August 4, 2008

The Honorable Peter Visclosky
Chairman, Subcommittee on Energy
and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am providing the enclosed report entitled, "Review of the U.S. Department of Energy's Regulatory Processes for the Hanford Waste Treatment Plant." Congress directed the NRC to conduct this review and report its assessment and recommendations to the Secretary of Energy and the House and Senate Committees on Appropriations in the report accompanying the Omnibus Appropriations Bill for Fiscal Year 2008.

The report describes in detail: (1) how the NRC conducted its review; (2) interactions with Federal, State, and Tribal organizations, and the public, during this process; (3) the NRC's high-level review of the Department of Energy's (DOE) regulatory processes for the Waste Treatment Plant (WTP); and (4) recommendations.

The report also responds to your letter dated May 2, 2008, recommending that the NRC include in its report an assessment of DOE's processes to ensure that the items previously identified by the NRC in its earlier Hanford Tank Waste Remediation System-Privatization closeout report (NUREG-1747) are addressed in a timely and responsible fashion. You also recommended that the report include an update on the resolution of any of these items.

DOE fully cooperated in this review and reviewed portions of a draft report for factual accuracy. However, DOE did *not* review NRC's conclusions and recommendations.

If you have questions regarding this report, please contact the Chairman's office at 301-415-1759.

Sincerely,

/RA/

Kristine L. Svinicki
Acting Chairman

Enclosure: As stated

cc: Representative David L. Hobson

Similar letter sent to:

The Honorable Peter J. Visclosky
Chairman, Subcommittee on Energy
and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515
cc: Representative David L. Hobson

The Honorable Byron Dorgan
Chairman, Subcommittee on Energy
and Water Development
Committee on Appropriations
United States Senate
Washington, D.C. 20510
cc: Senator Pete V. Domenici

The Honorable Samuel W. Bodman
Secretary of Energy
Washington, D.C. 20585
cc: James A. Rispoli, DOE

REVIEW OF THE U.S. DEPARTMENT OF ENERGY'S REGULATORY PROCESSES FOR THE HANFORD WASTE TREATMENT PLANT

Enclosure

THIS PAGE INTENTIONALLY LEFT BLANK

CONTENTS

FIGURES

TABLES

EXECUTIVE SUMMARY

The Conference Report for the Omnibus Appropriations Bill for Fiscal Year 2008 directed the U.S. Nuclear Regulatory Commission (NRC) to review the regulatory processes of the U.S. Department of Energy (DOE) for the Hanford Waste Treatment Plant (WTP) and report its assessment and recommendations to the Secretary of Energy and the House and Senate Committees on Appropriations. This review was completed with the cooperation of DOE, as directed by Congress.

NRC conducted a high-level review of DOE's regulatory processes for the WTP, to compare DOE's regulatory approach to NRC's process for nuclear-safety regulation (Chapter 2). The staff reviewed DOE's statutory authority, legal requirements, strategic plan, and activities that correspond to NRC's regulatory process. NRC also reviewed, using an appropriate standard review plan as a basis, some of DOE's programs and practices (Chapter 3), to assess the comparability to similar NRC programs and practices. This review addressed DOE's approaches for: (1) safety analysis; (2) radiation safety; (3) nuclear criticality safety; (4) chemical process safety; (5) fire safety; (6) environmental protection; (7) management measures; (8) inspection; (9) enforcement; (10) allegations; and (11) risk assessment. Finally, NRC reviewed DOE's processes to address comments received by external oversight organizations, including the NRC.

There are broad similarities between DOE's and NRC's regulatory processes for nuclear safety. However, there are some significant differences. Specifically, DOE's regulatory process reflects DOE's role as owner/operator – as opposed to pure regulator – of the WTP. In its role as owner/operator DOE essentially self-regulates the construction and operation of the WTP by its contractors. Thus, DOE has obligations to address general industrial safety, in addition to nuclear safety, and is also subject to additional regulatory requirements, as well as the milestone schedule of the Tri-Party Agreement. In addition, some of DOE's programs and practices vary substantially from NRC's practices.

DOE's additional responsibilities as owner/operator of the WTP lead to differences between the DOE and NRC regulations and guidance. DOE applies a nonradiological worker health-and-safety-in-the workplace regulation to its WTP program. Compared with the scope of NRC's regulatory guidance, DOE has added: (1) environmental protection guidance; (2) additional guidance for review of the integrated safety assessment and chemical process safety; and (3) expanded fire protection guidance. These added areas of guidance reflect DOE's responsibility as the owner/operator of the WTP and its responsibility for hazardous waste safety.

DOE documents its requirements for the WTP in a contract. The contract serves as the basis for safety and as the vehicle that DOE uses to ensure that its statutory and regulatory mandates for nuclear material processing activities are also met.

DOE's approach to authorizing construction and operation, although similar in some respects, is substantially different from NRC's approach to licensing commercial facilities, except for plutonium processing and fuel fabrication facilities. For plutonium processing, NRC issues an initial license (construction authorization) before the start of construction, and this license is subsequently modified prior to possession and processing of special nuclear material. DOE issues a construction authorization, and a separate authorization for operating the facility. There are five important differences between the NRC and DOE processes. First, DOE's

authorization decisions address both the design for operability and production, as well as safety. Second, DOE's use of a design-build approach allows the WTP to make more significant changes in the authorization basis during the construction period. This approach makes the change control process more important for ensuring safety, under DOE regulation, than it would under NRC regulation. Third, the contract commits DOE to a schedule to complete the regulatory review for certain contractor-proposed changes. There are no contractual nor regulatory requirements for NRC's licensing safety review duration. Fourth, NRC maintains its own documented licensing basis, whereas DOE allows the contractor to maintain, between DOE's biennial updating of the authorization basis during the construction phase of the WTP, a document that incorporates the many DOE-approved changes that occur between DOE's biennial updates. DOE only documents its complete authorization basis, in a single document, for each facility, every two years. Finally, NRC employs a program for adjudication in order to satisfy a statutory hearing requirement applicable to its licensing decisions, whereas DOE does not allow direct stakeholder involvement – for example members of the public can not raise issues of contention and have them addressed – in DOE's safety decision-making process. Interested parties must pursue contentions through the courts.

Both DOE and NRC regulatory oversight programs include inspection, enforcement, allegations assessment, and investigations. The programs appear to be generally comparable, but there are some important differences in terms of meeting the goals of effective and timely oversight.

DOE has a process for addressing issues identified by external oversight groups such as the Defense Nuclear Facilities Safety Board and the Hanford Advisory Board. DOE's process, which relies on a corrective action response system approach, was not used to address items identified in a 2001 NRC report (NRC, 2001a). That report summarized NRC's participation in, and observations on a predecessor of the current WTP (in the time period 1997-2000), and identified issues from NRC's perspective. Nevertheless, many of the 28 significant issues NRC documented in 2001 have been addressed by DOE as the WTP project has progressed.

Although NRC makes a number of specific conclusions on the differences in the regulatory framework and relevant programs and practices, NRC did not attempt to assess the significance of these differences on safety of the WTP project beyond identifying those conclusions on which the NRC would place priority, if NRC had a future role in overseeing the project. According to NRC's regulatory framework, an assessment of safety is conducted via a licensing review and through inspection and assessment, which is beyond the scope of this report. In addition, this assessment of DOE's regulatory processes is a snapshot in time (up to mid-March 2008) and did not attempt to assess comparable DOE programs, such as research activities, event assessment, and performance assessment, that are part of NRC's regulatory framework.

The regulations and requirements that DOE has in place, in most cases, are similar to the NRC's. Despite the issues identified in the report, the NRC believes that the DOE program, if properly implemented, is adequate to ensure protection of public health and safety. Therefore, the NRC makes no specific recommendations within the scope of this review.

Nevertheless, based on the review, NRC makes several suggestions for DOE's consideration. NRC suggests that DOE evaluate how these requirements are being implemented and how the transparency of its decisions and actions regarding the WTP could be improved. NRC also suggests that DOE consider the list of significant issues identified in Table 4.1 and the specific safety and regulatory issues in Table B.1 of this report. In addition, NRC suggests that DOE explore ways to gain and maintain more independence between regulatory oversight and project management functions.

ABBREVIATIONS

ACI	American Concrete Institute
AEA	Atomic Energy Act of 1954
AEC	Atomic Energy Commission
ALARA	As Low As Is Reasonably Achievable
ANSI/ANS	American National Standards Institute and American Nuclear Society
ANSI/EIA	American National Standards Institute and Electronic Industries Alliance
ASME	American Society of Mechanical Engineers
BNI	Bechtel National, Inc.
CARS	Corrective Action Response System
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOH	State of Washington Department of Health
DNFSB	Defense Nuclear Facilities Safety Board
EIS	Environmental Impact Statement
ENS	Engineering and Nuclear Safety
EPA	U. S. Environmental Protection Agency
ERA	Energy Reorganization Act of 1974
ERPG	Emergency Response Planning Guide
ESQ	Environmental Safety and Quality
FTE	Full-Time Equivalent
GAO	Government Accountability Office
HLW	High-Level Waste
HSW EIS	Final Hanford Site Solid (Radioactive and Hazardous) Waste Program EIS, Richland, Washington
IROFS	Items Relied on for Safety
ISO	International Organization for Standardization
MOU	Memorandum of Understanding
NEPA	National Environmental Policy Act of 1969
NFPA	National Fire Protection Association
NRC	U.S. Nuclear Regulatory Commission
NSD	Nuclear Safety Division
NTS	Noncompliance Tracking System
ORP	Office of River Protection, DOE
OSHA	Occupational Safety & Health Administration

ABBREVIATIONS, Cont.

PAAA	Price-Anderson Act Amendments
PSAR	Preliminary Safety Analysis Reports
QA	Quality Assurance
QHG	Quantitative Health Guidelines
QHO	Quantitative Health Objectives
RCRA	Resource Conservation and Recovery Act
SAIC	Science Applications International Corporation
SEPA	State Environmental Policy Act
TC&WM EIS	Tank Closure and Waste Management Environmental Impact Statement
TWRS-P	Tank Waste Remediation System-Privatization
WCD	Waste Treatment Plant Construction Oversight and Assurance Division
WTP	Waste Treatment Plant

CHAPTER 1 INTRODUCTION

This U.S. Nuclear Regulatory Commission (NRC) report responds to a Congressional request to review the U.S. Department of Energy's (DOE's) regulatory processes for the Waste Treatment Plant (WTP) program at the Hanford site in the State of Washington and provide recommendations. The report includes five chapters. The first chapter is an introduction and describes: (1) the Congressional request; (2) NRC's past involvement at the Hanford site and the scope of the NRC staff's review; (3) interactions NRC staff held as part of its review; and (4) the Hanford tank wastes and the WTP. The next three chapters present the assessment and results of the review. Chapter two compares the overall DOE regulatory framework for the WTP to the NRC regulatory framework for a comparable facility. Chapter three presents the results of the NRC staff review of DOE's regulatory programs and practices for selected topics. NRC considers these topics integral for a safety program for a comparable facility. NRC reviewed DOE's program and practices in these areas to understand DOE's regulatory processes within the overall WTP regulatory framework. Chapter four summarizes the results of the NRC staff's review and describes NRC's recommendations. Chapter five provides the references cited in the report.

1.1 Congressional Request

Congress tasked NRC with conducting a review of the DOE regulatory processes for the Hanford WTP. The Conference Report for the Omnibus Appropriations Bill for Fiscal Year 2008, (U.S. Congress, 2008) states:

> "In cooperation with the Department of Energy, the Nuclear Regulatory Commission is directed to review the regulatory processes of the Department for the Hanford Waste Treatment Plant and report its assessment and recommendations to the Secretary of Energy and the House and Senate Committees on Appropriations within 180 days of enactment."

In a March 21, 2008, letter from Chairman Klein, to the House and Senate Appropriations and NRC Oversight Committees, NRC described its plan for the staff's review (Klein, 2008). A May 2, 2008, letter from Chairman Visclosky and Representative Hobson of the House Appropriations Subcommittee, to Chairman Klein, recommended that the NRC include in its report an assessment of DOE's processes to ensure that the items identified by the NRC in its earlier Hanford Tank Waste Remediation System-Privatization (TWRS-P) closeout report (NRC, 2001a; described in Section 1.2) are addressed in a timely and responsible fashion (Hobson and Visclosky, 2008). The May 2008 letter (Hobson and Visclosky, 2008) also requested that the review include an update on the items identified in the closeout report with detail on the resolution of any of these items.

1.2 Scope of NRC Review

Unless expressly authorized by statute, NRC does not have authority to license or otherwise regulate DOE facilities. Under the existing statutory framework, NRC does not have licensing or general regulatory authority over DOE's activities at the Hanford WTP.

Between 1997 and 2000, NRC provided assistance, under a memorandum of understanding, to DOE on the TWRS-P program at Hanford. DOE's program focused on processing, through vitrification, radioactive waste stored in underground storage tanks at the Hanford Site. From 1997 to 2000, NRC gained an understanding of the wastes and potential treatment processes. NRC assisted DOE in performing reviews in a manner consistent with NRC's regulatory approach for commercial nuclear facilities. The NRC staff also worked on developing an effective regulatory program for the potential transition to NRC regulatory authority at a future time. The NRC prepared a report that summarized NRC's participation in, and observations on, the DOE program, and identified issues from NRC's perspective (NRC, 2001a). The current study does not update the issues identified, findings or conclusions from NRC's previous effort (NRC, 2001a). However, in response to the May 2, 2008, letter from Chairman Visclosky and Representative Hobson of the House Appropriations Subcommittee (Hobson and Visclosky, 2008), the NRC staff reviewed DOE's efforts to address the significant issues NRC raised (Appendix A in NRC, 2001a). An update on DOE's resolution of the significant issues is also included in Appendix A to this report. Due to time and budgetary constraints, NRC did not assess or inspect the resolution status of the over fifty specific topics in the WTP design and approach that required further efforts and analysis (NRC, 2001a).

The DOE WTP safety and environmental programs are, to some extent, unique relative to DOE requirements. Initially, the WTP project was to be a NRC-licensed facility (if NRC was given the requisite statutory authority), but it evolved back to a DOE-authorized project not subject to external regulation by the NRC. The WTP project took its own approaches to safety that, while intended to be within DOE's requirements, and acceptable to NRC, are different in many respects from then, and current, corporate DOE requirements. In subsequent chapters of this report, the limitation of NRC's review to DOE's regulatory processes regarding the WTP is not explicitly repeated, but should be inferred.

In this study, in which about 2.5 full-time equivalents (about 3500 hours) of NRC staff review effort were expended, the NRC staff reviewed DOE regulations, requirements, orders, and guidance for the Hanford WTP from the perspective of the NRC regulatory framework, which applies to commercial nuclear facilities. This evaluation included a review of areas such as: (1) human capital (staffing levels and technical expertise); (2) DOE's approach to problem solving; and (3) DOE plans for a transition from construction to operation of the WTP. NRC limited its review to safety and environmental programs and activities specific to the WTP. To accommodate time (< 180 days) and resource (no specific appropriation for the review) constraints, the NRC staff did not conduct: (1) a license review; (2) a detailed design review; (3) an audit of DOE's implementation of its own requirements; or (4) an assessment of security threat or vulnerability. Given the above constraints, NRC also did not attempt to assess the significance, relative to safety, of the differences found between NRC' and DOE's regulatory approaches. NRC's assessment also excluded: (1) security; (2) material control and accounting; (3) emergency planning; (4) management of plant output; and (5) decommissioning. NRC's review addresses DOE documents that are dated prior to mid-March 2008, when the field component of NRC's assessment was completed. DOE's WTP project terminology has changed, over the years, for certain types of documents and regulatory actions. The NRC uses the terminology that was in use at the time of the referenced documents, or when the regulatory actions occurred.

In Chapter two, NRC staff used its regulatory process, as a basis of comparison, to assess DOE's regulatory process at the WTP. NRC's regulatory process has five main parts. The first part is development of regulations and guidance for nuclear material applicants and licensees. The second part of the NRC regulatory approach is licensing or certifying applicants to possess

and use Atomic Energy Act materials (i.e., source material, byproduct material, and special nuclear material). Licensing normally involves providing an opportunity for hearings, as provided by the Atomic Energy Act. The third part is regulatory oversight of licensee operations to ensure safety and compliance with safety requirements. The fourth part is the NRC evaluation of relevant operational experience. The last part is conducting research and getting independent reviews to support NRC regulatory decisions. NRC staff describes DOE's process for addressing comments received by external oversight groups, including the NRC, as part of the review of DOE's oversight approach.

NRC staff compares the overall DOE regulatory framework for the WTP to NRC's regulatory framework for a comparable facility in Chapter two. The staff used NRC's standard review plan for safety and environmental reviews of license applications for fuel cycle facilities (NRC, 2002), as a basis for reviewing DOE's regulatory programs and practices (see Section 2.2.2.1.3). Chapter three provides the staff's review of DOE's regulatory programs and practices, including: (1) DOE's safety analysis (including hazard analysis); (2) radiation safety; (3) nuclear criticality safety; (4) chemical process safety; (5) fire safety; and (6) environmental protection practices. NRC also reviewed DOE's management measures, including: (a) configuration management; (b) maintenance; (c) training and qualifications; (d) procedures; (e) audits and assessments; (f) incident investigations; (g) records management; and (h) quality assurance elements. Finally, NRC reviewed DOE's programs for inspection during construction and operations, enforcement, allegation assessment, and risk assessment.

Chapter four summarizes the results of the NRC staff's review and describes NRC's recommendations.

1.3 Interactions

As part of the review process the NRC staff reached out to, and interacted with, various stakeholders. NRC notified the States of Washington and Oregon Governor-appointed State Liaison Officers and affected Tribal Groups before NRC's first visit to the WTP. NRC also briefed Congressional committee staff, as requested.

In February and March 2008, NRC staff toured the WTP and met with DOE and its contractor staff to gather information. During the February site visit, the NRC staff also met with staff of Washington State regulatory agencies involved with WTP oversight (Department of Ecology and Department of Health). On February 13, 2008, the staff held a public meeting, in Richland, Washington, to describe plans for the assessment. To support transparency during the review, the staff made two public presentations on the review to the Tank Waste Committee of the Hanford Advisory Board in February and May.

The NRC staff met twice with the Defense Nuclear Facilities Safety Board (DNFSB) staff, to discuss the Board's authority and oversight role for the WTP. The DNFSB staff provided copies of WTP-relevant documents to the NRC staff, to aid the NRC review process. NRC provided the DNFSB staff with an opportunity to review portions (Chapters 1, 2, 3, and 5) of a draft of this report for factual accuracy.

The Government Accountability Office (GAO) is also conducting a study that addresses some topics that overlap NRC's WTP review of regulatory processes. In March, NRC discussed the scope of the GAO study with the GAO staff. The GAO study focused on a review of the internal

oversight of DOE nuclear safety by the DOE Office of Health, Safety, and Security. NRC developed this report independently of the GAO efforts.

As requested by Congress, DOE fully cooperated with NRC in its review. DOE provided timely access to the site, full access to its employees and the DOE contractor staff, and provided rapid access to the information NRC requested. NRC and DOE kept one another informed of site and review activities as each agency progressed in its respective activities. NRC provided DOE with the opportunity to comment on the factual accuracy of NRC's characterization of DOE regulatory processes, to ensure that this report accurately reflects the DOE WTP project and associated regulatory processes. On May 6, 2008, the NRC conducted a public meeting to discuss the DOE factual accuracy comments on a preliminary draft of portions of the report. The conclusions of the staff review and the suggestions presented in Chapter 4 were not subject to DOE's review.

At the beginning of its review, NRC received oral comments from the State of Washington, and written comments from the State of Oregon concerning this review. NRC staff also conducted interviews by telephone with State of Washington Department of Ecology and Department of Health staff. These agencies provided copies of various permits and related information applicable to the WTP. In addition, NRC received written comments from a public interest group and oral comments from the Tank Waste Committee of the Hanford Advisory Board and members of the public. The NRC staff considered comments received throughout the review process and addressed them as appropriate. The NRC staff will hold another local public meeting to inform stakeholders of the results of its review once it delivers the report to Congress and the Secretary of Energy. Note that NRC referred comments outside the scope of this assessment to the relevant DOE offices.

1.4 Hanford Tank Wastes and the WTP

The DOE Hanford Site has more than 200 million liters (53 million gallons) of radioactive and chemically hazardous waste materials stored in 177 underground waste storage tanks. These tanks contain the chemical contents from processing spent nuclear fuels for more than 40 years at the site. The tanks contain about 7.04×10^6 TBq (190 million curies) of radioactivity, mainly from radioactive cesium and strontium, but with smaller contributions from other fission products and transuranic isotopes. Physically, the tank contents exist as liquids, sludges, salts, saltcakes, and mixtures.

When completed, the WTP will be an industrial complex of facilities for separating and vitrifying (immobilizing in glass) wastes stored in the Hanford waste tanks. The DOE Office of River Protection is responsible for the WTP program. The WTP will separate the waste into HLW (high-level waste) and low-activity waste fractions. The WTP has five major components. The Pretreatment Facility will separate the waste coming from the tanks into the two waste fractions. The separated fractions will be sent to the HLW and Low-Activity Waste facilities, where the waste will be immobilized in glass using melters. DOE will use the Analytical Laboratory facility for testing incoming waste and quality of the glass produced. The final component is the Balance of Facilities, which consists of the rest of the necessary infrastructure to use the WTP.

CHAPTER 2 REGULATORY FRAMEWORK

2.1 Introduction

This chapter documents the NRC staff's review of the overall DOE regulatory framework for the WTP and compares that to the NRC regulatory approach for a comparable facility. The review focused on nuclear-safety-related aspects of the regulatory framework that DOE uses to ensure that the contractor designs, constructs, and operates the WTP to protect worker and public health and safety and the environment. NRC did not review the DOE regulatory framework for reducing WTP risks involving malevolent acts (e.g., sabotage; loss, theft or diversion of hazardous material; and/or unauthorized disclosure of sensitive information and material). Also, NRC did not review the DOE regulatory framework for WTP-related emergency planning and decommissioning. The NRC staff presents its review of the overall regulatory framework in Section 2.2 and the results of this assessment in Section 2.3.

