *Regulatory Unit Position on New Safety Information and Back-fits*; and accept:
 - i. RL/REG-98-05, *Inspection Program Description for the Regulatory Oversight of TWRS Privatization Contractors*, and
 - ii. RL/REG-98-06, *Corrective Action Program Description*.

Revisions to the above four documents are acceptable if the changes are mutually agreed to by the Contractor and the Regulatory Official and do not impact project cost or schedule. (Part I, Section C, Standard 4, item c.2)(c))

10. The Contractor shall prepare and submit to the Regulatory Unit for review and approval, the radiological, nuclear, and process safety deliverables defined in Table S4-1, *Radiological, Nuclear, and Process Safety Deliverables for Part A and Part B*, of the TWRS-P Contract. Each deliverable is structured around the following six actions:
 - a. Standards Approval
 - b. Initial Safety Evaluation
 - c. Authorization for Construction
 - d. Authorization for Production Operations
 - e. Oversight Process Determination
 - f. Authorization for Deactivation. (Part I, Section C, Standard 4, item c.2)(d))

11. The Contractor shall submit, sufficiently in advance of the submission (at least 14 weeks) of the Construction Authorization Request to enable review and approval by the Regulatory Official, a revised Standards Approval Package, complete with all necessary supporting documentation. The four required elements of the Standards Approval Package may be incrementally submitted for review. The scope and content of the submittal shall be in accordance with the requirements for a Construction Authorization Request as stipulated in Section 4.3.2, Contractor Input, Items 6) and 8) of DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*. (Part I, Section C, Standard 4, item c.2)(e))

NOTE: This Contract requirement refers to Revision 0 of DOE/RL-96-0003. However, the RU has issued Revision 1 to DOE/RL-96-003 (July 1998) for implementation.

12. Seven months prior to the need for approval of the Authorization to Proceed with construction, the Contractor shall submit the Construction Authorization request, with the exception of the Standards Approval Package submitted in paragraph C.2)(e) of this *Standard*, for review and approval by the DOE Regulatory Official. (Part I, Section C, Standard 4, item c.2)(f))
13. At six months from authorization to proceed with Part B-1, the Contractor shall submit to the Regulatory Unit for review and comment (as defined Table C4-2.1 of Section C of the Contract) a generic detailed description of the design safety features that will be incorporated into the waste treatment facility design. The description shall include the Contractor's approach to defense in depth and shall describe generic design features that are relied upon for safety and protection of the environment. The document shall describe design features, not consequences or risk analyses.

Within two months from authorization to proceed, and prior to work commencing on the deliverable, the Contractor and the Regulatory Unit shall develop and agree upon the scope and content of this design safety features deliverable. (Part I, Section C, Standard 4, item c.2)(g))

14. The Regulatory Unit and the Contractor shall conduct periodic, approximately monthly, topical meetings. The subject and time of the meetings should be set to an agreed prearranged schedule. These meetings will be conducted in accordance with a prearranged protocol. The Regulatory Official will establish the minimum content of the meetings. To the extent practicable, the outcome of the meeting should result in the regulatory closure of the topic. Closure will result from approval of submitted written correspondence.

These meetings will be held in accordance with DOE RL/REG-97-04, *Policy for Openness and Openness Plan for the Office of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors*. (Part I, Section C, Standard 4, item c.2)(h))

15. Members of the Regulatory Unit may observe design reviews (and question the presenters) performed by the Contractor Safety Design Review Committees and Safety Review Committees, as ex-officio members. These reviews should be scheduled so that

the evolving design is completely reviewed at least semi-annually. These observations provide the Regulatory Official with continuing information concerning the safety aspects of the evolving design and do not constitute regulatory approval of the matters discussed. In so far as is practicable, the Regulatory Unit will utilize the same individuals as representatives over the course of the design. (Part I, Section C, Standard 4, item c.2)(i))

16. An Authorization Request associated with a particular Regulatory Action may be segmented and incrementally submitted. The Regulatory Unit review of a deliverable begins with receipt of the last component of the deliverable. For each request, the Contractor shall demonstrate the need for the phased authorization and provide sufficient detail in the request for the Regulatory Unit to review the request and reach an approval decision. The Contractor shall notify the Regulatory Unit of the intent to submit a partial authorization request, complete with scope and content of the proposed request, not less than six months prior to its submission.