The overall framework includes statutory and other mandates (Section 2.2.1), and the regulatory processes (Section 2.2.2). The statutory mandates define and influence the regulatory process. The NRC staff reviewed DOE's regulatory process as it relates to NRC policies, regulations, guidance, and consensus standards (Section 2.2.2.1), licensing/authorization process (Section 2.2.2.2), and regulatory oversight (Section 2.2.2.3).

NRC designed its review effort to assess DOE's overall regulatory framework and DOE's regulatory programs and practices. The review of DOE's programs and practices (described in Chapter 3) focuses on how DOE implements the safety program for the WTP within its regulatory framework. NRC used its standard review plan for fuel cycle facilities to review DOE's regulatory programs and practices, and as the basis for assessing DOE's regulatory process for the WTP. The NRC standard review plan is applicable for safety and environmental reviews of applications to construct or modify and operate nuclear fuel cycle facilities (NRC, 2002). Site visits by NRC staff, interviews with relevant DOE and contractor staff, and a review of DOE and contractor documents form the basis for the review that follows.

2.2 Review of Regulatory Framework

2.2.1 Statutory and Other Mandates for Safety

The Energy Reorganization Act of 1974 (ERA, 1974) abolished the Atomic Energy Commission (AEC) and created the NRC and DOE (in the form of its predecessor agency, the Energy Research and Development Administration). Through the ERA, Congress divided the functions of the AEC between the agencies; with the AEC's licensing and related regulatory functions transferring to the NRC, and AEC's promotional, defense nuclear, operational, and other functions transferring to DOE. Specifically, the NRC inherited part of the AEC's mission under the Atomic Energy Act of 1954 (AEA). This mission includes the regulation of civilian commercial, industrial, academic, and medical uses of nuclear materials in order to protect the public health and safety, and promote the common defense and security. But the NRC does not generally have licensing or related regulatory authority over DOE facilities. While there are a few exceptions to this general rule, the WTP does not fall within them. Thus, the NRC does not have licensing or regulatory authority over DOE's construction and operation of the WTP. Instead, DOE is responsible for nuclear safety at the WTP, in addition to having responsibility

for constructing and operating the facility. This illustrates a fundamental difference between the agencies: NRC is purely a regulatory agency, only having responsibility for regulating safety and security, whereas DOE plays a dual role, having responsibility for constructing and operating the WTP, as well as ensuring nuclear safety. Nevertheless, both agencies are responsible for protection of worker and public health and safety and compliance with the National Environmental Policy Act of 1969, as amended (NEPA). Both agencies consider environmental consequences and impacts as part of the decision making process, consistent with NEPA.

DOE's regulation of the WTP is also subject to the Hanford Federal Facility Agreement and Consent Order (also known as the Tri-Party Agreement; Ecology, et al., 1989). The Tri-Party Agreement is a legal agreement between DOE, the U.S. Environmental Protection Agency, and the State of Washington Department of Ecology. The purpose of the agreement is to achieve compliance with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remedial action provisions (CERCLA, 1980) and with the Resource Conservation and Recovery Act (RCRA) treatment, storage, and disposal unit regulations and corrective action provisions (RCRA, 1976). The Tri-Party Agreement defines and ranks CERCLA and RCRA cleanup commitments and establishes responsibilities. The agreement describes the roles, responsibilities, and authority of the three agencies in the cleanup, compliance, and permitting processes. The agreement includes an action plan to implement the cleanup and permitting efforts that includes enforceable milestones for initiating and completing specific work (Ecology, et al., 1989).

In summary, DOE's role includes both construction and operation of nuclear facilities like the WTP, and environmental protection and safety responsibilities; whereas NRC's role is protection of health and safety and promotion of the common defense and security. The DOE's framework for the WTP also includes added safety, schedule, and production responsibilities legally required by the Tri-Party Agreement (Ecology, et al., 1989).

2.2.2 Regulatory Process

Both DOE and NRC have well developed regulatory processes. Figure 2.1 summarizes NRC's regulatory process. NRC's regulatory process has five main components or parts. The first part is developing regulations and guidance for applicants and licensees. The second part is licensing or certifying applicants to use nuclear materials or operate nuclear facilities. This part includes providing the opportunity for hearings to consider the concerns of parties affected by licensing (and enforcement) proposals and obtaining independent reviews (e.g. from ACRS). The third part is regulatory oversight of licensed activities, to ensure that licensees operate safely and comply with safety requirements. The fourth part is evaluating operational experience at licensed facilities or operational experience involving licensed activities. The fifth part is conducting research and obtaining independent reviews to support NRC's regulatory decisions. NRC also strives to improve its processes in these five areas through risk-informed and performance-based regulation.

DOE documents its requirements (DOE orders, standards, and guidance) for the WTP in a contract (DOE, 2000a). The contract serves not only as the basis for safety, but also contains DOE's general requirements for construction and operation of the WTP. Section C.3(b) of the contract (DOE, 2000a) states that "DOE is responsible as the 'Owner' and 'Regulator' of the WTP." Section C.3(b)(2) states that "DOE will regulate radiological, nuclear, and process

safety, and non-radiological worker safety and health." NRC staff reviewed both DOE and contractor activities and documents associated with DOE's regulatory process.

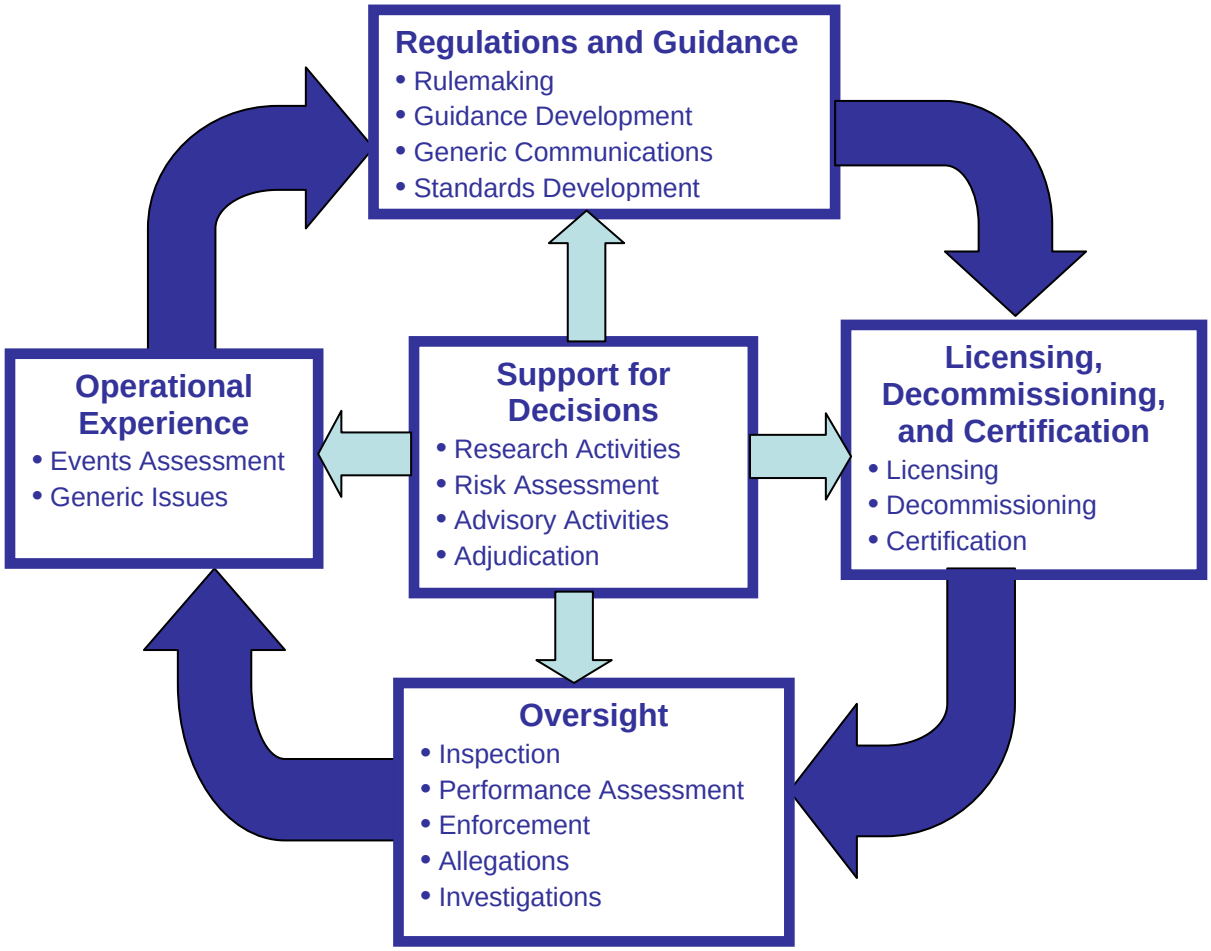

Figure 2.1. Overview of NRC's Regulatory Process. (NRC, 2008b)

2.2.2.1 Policies, Regulations, Guidance, and Consensus Standards

Safety regulations consist of subject-matter-specific requirements that must be satisfied for reasonable assurance of adequate protection of worker and public health and safety and the environment. Each regulation is supported by policies, guidance, and programs and practices. This section only discusses a comparison of the safety policies, regulations, guidance, and consensus standards for DOE and NRC (differences in programs and practices are discussed in Chapter 3).

2.2.2.1.1 Policies

Both DOE and NRC have a nuclear-safety-related policy addressing safety goals. Safety goals broadly define an acceptable level of radiological risk (NRC, 2008c). NRC does not directly apply safety goals to its fuel cycle facility licensing process (see Section 3.2.12.2.1). The DOE policy (DOE, 1991) adopts two quantitative safety goals that "...should be viewed as aiming points for performance." These goals are the same as the NRC reactor safety goals (NRC, 2008c). As stated, the goals are numerically equivalent to 0.1 percent of the corresponding U.S. average accident and cancer fatality risks. DOE's policy (DOE, 1991) further states that these goals are not a substitute for compliance with DOE directives and rules. DOE has a number of other nuclear-safety related policies that have no direct equivalent policy statements in NRC's regulatory framework. Each DOE policy has one or more implementing documents (e.g. Orders, Manuals, and Guides) associated with it. NRC focused its review, with the exception of the above-mentioned policy, on the implementing documents.

2.2.2.1.2 Regulations

Both DOE and NRC promulgate safety regulations in accordance with the Administrative Procedure Act (1946). DOE has four principal safety regulations for WTP site selection, design, and construction. DOE indicates the same regulations will apply to WTP future facility start-ups and operations involving radioactive material. DOE has regulations for nuclear safety management (10 CFR Part 830), occupational radiation protection (10 CFR Part 835), nuclear safety enforcement (10 CFR Part 820), and worker health and safety (10 CFR Part 851). Under the regulatory umbrella of Part 830, DOE has a number of nuclear-safety related Orders, Manuals, and Policies.

Combined, DOE's regulations for nuclear safety management and occupational radiation exposure (Parts 830 and 835) and an order (DOE Order 420.1B; DOE, 2005a) are similar to NRC's comparable regulation (10 CFR Part 70). One minor difference is that DOE uses integrated safety management (ISM) (DOE, 1996a), including accident analysis, for the evaluation and control of hazards, whereas NRC uses an integrated safety analysis (ISA) approach. Integrated safety analysis means (Part 70) "…a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety [IROFS]." DOE requires (DOE, 2000a) the contractor for the WTP to develop and implement an ISM program, based on industry standards, to ensure that radiological, nuclear, and process safety requirements are defined, implemented, and maintained. Further, DOE requires that the ISM program comply with the specific nuclear safety regulations in 10 CFR Part 800 series (DOE, 2000a). DOE's ISM program includes employees' occupational safety, whereas NRC's ISA evaluation does not cover licensee's occupational safety because it's under OSHA's jurisdiction.

Another difference is that DOE categorizes structures, systems, and components into two classes, which are defined, in Part 830, as either safety-class or safety-significant structures, systems, and components, depending on the nature of their mitigative or preventive functions. In contrast, NRC uses the concept of IROFS (Part 70). That concept means "…the structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents, at a facility, that could exceed the performance requirements in § 70.61, or to mitigate their potential consequences." Additional discussion of DOE's classification of structures, systems, and components, is provided in Section 2.2.2.1.3.

NRC's regulation for domestic licensing of special nuclear material (Part 70) includes, by reference, standards for: (1) radiation protection (10 CFR Part 20); (2) environmental protection (10 CFR Part 51); and (3) rules of practice for domestic licensing proceedings and issuance or orders (10 CFR Part 2). DOE has comparable regulations for radiation protection (Parts 830 and 835) and environmental protection (10 CFR 1021). NRC does not regulate non-radiological worker health and safety in the workplace and therefore does not have a regulation comparable to DOE's Part 851. DOE's regulation (Part 851) includes requirements similar to Occupational Safety & Health Administration's (OSHA's) regulatory requirements.

2.2.2.1.3 Guidance

DOE has guidance for implementing its safety regulations, and the contract (DOE, 2000a) for the WTP, and NRC has guidance (NRC, 2002) for implementing its comparable regulation. DOE has six principal guidance documents (DOE, 2001a, 2001b, 2001c, 2001d, 2004, and 2005b) that are considered the safety governing documents. DOE also developed position papers (e.g., DOE, 2001e) that explain regulatory expectations for essential safety topics. These position papers clarify acceptable methods to meet contract requirements or to address issues raised during the regulatory process. DOE also has guidance (DOE, 2002a), for the contractor, for implementing the nuclear facility documented safety analyses requirements of 10 CFR Part 830 and facility safety requirements of DOE Order 420.1B (DOE, 2005a).

The contract requires the contractor -- Bechtel National, Inc. (BNI) -- to use a Safety Requirements Document. The safety requirements document (BNI, 2007a) contains the set of tailored (as per DOE, 2001e) environmental, safety, quality, and health requirements (e.g., DOE Orders, DOE Manuals, and guidance) applicable to WTP. The applicable laws and regulations are prescribed in the WTP contract. The contract requires development and use of a quality assurance (QA) manual (BNI, 2007b) and a radiation protection plan (BNI, 2001). DOE reviews, using its regulatory process for radiological, nuclear and process safety (DOE, 2001b), these three documents (BNI, 2001, 2007a, 2007b) and approves them, with any required modifications. DOE is correcting inconsistencies between its WTP safety classification system terminology and the Part 830 terminology and guidance.

Structures, systems, and components that serve to provide reasonable assurance that the WTP facility can be operated without undue risk are classified as important-to-safety and are defined in safety criterion 1.0-6 (BNI, 2007a). Important-to-safety structures, systems, and components are identified and subclassified as safety-class, safety-significant, and additional-protection class (BNI, 2007a). Specific safety criteria implementing codes and standards are specified for the different subclasses (BNI, 2007a).

NRC's principal guidance for implementing Part 70 is the "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520 (NRC, 2002). This guidance, which is the basis for this assessment, reflects a 2002 update in NRC's regulations to incorporate the integrated safety analysis approach. NRC had previously developed a standard review plan (NUREG-1702; NRC, 2000a) to address its involvement with DOE's Tank Waste Remediation System Privatization Project at Hanford (NRC, 2001a). NUREG-1702 provided guidance to the NRC staff for the performance of safety and environmental reviews of the Tank Waste Remediation System Facility (NRC, 2001a). This guidance has been superseded by NUREG-1520.

DOE and NRC safety requirements and implementing guidance can be generally categorized into the topics listed below. These topical areas provide a framework for the regulatory review and licensing process for the design, construction, start-up, and operation of a facility for processing special nuclear material:

- General Information
- Organization and Administration Information
- Safety Analysis
- Radiation Protection
- Nuclear Criticality Safety
- Chemical Process Safety
- Fire Safety
- Environmental Protection
- Management Measures

NRC staff conducted only a high-level comparison of general information and organizational and administrative information. General information includes a facility description, institutional information, and a site description. The general information provides the purpose of the facility and an overview of the design of its processes. DOE and NRC guidance for this information is essentially the same.

In an NRC license application, an applicant will provide organizational and administrative information applicable to the proposed activity. Organizational and administrative information identifies the entity responsible for site selection, design, construction, startup, and operations involving radioactive material. The applicant will describe its organizational structure and associated administrative program to include administrative policies, procedures and management policies, and qualifications of staff in key management positions, and will describe how these will provide reasonable assurance that the health, safety, and environmental protection functions will be effective (NRC, 2002). DOE, through its contract, receives similar information from its contractor on the proposed project's organizational and administrative programs.

The discussion that follows provides a high-level comparison of the DOE's programs and practices for the topical areas compared to the NRC programs and practices. A more detailed comparison of topical area programs and practices (except general information and organization and administrative information) is included in chapter 3.

In its regulations, NRC requires fuel cycle facility licensees and applicants to prepare an ISA to demonstrate compliance with risk-informed performance requirements. The performance requirements address the risks of credible high-and intermediate-consequence accidents and releases to the environment. The ISA is a systematic evaluation of credible accidents and their consequences. Based on the ISA, the licensee or applicant identifies IROFS. The IROFS are engineered or administrative features that are needed to prevent or mitigate accidents that could exceed the performance requirements. NRC also requires that management measures be established to ensure that IROFS will be available and reliable to perform their functions when needed. DOE's safety analysis uses an ISM approach, instead of an ISA approach. DOE's approach involves characterizing WTP radioactive hazards and the engineered and

human performance relied on to reduce risks to levels that provide reasonable assurance of adequate protection of workers, the public, and the environment.

DOE's safety analysis serves as the safety basis for site selection, design, construction, and operation of the WTP. Compared with NRC requirements, DOE includes a broader range of hazardous chemicals (both nuclear safety- and Tri-Party-Agreement-related) in its requirements and guidance for safety analysis. NRC's safety analysis addresses chemical risks from licensed materials and hazardous chemicals produced from licensed materials. NRC's review of DOE's programs and practices for safety analysis is in Section 3.2.1.

NRC requires a radiation protection program to use engineered and human measures to maintain exposures within prescribed safe limits and achieve as low as is reasonably achievable levels of exposure. Radiation protection guidance is similar for DOE and NRC requirements for radiation and toxic uranium protection. NRC's review of DOE's programs and practices for radiation protection is in Section 3.2.2.

Nuclear criticality safety requirements and implementing guidance are similar for DOE and NRC. Both DOE and NRC guidance documents require review of the nuclear criticality program and the application of the "double-contingency" principle, to reduce the risk of inadvertent nuclear criticality. NRC's review of DOE's programs and practices for nuclear criticality safety is in Section 3.2.3.

Chemical process safety is a key aspect for prevention and mitigation of fire, explosion, and release of hazardous chemicals and radioactive materials. DOE and NRC regulatory requirements and implementing guidance for chemical process safety are similar. However, NRC's review guidance only addresses chemical safety issues related to: (1) radiation risks of licensed materials; (2) chemical risks of licensed materials; and (3) plant conditions that affect, or may affect, the safety of licensed materials. Also, NRC has no guidance on plant conditions, including chemical hazards that do not affect or involve the safety of licensed materials. NRC's review of DOE's programs and practices for chemical process safety is in Section 3.2.4.

Fire safety is a significant risk contributor that can cause the failure of engineered structures, systems, and components and significantly impact the ability of operators to complete actions that are relied on for safety. DOE and NRC fire safety requirements and implementing guidance are similar. One additional aspect of DOE's requirements (DOE Order 420.1B; DOE, 2005a), and implementing guidance, is a focus on minimizing property loss. NRC's review of DOE's programs and practices for fire safety is in Section 3.2.5.

NRC and DOE have similar programs and guidance for complying with NEPA (NEPA, 1969). NRC and DOE also have similar guidance for meeting limited environmental requirements during site selection and for the design, construction, and operation of facilities. However, DOE as an owner/operator must comply with a range of environmental laws and regulations that are not applicable to NRC as a regulatory agency. Further, the Tri-Party Agreement (Ecology, et al., 1989) imposes additional environmental protection requirements on DOE (e.g., in DOE's role as a co-permitee under RCRA). DOE has guidance for complying with environmental requirements and Tri-Party Agreement requirements. NRC's review of DOE's programs and practices for environmental protection is in Section 3.2.6.

DOE and NRC regulatory requirements and implementing guidance for management measures are similar and ensure safety by including: (1) configuration management; (2) maintenance; (3) training and qualifications; (4) procedures; (5) audits and assessments; (6) incident

investigations; (7) records management; and (8) quality assurance (NRC, 2002). NRC's review of DOE's programs and practices for management measures is in Section 3.2.7.

2.2.2.1.4 Consensus Standards

Consensus standards development is a key activity supporting the regulation and guidance component in NRC's regulatory process (Figure 2.1). Consistent with the National Technology and Transfer Act (1995) and Office of Management and Budget Circular A-119 (OMB, 1998), both DOE (DOE, 2000b) and NRC work with industry standards organizations. Both agencies work to develop consensus standards associated with systems, human performance, equipment, and materials used by the nuclear industry. These standards may then be referenced in NRC and DOE regulations or guidance.

DOE Order 252.1 (DOE, 1999a) requires that DOE use voluntary consensus standards to the maximum extent possible in the conduct of its activities. DOE adopts voluntary consensus standards by referencing them in: (1) policy statements; (2) requirements documents (e.g., rules and Orders); (3) guides; (4) contract documents; (5) site/facility implementation plans; and (6) DOE-approved sets of "work-smart" standards (DOE, 2000b). The safety requirements document (BNI, 2007a) contains the list of consensus standards used by the contractor for WTP.

NRC has an agency policy governing NRC's standards activities (NRC, 1999). NRC's policy is to increase the involvement of stakeholders in our regulatory development process and, consistent with the provisions of the National Technology Transfer and Advancement Act (1995), to encourage NRC staff participation in the development of consensus standards in support of its mission and to encourage industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by the industry.

2.2.2.1.5 Summary of NRC's Review of Regulations and Guidance

The DOE contractor is required (DOE, 2000a) to develop and implement an integrated standards-based safety management program that complies with the DOE regulatory program established by the principal DOE guidance documents (DOE, 2001a, 2001b, 2001c, 2001d, 2004, and 2005b).

Both DOE and NRC address nuclear-safety-related policy, regulations, guidance, and the use of consensus standards. Both agencies have a safety goal policy with the same acceptable level of radiological risk. However, NRC does not directly apply the reactor safety goals to licensing of fuel cycle facilities. NRC and DOE apply comparable regulations, with the following exceptions. NRC does not regulate non-radiological worker health and safety in the workplace. Industrial safety at NRC-regulated facilities is overseen by OSHA. DOE regulates worker safety and health at its facilities in accordance with its requirements in Part 851. Although DOE is the regulator for nuclear safety, it is also subject, as an owner/operator, to environmental regulations of the State of Washington and to the requirements of the Tri-Party Agreement (Ecology, et al., 1989).

The NRC and DOE frameworks for regulatory guidance are similar, with the following exceptions. The WTP contractor is required to propose which DOE directives, guidance, and consensus standards should be applicable to the contractor's WTP work. DOE is responsible for approving, subject to modifications, the proposed requirements. The WTP project now has

three classes for structures, systems and components, compared to NRC's safety classification system, which only has one class (IROFS). Each safety class has separate requirements, and a structure, system, or component can be reclassified. DOE's safety analysis guidance uses an integrated safety management approach, whereas NRC uses an integrated safety analysis approach. DOE's regulatory guidance addresses four additional areas that are not addressed in NRC's guidance. First, the Tri-Party Agreement (Ecology, et al., 1989) requires additional DOE guidance for complying with environmental requirements. Second, DOE includes hazardous chemicals (additional Tri-Party Agreement-related) in its guidance for safety analysis. Third, DOE's added responsibility for chemical hazard safety leads to additional guidance for the review of chemical process safety. Fourth, DOE's guidance for fire protection is expanded, relative to NRC's guidance, to reflect DOE's responsibility as the owner of the WTP. DOE and NRC implement a comparable program for using and adopting voluntary consensus standards.

2.2.2.2 Licensing/Authorization Process

Section 2.2.2.2.1 discusses licensing and the concept of authorization basis. Section 2.2.2.2.2 compares the DOE authorization and NRC licensing change control processes. Section 2.2.2.2.3 briefly discusses NRC's adjudication process, and Section 2.2.2.2.4 summarizes the comparison of the two agencies' approaches to authorization and licensing.

2.2.2.2.1 Licensing and Authorization Basis

The NRC licensing process includes approving the initial license, and subsequent license modifications. To be licensed to construct certain nuclear facilities and to use nuclear materials or operate a facility that uses nuclear materials, an entity or individual submits an application, which includes an integrated safety analysis summary and environmental report (addressing 10 CFR Part 51 requirements) to NRC. The staff reviews this information, using standard review plans, to ensure that the applicant's safety basis is technically correct, complete, and meets NRC requirements, and that the environmental report meets NRC requirements. NRC licenses the construction and operation of fuel cycle facilities in a one-step process, with one exception, using 10 CFR Part 70 and NUREG-1520 (NRC, 2002). The one exception is that Part 70 allows a two-step process for licensing of plutonium processing and plutonium fuel fabrication plants. Upon satisfaction that the requirements have been fulfilled, the NRC issues a license.

While generally analogous to NRC licensing, DOE's authorization process differs in several important respects. First, because DOE is responsible for constructing and operating the WTP – in addition to ensuring safety – DOE's WTP decisions must address operability and production design aspects, as well as safety aspects.

DOE makes decisions, regarding "operability and production design aspects" that are unrelated to safety, using project management avenues available under the contract. DOE does not license its facilities, but it self-regulates nuclear, radiological, and process safety at WTP. DOE issues a construction-authorization agreement between DOE and the contractor, following DOE's safety evaluation report of the preliminary safety analysis report. DOE issues a operations-authorization agreement between DOE and the contractor, following DOE's safety evaluation report of the documented safety analysis (formerly referred to as the Final Safety Analysis Report). The construction-authorization agreement is the documented authorization basis of the facility. The authorization basis includes the safety requirements, facility description, hazard analyses, safety analyses, and limiting conditions for operation. It is

analogous to an NRC license, to the extent that it describes the specific requirements that the contractor must observe during construction, and later, during operation. The authorization agreement and the authorization basis are only concerned with nuclear, radiological and process safety aspects of the design.

Second, DOE uses a design-build approach to the WTP. Portions of the facility are under construction while design efforts are continuing. Although DOE's authorization process is essentially a two-step process -- requiring authorization for construction, and separate authorization for operation -- the design-build approach results in a program involving multiple construction authorization decisions, as facility design and construction activities progress.

DOE's safety regulation process consists of six regulatory actions (DOE, 2001b). The six regulatory actions are: (1) standards approval; (2) initial safety evaluation; (3) authorization for construction; (4) operating authorization; (5) oversight process determination; and (6) deactivation authorization. In particular, the discussion in this section focuses on actions one through three because they are most germane to the current stage of the WTP project. The oversight determination process is discussed briefly in Section 2.2.2.3.

DOE fulfilled the first regulatory action, standards approval, by approving the contractor's Safety Requirements Document (BNI, 2007a). The contractor identified the standards necessary to conduct the hazard and accident analyses in the safety requirements document. To inform its standards-approval action, DOE also reviewed the BNI's initial WTP preliminary safety analysis report, prepared in 2002, in accordance with 10 CFR 830.206.

The second regulatory action is the initial safety evaluation. DOE reviewed each facility-specific preliminary documented safety analysis, and the subsequent updates, and documented its review in a safety evaluation report. DOE's approval of the documented safety analysis is required in DOE's regulations in 10 CFR 830.207. On a high level, the depth of review in the safety evaluation report appears to be in line with that of an NRC safety evaluation report on a comparable fuel cycle facility.

The third regulatory action is authorization for construction. The WTP construction authorization was granted to the contractor on issuance of a preliminary safety evaluation report. At its discretion, DOE may impose conditions of acceptance on the contractor, as further requirements to construct and operate the WTP. Conditions of acceptance are analogous to NRC's license conditions, and are included in the safety evaluation report.

The other three DOE regulatory actions-operating authorization, oversight process determination, and deactivation authorization-will only be implemented at the WTP sometime in the future (SOE, 2001b). Because the regulatory processes that DOE would use to support these actions have not yet been completely developed, the NRC staff did not focus its review on these topics.

As part of authorization process DOE uses the term "authorization basis," which is similar in concept to the NRC licensing basis. The authorization basis is defined in RL/REG-97-13 (DOE, 2005b) as: "…the composite of information, provided by the contractor in response to radiological, nuclear, and process safety requirements, that is the basis on which the DOE Office of River Protection (ORP) grants permission to perform regulated activities." The preliminary safety analysis report and the corresponding DOE safety evaluation report are considered integral to the authorization basis. The authorization basis is required to be updated every 2 years and is based on DOE's review of the contractor's safety analysis report (DOE,

2005b). The preliminary safety analysis reports, for all WTP facilities, were updated in 2004 and 2006, and further updates are expected in 2008 (additional details are provided in Section 3.2.1.2.1). According to DOE staff, this biennial authorization basis updating review usually takes a team of 5 to 10 people to review, over a 3-month period. The reviews are documented in a safety evaluation report issued by DOE ORP.

2.2.2.2.2 Controlling Changes to the Licensing or Authorization Basis

Another important licensing aspect for ensuring safety is controlling changes after the facility is initially authorized (this topic is also addressed in Section 3.2.1.2.4, where a side-by-side comparison of the DOE and NRC change process is provided). NRC requirements for facility changes and the change process are described in 10 CFR 70.72. Once a license is issued by NRC, the licensee is required (10 CFR 70.72) to maintain a configuration-management system, to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. Written documentation and requirements must be addressed before implementing changes. Changes may be made without prior NRC approval if the change:

- "Does not:
    - Create new types of accidents and sequences that, unless mitigated or prevented, would exceed the performance requirements of § 70.61 and that have not been previously described in the integrated safety analysis summary; or
    - Use new processes, technologies, or control systems for which the licensee has no prior experience;"
- "Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary and is necessary for compliance with the performance requirements of § 70.61;
- Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and
- Is not otherwise prohibited by this section, license condition, or order."

Revised integrated safety analysis summary pages on changes not requiring prior NRC approval are supplied to NRC annually.

Changes requiring prior NRC approval require a licensee to provide a written license amendment with supporting documentation. NRC reviews the amendment request. Approval from NRC is required before the licensee implements the changes covered by the amendment process.

Authorization basis changes are subject to the DOE requirements in RL/REG-97-13 (DOE, 2005b). DOE prior approval is required if the authorization basis changes involve:

- Modification to the contractor's safety requirements document;
- Creation of a new design-basis event or significant alteration to an existing design-basis event; or
- Significant decrease of safety functions of important-to-safety structures, systems, or components.

- Changes in how a safety-class structure, system, or component meets its respective safety function, or for radiological protection of co-located workers or facility workers, changes in how a safety-significant structure, system, or component meets its respective safety function.

The contractor may deviate from the authorization basis (during construction), without prior DOE approval, provided that the deviations are not subject to the four constraints identified above, and are documented in a safety evaluation. However, the contractor must orally inform ORP about any proposed deviation from the authorization basis within 24 hours, provide written notice with 72 hours, and submit an authorization-basis-change package within 60 days of identifying the proposed deviation. This package is called an authorization basis amendment request. Once the authorization-basis amendment request is submitted to ORP, ORP must document concurrence or rejection of the proposed deviation in a safety evaluation report within an additional 60 days after the amendment request submittal. Extensions to these time frames are granted by ORP on a case-by-case basis. The amendment requests, that address contractor deviations, are a small fraction of the total amendment requests submitted.

DOE ORP staff stated that in many instances, however, the original contractor submittal authorization-basis amendment request, addressing a deviation, is not adequate, and must be revised. The revision delays DOE approval beyond the 60-day requirement. However, the contractor is permitted to continue with design, advancing to a final design, pending approval by DOE of the authorization-basis amendment request. In instances where, based on the DOE review, there are significant weaknesses in the safety evaluation supplied with the notification of a need-to-deviate authorization-basis amendment request, the contractor is advised not to proceed with the deviation from the authorization basis, but to wait until DOE approves the authorization-basis amendment request.

Authorization-basis amendment requests are used for authorization-basis changes between the biennial updates in DOE's program. There are no schedule constraints on DOE for authorization-basis amendment-request reviews for amendments that are not seeking to deviate from the existing authorization basis. All authorization-basis amendment-requests are formally approved, unless disapproved or withdrawn by the contractor, by the issuance of an ORP safety evaluation report.

BNI uses a safety envelope document, one for each of the main components of the WTP, as the working document for the WTP's authorization basis, between the biennial authorization basis updates. The safety envelope is a contractor-issued and contractor-controlled document that ORP does not review and approve. BNI updates the safety envelope after each authorization-basis amendment request approval to reflect the ORP approved preliminary safety analysis report changes. DOE reviews and approves all the intervening detailed preliminary safety analysis changes during the biennial preliminary safety analysis report reviews.

2.2.2.2.3 Adjudication

The NRC uses an adjudicatory hearing process to support NRC licensing decisions and satisfy the hearing requirement contained in section 189a of the AEA. Through its hearing process, the NRC considers the concerns of parties affected by its licensing actions. Typically, independent judges on the Atomic Safety and Licensing Board Panel hear and address concerns of individuals or entities that are directly affected by NRC licensing actions. The Atomic Safety and Licensing Board Panel is composed of technical and administrative judges that are

independent from the NRC staff and from the Commission. As DOE is not licensing a commercial entity to construct and operate the WTP – but, rather, is itself responsible for constructing and operating the WTP – DOE has no statutory directive to hold hearings on its authorization decisions. Thus, DOE has no comparable adjudicatory hearing process for its authorization decisions at the WTP. While NRC recognizes that DOE has no statutory directive to hold hearings, DOE also does not have any other process for considering the concerns of parties affected by its authorization actions.

2.2.2.2.4 Summary of NRC's Review of the Licensing and Authorization Processes

The DOE authorization and NRC licensing processes for construction and operation of a nuclear facility are generally similar; however there are some important differences. First, because DOE is responsible for constructing and operating the WTP, DOE's authorization decisions must address both the design for operability and production, as well as safety aspects. Second, because DOE takes a design-build approach to constructing the WTP, the change-control process is more important for ensuring design integrity and safety under DOE regulation than it would be under NRC regulation. Third, the contract commits DOE to a schedule to complete the regulatory licensing review for certain contractor-proposed changes, whereas the duration of NRC's licensing safety review is not set by contract or by regulation, and generally takes longer than the periods required in DOE's contract (DOE, 2000a). Fourth, NRC maintains its own licensing basis, whereas DOE allows the contractor to maintain safety engineering documents, between the biennial authorization-basis updates, and DOE updates the complete authorization basis, in one document for each facility during the biennial authorization-basis updates. Finally, NRC has a process for adjudication of its licensing actions. DOE does not have a comparable program. Some topical areas that are subject to NRC's licensing review (NRC, 2002) are reviewed further in Chapter three. The focus of that review is on DOE's program and practices in each of the topical areas addressed.

2.2.2.3 Oversight

Key activities in oversight include inspection, enforcement, allegations, assessment, and investigations. Each of these activities is part of NRC's regulatory process for fuel cycle facilities. This section provides a high-level comparison between NRC and DOE programs for the key activities.

The purpose of the inspection activity is to verify that a licensee's activities are properly conducted to ensure safe operations in accordance with NRC's regulations. Fuel cycle facility inspections occur several times a year and focus on the areas that are most important to safety and safeguards. Inspectors follow the guidance contained in the NRC Inspection Manual which includes objectives and procedures to use during inspections. The results of the fuel cycle facility inspections are documented in inspection reports. DOE's inspection program is defined through its regulations (Part 830) and guidance (DOE, 2004) and is implemented via the contract (DOE, 2000a). DOE, as owner of the WTP, requires inspection activities that include a focus on non-safety-related areas and operability. Industrial safety inspections are also within the scope of the DOE inspection program for the WTP (e.g., Part 851, "Worker Safety and Health Program"). The NRC and DOE inspection key activities are broadly comparable for safety; however DOE has additional responsibility for operability and industrial-safety inspection requirements.

As part of its oversight process, NRC issues sanctions called enforcement actions, to licensees that violate its regulations. Enforcement actions are used as a deterrent, to emphasize the importance of compliance with regulatory requirements, and to encourage prompt identification and prompt, comprehensive correction of violations. DOE's nuclear safety requirements (Part 830) are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties, in accordance with the provisions of Part 820. Enforcement is incorporated into the contract (DOE, 2000a) by inclusion of RL/REG-98-06 (DOE, 2002b) and DOE Order 226.1 (DOE, 2007a). The DOE enforcement program is administered under the Director, Office of Price-Anderson Enforcement (DOE, 2002b). In terms of a high-level review, both the NRC and DOE regulatory processes address, at a comparable level, the key enforcement activities.

The DOE oversight program for the WTP, as established through DOE Order 226.1 (DOE, 2007a), has multiple organizations that fulfill oversight functions, which is similar to NRC's use of different organizations to oversee safety. Figure 2.2 depicts the DOE oversight model (page 5 of DOE, 2007a), revised to be specific to the WTP. According to DOE Order 226.1, independent oversight refers exclusively to oversight by DOE Headquarters organizations that do not have line management responsibility for the activity. The primary responsibility for contractor oversight is ORP, whereas line management oversight is conducted by the Office of Environmental Management. In addition, there is independent line management oversight by the Under Secretary, who serves as central technical authority, and his Chief of Nuclear Safety.

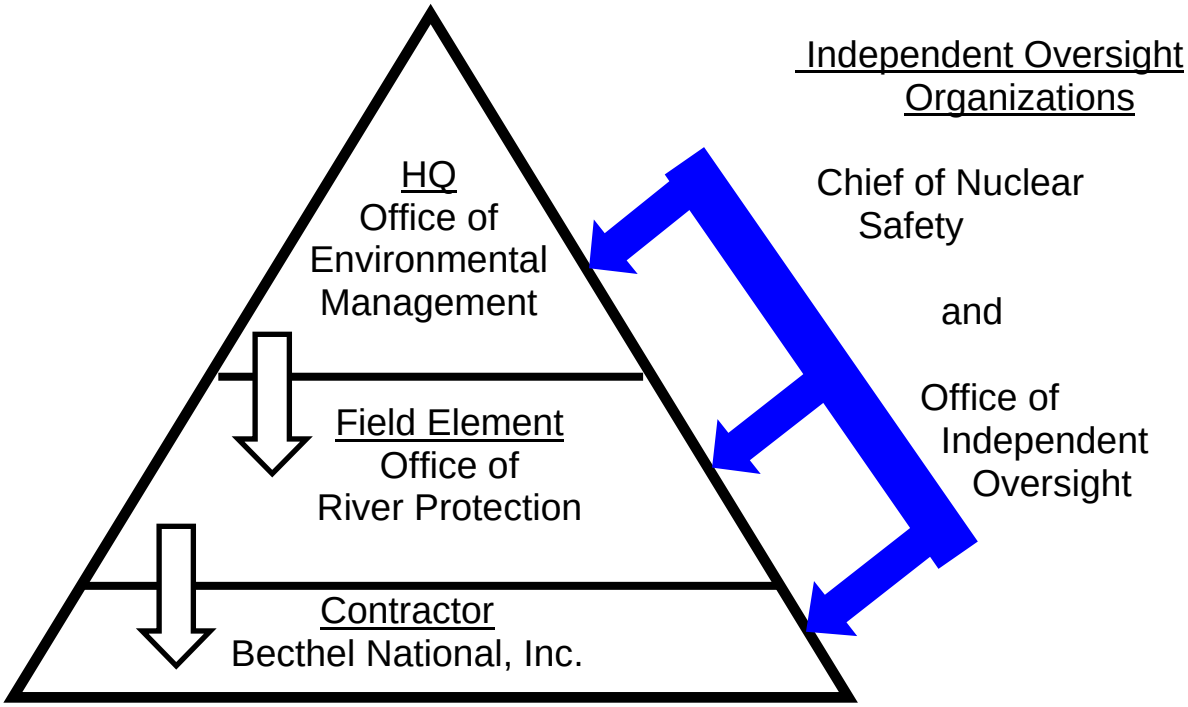

Figure 2.2. DOE Oversight Model for the WTP.

The Office of Independent Oversight, within the Office of Health, Safety and Security, also provides independent line management oversight. The primary focus of the Chief of Nuclear Safety, and the Office of Independent Oversight, is safety. Both organizations are independent of the line management operational responsibilities.

In addition to internal oversight, the DOE WTP program is also subject to independent external oversight. The Defense Nuclear Facilities Safety Board (DNFSB) is an independent executive branch agency responsible for providing advice and recommendations to the President and the Secretary of Energy regarding public health and safety issues at DOE defense nuclear facilities. DNFSB was established by Congress in 1988 to: (1) review and evaluate the content and implementation of the standards relating to the design, construction, operation, and decommissioning of DOE defense nuclear facilities (including applicable Departmental Orders, regulations, and requirements); (2) investigate any event or practice at DOE defense nuclear facilities that has adversely affected or may adversely affect public health and safety; (3) analyze design and operational data, including safety analysis reports, from any DOE defense nuclear facility; (4) review the design and construction of a new DOE defense nuclear facility and make recommendations considered necessary to protect public health and safety; and (5) make such recommendations to the Secretary with respect to DOE defense nuclear facilities, including operations of such facilities, standards, and research needs, as the DNFSB determines are necessary to ensure adequate protection of public health and safety. DOE is obligated by statute (AEA, 1954) to respond to safety issues raised by the DNFSB, but is not required to implement recommendations made by the DNFSB.

DOE obtains other external input through its public participation programs. The purpose of DOE's Policy 141.2 (DOE, 2003) is to ensure public participation is open, ongoing, two-way communication, both formal and informal, between DOE and its stakeholders concerning DOE's missions and activities. One major activity that DOE financially supports is the Hanford Advisory Board. The Hanford Advisory Board is an independent, non-partisan, and broadly representative body consisting of a balanced mix of the diverse interests that are affected by Hanford cleanup issues. As set forth in its charter, the primary mission of the Hanford Advisory Board is to provide informed recommendations and advice to the DOE, the U.S Environmental Protection Agency, and the Washington Department of Ecology on selected major policy issues related to the cleanup of the Hanford site, including the WTP. DOE does not use its public participation programs as part of the DOE authorization process.

The purpose of NRC's allegations program is to respond to reports of wrongdoing by NRC licensees, applicants for licenses, or licensee contractors or vendors. DOE addresses allegations through an employee concerns program, as established by DOE Order 442.1A (DOE, 2001f). That DOE order is incorporated in the contract (DOE, 2000a); thus, both DOE and the contractor have employee concerns programs. NRC's allegation program and DOE's employee concerns program are reviewed in Section 3.2.11.

NRC has a program that is implemented by its Office of Investigations, to investigate wrongdoing by NRC licensees. DOE implements an investigation-of-wrongdoing program through the DOE Office of Inspector General and has no separate investigation of wrongdoing in the contract (DOE, 2000a). That office performs investigations into allegations of fraud, waste, and abuse in programs and operations of the Department. Particular focus is placed on the prevention and detection of contract and grant fraud and environmental, health, and safety violations.

2.2.2.3.1 Process for Addressing External Oversight Items

DOE's principal system for tracking status of independent audit corrective actions is its Corrective Action Response System (CARS). As audits occur, corrective actions from the audits are entered as items in this database. The level of detail in this database is variable, depending on the extent of the audit, and its perceived significance. Some audits generated

one CARS item for each audit finding. Other audits generate a single item for the entire review. This system has been in effect for several years at the DOE ORP, but was not in effect in 2001.