The Contractor may provide the following limited authorization requests:

- i. Limited Construction Authorization for site preparation and excavation.
- ii. Feed Tank modifications to DST 241-AP-106 and waste transfer systems.
- iii. Others, as mutually agreed.

The Regulatory Official will establish review guidance for these partial authorization requests in advance of the submission of the request. The review guidance will incorporate existing requirements of the contract but will be tailored to the scope of the work that the Contractor proposes to accomplish. (Part I, Section C, Standard 4, item c.2)(j))

17. Except for those differences identified in Standard 4 of the TWRS-P Contract, specific requirements for the radiological, nuclear, and process safety deliverables are provided in the documents referenced in paragraph c.2)(b) of Standard 4 of the TWRS-P Contract. (Part I, Section C, Standard 4, item c.2)(k))
18. During Part B, the Regulatory Unit shall develop and provide additional guidance for the preparation and review of documents and activities identified in Table S4-1. The format and content of guidance shall establish the approach and basis that the Regulatory Unit will use to review the Contractor's submittals and to report the results of the reviews. The Authorization for Construction guidance and the Authorization for Production Operations guidance shall be provided to the Contractor no less than nine months prior to the scheduled submission of the Contractor's authorization request. Guidance for Authorization for Deactivation shall be provided prior to final production operations. (Part I, Section C, Standard 4, item c.2)(l))
19. During Part B, all submitted regulatory information will be handled in accordance with RL/REG-97-05, *Office of Radiological, Nuclear, and Process Safety Regulation for TWRS Privatization Contractors*, Management Directive 2.1, "Information Management," and, as appropriate, shall be made immediately available to the public by

the Regulatory Unit. (Part I, Section C, Standard 4, item c.2)(m))

20. The Contractor shall permit inspection, by duly authorized representatives of the Regulatory Unit, of his records, premises, activities, and of radioactive materials in possession or use related to the Contractor facility, as is necessary to effectuate the responsibilities of the Regulatory Unit. The Contractor shall provide adequate office space, at the processing facility, for the exclusive use of two full-time Regulatory Unit inspection personnel and temporary space for up to four transient Regulatory Unit personnel. The offices shall be convenient to and have full access to the facility, provide both visual and acoustic privacy and be generally commensurate with other offices at the site.

The Contractor shall afford any inspector, identified by the Regulatory Official as likely to inspect the facility, immediate unfettered access, equivalent to the access provided to regular facility employees, following proper identification and compliance with applicable access control measures for security, radiological protection and personal safety. (Part I, Section C, Standard 4, item c.2)(n))

21. The Radiological, Nuclear and Process Safety regulatory program for this Contract as set forth in Section C.5, Standard 4, *Safety, Health and Environmental Program*, shall implement the requirements of DEAR 952.223-72, *Radiation Protection and Nuclear Criticality* and DEAR 952.223-74, *Nuclear Facility Safety Applicability*. (Part I, Section H, item H.27a)
22. The Regulatory Official will have the authority to: (1) stop work if the Contractor fails to provide the required levels of radiological, nuclear, and process safety; (2) authorize the resumption of work upon completion of corrective actions; and (3) authorize start of construction, initiation of radiological hot operations, start of production operations, and start of deactivation. The Regulatory Unit's authority for radiological, nuclear, and process safety is independent and distinctly severable from the authority of the Contracting Officer under the TWRS-P Contract. The Regulatory Unit intends to utilize pre-established processes and action criteria whenever possible in order to minimize the impact to the Contractor. The Contractor shall be entitled to an equitable adjustment in Contract time or price for any additional delay or costs resulting from the issuance of a stop work order hereunder by the Regulatory Unit unless the issuance of such stop work order was the result of actions of the Contractor that were not in conformance with the terms of the Contract. (Part I, Section H, item H.27b)