Between 1997 and 2000, NRC provided assistance, under a memorandum of understanding, to DOE on the Tank Waste Remediation System-Privatization (TWRS-P) program at Hanford. A report summarized NRC's participation in, and observations on, the DOE program, and identified issues from NRC's perspective (NRC, 2001a). NRC staff identified over 28 significant issues and over 50 specific topics in the design and approach that would require further efforts and analysis to achieve adequate closure. The significant issues include both programmatic aspects of TWRS-P (e.g., maintenance of design/authorization basis, level of detail) and technical issues (e.g., large volumes of tankage and radionuclide inventories, combined chemical and radiological hazards, melter corrosion). DOE, as the current regulator, had also identified similar issues (NRC, 2001a). When NUREG-1747 (NRC, 2001a) was issued in 2001, DOE did not enter the items from NUREG 1747 into CARS, or other previous corrective action tracking systems. The 28 significant issues arising from the NRC's previous report (2001a), and the DOE's status of individual issue disposition, are provided in Appendix A.

Once the memorandum of understanding agreement between DOE and the NRC was suspended, the DNFSB initiated safety oversight of the WTP. At that time, the DFNSB reviewed NUREG-1747 (NRC, 2001a) and met with NRC staff to discuss their observations and concerns. The information gained from those efforts was used to assist the DNFSB in its technical safety reviews of the WTP project. The DNFSB has conducted a program of frequent, independent oversight of ORP and the WTP Contractor, BNI. The DNFSB has focused on a variety of technical issues, most notably seismic performance, process safety, and safety analysis methodology. Open issues from correspondence with the DNFSB are tracked at ORP in CARS, tracked in greater detail by BNI, and are also tracked by DOE Headquarters. As provided by the Atomic Energy Act of 1954 (AEA, 1954), as amended, the DNFSB determines when issues it has raised have been adequately closed.

2.3 Results of NRC's Assessment of DOE's Regulatory Framework

NRC reviewed DOE's statutory and other mandates for safety and DOE's regulatory process. The NRC staff reviewed DOE's regulatory process through a comparison to NRC's regulatory process.

DOE's responsibilities include constructing and operating the WTP, in addition to ensuring nuclear safety at the facility. In contrast, NRC is purely a regulatory agency with responsibility for regulating civilian commercial, industrial, academic, and medical uses of nuclear materials in order to protect the public health and safety, and promote the common defense and security. DOE's regulatory framework for the WTP also includes additional safety (e.g., hazardous materials) and production responsibilities, whereas NRC is not responsible for these aspects of licensed facilities. Of the components of NRC's regulatory process that were reviewed, only an adjudication process is missing from DOE's regulatory process.

The DOE oversight program for the WTP has multiple layers of oversight, both internal and external, whereas NRC is the sole oversight authority for safety of civilian nuclear facilities of the same scale and complexity of the WTP. DOE has a process for addressing items received by external oversight groups such as the DNFSB and the Hanford Advisory Board. DOE's process, which relies on a corrective action response system approach, was not used to address the significant issues identified in NRC's report on TWRS-P project (NRC, 2001a).

THIS PAGE INTENTIONALLY LEFT BLANK

CHAPTER 3 PROGRAMS AND PRACTICES

This chapter presents NRC's review of DOE's WTP regulatory programs and practices. NRC reviewed DOE's programs and practices for: (1) safety analysis (including hazard analysis); (2) radiation safety; (3) nuclear criticality safety; (4) chemical process safety; (5) fire safety; and (6) environmental protection. NRC also reviewed DOE's programs and practices for management measures (including: (a) configuration management; (b) maintenance; (c) training and qualifications; (d) procedures; (e) audits and assessments; (f) incident investigations; (g) records management; and (h) quality assurance elements). NRC's guidance for reviewing license applications for nuclear fuel cycle facilities (NRC, 2002) addresses each of these topics. The reviews focus on DOE regulations and guidance, and licensing actions relevant to each topic. NRC's regulatory process includes programs related to oversight, operational experience, and support for decisions (see Figure 2.1). Staff reviewed DOE's program and practices for inspection during construction and operations, enforcement, allegation, and risk assessment.

3.1 Basis

NRC staff visited the site, interviewed relevant DOE and contractor staff, and reviewed DOE and contractor documents. The reviews in Section 3.2 describe the specific scope of staff review for each topic. The staff's reviews provide an assessment of DOE's regulatory programs and practices compared with a comparable NRC regulatory program and practice. The Section 3.2 reviews summarize the results of the assessment. NRC based its reviews on both the document review and site visit, unless otherwise noted. The reviews note specific NRC and DOE and contractor staff interactions.

3.2 Topical Reviews

3.2.1 Safety Analysis

3.2.1.1 Scope

NRC evaluated the WTP safety analysis and hazard analysis processes. The hazard analysis includes hazard identification, evaluation, and the associated methods. NRC based its evaluation on reviews of DOE, DNFSB and contractor documents, and interviews with relevant DOE, DNFSB and DOE contractor staff. NRC used its safety review process and the hazard analysis approach (integrated safety analysis) for comparison purposes.

3.2.1.2 Assessment

3.2.1.2.1 DOE Safety Analysis

DOE's WTP prime contractor BNI prepared four Preliminary Safety Analysis Reports (PSARs) in 2002. BNI prepared the PSARs in accordance with 10 CFR 830.206. BNI completed a PSAR for the Pretreatment, Low Activity Waste, and High Level Waste facilities, and a PSAR on general information. The PSARs were updated biennially, in 2004 and 2006. In 2004, BNI submitted a new PSAR for the Analytical Lab facility. The 2004 general-information PSAR update included safety analysis of the balance of the WTP facilities. The next PSAR update is expected to be issued in spring 2008. The BNI Safety Analysis and Safety Implementation Groups have the lead responsibility in preparing the PSAR and updates. The level of

information and the rigor of hazard analysis in the BNI's PSAR appear to be comparable to those submitted by NRC fuel cycle licensees and applicants.

Table 3.1 summarizes the areas of review identified in DOE and NRC safety-analysis-report review-guidance documents and compares that to how BNI organizes its PSARs.

Table 3.1. Areas of Review in DOE and NRC Guidance		
DOE's Guidance	**NRC Guidance**	**BNI PSARs**
1. Site Characteristics	Site Description	1. Site Characteristics
2. Facility Description	Facility and Process Description	2. Facility Description
3. Hazard and Accident Analyses	Processes, Hazards, and Accident Sequences	3. Hazard and Accident Analyses
4. Safety Structures, Systems, and Components	List of Items Relied on for Safety (IROFS), and List of Sole IROFS	4. Important to Safety Structures, Systems, and Components
5. Derivation of Technical Safety Requirements	Not Applicable	5. Derivation of Technical Safety Requirements
6. Prevention of Inadvertent Criticality	Nuclear Criticality Safety	6. Criticality Safety Program
7. Radiation Protection	Radiation Protection	7. Radiation Protection
8. Hazardous Material Protection	Chemical Process Safety	8. Hazardous Material Protection
9. Radioactive and Hazardous Waste Management	Environmental Protection	9. Waste Management
10. Initial Testing, In-Service Surveillance, and Maintenance	Maintenance	10. Initial Testing, In-Service Surveillance, and Maintenance
11. Occupational Safety, including Fire Protection	Not Applicable	11. Operational Safety
12. Procedures and Training	Training & Qualifications Procedures	12. Procedures and Training
13. Human Factors	(NRC, 2000b) Human Factors Engineering for Personnel Activities	13. Human Factors
14. Quality Assurance	Management Measures	14. Quality Assurance
15. Emergency Preparedness Program	Emergency Management	15. Emergency Preparedness
16. Provisions for Decontamination and Decommissioning	Decommissioning	16. Deactivation and Decommissioning
17. Management, Organization, & Industrial Safety Provisions	Institutional Information Organization & Administration	17. Management, Organization, and Institutional Safety Provisions
	Fire Safety	18. Fire Protection

DOE's guidance lists 17 areas that should be included in a safety analysis. NRC's comparable areas of review are not numbered in the NRC guidance, and are listed adjacent to DOE's numbered areas of review. BNI organized the PSAR in accordance with DOE guidance (DOE, 2002a), with one exception (fire protection). DOE addresses fire protection in review area eleven, occupational safety, including fire protection. NRC does not regulate activities that do not impact the safety of licensed materials, such as occupational safety, other than occupational radiation protection. Safety concerns involving occupational safety are referred to the Occupational Safety and Health Administration (OSHA), per a memorandum of understanding (NRC/OSHA, 1988). There are no topics in NRC guidance (NRC, 2002) that are not addressed in DOE's guidance.

3.2.1.2.2 DOE Hazard Analysis

As shown in Table 3.1, Chapter 3 of DOE's guidance (DOE, 2002a) is titled *Hazard and Accident Analyses*. The basic elements (e.g., hazard identification, accident sequence development, consequence analysis, etc.) of the DOE hazard analysis process, as well as the referenced codes and standards, are similar to those in NRC's guidance (NRC, 2002; Section 3.3.2 (3) *Processes, Hazards, and Accident Sequences*). However, there are differences between the two documents. For example, DOE's likelihood-of-occurrence definition differs from that of NRC's. Table 3.2 provides numerical values used by DOE. The values of likelihood listed for NRC in Table 3.2 are guidelines, rather than definitions. A second area of difference is DOE puts the derivation of technical safety requirements (e.g., safety limits, limiting conditions for operation, etc.) in its guidance (DOE, 2002a), as part of the safety analysis, whereas NRC does not address those items in NRC's safety analysis guidance (NRC, 2002). For the WTP Project, BNI defers the development of the numerical values for those technical safety requirements until the project becomes ready for commissioning. BNI's approach is consistent with DOE guidance (DOE, 2001b; Section 3.3.4, *Authorization for Production Operations*). Finally, in several instances, point estimates were used in the BNI's hazard analyses (e.g., frequency assessments and consequence analysis). BNI compared its results to the numerical values given in DOE's guidance [DOE, 2002a (e.g., the frequency definition)]. BNI drew conclusions based on a single-value comparison. NRC's guidance provides an acceptable method (NRC, 2002; Appendix A), using quantitative consequence-severity categories, combined with the likelihood categories (Table 3.2) to assess likelihoods associated with the performance objectives in Section 70.61.

Table 3.2. Likelihood Classes and Values in DOE and NRC Guidance

DOE (DOE, 2002a) Table 3-4, page 46	**Likelihood, per event per year**	**NRC (NRC, 2002) Table A-6, page 3-A-7**	**Likelihood, per event per year**
Anticipated	$10^{-1} – 10^{-2}$	Not Unlikely	$> 10^{-4}$
Unlikely	$10^{-2} – 10^{-4}$	Unlikely	$10^{-4} – 10^{-5}$
Extremely Unlikely	$10^{-4} – 10^{-6}$	Highly Unlikely	$< 10^{-5}$
Beyond Extremely Unlikely	$< 10^{-6}$		

3.2.1.2.3 Safety Evaluation Report

DOE reviewed each facility-specific PSAR and documented its review in a safety evaluation report. The authorization-basis group of the DOE ORP has the lead responsibility in preparing the safety evaluation reports and updates. On a high level, the depth of review, and level of effort expended, for review of the PSARs and development of the safety evaluation reports,

appears to be in line with that of an NRC review for a comparable facility. One of the main focuses of the PSAR review team is to look at the cumulative safety implications when all analyses, including the changes arising from authorization-basis amendment-request approvals (described in Section 3.2.1.2.4) occurring during the preceding two years, are combined. At its discretion, DOE may impose conditions of acceptance on BNI, which are then included in the safety evaluation report. DOE's conditions of acceptance are analogous to NRC's license conditions. DOE will review and approve the documented safety analysis prior to allowing the WTP to begin waste processing operations.

As the WTP design matures over time, ORP spends fewer staff hours to review the PSAR in each successive safety evaluation report update. For instance, DOE used approximately 30 staffers (both full- and part-time ORP personnel and non-BNI contractors) to prepare the 2002 safety evaluation report. Currently, there are four full-time ORP in the WTP authorization-basis group. These four ORP staffers, with help from other staffers on an as-needed basis, are responsible for preparing the 2008 safety evaluation report update. The ORP safety analysis reviewers have similar educational and experiential background compared to NRC technical reviewers. The four ORP staffers either have been with the WTP project for an extended period of time, or they have similar nuclear experience from prior employment. Both NRC and DOE have a formal training program for technical reviewers. Training of new DOE reviewers is mainly conducted through hands-on coaching by senior staff. This approach is similar to that used by NRC. Individual coaching by senior staff to junior staff is typically an integral part of NRC's knowledge-transfer program. The level of staffing that NRC applies to safety analysis reviews is broadly comparable to DOE's staffing level.

3.2.1.2.4 Authorization-Basis Change

BNI makes changes to its authorization basis through a process known as authorization-basis amendment request. The DOE ORP approves all authorization-basis changes. BNI is required to obtain prior approval from DOE if the authorization-basis changes involve: (1) modification to the safety requirements document (BNI, 2007a); (2) creation of a new design basis event; (3) significant alteration to an existing design-basis event, or decreased safety function(s) of important-to-safety structures, systems or components; or (4) changes in how a safety-class structure, system, or component meets its respective safety function, or for radiological protection of co-located workers or facility workers, changes in how a safety-significant structure, system, or component meets its respective safety function. BNI may initiate changes that do not result in a significant facility design change based on safety evaluations (DOE, 2005b). BNI submits all non-significant safety evaluations to ORP for monthly review. ORP reviews the safety evaluations that result in non-significant changes, to ensure consistency in determining safety significance.

BNI is permitted to deviate from its authorization basis during the WTP construction phase, if it follows a prescribed notification process to DOE (known as decision to deviate). The ORP authorization basis change process and the NRC 10 CFR 70.72 Facility Changes and Change Process are summarized in Table 3.3. The NRC reviewer was shown examples of the authorization-basis amendment request process during interviews. It appeared that both DOE and BNI followed the authorization-basis change process outlined in Table 3.3.

Authorization-basis amendment requests generally trend downward as the WTP design matures over the years. For instance, the number of authorization-basis amendment requests in 2002 was around 100. The number dipped and has averaged around 30 per year since 2005.

Table 3.3. Comparison between the DOE ORP and NRC Change Process	
DOE Authorization-Basis Change Process (DOE, 2005b)	**NRC Change Process (10 CFR 70.72)**
• Contractor must seek ORP approval if: 1. The changes impact the safety requirements document; 2. The changes create a new design-basis event, or change an existing one significantly; 3. Decrease safety functions of important-to-safety structures, systems, and components significantly; 4. Change how a safety-class structure, system, or component meets its respective safety function, or for radiological protection of co-located workers or facility workers, change how a safety-significant structure, system, or component meets its respective safety function. • The contractor may initiate changes that are not significant facility changes; • During the WTP construction phase, the contractor may initiate deviation to the authorization basis, if it adheres to the following schedule: 1. Verbal notification to ORP within 24 hours; 2. Written notice to ORP within 72 hours; 3. Authorization-basis amendment request is submitted to ORP within 60 days of the decision to deviate; 4. ORP approves the authorization-basis amendment request within the subsequent 60 day period; • Contractor maintains records of all the authorization-basis changes, and updates the PSAR biennially.	• Licensee may make changes without prior NRC approval if: o The changes do not: 1. Create new types of accident sequences that, if unmitigated or not prevented, would exceed the §70.61 performance requirements, and that have not previously been described in the integrated safety analysis summary; 2. Use new processes, technologies or control systems for which the licensee has no prior experience; 3. Remove, without at least an equivalent replacement of the safety function, an item relied on for safety; o The changes do not alter any item relied on for safety that is the sole item preventing or mitigating an accident sequence; o Licensee submits a summary of all § 70.72 changes to NRC annually; o Licensee submits the revised integrated safety analysis summary pages (affected by the changes) to NRC annually; o Licensee maintains written records of the changes.

3.2.1.3 Results of Assessment

The framework of the DOE safety analysis process is generally similar to NRC's. Specifically, the DOE hazard analysis process is comparable to NRC's process. However, differences (e.g., event-frequency definition, the facility authorization-basis change process, etc.) between the two agencies' change processes were noted. The impact of these differences on overall safety at the WTP was not evaluated. However, given the overall similarity between DOE's and NRC's processes, it is anticipated that, if implemented properly and consistently, DOE's hazard-analysis process should yield comparable results to NRC's integrated safety analysis process.

3.2.2 Radiation Safety

3.2.2.1 Scope

NRC reviewed the requirements and programs for establishment and implementation of the radiation protection program. NRC staff reviewed the DOE regulatory and contract requirements, applicable radiation protection program documents, and implementing procedures. Interviews were held with the one full-time ORP staff person responsible for regulatory oversight of the ORP radiation protection program implementation, and a DOE Richland Operations Office radiation protection staff person who was assisting the employee during a transition period. The NRC staff reviewed and evaluated DOE's radiation safety program in comparison to NRC requirements and expectations for similar licensed fuel cycle facilities.

3.2.2.2 Assessment

DOE's radiation protection regulatory requirements are found in 10 CFR Part 835. As discussed in Chapter two, Part 835 is quite similar to NRC's "Standards for Protection Against Radiation" (10 CFR Part 20). As part of this assessment of the programs and practices, some differences between the regulations were noted. Areas found in Part 20 and not covered by Part 835 include: (1) respiratory protection, including respirator protection factors; (2) sealed radioactive source control; (3) radioactive waste disposal; and (4) packaging receipt. The contractor addresses these issues within its safety requirements document (BNI, 2007a). Where differences in dose values exist between the two regulations, the DOE requirements are usually more restrictive.

One potentially significant difference in DOE's practice of radiation protection is the concept of the co-located worker. This concept is in addition to the categories of general employee and radiological worker (defined in Part 835) and member of the public (defined both in Part 835 and in Part 20). DOE defines the co-located worker concept in its guidance (DOE, 2004). DOE uses the concept of "co-located" as a worker on the DOE site who is not working in the facility being evaluated. A co-located worker is an individual within the Hanford site, beyond the WTP-controlled area, performing work for or in conjunction with DOE or utilizing other Hanford site facilities. DOE's classification of some workers conducting other DOE activities on the Hanford site as co-located workers results from the numerous, diverse, and often unrelated facilities and activities involving radioactive materials located at a common site. While the co-located worker is subject to most all of the radiological worker dose standards, the co-located worker is not subject to additional requirements for radiological workers such as training, monitoring, and records. NRC would usually consider the workers located on the site, but not working in a specific facility, as members of the public, for accident-scenario evaluation. That difference may

produce differing classifications for systems, structures, and components required for risk reduction to workers and the public. NRC staff previously addressed the issue of DOE's use of a co-located worker, including the potential impact between the different DOE and NRC approaches for radiation protection on DOE's classification of structures, systems, and components at the Hanford Site (NRC, 1998a). The Commission approved (NRC, 1998b) the staff's interpretation with respect to co-located workers, that co-located workers would be treated as members of the public if the NRC were to assume regulatory jurisdiction of the Hanford tank waste remediation system privatization.

Radiation protection guidance is essentially the same for satisfying DOE and NRC requirements for radiation and toxic uranium protection. For instance, DOE guidance (DOE, 2004) has an objective to ensure that, during normal operation, radiation exposure, within the facility, and radiation exposure and environmental impact from any release of radioactive material from the facility is kept as low as is reasonably achievable (ALARA) and within prescribed limits. DOE guidance also has an objective to ensure mitigation of the extent of radiation exposure and environmental impact caused by accidents. DOE guidance indicates that an acceptable system of radiation protection practices should be followed in the design, construction, and pre-operational testing phases of the facility, for the protection of workers and the public.

The contractor has recently submitted its revised radiation protection program, as required by 10 CFR 835.101(g)(2). The revised radiation protection program retains the plans and measures implemented previously during the design phase, and includes the plans and measures for achieving compliance, with Part 835, that are applicable to the radiation protection program for the WTP construction phase. The radiation protection program document (BNI, 2001; and as revised) is the documentary basis of the radiation protection program for achieving compliance with Part 835 requirements. The contractor's radiation protection program (BNI, 2001) relies on the radiological control manual (DOE, 1994) for developing its processes and procedures for implementing the radiation protection program.

3.2.2.3 Results of Assessment

DOE's radiation protection regulations and guidance are similar to NRC's program. However, the NRC staff identified minor areas of NRC's radiation protection program are missing from DOE's radiation protection regulations, but incorporated into the contractor's radiation protection program. DOE's practice of using the concept of a co-located worker is a significant difference from NRC's approach and may produce differing classifications for systems, structures, and components required for risk reduction to workers and the public.

3.2.3 Nuclear Criticality Safety

3.2.3.1 Scope

This section describes DOE's programs and practices for nuclear criticality safety at the WTP and compares them to those used by NRC for licensing special nuclear material (10 CFR Part 70). Staff reviewed DOE's requirements for criticality safety, how the requirements were established for construction authorization, and DOE's authorization for construction. Staff reviewed DOE's acceptance criteria for nuclear criticality safety that will be used to approve process operations at WTP. NRC staff interviewed the ORP staff member responsible for nuclear criticality safety oversight of the contractor. The adequacy of the contractor's nuclear

criticality safety program and nuclear criticality safety evaluations is not addressed as part of this review.

3.2.3.2 Assessment

The WTP contract requires that the contractor develop a safety program that complies with DOE nuclear safety regulations (10 CFR Part 830) and DOE WTP standards (DOE, 2004). Section 830.204(6) of Title 10 of the *Code of Federal Regulations* requires that a nuclear criticality safety program be defined, in the documented safety analysis, that can ensure that operations with fissionable material remain subcritical under all normal and credible abnormal conditions. According to 10 CFR 830.204(6), the contractor is also required to identify applicable nuclear criticality safety standards and describe how the nuclear criticality safety program meets those standards. Section 4.2.2.5 of DOE's top-level safety standards (DOE, 2004), states that the facility should be designed and operated in a manner that prevents nuclear criticality.

The NRC regulation (Part 70) requires that operations be subcritical under normal and credible abnormal conditions. NRC's regulation also stipulates that preventive controls must be the primary means for protecting against a criticality accident. Section 70.64(a)(9) of Title 10 of the *Code of Federal Regulations* requires that the design must provide for criticality control, including adherence to the double-contingency principle. NRC's regulation has no explicit requirement regarding consensus nuclear criticality safety standards; however, the regulations do require that license applications contain proposed procedures to avoid nuclear criticality accidents. Regulatory Guide 3.71 (NRC, 2005a) indicates that compliance with this requirement can be accomplished by committing to follow the relevant consensus nuclear criticality safety standards of the American National Standards Institute (ANSI) and American Nuclear Society (ANS) Subcommittee 8 (e.g., ANSI/ANS, 1983).

The WTP contract (DOE, 2000a) requires the contractor to develop a safety requirements document (BNI, 2007a). The two nuclear criticality safety criteria listed are Criterion 3.3-1 and Criterion 3.3-2 (BNI, 2007a). Criterion 3.3-1 states that the contractor shall comply with DOE Order 420.1A, Section 4.3, "Nuclear Criticality Safety" (DOE, 2002c). Order 420.1A (DOE, 2002c) requires nuclear criticality safety programs to satisfy the requirements, with certain modifications, for 12 out of the 15 ANSI/ANS standards that existed when the Order was approved in 2002. Five of the standards listed in the Order 420.1A were revised between 1996 and 1998, but the Order required compliance with earlier versions of these standards. The DOE order is similar to NRC Regulatory Guide 3.71 (NRC, 2005a), except that NRC's guidance is limited to the ANSI/ANS standards, whereas the DOE Order has some additional nuclear criticality safety requirements and recommendations. Order 420.1A was superseded by DOE Order 420.1B (DOE, 2005a); however the safety requirements document (BNI, 2007a) has not been revised to require compliance with the new order.

New DOE Order requirements, such as Order 420.1B do not automatically become applicable to the contractor, unless there is a formal backfit (DOE, 2000a). The DOE construction-authorization agreement specifies the process used to backfit new safety requirements. The DOE backfit procedure, required by the construction-authorization agreement, is RL/REG 98-14, "Regulatory Unit Position on New Safety Information and Backfits" (DOE, 2001d). DOE has not invoked this process, which requires an explicit cost versus safety benefit (averted exposure) analysis, similar to NRC's backfit rule for power reactors. The nature of the changes relate to enhanced safety management processes, rather than designs changes. DOE stated that it

seems unlikely that sufficient benefit in reduced exposure would be substantiated to justify a safety backfit. Nevertheless, DOE stated that they were evaluating whether or not to directly impose the new standards as a project contractual matter.

Criterion 3.3-2 in the Safety Requirements Document (BNI, 2007a) specifies the methodology that the contractor must use to establish a subcritical limit for the calculated neutron multiplication factor (k_{eff}). NRC does not require a specific methodology for establishing a subcritical limit for k_{eff}, but does require that its licensees use an approved methodology. The WTP methodology (BNI, 2007a) is slightly less conservative than what has been approved by NRC. The WTP methodology would lead to a subcritical limit (i.e., maximum allowed k_{eff}), under certain conditions, that could be higher than what an NRC licensee would be permitted under the same conditions. However, this would only be a concern if the calculated k_{eff} for a specific application was actually higher than the limit that NRC would permit.

Authorization for construction was initiated when the contractor submitted its construction-authorization request to DOE ORP. The BNI submittals consisted of a number of safety-related documents, including the PSARs and the current safety requirements document. The general-information PSAR describes the nuclear criticality-safety program. The PSAR sections for each facility describe the criticality-hazards analysis that was conducted for specific processes. The contractor's nuclear criticality-safety program relies on the determination that a criticality accident is not credible. The basis for this determination is found in the criticality-safety evaluation report.

The contractor has provided its preliminary criticality-safety evaluation report, for the WTP, to DOE ORP. The latest version of the criticality-safety report is dated 2006 (BNI, 2006). BNI controls and maintains the criticality-safety evaluation reports as part of the authorization basis.

The DOE ORP staff uses Chapter 6.0 of the "Review Guidance for the Construction Authorization Request (CAR)" (DOE, 2001g) to determine the adequacy of the contractor's nuclear criticality-safety program and measures to prevent a criticality accident. The DOE guidance (DOE, 2001g) was derived from a draft of NRC NUREG-1520 (NRC, 2002). There are three major review areas for the nuclear criticality-safety program: nuclear criticality-safety organizational responsibilities; management measures for nuclear criticality safety; and nuclear criticality-safety technical practices (DOE, 2001g). Both NRC and DOE guidance documents were similar in content. The DOE guidance (DOE, 2001g) does contain some acceptance criteria that are specific to the nuclear criticality-safety portion of the WTP hazards analysis.

The DOE ORP staff reviewed the construction-authorization request, associated PSARS, and criticality-safety evaluation report, and documented its findings in the safety-evaluation reports for the WTP. The safety-evaluation reports form the basis for the construction-authorization agreement. The agreement is the document that permits the contractor to proceed with construction of the WTP. The PSARs become part of the authorization basis for the facility; thus the contractor must implement its nuclear criticality-safety program as described in the PSARs. Several conditions of acceptance related to nuclear criticality safety were included in the initial construction-authorization agreement. These conditions of acceptance require the contractor to address specific deficiencies that the DOE ORP staff found in the PSARs and the criticality-safety evaluation report. Updates to the PSARs and criticality-safety evaluation report have been submitted to the DOE ORP, to address some of the conditions of acceptance. These updates were reviewed and approved following the same process as the original construction-authorization request. The construction-authorization agreement has been revised to reflect these revisions, including the addition and removal of conditions of acceptance.

The nuclear criticality-safety review of a construction-authorization request submitted to NRC would be conducted in a similar manner. The primary focus for NRC would be on the nuclear criticality-safety program and not on the hazards analysis and criticality-safety evaluation report. NRC would also document its evaluation in a safety-evaluation report, and could authorize construction, with some additional requirements imposed on the applicant.

It was noted that the general-information PSAR contains detailed information about the nuclear criticality-safety organizational responsibilities and management measures for nuclear criticality safety. However, there is less information in the PSAR on the technical practices used by the nuclear-criticality-safety program than NRC would typically accept for construction authorization.

All three ANSI/ANS standards (ANSI/ANS, 1983) that clearly applied to WTP operations were discussed in the PSAR. The remaining ANSI/ANS standards (ANSI/ANS, 1983) required by the safety-requirements document (BNI, 2007a) were not discussed. The NRC review did not examine the applicability of all these remaining standards, but it was noted that some clearly do not apply to WTP operations.

Authorization for production operations will begin when the contractor submits an operating authorization request to DOE ORP. This is expected to occur near the end of the construction and preoperational testing period. The operating authorization request will include the final safety-analysis report, with a fully defined and analyzed safety basis for the WTP.

The DOE ORP staff will proceed with its review and approval of the operating authorization request in a manner similar to what was done with the construction-authorization request. The regulatory action is completed when DOE ORP staff issues the final safety-evaluation report and the DOE ORP manager issues an operating authorization agreement to the contractor.

The nuclear criticality-safety review of a license application to NRC would be conducted in a similar manner. NRC would review the applicant's nuclear criticality-safety program. The nuclear criticality-safety staff would also conduct a detailed technical review of the criticality-safety evaluation report and the hazards-analysis portions of the safety-analysis report. NRC would expect that all the technical issues be addressed before issuing a safety-evaluation report and a license to operate. However, NRC can issue a license with conditions that permit some issues to be addressed at a later time.

The DOE ORP has one staff member who is responsible for oversight of the WTP contractor's nuclear criticality-safety program, among other duties. A consultant is also used to perform technical reviews.

The ORP staff conducted an audit of the contractor's nuclear criticality-safety program from December 10, 2007, through January 15, 2008. The audit found that the contractor could not demonstrate that its nuclear criticality safety staff was systematically involved in the review of new or changed designs (DOE, 2008a). The audit noted that design changes go through a "safety screening" to determine if the change would require a safety review. The audit determined that the contractor staff which performs these safety screenings is "…not likely to recognize the impacts of design changes on criticality hazards to ensure these changes are forwarded for review by [nuclear criticality safety] staff."

3.2.3.3 Results of Assessment

This assessment determined that DOE ORP has nuclear criticality-safety regulations and guidance that are similar to those used by at NRC. DOE's authorization process for the contractor's WTP activities did not affect nuclear criticality safety.

The following items were noted as a part of this assessment:

- There is less information in the PSAR on nuclear criticality-safety technical practices than NRC would typically accept in a safety-analysis report;
- The three primary ANSI/ANS standards (ANSI/ANS, 1983) that are used by the contractor are outdated, and were outdated when DOE Order 420.1A was issued;
- Order 420.1A (DOE, 2002c) was superseded by DOE Order 420.1B (DOE, 2005a); however the safety requirements document (BNI, 2007a) has not been revised to require compliance with the new order. Because there may not be any safety benefit in backfitting, DOE is evaluating whether or not to directly impose the new ANSI/ANS standards and new Order as a project contractual matter;
- The contractor uses a methodology, for calculating the neutron-multiplication factor, that is slightly less restrictive than what NRC has approved;
- The contractor's nuclear criticality safety staff does not appear to be systematically involved in the review of new or changed designs;
- The contractor staff which performs safety screenings is not likely to recognize the impacts of design changes on criticality hazards to ensure these changes are forwarded for review by nuclear criticality safety staff.

These last two items are the most serious concerns because they could result in a deficient safety basis for the facility. The contractor's nuclear criticality staff is not procedurally required to review new or changed designs, and is not sufficiently documenting the reviews they are conducting. If a design change introduced or changed a nuclear criticality hazard, then the unreviewed criticality hazard could become an unreviewed safety issue.

This assessment noted that nuclear criticality safety at the WTP centers on the determination that a criticality accident is not credible. The WTP design includes sampling controls to ensure that criticality is and remains an incredible event. These sampling controls are the subject of existing conditions of acceptance. If the contractor's approach to nuclear criticality safety changes such that criticality accidents are considered credible, then additional nuclear criticality-safety controls must be established. This would be a major change for the DOE WTP nuclear criticality-safety program.

3.2.4 Chemical Process Safety

3.2.4.1 Scope

This section describes DOE's regulatory programs and practices for chemical process safety at the WTP and compares them to those used by NRC for licensing special nuclear material (Part

70). Staff reviewed DOE's requirements, guidance, applicable documentation, and other support for decisions affecting chemical process safety, primarily related to ongoing activities with the WTP (design, safety reviews, and construction). Staff also visited the WTP site and held discussions with DOE ORP staff.

3.2.4.2 Assessment

3.2.4.2.1 Comparison of Regulatory Approaches for Chemical Process Safety

The DOE regulatory process has similarities with the regulation of chemical process safety by NRC and other agencies. The DOE approach emphasizes the use of a hazard-analysis process, estimation of accident sequences and consequences, and the comparison with appropriate chemical-consequence criteria. The safety-analysis reports and other documentation contain chemical-safety information and descriptions that NRC would likely accept as sufficiently detailed and complete for conducting a licensing review. However, there are a number of noticeable differences between the NRC/DOE regulatory approaches and processes.

The NRC reviewers were informed that the WTP was one of several facilities that are planned for treating the tank wastes. Interfaces between the other facilities, on the Hanford site, and the WTP were not described in the WTP safety documents. The integration of interfaces between these facilities and the WTP, their safety implications, and appropriate safety controls would need to be adequately identified and described in the WTP safety documents if NRC were to review this facility for licensing. Schedules and availabilities for these facilities as they relate to the WTP would need to be identified to ensure an understanding of the plans for operation of the WTP and the necessary operational readiness reviews for startup of operations. NRC would require more integrated information and integrated considerations in the licensing basis (authorization basis).

The NRC review of authorization-basis amendment requests found that DOE safety reviews lagged actual change implementation in about 10% of the requests reviewed. The contractor's evaluation of significant facility changes may conclude there is no impact on facility safety, and, thus, DOE approval is not necessary before implementation of the change. Ultimately, DOE does approve all the changes as part of the biennial BNI safety-analysis report and DOE safety-evaluation-report update process. For comparison, NRC uses the change process outlined in 10 CFR 70.72. The NRC regulation requires significant changes to be documented and submitted as an amendment to the license for approval. NRC approval is required before implementation of the proposed changes.

DOE ORP reorganized during NRC's review. For both organizational structures, DOE ORP consists of several sub-offices, none of which has the exclusive functions of regulations and safety (DOE, 2008b). All include construction and ongoing activities in support of the WTP and the tank farms. Chemical-process regulatory and safety oversight are not independent of construction of the facility. The ORP Engineering and Nuclear Safety (ENS) sub-office includes a Nuclear Safety Division (NSD), which has eight full-time equivalents (FTEs). Four FTEs are dedicated toward the WTP authorization basis. NSD reports to the ORP manager through ENS. The WTP Engineering Division has one chemical-process-safety person identified, one vacancy, and two part-time consultants; this division reports through WTP Projects to ORP management. NRC is a separate organization with independent regulatory and safety functions. NRC staff does not have conflicting duties involving non-safety matters.

NRC does not use a co-located worker receptor in its regulatory framework (See discussion in Section 3.2.2.2). The Commission approved (NRC, 1998b) the staff's interpretation with respect to co-located workers, that co-located workers would be treated as members of the public if the NRC were to assume regulatory jurisdiction of the Hanford tank waste remediation system privatization.

The WTP is a large, complex facility, processing multiple waste streams, using unique processes and chemicals. Many interactions, both routine and accidental, are possible, that have the potential for unintended consequences and degraded performance of safety systems. From this brief review, there is a clear DOE regulatory process requirement to review and address these types of interactions, but it is not clear that the contractor has met the requirement. DOE requires that design provisions be included to limit the loss of safety functions due to damage to several structures, systems, or components important to safety resulting from a common-cause or common mode failure (Criterion 4.2.2.2 in DOE, 2004). DOE identified that BNI's construction authorization request did not adequately describe how that criterion was met from a chemical safety perspective. DOE generated a condition of approval that required BNI to further develop this consideration in the design. BNI's corrective action is still in progress. NRC's regulation (Part 70) requires that the integrated safety analysis address potential interactions, among materials or conditions, that could result in hazardous situations associated with normal operations, maintenance, testing, and postulated accidents that could otherwise adversely impact safety.

The safety requirements document (BNI, 2007a) is the contractor's key regulatory document. That document contains chemical-consequence levels as part of Criterion 2.0-2. These levels are based on specific lists of chemical-concentration criteria. The chemical-concentration criteria are primarily Emergency Response Planning Guide (ERPG) values, supplemented by temporary emergency-exposure limits, commonly known as TEELs, for missing data. The WTP Criterion 2.0-2 identifies accidents affecting the facility worker that could cause in-patient hospitalization of at least 3 facility workers, or at least a single fatality, as the consequence level. In contrast, the NRC approach is based on the onset of symptoms from exposure and does not use specific chemical-concentration criteria. However, NRC guidance (NRC, 2002) does state a preference for acute-exposure guideline levels, commonly known as AEGs, followed by ERPGs. NRC does not use in its regulation (Part 70) fatality as a consequence limit. In effect, the NRC approach represents a probability of the effect on the exposed population.

For the worker, the NRC high-consequence limit is endangerment of the life of the worker. That limit is different than the WTP fatality limit, and the three or more hospitalizations' limit in the WTP safety requirements document (BNI, 2007a). The contractor uses exceedance of the ERPG-3 limit for high consequence to the co-located worker (BNI, 2007a). ERPG-3 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects. For the public, the contractor applies ERPG-2 as the high-consequence limit (BNI, 2007a). ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action. NRC applies a public-like limit, based on irreversible, serious, or long-lasting effects, which, for the WTP, would most likely be applied to the receptor at 100 meters (328 feet). Thus, the DOE and BNI regulatory performance requirements are different for the workers and the public than those accepted by NRC.

3.2.4.2.2 Comparison of Guidance for Chemical-Process-Safety Reviews

DOE has a review guidance document for WTP safety analysis report submittals (DOE, 2001g). Chapter 7 of that guidance discusses chemical process safety. It states that the description of chemical-process safety reviews should be consistent with the current level of design. The DOE review is intended to confirm the WTP contractor's assessment of whether portions of WTP are regulated under OSHA Process Safety Management or U.S. Environmental Protection Agency (EPA) Risk Management Program regulations. The DOE review is intended to confirm implementation or commitment to implementation of the 12 elements of process management. The 12 elements are: (1) process safety information; (2) process-hazard analysis; (3) operating procedures; (4) training; (5) subcontractors; (6) prestartup safety review; (7) mechanical integrity; (8) hot-work control; (9) management of change; (10) incident investigation; (11) emergency planning, and (12) compliance audits.

NRC's NUREG-1520 (NRC, 2002) provides guidance for reviewing fuel cycle facility license applications. NUREG-1520 (NRC, 2002) provides guidance on chemical- and process-safety review areas. The NRC guidance addresses: (1) chemical-process description; (2) chemical-accident sequences; (3) chemical-accident consequences (including modeling); (4) chemical-safety controls (items-relied-on-for-safety); (5) chemical-safety interfaces and coordination; and (6) chemical baseline-design criteria. The two agencies' guidance approaches are similar.

3.2.4.2.3 Documentation and Support for Decisions

The DOE regulatory process includes many documents that are subject to DOE's approval. The WTP construction-authorization basis (DOE, 2008c) is approved by DOE and is based on DOE reviews and approvals of the following documents:

- Six 2006 PSARs (including: (1) "General Information"; (2) "Pretreatment Facility"; (3) "High-Level Waste Facility"; (4) "Low-Activity Waste Facility"; (5) "Analytical Laboratory"; and (6) "Balance of Facilities"), five 2004 PSARs, a 2003 PSAR update, and three 2002 PSARs.
- Radiation Protection Program (BNI, 2001)
- Quality Assurance Program (BNI, 2007b)
- Safety Requirements Document (BNI, 2007a)
- Previous authorization-basis change notices
- Previous authorization-basis amendment requests. The authorization-basis amendment-requests terminology replaced the authorization-basis change-notice terminology.

DOE has approved the construction-authorization basis (DOE, 2008c), and construction is continuing. Changes to the authorization basis are handled by the REG 97-13 process (DOE, 2005b). Authorization-basis amendment requests are approved separately by letter documentation. Some changes to the authorization basis are not subject to DOE's approval. The DOE authorization basis and the change-control process are discussed in Chapter 2 of this report. The safety-analysis reports are currently updated every 2 years.

The authorization-basis process has similarities to the NRC regulatory process, such as applicant submission of a safety-analysis report, NRC reviews are documented in a safety-

evaluation report, and through approval of applicant plans (e.g., quality assurance and radiation programs). However, the contract and safety-requirements document approach is unique to the DOE WTP regulatory process.

The brief NRC review found a large number of changes. Some of these changes were initiated and implemented by the contractor without prior DOE approval, because assessments indicated less than a 10 percent increase in consequences (i.e., the criterion in the contractor's procedures). NRC found some of these consequence assessments to be based on mass-balance calculations that did not seem to include changes in safety characteristics. This suggests that some of the changes, below the 10 percent consequence threshold, could be subject to the significant facility design change thresholds criteria (DOE, 2005b), if the changes in the safety characteristics were considered. As mentioned in Section 3.2.1.2.4, these non-significant changes are reviewed monthly by ORP.

In addition, the NRC staff found it difficult to follow the many changes through the documents and clearly understand the actual changes, their bases and supporting rationale, and the assessment and resolution of any safety issues. Sometimes, sections are simply noted as deleted, without a succinct explanation or reference. Change documentation is simply listed in reference areas, without further explanation. The number of changes appears to be much larger than typically encountered during NRC licensing and amendment reviews. NRC also requires more frequent updating of changes in the integrated safety analysis and integrated safety analysis summary (annually, as compared to the biennial safety-analysis-report updating at WTP) and requires rationale for changes to be included in the updates.

3.2.4.3 Results of Assessment

The DOE regulatory process has similarities to NRC's regulation of chemical-process safety. The DOE approach emphasizes the use of a hazard-analysis process, estimation of accident sequences and consequences, and the comparison with appropriate chemical-consequence criteria. The PSARs and other documentation contain chemical-safety information and descriptions that NRC would likely accept as sufficiently detailed and complete for conducting a licensing review.

However, there are a number of noticeable differences between the regulatory approaches and processes. These include the following areas:

- The DOE regulatory process does not require the same level of process-safety-integration review for changes to the authorization basis as NRC would require.
- The DOE regulatory process allows, subject to DOE safety review and approval, process changes to be made for production and schedule purposes.
- The regulatory process also allows flexibility for the contractor to implement non-significant changes without prior DOE approval. These changes are, however, reviewed monthly by DOE.
- The DOE regulatory process allows the contractor to initiate a deviation to the authorization basis provided that the contractor complies with the authorization-basis change process described in Table 3.3.
- The DOE regulatory process has no separate and independent regulatory and chemical safety organization within the ORP. ORP staff for regulation and chemical process-

safety is relatively small and has competing owner (e.g. routine design and flow-sheet reviews) responsibilities.

- The regulatory process may not be adequately considering and evaluating environmental and dynamic effects associated with chemical-process safety.
- The DOE regulatory process allows consideration of costs and schedule. Cost and schedule are not explicitly included in the NRC regulatory process.
- The DOE chemical-process-safety approach includes all aspects of chemical safety, whereas the NRC regulations focus on chemical safety associated with licensed radioactive material processing. OSHA has the regulatory authority for chemical safety not affecting licensed radioactive materials at NRC-licensed facilities, and EPA (or designated State) has regulatory responsibility for offsite chemical safety.
- The DOE regulatory process uses chemical-consequence levels that are different than NRC criteria.
- The DOE regulatory process has a co-located worker receptor category; NRC requires that these workers are protected as members of the public.

These last two items are of most concern because they could result in exposure thresholds that are less conservative than those of the NRC.

3.2.5 Fire Safety

3.2.5.1 Scope

This section describes DOE's programs and practices for fire safety at the WTP and compares them to those used by NRC for licensing special nuclear material (Part 70). NRC staff reviewed the regulatory basis, guidance, and oversight associated with ORP's program for fire safety. The staff visited the WTP site, reviewed relevant documents, and interviewed DOE staff.

3.2.5.2 Assessment

The regulatory basis for DOE's fire protection requirements, including those applicable to the WTP, can be found in 10 CFR 830.204 and DOE Order 420.1A (DOE, 2002c). In brief, a DOE-approved fire protection program is required to minimize the potential for an occurrence of a fire or related-event that causes: (1) an unacceptable onsite or offsite release of hazardous or radiological material that could impact the health and safety of employees, the public, or the environment; (2) unacceptable interruption of vital DOE programs as a result of fire and related hazards; (3) property loss from fire exceeding limits established by DOE; and (4) fire damage to critical process controls and safety-class systems, structures, and components (as documented by appropriate safety analysis).

The NRC regulation established in 10 CFR 70.62(a) requires an applicant to develop, implement, and maintain a safety program that will reasonably protect health and safety of the public and the environment from the fire and explosive hazards associated with processing, handling, and storing licensed materials during normal operations, anticipated operational occurrences, and credible accidents. Also, new facilities are required to meet the baseline design criteria set forth by 10 CFR 70.64, which specifically states that the design must provide adequate protection against fire and explosions.

The regulatory basis governing fire protection requirements for both agencies are very similar. Prevention of fires, and protecting people and the environment from the effects of fires, are requirements for both agencies. The obvious difference is that DOE also places a high priority on property protection.

The development of regulatory guidance from both agencies reflects the fact that national consensus standards and other design criteria do not comprehensively or, in some cases, adequately address fire protection issues at the facilities they regulate. The guidance developed by both agencies focuses on similar elements.

DOE regulatory guidance on fire protection can be found in DOE-STD-1066-99 (DOE, 1999b) and in WTP specific guidance (DOE, 2001g). DOE-STD-1066-99 (DOE, 1999b) constitutes the basic criteria for satisfying DOE fire- and life-safety objectives for the design and construction or renovation of DOE facilities. The WTP guidance (DOE, 2001g) further elaborates by stating that the fire safety program at WTP will include the following elements:

- Organization and management control systems, which include: (1) the adequacy of fire-safety-program documents such as policies, procedures, and practices; (2) the roles and responsibilities for fire safety; (3) the review of facility design aspects by a qualified fire protection engineer; (4) quality assurance for fire protection features; and (5) the adequacy of fire protection recordkeeping and related documentation.
- Training and qualification, which includes the qualifications and training of the fire safety and emergency response staff, with particular emphasis on the facility's unique operations and resulting hazards.
- Fire prevention program, which includes the policies, programs, and procedures intended to limit the amount of combustible material and instill a safe staff attitude toward fire and explosion prevention.
- Fire protection features and systems, which include: (1) passive fire-rated barriers; (2) process and operational features; (3) the water supply for fire fighting; (4) fire detection, alarm, and signaling systems; (5) fire suppression systems and equipment; (6) design-basis documents; and (7) the inspection, maintenance, and testing program for fire protection measures.
- Manual fire-fighting capability, which includes: (1) minimum staffing; (2) organization; (3) coordination of onsite and offsite fire-fighting resources; (4) personal protective and fire-fighting equipment; (5) emergency communication capability; (6) training; and (7) pre-fire emergency planning.
- Fire-hazard analysis, which includes: (1) performing a comprehensive and systematic analysis of facility fire and chemical explosion hazards; (2) identifying specific features and systems important to plant fire safety; (3) developing design-basis fire scenarios; (4) evaluating anticipated consequences; and (5) determining the adequacy of the plant fire safety program to mitigate the hazards.

NRC regulatory guidance on fire protection is in NUREG-1520 (NRC, 2002). This guidance states that an applicant should provide commitments, pertaining to fire safety, for:

- Fire safety management, which includes: (1) safety organization; (2) engineering review; (3) fire prevention; (4) inspection, testing, and maintenance; (5) pre-fire plans; and (6) personnel qualifications, drills, and training.

- Fire-risk identification, which includes the fire-hazard analysis and the integrated safety analysis summary. Additional guidance for fire protection portions of the integrated safety analysis summary can be found in NUREG-1513 (NRC, 2001b).

- Facility design, which includes information on building construction, fire areas, life safety, ventilation, and electrical system design. The facility design should also consider competing requirements among fire safety and security, criticality, and environmental concerns.
- Process fire safety, which includes design considerations to prevent an accident, or to mitigate the consequences of an accident resulting from using: (1) process chemicals; (2) combustible metals; (3) flammable and combustible liquids and gases; (4) high-temperature equipment; (5) hot cells and glove boxes; and (6) laboratories.
- Fire protection systems, which include: (1) fire detection, alarm, and suppression systems; (2) portable extinguishers; (3) water supplies; and (4) emergency response organizations.

A key uniformity found in both DOE and NRC regulatory guidance on fire safety is the acceptance of the National Fire Protection Association (NFPA) codes and standards. The regulatory guidance provided by both agencies is intended to be used in conjunction with the applicable building code, NFPA Codes and Standards, and any other applicable construction criteria. Specifically, NFPA Standard 801 (NFPA, 2003) is strongly endorsed by both agencies. From discussion with DOE staff, it also appears that much of the interpretation and application of this standard is consistent with that of the NRC staff.

The major difference between the regulatory guidance provided by both agencies is the focus on level of protection based on potential financial loss, which is exemplified in various portions of Chapter 5 of DOE STD-1066-99 (DOE, 1999b). Several requirements in this chapter dictate when redundant fire protection systems are required, based on various monetary thresholds, to limit loss potential. In NRC regulatory space, the requirements for redundant fire protection systems are based strictly around the potential risk to people and the environment. Based on observations at the WTP, many of the design-basis fire scenarios were viewed as large-loss fires, so the requirements of the two agencies have some overlap. Further technical review would be needed to determine if the requirements are equivalent.

Regulatory oversight programs for NRC and DOE share many commonalities. The application of regulatory guidance by ORP staff appeared to be consistent with that typical of NRC staff. Traditional methods of fire protection performance assessment, inspection, and enforcement were observed while onsite during construction of the WTP, and plans are in place to adequately insure safe operation. There are, however, differences for regulatory oversight in fire protection at the WTP. Specifically, these include the design-build process and the quantity of DOE fire protection review staff.

Using the design-build process for a facility as complex as the WTP has many advantages, the most obvious of which is the time that can be saved as construction progresses, without having a complete design. The design-build process does, however, present a challenge to fire protection. The fire-hazard analysis for the WTP uses fire modeling, which is very dependent on geometry and configuration, as well as the type of hazard. If the configuration of a space changes, as may occur during a design-build, the input for the fire-hazard analysis must be re-evaluated and possibly reanalyzed, if needed. A tracking and review process to ensure a safe end result was observed to be in place at the WTP, but the number of design changes has

slowed the process. Also, it was not clear if the cumulative impact of design changes affecting the fire-hazard analysis was being considered as construction progresses. Adequate inspections and assessments are scheduled to occur at the completion of construction. However, as the design evolves, it is possible that the fire protection safety measures needed to ensure safe operation of the facility could change.

For a project as large as the WTP, NRC would likely dedicate 1 FTE to serve as the fire protection analyst on the regulatory review team. The sole responsibility of this employee would be to review regulatory compliance of the fire protection program at the WTP and assist in related inspections. The current ORP fire protection engineer responsible for regulatory compliance at the WTP was found to be highly qualified, extremely knowledgeable, and adequately involved in the regulatory process. However, he was also responsible for regulatory compliance at the existing tank farm on the Hanford reservation. NRC noticed that an effort to train, and/or hire other qualified personnel seemed to be beginning. Nonetheless, there appears to be a significant amount of responsibility being placed on a single individual. As the WTP project progresses, DOE may need to assess the need for additional, qualified fire protection engineers.

3.2.5.3 Results of Assessment

The majority of the fire protection aspects of DOE's regulatory processes for the WTP are very similar to NRC's. The major differences are in the design-build process, the focus on the level of protection based on financial loss, and staffing levels. Level of protection based on financial loss is of particular concern given that the NRC bases the requirement for redundant fire protection systems on the potential risk to people and the environment. Also of concern is the staffing level for fire protection which places responsibility for regulatory compliance at both the WTP and the existing tank farm on one person. Although these present challenges, sufficient DOE regulatory processes appear to be present in fire protection to ensure safe construction and operation of the WTP.

3.2.6 Environmental Protection

3.2.6.1 Scope

NRC staff reviewed DOE's requirements and organizational responsibilities, the DOE National Environmental Policy Act (NEPA) program, and DOE's programs for complying with various environmental laws, regulations, permits, consent orders, and interagency agreements. NRC staff visited the WTP site, reviewed DOE and other relevant documents (e.g., State-issued permits), and interviewed DOE and State of Washington staff.

3.2.6.2 Assessment

For WTP construction and operation activities, DOE is subject to Federal, State, and local environmental laws and regulations, a consent order (Tri-Party Agreement), and memoranda of agreement between DOE and Federal and State agencies. These laws and regulations include the NEPA and State Environmental Policy Act (SEPA), and the Resource Conservation and Recovery Act (RCRA, 1976), Clean Air Act (1963), Clean Water Act (1977), and other environmental laws, as well as the regulations of the EPA, DOE, or Washington State, that implement these laws.

DOE has developed orders for meeting environmental requirements. DOE Order 450.1, "Environmental Protection Program," requires that DOE organizations implement an environmental management system at each site (DOE, 2005c). Order 451.1B, "National Environmental Policy Act Compliance Program," establishes the requirements for implementing NEPA and DOE's NEPA regulations (DOE, 2002d).

The Environmental Safety and Quality (ESQ) group within ORP is responsible for ensuring ORP compliance with environmental requirements and quality assurance. ORP has issued guidance that describes ESQ functions and various roles.

The primary contractors engaged in WTP environmental compliance activities are Science Applications International Corporation (SAIC) and BNI. SAIC is responsible for developing the Tank Closure and Waste Management Environmental Impact Statement (EIS), which will provide an updated description of WTP activities that were already addressed under a previous EIS. BNI is responsible, as specified in the contract (DOE, 2000a), for maintaining compliance with environmental laws, regulations, and procedures applicable to work performed under the contract.

The WTP contract contains environmental requirements to which BNI is subject. The contract specifies (Standard 7 in DOE, 2000a) requirements for the WTP contractor to ensure compliance with DOE and State environmental regulations, orders, and permits. The contractor has primary responsibility for developing work plans, permit applications, and other documents required for environmental programs. The contract discusses (Section H.26 in DOE, 2000a) the contractor's responsibility for developing permit applications and for taking full responsibility as a permittee or co-permittee (with DOE and/or other WTP contractors).

Standard 7 of the contract (DOE, 2000a) addresses integration of ESQ and health activities and deliverables with other aspects of the WTP project. NRC staff reviewed a DOE description and summary of the status of the Tri-Party Agreement (Ecology, et al., 1989), air permits, RCRA activities, and NEPA activities. In addition, staff reviewed a BNI planning document that also addresses the broad scope of environmental requirements and activities for the WTP. This BNI plan describes WTP environmental programs and identifies numerous WTP-specific contractor procedures that address environmental permit management generally, specific media permit maintenance (e.g., maintenance of air emissions permits), and design-change controls. An additional WTP-specific procedure developed by BNI requires that environmental permits, modifications, and supporting documents undergo multi-disciplinary review, and that environmental personnel review WTP design-change documents to determine whether the permits need modification.

NEPA is implemented by DOE in 10 CFR Part 1021, which adopts the procedural provisions of the Council on Environmental Quality NEPA regulations (40 CFR 1500 – 1508). DOE Order 451.1B (DOE, 2002d) establishes DOE internal requirements and responsibilities for implementing NEPA and the regulations. DOE's NEPA activities are overseen by the Office of NEPA Policy & Compliance, which reports to the General Counsel's office.

To comply with NEPA and SEPA, DOE's Richland Operations Office and State of Washington Department of Ecology, hereafter Ecology, addressed pretreatment and vitrification activities in the "Tank Waste Remediation System Environmental Impact Statement [EIS] of 1996" (DOE, 1996b) and subsequent supplemental analyses. This EIS provides the NEPA and SEPA coverage for any future supplemental treatment and potential enhancements to the WTP. The latest scope of WTP plans and activities will also be discussed in a new EIS that ORP is

developing (DOE, 2006b) titled the "Tank Closure and Waste Management Environmental Impact Statement" (TC&WM EIS). SAIC is the contractor responsible for developing the TC&WM EIS and, per Contract requirements, BNI must provide input as needed. ORP is developing the TC&WM EIS to comply with a January 9, 2006, legal settlement (DOE, 2006c) that resulted from a Washington State lawsuit against DOE concerning the "Final Hanford Site Solid (Radioactive and Hazardous) Waste [HSW] Program EIS, Richland, Washington." The settlement agreement acknowledges a concurrent memorandum of understanding (MOU) (DOE, 2006d) between Ecology and DOE for the development of the TC&WM EIS. This MOU discusses the roles and responsibilities of Ecology and DOE as cooperating agencies for the EIS. As both a cooperating agency and a regulatory agency with jurisdiction over DOE's Hanford activities, Ecology ensures compliance with the SEPA.

In October 2006, DOE published its "Report of the Review of the Hanford Tank Closure & Waste Management Environmental Impact Statement," (DOE, 2006e) which reported on a review of data sets, NEPA compliance responsibilities, and DOE and SAIC quality assurance programs associated with the TC&WM EIS . In response to quality assurance issues identified with the HSW EIS, an external panel was convened to review assumptions used in the groundwater model for the TC&WM EIS. The panel's members do not include Hanford, DOE or contractor personnel. Additionally, Ecology is conducting periodic specific reviews throughout the EIS process.

DOE is subject to other environmental laws and regulations. Washington State has authority to administer regulatory programs for complying with RCRA (1976), the Clean Air Act (1963), and the Clean Water Act (1977). The BNI environmental plan describes the environmental programs and requirements applicable to the WTP. Applicable programs include: (1) the dangerous-waste permitting program; (2) air-emission permitting and monitoring; (3) wastewater-discharge permitting; (4) management of toxics; (5) emergency planning; (6) site monitoring; (7) recordkeeping; and (8) other programs. The State of Washington's dangerous-waste permitting program is most closely and comprehensively linked with plans and activities for the WTP, because the entire WTP is regulated as a waste treatment, storage, and disposal facility under this State program. The State's dangerous-waste permitting program process is described in more detail below.

Ecology issued a dangerous-waste permit for the WTP in 2002 (Ecology, 2007), and this permit is part of the overall Hanford RCRA permit (Hanford Facility Resource Conservation and Recovery Act Permit, Dangerous Waste Portion WA7890008967). The permit was issued under Washington's Dangerous Waste Regulations, which implement the requirements of RCRA for hazardous-waste treatment facilities. The WTP is identified in the permit as Operating Unit 10. DOE and BNI are co-permittees. The State's established process for issuing RCRA permits is to require a complete application for decision-making. However, DOE and BNI submitted a demonstration, pursuant to regulatory requirements, that certain information needed for the permit application was not available and suggested dates when the information would be available. Ecology documented the basis for this exception in a Fact Sheet issued in September of 2002 (Ecology, 2002). As a result, the operating Unit 10 specific-conditions portion of the permit (Ecology, 2007) contains a compliance schedule and numerous conditions. Many of the conditions are requirements to submit information in accordance with the compliance schedule, to ensure compliance with regulatory requirements. As DOE plans to construct new portions of the WTP, the applications for those portions are submitted to Ecology as "design packages." The "design packages" are reviewed for approval under Ecology's requirements for agency-initiated changes to the permit (requiring a public-comment period).

DOE and BNI, the permittees, estimate that about 150 design packages will need to be submitted for the complete permit.

Ecology has stated that the submittal schedule developed by ORP and BNI will allow most design packages to undergo public comment and be incorporated into the Permit before construction of those areas. However, Ecology is authorized to grant temporary authorizations for the permittees to start construction on a design package after Ecology approval, but before the draft permit modification process is complete. As stated by Ecology, construction that takes place under a temporary authorization is at the permittees' risk, because public comment on the proposed permit modification may result in a requirement to modify something that was already constructed. Ecology used this process during the beginning stages of WTP construction, but now uses the requirements for agency-initiated changes to the permit.

Changes to information already in the dangerous-waste permit are handled as permittee-initiated modifications in accordance with the State regulations. BNI submits all proposed changes to Ecology for review. Major substantive changes (classes 2 and 3) require a public comment period before they are incorporated into the final permit. Examples of major changes are the removal of the Technetium-99 ion-exchange system and the change in the number of low-activity waste glass melters.

Ecology has substantial resources dedicated to WTP oversight for the dangerous-waste permit: approximately 10 FTEs are assigned to the WTP, serving engineering, permit-writing, or on-site representative functions. Engineers and on-site representatives attend weekly meetings at the WTP.

Ecology issued multiple letters of concern and two notices of violation (both in July 2004) for WTP-related activities. The violations pertained to the deletion of wear plates in tanks, and the failure to consider corrosion in pipe stress analyses. The violation, associated with deletion of wear plates in tanks, is still in the process of being resolved. Additionally, the compliance schedule, as reflected in the permit, has slipped. The State has not modified the permit to reflect a new schedule pending negotiations for updating the Tri-Party Agreement milestone schedule.

Several air permits for radioactive and nonradioactive air emissions and for ambient monitoring have been issued for the WTP. Ecology issued permits for criteria pollutants, the Prevention of Significant Deterioration program, non-radiological toxic air pollutants, and the all-encompassing Hanford-wide Title V permit (air-operating permit). The Washington Department of Health (DOH) issued a radioactive-emissions license for excavation activities and an approval for construction of each of the WTP facilities. Ecology and DOH both inspect the WTP for compliance with standards.

Ecology has issued a Hanford-wide discharge permit for stormwater, hydro-testing, cooling water, and condensate discharges. The Hanford-wide permit applies to the WTP. WTP permits have been issued to cover concrete batch-plant operations and Pit 30 aggregate production. A septic permit has also been issued.

Other environmental regulatory compliance programs cover the Toxic Substances Control Act (1976) for polychlorinated biphenyls in some of the double-shell tank wastes; monitoring (groundwater monitoring and an air-monitoring network); and reporting. Radiation monitoring for air and liquid effluents is addressed in the safety requirements document (BNI, 2007a;

Section 5.2) and references Washington regulations and "Federal National Emission Standards for Hazardous Air Pollutants" regulations.

3.2.6.3 Results of Assessment

As a government agency undertaking a major federal action, DOE is required to comply with NEPA, and several mechanisms are in place to ensure that the TC&WM EIS is developed to comply with NEPA. Washington State is a cooperating agency and will help ensure the EIS meets both NEPA and the SEPA. Because NEPA is a procedural law, NRC's NEPA activities associated with a licensing process would be similar to DOE's.

During the transition from construction of the WTP to operations, BNI would need to ensure adequate information exchange and transfer to any future contractor for operations. SAIC would need to ensure adequate transfer of information to any future contractor for NEPA-specific activities that may pertain to the WTP.

For other environmental programs, DOE's role with regard to Washington State permitting is as a permittee or licensee (owner/operator). DOE does not have a regulatory role with regard to the State's permit processes. The WTP design and construction, which are determined or approved by DOE, also must be approved by Ecology and the DOH, for the dangerous-waste permit and for air-emissions permits. DOE is required to comply with hazardous waste and other environmental effluent and monitoring requirements.

NRC's process for licensing a private or government entity would include attaining assurance that the applicant is complying with all applicable Federal and State requirements. Typically, NRC would document these requirements in its EIS for a licensing action. As a rule, NRC itself would not be subject to these regulations because it does not serve in an owner/operator capacity.

3.2.7 Management Measures

Management measures, as defined in 10 CFR 70.4, are functions, performed by a licensee. A licensee applies the measures to IROFS to provide reasonable assurance the IROFS are available and able to perform their functions when needed. Management measures are implemented to provide reasonable assurance of compliance with the performance requirements, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the IROFS and the measures (NRC, 2002). The following subsections address each of the eight management measures identified by NRC for licensing special nuclear material (Part 70) and compare them to similar management measures used by DOE for the WTP. The eight management measures are: (1) configuration management; (2) maintenance; (3) training and qualifications; (4) procedures; (5) audits and assessments; (6) incident investigations; (7) records management; and (8) other quality assurance elements.

3.2.7.1 Configuration Management

3.2.7.1.1 Scope

The requirements and programs for establishment and implementation of configuration management for the WTP were reviewed and evaluated in comparison to NRC requirements and expectations for similar licensed fuel cycle facilities. The DOE regulatory and contract

requirements, applicable configuration-management program documents and plans, and DOE assessment and program-status reports were reviewed. Interviews were held with BNI configuration management staff and ORP staff responsible for regulatory oversight of the WTP configuration-management program implementation.

3.2.7.1.2 Assessment

Configuration management is defined by NRC, in 10 CFR 70.4, as a management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of IROFS to perform their functions when needed. Configuration management is an integrated management process that:

- Identifies, documents, and maintains, through formal change and document control processes, consistency among the technical basis, documentation, and the physical and functional configuration of a facility, and
- Manages the development and establishment of the technical and safety requirements, design and operations, and physical and functional configuration of structures, systems, and components, and maintains consistency among these items as the facility is designed, approved, constructed, and operated, and as modifications and changes are made.

A configuration management system is also required by 10 CFR 70.72, to control changes to the facility. NUREG-1520 (NRC, 2002) provides guidance for management measures and identifies specific acceptance criteria for the configuration management function in the areas of policy, design requirements, document control, change control, and assessments.

As a contractual and policy matter, DOE imposes WTP configuration-management requirements on the contractor using a commitment to DOE Order 413.3A (DOE, 2006f). That order requires a configuration management process that is in compliance with the ANSI and Electronic Industries Alliance (EIA) standard ANSI/EIA-649. The ANSI/EIA-649 standard (ANSI/EIA, 1998) ensures that the configuration is in agreement with the performance objectives identified in the technical baseline and the approved quality assurance plan. DOE Order 413.3A (DOE, 2006f) and DOE's top-level principles document (DOE, 2004), which identifies configuration management as one of the fundamental principles to achieve safety, are applicable to the BNI contract.

DOE's regulatory process for nuclear safety captures configuration management requirements in the Criterion 7.3-1 in the safety requirements document (BNI, 2007a). The construction-authorization agreement identifies American Society of Mechanical Engineers (ASME) NQA-1 standard (ASME, 1994) and Part 830, Subpart A ("Quality Assurance Requirements"), as configuration management requirements.

BNI has an approved WTP configuration management plan which is based on International Organization for Standardization (ISO) Standard 10007:1995 (ISO, 1995). Commitments in BNI's plan address configuration management-program organization and management, the configuration management process, and configuration identification. Configuration identification includes item selection and hierarchy, structures and numbering, component databases and tools, and master equipment list. BNI commitments also include configuration control. These controls include types of changes, equivalent changes, temporary modifications, and interface

change control. Other configuration controls included in the commitments are: (1) the design-change control and process; (2) supplier deviations; (3) nonconformance and construction deficiency reports; (4) status tracking; and (5) reporting and configuration management audits. BNI's configuration management program is implemented through implementing procedures and an interface management plan. The interface management plan describes how the WTP interfaces with the Hanford Tank Farms and DOE. The WTP configuration management program is also implemented and controlled in accordance with the BNI QA manual (BNI, 2007b). ORP conducts its project-management configuration management activities and oversight of the BNI configuration management program in accordance with the ORP QA program manual. ORP focuses on those WTP activities that can impact safety and quality.

A new revision of the BNI configuration management plan is expected to be approved in 2008. The new version would fully address the ANSI/EI-649 (ANSI/EIA, 1998), other consensus standards, and DOE Standard 1073 (DOE, 1993).

The reviewers interviewed ORP managers and staff with oversight responsibility, and the BNI lead for configuration-management program development. The reviewers queried the ORP and BNI staff knowledge of configuration management issues and problems on the WTP, or in industry, in a number of technical areas. NRC staff discussed with the ORP and BNI staff the processes for: (1) control of safety basis; (2) design control; (3) engineering products; (4) procurement planning and control; (5) quality assurance; and (6) oversight, and construction.

The reviewers evaluated and discussed with ORP staff the 2006 and 2007 enforcement actions (DOE, 2008d, 2008e) and a 2008 notice of investigation letter issued to BNI under the Price-Anderson Act Amendments (PAAA). DOE's Office of Enforcement administered these enforcement actions. Configuration management and quality assurance programs are designed to have multiple checking, verification, and oversight features to provide assurance of the process, and product control and quality. The evaluation and discussion indicates the two enforcement actions and the notice of investigation had similarities. The similarities may indicate WTP issues had not been fully addressed and resolved initially. The program requirements for configuration management for safety basis, design basis, procurement planning and verification, component verification, and corrective action may not have been effectively implemented for the activities noted in the enforcement actions (also addressed in Section 3.2.10).

3.2.7.1.3 Results of assessment

The BNI contractual requirements and commitments, combined with the ORP DOE Orders and quality assurance requirements and commitments, are comparable to NRC's quality assurance regulatory requirements and guidance for an NRC regulated configuration management program. The BNI and ORP configuration management commitments, when properly implemented, can be equivalent to NRC licensee's program requirements. The enforcement actions on this project to date indicate that configuration management functions and interfaces may not have been effective over an extended period.

3.2.7.2 Maintenance

3.2.7.2.1 Scope

The team reviewed DOE and contractor programs for maintenance of plant structures, systems, and components, during the ongoing construction phase of the WTP. Staff held discussions with the responsible DOE maintenance engineers and the engineering supervisor, and conducted a review of associated documents. Staff obtained additional information from DOE during a public meeting on the factual accuracy of the draft report (see Section 1.3).

3.2.7.2.2 Assessment

During discussions with the DOE maintenance engineers, the team learned the need for an active maintenance program for structures, systems, and components, during the construction phase, had not been initially completely addressed. BNI did not consider that equipment maintenance programs were critical for a facility under construction. According to the interviewees, BNI used DOE's tailoring guidance document (DOE, 2001e) to tailor DOE Order 433.1 (see DOE Order 433.1A; DOE, 2007b) in a way that made it more difficult for DOE to oversee and regulate a maintenance management program during the construction phase of the contract. BNI's tailoring of DOE Order 433.1 eliminated reference to DOE's companion order, DOE Order 430.1 (see DOE Order 430.1B, Chg 1; DOE, 2008f). Thus, DOE Order 430.1, dealing with real property asset management was not a standard imposed on the WTP. The interviewees indicated that DOE approved the BNI's safety-requirements document version, which did not fully address the need for maintenance during construction. As part of the meeting on factual accuracy, DOE management indicated that it considered that the requirements for maintenance, during construction, were adequately covered by the Federal Acquisition Requirements clause in the contract (DOE, 2000a). DOE ORP site maintenance engineers explained that the contract and standard requirements document had left them without the full weight of current or past versions of DOE Order 433.1, or the use of DOE Order 430.1. The engineers indicated that DOE has subsequently been able to use Executive Order 13327 (President, 2004). That order was issued to improve the management of Federal real property. As part of the meeting on factual accuracy, DOE management indicated that maintenance requirements for adequate nuclear safety are specified in Criterion 7.6 of the safety requirements document (BNI, 2007a).

The team was informed, in site interviews, that DOE had conducted an assessment of the BNI maintenance management program in 2005 and had written a finding against the program. The DOE written finding requires BNI's written response, with corrective action commitments. By its own admission, DOE apparently did not fully follow up on the 2005 assessment finding until a follow-up assessment in 2007. The interviewees indicated that DOE's use of Executive Order 13327 (President, 2004) allowed it to provide focus for the 2007 assessment, and the resulting findings, on the need for maintenance and preservation of all government-purchased structures, systems, and components.

According to the staff interviews, BNI developed a program and a family of procedures for asset preservation as a result of the findings of the 2007 assessment, and DOE's focus on the requirements of the Executive Order. Because the focus of Executive Order 13327 is the management of Federal real property, the BNI program is all-inclusive and not focused on items important to safety. The program procedures were developed by the end of calendar year

2007, to meet corrective action commitments from the 2007 DOE assessment. BNI is currently in the process of fully implementing the program. The first stage of implementation involved a complete inventory of all components purchased and received by BNI for the WTP project.

The team reviewed BNI's procedure for the asset-preservation maintenance process. This procedure became effective on December 31, 2007. This procedure defines the process by which BNI is to identify assets with a standard component-numbering system and a computerized maintenance management system. The procedure identifies how inventory control, field material management, periodic maintenance, and surveillance processes should occur. The procedure also stipulates how maintenance work control; asset receipt, evaluation, and maintenance readiness; material control; and nonconformance reporting and control should occur.

NRC's guidance (NRC, 2002) identifies four areas of activity for a maintenance program. First, the surveillance and monitoring activity should support the determination of performance trends for IROFS, thus providing data useful in determining preventive maintenance frequencies. Second, corrective maintenance activities are needed to perform corrective actions or repairs on IROFS and, if necessary, functional testing prior to returning an IROFS to operational status. Third, a preventative maintenance program should demonstrate a commitment to conduct preplanned and scheduled periodic refurbishing, or partial or complete overhaul, for the purpose of ensuring that unanticipated loss of IROFS does not occur. Fourth, functional testing, including a description of the methods used and the commitment to perform functional testing, as needed, of IROFS after preventive maintenance or corrective maintenance, is an acceptance criterion (NRC, 2002).

3.2.7.2.3 Results of assessment

As described by DOE site staff, DOE was able, through use of an Executive Order, to ensure that BNI provide and implement a program for the preservation and maintenance of all structures, systems, and components purchased for the WTP, during the time between receipt of each structure, system, and component and the commissioning of the facility. This is a good example of the implementation of DOE owner responsibilities, as defined in Section C.3 of the contract (DOE, 2000a), with BNI. These activities also provide assurance that structures, systems, and components required for DOE regulation of radiological, nuclear, and process safety, and non-radiological worker safety and health, are preserved and maintained.

NRC and DOE have comparable requirements and guidance for maintenance. The NRC regulations for licensing of special nuclear material (Part 70) also do not provide specific requirements for preservation and maintenance, of safety-related or important-to-safety structures, systems, and components, between construction acceptance inspections, and start of plant operations. NRC, like DOE, relies on focused inspections of licensees' approved quality assurance programs, for the assurance of preservation and maintenance of important structures, systems, and components.

3.2.7.3 Training and Qualifications

3.2.7.3.1 Scope

NRC reviewed DOE requirements and programs for training and qualification for the WTP and compared them to NRC requirements and expectations for similar licensed fuel cycle facilities.

Staff reviewed DOE regulatory and contract requirements, applicable DOE and BNI documents and plans, and DOE assessment and program status reports. NRC staff conducted interviews with ORP staff responsible for WTP regulatory oversight functions and implementation of training and qualification. The team conducted a walk-through tour of the WTP training simulator facility.

3.2.7.3.2 Assessment

Training and qualification for abnormal events are specified in NRC regulations, in Part 70, as a management measure. This measure is to ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function when needed. Also Criterion 2 ("Quality Assurance Program") of the NRC regulation for quality assurance programs for reactors and plutonium-processing facilities (10 CFR Part 50, Appendix B), and the ASME NQA-1 standard (ASME, 1994), specify additional requirements. Together, these documents require that the quality assurance program takes into account the need for special skills, to attain the required quality, and provides for indoctrination and training of personnel performing activities affecting quality, as necessary, to assure that suitable proficiency is achieved and maintained.

NUREG-1520 (NRC, 2002) provides guidance for management measures. The guidance identifies specific acceptance criteria for training and qualification in the areas of training, organization, and management. NRC identifies acceptance criteria for analysis and identification of activities requiring training, position requirements and training basis, and lesson plans (NRC, 2002). NUREG-1520 stipulates acceptance criteria for evaluation of trainee accomplishment and training effectiveness, and personnel qualification.

The BNI quality assurance manual (BNI, 2007b) addresses general requirements for project personnel, and specific requirements for personnel training and qualification. BNI's manual has specific commitments for qualification and certification of auditors. Additional BNI manual commitments include qualification and certification of inspectors and testers, including non-destructive evaluation personnel. BNI implements its training and qualification programs through specific procedures, including a procedure on training, and another procedure on a systematic approach to training implementation.

The ORP has commitments and requirements for training and qualification from the quality assurance rule (Part 830, Subpart A), DOE Order 414.C (DOE, 2005d), and other DOE Orders that are addressed in the ORP QA requirements document.

The reviewers interviewed ORP and BNI staff. NRC staff reviewed the quality assurance manual (BNI, 2007b), DOE's QA requirements document, and BNI implementing procedures. Through the interviews and document reviews, NRC assessed the ORP and BNI staff knowledge of the requirements, issues, reports, and problems regarding the WTP, and of industry standards, requirements, and practice.

The team conducted a walk-through tour of the WTP training simulator, which is located on property adjacent to the DOE HAMMER training facility near Richland, Washington. URS Washington Division is a subcontractor to BNI and is responsible for the set-up and operation of the training simulator facilities. The simulator training facility contains full-scale simulations of the control rooms for the Pretreatment Facility, the High-Level Waste (HLW) Facility, and the Low-Activity Waste Facility. Included with each simulated control room is an adjacent room with

a simulator for each facility's crane-operator control room. At the time of the review, the simulated control rooms had not been furnished with the control panels and furnishings, and in fact were being used to store some of the furnishings in their original shipping containers.

The team also toured the development room and reviewed an overview of the facility computer systems for use in the development of the training simulations. Facility staff pointed out that the training facility has three separate computer local-area networks for the simulator training functions. One network is for introduction, review, and certification of software to be used at the facility. The second network is for the development of the control room simulations. The third network is for the operation of the simulators. All these training-related computer systems are completely isolated from any computer network serving the ORP and the WTP site.

At the time of the review, the training facility was being reactivated after an extended lay-up, because of delays in construction at the WTP site. Staffing at the time of the review included only the simulator manager and his assistant. Facility staff members informed NRC that they were actively engaged in increasing staff levels, to begin building the computer models for systems that have finalized designs.

3.2.7.3.3 Results of Assessment

The BNI contractual requirements (BNI, 2007b), combined with the ORP QA requirements document, are similar to NRC's QA regulatory requirements and program guidance for training and qualification for similar facilities. The BNI commitments (BNI, 2007b) and ORP commitments are comparable to the NRC licensee programs in this area.

The WTP simulator training facility should provide excellent opportunities for training of plant operators, as well as engineering and design personnel. The facility can serve as a good tool for other project staff, including inspection, audit, and assessment personnel. This facility, as planned, exceeds the NRC requirements for similar licensed fuel cycle facilities.

3.2.7.4 Procedures

3.2.7.4.1 Scope

NRC reviewed DOE requirements and programs for procedures for the WTP and compared them to NRC requirements and expectations for similar licensed fuel cycle facilities. Staff reviewed DOE regulatory and contract requirements, applicable DOE and BNI documents and plans, and DOE assessment and program status reports. NRC conducted interviews with ORP staff responsible for WTP regulatory oversight functions and for implementation of procedures.

3.2.7.4.2 Assessment

Procedures are specified in NRC regulations in Part 70, as a management measure. The purpose of this measure is to ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function, when needed. Together, Criterion 5 ("Instructions and Procedures") of the NRC regulation for quality assurance programs for reactors and plutonium-processing facilities (Part 50, Appendix B), and NQA-1 standard (ASME, 1994), require that activities affecting quality be prescribed by instruction, procedures, and drawings, of a type appropriate to the circumstances. Further

these documents require that the instructions, procedures, and drawings be completed in accordance with the procedural program requirements. The NRC regulations and the consensus standard for quality assurance (ASME, 1994) require that appropriate quantitative or qualitative acceptance criteria, for determining that important activities have been satisfactorily accomplished, are included in instructions, procedures, or drawings.

NUREG-1520 (NRC, 2002) provides guidance for management measures, and identifies specific acceptance criteria for the applicant's process for developing and implementing procedures.

The reviewers interviewed ORP and BNI staff, and reviewed the BNI quality assurance manual (BNI, 2007b), ORP's quality assurance requirements, and ORP and BNI implementing procedures. NRC staff, based on the document review and interviews, assessed the ORP and BNI staff knowledge of the requirements, WTP issues, and of industry standards, requirements, and practice.

The BNI quality assurance manual addresses general requirements for procedures (BNI, 2007b; Section 1.1.4) and specific commitments in Section Policy Q-17.1.

The ORP has commitments and requirements for procedures from the quality assurance rule (Part 830; Subpart A) and DOE Order 414.C (DOE, 2005d). ORP documents these requirements in the ORP QA requirements document. ORP also implements requirements from other DOE Orders, including DOE Order 1324.5B, which addresses the procedures program (see DOE Guide 1324.5B; DOE, 1996c).

3.2.7.4.3 Results of Assessment

The BNI contractual requirements and commitments (BNI, 2007b), combined with the ORP QA requirement document, are comparable to NRC's QA regulatory requirements and program guidance, for procedures for similar facilities. The BNI commitments (BNI, 2007b), and DOE commitments are similar to the NRC licensee programs for procedures.

The reviewers did note that the ORP procedures and manuals, in some areas, including assessments, were written in a general narrative manner. NRC's expectations for procedure content and approach include specific requirements and procedural direction. NRC did not find specificity in the WTP assessment procedures and manuals.

3.2.7.5 Audits and Assessments

3.2.7.5.1 Scope

NRC reviewed DOE requirements and programs for audits and assessments for the WTP and compared them to NRC requirements and expectations for similar licensed fuel cycle facilities. Staff reviewed DOE's regulatory and contract requirements, applicable DOE and BNI documents and plans, and DOE assessment and program status reports. NRC conducted interviews with ORP staff responsible for WTP regulatory oversight functions and audit and assessment program implementation.

3.2.7.5.2 Assessment

Audits and assessments are specified in NRC regulations, in Part 70, as a management measure. This measure is to ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their function, when needed. Together, NRC's regulation for quality assurance programs for reactors and plutonium-processing facilities (Part 50, Appendix B), and the NQA-1 standard (ASME, 1994), require a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program. These documents also require a determination of the effectiveness of the quality assurance program.

NUREG-1520 (NRC, 2002) provides guidance for management measures, and identifies specific acceptance criteria for audits and assessments. NRC provides acceptance criteria for policy, and internal audits and independent assessments. Other acceptance criteria address audit and assessment scope, objectives, and areas. NRC includes acceptance criteria on auditor and assessor qualifications and independence.

The BNI quality assurance manual addresses requirements (BNI, 2007b; Section 1.3) for management assessments, audits (independent assessment), and quality assurance surveillances. BNI documents specific management assessment commitments in Section Policy Q-02.2 (BNI, 2007b). BNI stipulates specific commitments for audits in Section Policy Q-18.1. BNI identified specific requirements for quality assurance surveillances in Section Policy Q-02.3. The BNI audit and assessment program documented in the quality assurance manual (BNI, 2007b) addresses the same topics as in NRC's guidance (NRC, 2002).

ORP has commitments and requirements for audits and assessment in the quality assurance Rule (Part 830, Subpart A) and in DOE Order 414.C (DOE, 2005d). DOE documents these commitments and requirements in the ORP QA requirements document. DOE uses these commitments and requirements, as well as those that address the requirements of DOE Order 226.1, "Implementation of Department of Energy Oversight Policy" (DOE, 2007a).
ORP addresses and implements these commitments and requirements using an ORP integrated-assessment program manual. The ORP QA requirements document addresses many DOE and ORP management processes and policies, as well as the quality- and safety-affecting activity oversight. The ORP staff, in its function as owner, performs many activities that would be performed by a licensee's organization on its construction contractors or operational organizations.

The reviewers interviewed numerous ORP, and selected BNI, staff persons, with oversight responsibility. The reviewers assessed the ORP and BNI staff knowledge of the requirements, issues, reports, and problems regarding the WTP, and of industry standards, requirements, and practice.

The reviewers evaluated and discussed with ORP staff the 2006 and 2007 enforcement actions (DOE, 2008d, 2008e) and a 2008 notice of investigation letter issued to BNI under the Price-Anderson Act Amendments (PAAA). The enforcement program under PAAA is administered by DOE's Office of Enforcement.

The NRC requirement for audits and assessments is one component of a quality assurance program designed to have multiple checking, verification, and oversight features. The purpose

of multiple assessment features is to provide assurance of the process and product control, and thus quality and safety. Assessments can be used as basis of information for the enforcement program.

The reviewers noted that, with the approval of the new ORP organization structure (DOE, 2008b), and the planned issuance of a new QA requirements document, to reflect the changes, the integrated-assessment program manual would be replaced with specific area or functional procedures. ORP quality assurance audits of ORP organizations performing safety- or quality-affecting activities will be initiated with the revised QA requirements document.

3.2.7.5.3 Results of Assessment

The BNI contractual requirements (BNI, 2007b), combined with the ORP QA requirements document and integrated-assessment program manual (or equivalent) requirements, are comparable to NRC's QA regulatory requirements and program guidance for audits and assessment for similar facilities. The BNI quality assurance commitments (BNI, 2007b) and ORP commitments are similar to the NRC licensee's programs.

The scope and implementation of the ORP assessment program covers many DOE and ORP management processes and policies. DOE's program is much broader and multi-purposed than the QA and safety-affecting oversight required by NRC regulations. The DOE WTP assessment program has multiple DOE Orders and Directives that address requirements regarding their owner function and responsibilities.

There are various ORP organizations performing audits, assessments, and surveillances. According to those interviewed, identifying the objectives and priorities of particular groups -- and distinguishing between owner, versus regulator, activities and safety functions -- is difficult. The conflicts of goals and priorities are inherent in DOE's dual roles. The review team could not distinguish whether audits and assessment were an owner or regulatory oversight action. Because of the dual roles and responsibilities and lack of independence of the ORP oversight organizations and staff, the ORP assessment program cannot be considered equivalent to NRC staff inspection programs (which are described in Section 2.2.2.3), where the only, and clear, focus is safety.

The NRC document review, and discussions with DOE and BNI staff, indicate that the two enforcement actions and the notice of investigation had similarities. The program requirements for audits and assessment for: (1) safety basis; (2) design basis; (3) procurement planning and verification; (4) component verification; and (5) response to findings and corrective actions, should have been effective in addressing and resolving the conditions noted in the enforcement actions. The similarities could indicate that WTP issues had not been fully addressed and resolved initially. The PAAA issues (also addressed in Section 3.2.10) indicate that significant safety program and quality functions and interfaces, such as design control and verification, procurement planning and verification, receipt inspection, and corrective action, were not effective over several years. The audit and assessment program may not have been effective in identifying these issues, the extent of condition, and in resolving the issues. Although DOE's regulations and guidance are comparable to NRC's regulation and guidance, the results of DOE programs and practices for audits and assessments suggest implementation is not effective. Thus, DOE and NRC management measure programs for audits and assessment are not comparable.

3.2.7.6 Incident Investigations

3.2.7.6.1 Scope

NRC reviewed DOE requirements and programs for incident investigations for the WTP and compared them to NRC requirements and expectations for similar licensed fuel cycle facilities. Staff reviewed DOE's regulatory and contract requirements, applicable DOE and BNI documents and plans, and DOE's assessment and program status reports. NRC interviewed ORP and BNI staff, reviewed the quality assurance manual (BNI, 2007b), ORP's QA requirements document, and BNI implementing procedures. NRC assessed the ORP and BNI staff member knowledge of the requirements, issues, reports, and problems regarding the WTP, and regarding industry standards, requirements, and practice.

3.2.7.6.2 Assessment

Incident investigations for abnormal events are specified in NRC regulations, in Part 70, as a management measure. The purpose of the management measure is to ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed. Together, Criterion 16 ("Corrective Action") of the NRC regulation for quality assurance programs for reactors and plutonium-processing facilities (Part 50, Appendix B), and NQA-1 standard (ASME, 1994), require that measures be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances, are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.

NUREG-1520 (NRC, 2002) provides guidance for management measures, and identifies specific acceptance criteria for incident investigations. NRC acceptance criteria address policy, planning, process, procedures, and documentation, including failures of IROFS. NRC's acceptance criteria also address the management structure for investigating abnormal events, completion of appropriate corrective actions, and for reporting abnormal events to NRC.

The BNI quality assurance manual addresses requirements (BNI, 2007b; Section 1.1.3) for control of nonconforming items and corrective action. BNI has specific commitments for control of nonconforming items in Section Policy Q-15.1. BNI stipulates specific corrective-action requirements, in Section Policy Q-16.1. These sections list requirements for nonconforming item control, and for corrective action policy, process, and communication. The requirements in those sections also include reporting of adverse conditions, stopping of work, investigation, and completion and trending. There are two reporting and tracking systems: the Occurrence Reporting System; and the PAAA Noncompliance Tracking System (NTS). These systems allow DOE to gather and analyze incidents and deficiencies, for DOE action, or to identify adverse trends.

ORP has commitments and requirements for control of nonconforming items and corrective action in the quality assurance rule (Part 830, Subpart A) and DOE Order 414.C (DOE, 2005d). ORP addresses these commitments and requirements in the ORP QA requirements document.

The reviewers evaluated and discussed with ORP staff the 2006 and 2007 enforcement actions (DOE, 2008d, 2008e) and a 2008 notice of investigation letter issued to BNI under the PAAA. The NRC requirement for incident investigations is one component of a quality assurance program designed to have multiple checking, verification, and oversight features. These multiple features are meant to provide assurance of the process and product control, and thus quality and safety.

3.2.7.6.3 Results of Assessment

The BNI contractual requirements (BNI, 2007b), combined with the ORP QA requirements document, integrated-assessment-program manual (or equivalent) requirements, and DOE Orders and contract reporting, are generally similar to NRC's QA regulatory requirements and program guidance for incident investigations for similar facilities. The BNI quality assurance commitments (BNI, 2007b) and DOE commitments are comparable to NRC licensee programs.

3.2.7.7 Records Management

3.2.7.7.1 Scope

NRC reviewed DOE's requirements and programs for records management for the WTP and compared them to NRC requirements for similar licensed fuel cycle facilities. Staff reviewed DOE's regulatory and contract requirements, applicable DOE and BNI documents and plans, and DOE assessment and program status reports. The reviewers reviewed the quality assurance manual (BNI, 2007b), ORP's QA requirements document, and BNI implementing procedures. NRC conducted interviews with ORP staff responsible for WTP regulatory oversight functions and implementation of records management. NRC staff assessed, through the interviews, the ORP and BNI staff member knowledge of the requirements, issues, and of industry standards, requirements, and practice.

3.2.7.7.2 Assessment

Records management is specified in NRC regulations, in Part 70, as a management measure. The purpose of the management measure is to ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure that they are available and reliable to perform their functions when needed. Together Criterion 17 ("Quality Assurance Program") of the NRC regulation for quality assurance programs for reactors and plutonium-processing facilities (Part 50, Appendix B), and the NQA-1 standard (ASME, 1994), require that sufficient records be maintained to furnish evidence of activities affecting quality. NUREG-1520 (NRC, 2002) provides guidance for management measures, and identifies specific acceptance criteria for records management.

The BNI quality assurance manual addresses general requirements for records management (BNI, 2007b; Section 1.1.4). BNI has specific commitments in Section Policy Q-17.1. The BNI records management program is implemented through procedures and in accordance with a DOE records-retention and turnover plan.

ORP has commitments and requirements for records management in quality assurance rule (Part 830, Subpart A) and DOE Order 414.C (DOE, 2005d). DOE documents these commitments and requirements in the ORP quality assurance requirements document. DOE

implements requirements from other DOE Orders, including DOE Order 1324.5B, "Records Management Program" (see DOE Guide 1324.5B; DOE, 1996c).

3.2.7.7.3 Results of Assessment

The BNI contractual requirements (BNI, 2007b), combined with the ORP QA requirements document, are similar to NRC's QA regulatory requirements and program guidance for records management for similar facilities. The BNI commitments (BNI, 2007b) and ORP commitments are comparable to the NRC licensee programs for records management.

3.2.7.8 Quality Assurance Elements

3.2.7.8.1 Scope

NRC reviewed DOE's requirements and programs for establishment and implementation of quality assurance (QA) elements for the WTP and compared them to NRC requirements for similar licensed fuel cycle facilities. Staff reviewed DOE's regulatory and contract requirements, applicable QA program documents and manuals, implementing procedures, and DOE assessment and program status reports. NRC conducted interviews with ORP staff responsible for regulatory oversight of the WTP QA program implementation.

3.2.7.8.2 Assessment

The BNI WTP QA requirements are specified in the contract (DOE, 2000a; Standard 7). The requirements include the development of a QA program for radiological, nuclear, and process safety in accordance with Part 830, Subpart A. BNI is required to use a technically defensible graded approach to develop the QA program. The contract amplifies specific requirements (DOE, 2000a; Standards 2 and 6) for process development, waste-form qualification, and testing. The contract requires implementation of the "Office of Civilian Radioactive Waste Management Quality Assurance Requirements Program Description" for immobilized HLW (DOE, 1996d). The contract also requires implementation of the NQA-1-1989 standard (see ASME, 1994) for immobilized low-activity waste and other activities. The BNI QA manual (BNI, 2007b) describes the requirements for implementing BNI's QA program. BNI submitted its QA manual as required by Part 830, Subpart A. ORP approved the BNI program as required by Part 830, Subpart A. The BNI program (BNI, 2007b) addresses the 18 QA program criteria specified in the NRC regulation for QA programs for reactors and plutonium-processing facilities (Part 50, Appendix B). These criteria are described in NQA-1 (ASME, 1994). The BNI QA manual (BNI, 2007b) also addresses requirements for the applicable areas of electronic management of data control, sample control, and scientific investigation. The BNI QA manual appears to address the QA areas, activities, and criteria that are within BNI scope, as a contractor for the WTP. BNI describes its organization and QA program, and addresses design control and procurement control (BNI, 2007b). BNI identifies requirements for: (1) instructions, procedures, and drawings; (2) document control; (3) and control and identification of items; (4) control of special processes; (5) measuring and test equipment; and (6) tests (BNI, 2007b). The QA manual also addresses requirements for: (1) handling, storage, and shipping; (2) inspection; (3) test, and operating status; (4) control of nonconforming items; (5) corrective action; (6) records; and (7) audits.

The NRC QA requirements for facilities, similar to the WTP in terms of risk significance are the criteria of 10 CFR 50, Appendix B. In their license application the applicant/licensee would be

required to describe their QA program to implement the criteria and/or a commitment to an acceptable consensus standard such as NQA-1-1994 (NUREG-1510 and NUREG-1718).

The reviewers noted that ORP, as a part of its management system, has committed to achieving quality in accordance with the QA rule (Part 830, Subpart A) and DOE Order 414.C (DOE, 2005d). ORP has developed and implemented a QA program manual for those WTP (and other) activities that can impact safety and quality. The ORP manual addresses many DOE and ORP management processes and policies, as well as the design, engineering, QA, and safety oversight that the ORP staff performs in its function as owner. Many of these activities would be performed by the owner's organization of their construction contractors or operational organizations. Some of these activities, particularly design reviews and assessments, may be comparable to NRC regulatory activities for licensing reviews and inspections. However, distinguishing between DOE owner versus regulator activities and functions was difficult.

The reviewers interviewed several ORP managers, area leads, and engineers, with oversight responsibility for QA program, construction, procurement, and design-engineering oversight, inspections, and assessments. The reviewers assessed the ORP staff knowledge of QA issues and problems regarding the WTP or regarding industry, in a number of technical areas. These areas included procurement QA, commercial-grade items and dedication, and software QA. NRC discussed digital instrumentation and control, design, and special processes with WTP staff. NRC sampled condition reports to review and assess the ORP response, and actions, to WTP issues.

The reviewers evaluated and discussed with ORP staff the 2006 and 2007 enforcement actions (DOE, 2008d, 2008e) and a 2008 notice of investigation letter issued to BNI under the PAAA.

3.2.7.8.3 Results of Assessment

The BNI contractual requirements (BNI, 2007b), combined with the ORP QA requirements, are similar to NRC's QA regulatory requirements and guidance for QA programs for similar facilities. The BNI commitments (BNI, 2007b) and ORP QA commitments are comparable to NRC licensee programs.

The evaluation and discussion indicates that the two enforcement actions and the notice of investigation had similarities. These similarities could indicate WTP issues had not initially been fully addressed and resolved (also addressed in Section 3.2.10). The PAAA issues indicate that significant QA functions and interfaces, such as design control and verification, procurement planning and verification, receipt inspection, and corrective action may not have been effective over several years. Although DOE's regulations and guidance are comparable to NRC's regulation and guidance, the results of DOE programs and practices for QA suggest implementation may not have been effective. Thus, DOE and NRC management measure programs for QA are not comparable.

3.2.8 Inspection During Construction

3.2.8.1 Scope

The team evaluated DOE and contractor inspection programs for the ongoing construction phase of the WTP. The NRC assessment consisted of interviews with DOE supervisors and

personnel in the WTP Construction Oversight and Assurance Division (WCD), and BNI quality control supervisors, and a review of DOE inspection procedures and surveillance reports.

3.2.8.2 Assessment

The DOE construction inspectors are assigned to the WCD. The Director of the WCD reports to the WTP Manager. Within WCD, there are two groups of inspectors -- facility representatives, with individual facility assignments -- and DOE acceptance inspectors and contract-support site inspectors, with assignments in special technical areas.

During discussions with BNI quality control supervisors, the team learned that BNI quality control inspections only involve safety-related construction activities. Quality inspections for the remaining construction activities are conducted by BNI field engineering. DOE acceptance inspectors and site inspector personnel provide oversight through surveillances of both of these BNI organizations.

During the review of the responsibilities assigned to the WCD, the team learned that the WTP Manager serves as the defined individual responsible for three consensus standards. The WTP manager is the "Owner Inspector," responsible for verifying that piping meets the ASME B31.3, *Process Piping* (ASME, 1996), manual requirements. The WTP Manager serves as the "Owner Representative," responsible for verifying that applicable NFPA 13 (NFPA, 2007), *Installation of Sprinkler Systems,* Chapter 10, "Sprinkler Acceptance," requirements, are addressed. The WTP manager serves as the "Owner Representative," responsible for verifying that applicable American Concrete Institute (ACI) 349-01 (ACI, 2001), *Code Requirements for Nuclear Safety-Related Concrete Structures,* Chapter 13, "Inspections and Records Keeping," requirements, are met. The acceptance inspectors' and site inspectors' inspection and surveillances, in the areas of piping, fire protection sprinkler systems, and safety-related concrete, assist the WTP Manager in the completion of these assigned owner responsibilities.

WTP facility representatives, acceptance inspectors, and site inspectors are also charged with conducting inspections and assessments of industrial safety conditions at the site, in accordance with the requirements of 10 CFR Part 851 ("Worker Safety and Health Program"). The NRC team interaction with the facility representatives involved discussions with each individual facility representative, during tours of each of the major facilities. Discussions concerned the approximate percent completion of the design and construction of the major facilities, description and status of current problem areas, and level of effort by the contractor.

The NRC team concentrated most of the review effort in the assessment of the activities of the acceptance inspectors and site inspectors; because it appeared that the activities assigned to these inspectors seemed to be, in some ways, similar to the NRC inspections conducted by resident and specialist inspectors at NRC-licensed facilities.

The team was informed that the acceptance inspectors and site inspectors conduct about 80 – 100 construction quality inspections and surveillances, and at least two supplier inspections, each calendar quarter. The results of the inspection and surveillance activities are documented in individual surveillance reports, which are summarized in a "Quarterly Construction Surveillance Summary Report" addressed to the contractor.

Problems identified by the acceptance and site inspectors are characterized in the quarterly reports as "Findings," or "Non-cited Findings," with a written response requested for each of the "Findings". The NRC team was informed that when findings are identified, the individual

surveillance report documenting the circumstances and details of each finding are informally transmitted to the contractor, so that timely corrective actions can be initiated.

The team reviewed the latest available quarterly report, and the 89 supporting surveillance reports. The quarterly report documented inspection and surveillance activities between October 1, 2007, and December 31, 2007. Along with the review of site construction activities, this quarterly report included supplier inspections for two companies with contracts to fabricate pipe and tubing supports. These supplier reports documented the results of DOE review of the BNI supplier oversight program, as well as the supplier QA program, implementation.

The NRC team also reviewed a series of four "On-location Inspection Reports" for February through August 2002, which documented the inspections for the preparations to place safety-related concrete, in accordance with ACI 349-01 (ACI, 2001). These reports document the DOE "owner-representative" inspections of the concrete-batch plants, verification of the concrete-mix designs, and the readiness of concrete testing facilities and procedures. The reports also document problems associated with temperature control of the safety-related concrete, during a hot day.

A compilation of 32 WCD supplier inspection reports, from inspections conducted between July 2004 and January 2008, was reviewed by the team. This sample of inspection reports was provided as an example of DOE inspections that could be compared to the responsibilities assigned to NRC vendor inspectors.

For comparable NRC facilities, inspections during construction are handled on a case-by-case basis through the implementation of a project-specific inspection plan or inspection manual chapter. An NRC construction inspection program focuses on: (1)verifying that the design bases of the principal systems, structures, and components and the QA program are being adequately implemented during construction to provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents; and (2) verifying that the construction of the principal systems, structures, and components and IROFS have been completed in accordance with the construction authorization or license application to possess and use special nuclear material. For comparable facilities, NRC could have a resident inspector at the facility, supported by technical specialists and inspectors. The licensee is also required to have its own oversight program including inspections and assessments.

3.2.8.3 Results of assessment

The DOE construction inspection and surveillance activities, within the WCD, are well-structured and documented. The sample of inspection reports provided the team with insights about the need for vigilance when procuring safety-related goods and services for the nuclear industry. Based on the review of documents, discussions with DOE personnel, and observations at the site, the team concluded that the DOE construction inspection program goes beyond the requirements of the programs and methods used by NRC to inspect licensee construction programs, for the following reasons:

- The responsibilities associated with representing the "Owner Inspector" or "Owner Representative" for three very important construction Codes, require that the DOE inspection activities go well beyond the sampling inspections normally conducted by NRC resident and specialist inspectors.
- The additional owner-required activity involving emphasis on worker health and safety requires that the DOE inspectors spend a considerable amount of time in inspections of

OSHA-related areas like temporary power supply, handrails, safety harnesses, etc., that NRC generally does not inspect on a regular basis.

- The supplier inspections that DOE conducts involve suppliers of other than safety-related goods and services, which goes beyond the scope of the NRC vendor inspection program.

3.2.9 Inspection During Operations

3.2.9.1 Scope

NRC reviewed inspection programs associated with the operational phase of the WTP. Although WTP is not in an operational phase, NRC reviewed DOE and DOE contractor programs associated with oversight and performance monitoring of programs and operational and maintenance activities. A generic evaluation of the process and methods used by DOE, relating to contractor oversight at operational projects, was undertaken to evaluate those elements that are reasonably expected to be included in DOE's operational oversight program. NRC's evaluation consisted of interviews with DOE personnel knowledgeable in the development of DOE contractor oversight programs for operating facilities. Staff reviewed documents commonly associated with DOE operational contracts, to gain an understanding of the requirements typically imposed on contractors, based on existing DOE standards and practices.

3.2.9.2 Assessment

Initial operation of the WTP is not anticipated for several more years. The WTP will consist of four major facilities. These facilities include the Pretreatment Facility, HLW Facility, Low-Activity Waste Facility, and Analytical Laboratory, in addition to various support facilities. Major activities in progress at this time are primarily associated with construction work. Currently the Low-Activity Waste and Analytical Laboratory facilities construction work are the farthest along, with anticipated completion between 2009 and 2012. Completion of the Pretreatment Facility and HLW Facility will follow several years later. Currently, the primary WTP focus is construction activities. Programs associated with commissioning of the facilities and subsequent operations are currently in the preliminary stages of development.

Several key documents are typically invoked to cover operations at DOE facilities. These documents detail process safety standards and principles prescribed by DOE to ensure that appropriate operational safety standards are established and maintained by contractor organizations. Contractor organizations responsible for operation must implement 10 CFR Parts 820, 830, 835 and 851, as a minimum. Detailed requirements are specified in various DOE documents that are included in DOE contracts. Since these documents are referenced within applicable contracts, contractor organizations must ensure that their programs are implemented in compliance with these requirements.

DOE ORP has six key documents (DOE, 2001a, 2001b, 2001c, 2001d, 2004, and 2005b) for the WTP program. DOE/RL-96-0006 (DOE, 2004) specifies the top-level standards and principles. This document describes those programs that contractor organizations are required to employ while constructing and operating the WTP. Program areas addressed by this document are wide-ranging and include general safety, radiation protection, and technical safety objectives. Principles of operation include such programs as: (1) defense-in-depth; (2) configuration management; (3) quality assurance; (4) engineering practices; (5) conduct of

operations; (6) training and qualifications; (7) safety oversight; (8) and radiation protection, in addition to several other key areas normally included in NRC operational inspection programs.

ORP intends to provide regulatory oversight during the operational phase of the WTP project. DOE/RL-96-0003 (DOE, 2001b) details the actions and responsibilities the contractor is required to complete before the "Authorization of Production Operations" regulatory action. This "regulatory action" is a formalized program requiring specified actions to be completed before granting the authorization for operation of the facility to proceed. The DOE ORP Manager is responsible for granting this approval. This regulatory action requires that the contractor demonstrate acceptable performance as part of an operational readiness review and that extensive program elements be established and available to support safe plant operation. On successful review and concurrence, a final safety evaluation report is issued (DOE, 2001b). DOE's Safety Regulation Official is responsible for making the recommendation to the ORP Manager, signifying that all necessary prerequisites have been completed to ensure safe operation of the plant (DOE, 2001b). The ORP Manager may then grant an operation-authorization agreement.

DOE envisions that four key documents (DOE, 2001a, 2001b, 2001c, and 2004) may need to be revised before entering the operational phase of the project. The final outcome at this time, in terms of a decision to revise the key documents, is not known. These documents could be incorporated into the operational contract as written, as revised documents, or the documents could be eliminated. Elimination of these documents would not have a material impact on DOE's oversight function once the facility enters operation. Various DOE standards, manuals and instructions, and applicable Code of Federal Regulations parts, associated with operational facilities, address oversight and inspection requirements for an operational facility.

DOE plans to assign facility representatives to monitor the daily performance of the WTP and its operations. This is a normal practice for major DOE contractor-operated facilities. The responsibilities, functions, and reporting requirements for the facility representatives are detailed in various DOE documents. DOE Order 5480.19 (DOE, 2001h) and DOE-STD 1063-2000 (DOE, 2000c) are two documents that specify the function and duties of the facility representative position that are relevant to the WTP. Additionally, DOE has developed specific instructions, a manual, and qualification guides for the ORP facility representative program. These documents address: (1) implementation of the ORP facility representative program; (2) staffing and coverage of facility representatives; (3) qualifications; (4) stop work; (5) functional-area qualification record; and (6) facility-specific qualification standard and record.

The facility representative position has a function and purpose similar to the NRC resident inspector's position. DOE documents relating to the facility representative position state that this person is the primary point of contact with the contractor. These documents also state that the facility representative is responsible for conducting daily observations of operation and maintenance activities. The facility representative has the authority to review and observe all contractor activities and to monitor compliance with DOE standards and policies. Consequently, this person has a key position, with significant responsibility regarding the ongoing assessment and evaluation of contractor performance, and compliance with applicable standards and regulations. Because of the complexity and overall magnitude of the WTP project, the facility representative's area of responsibility and scope of activities to be monitored may be significantly greater and more complex than those previously encountered by facility representatives at other DOE facilities. DOE anticipates that a minimum of several facility representatives will be required during the operational phase of the project. It is essential that

facility representatives, for the operating facilities, be trained and qualified in accordance with established DOE programs, before granting authorization for operation.

Various reporting mechanisms are associated with DOE's contractor oversight program and facility representative assessment activities. Routine reports are issued that summarize field observations and findings from various assessment sources. A formalized program exists to classify the safety significance of inspection and assessment findings and to assess the effectiveness of the contractor's corrective action program. Assessment results are communicated to both DOE and contractor management. In addition, mechanisms to allow for periodic formal reviews of assessment results have been established by DOE (e.g., the Assessment Program Committee). These formalized reviews include provisions to monitor and track adverse trends for key performance indicators. Current practices include morning conference calls between facility representatives and DOE project team personnel, to review and discuss issues. This provides a way to communicate issues of interest in a timely manner.

ORP has an integrated assessment program that details the assessment processes associated with ORP's oversight of the WTP. This is a comprehensive assessment program that uses various input data to assess contractor compliance with Federal regulations, codes, and standards, and contract requirements, and authorization-basis requirements. This program is similar to the NRC Licensee Performance Review process for fuel cycle facilities and the annual reviews NRC conducts for nuclear power plants. The integrated assessment program is a formalized program that involves DOE management and committee reviews of key performance indicators, assessment results from various sources, and documents and tracks assessment actions. Based on these integrated assessments, overall contractor performance is evaluated and any underlying generic issues identified. Assessment results are used to develop future assessment schedules, based on program reviews.

The NRC focuses on risk-informed inspection and assessment of fuel cycle facility performance. The inspection program uses the risk information from integrated safety analysis to provide more emphasis on those systems, processes, and activities that have higher risk. For comparable facilities, NRC would have a resident inspector at the facility, supported by technical specialists and inspectors. The licensee is also required to have its own oversight program including inspections and assessments.

The NRC inspection program for a comparable facility includes the following major program elements: (1) core inspections, including resident inspections; (2) plant specific reactive inspections; (3) plant specific supplemental inspections; and (4) licensee performance reviews. The core inspection program is the minimum required inspection program appropriate to determine whether a fuel cycle facility is operating safely and securely in accordance with regulatory requirements and to identify indications of declining safety or safeguards performance. Reactive inspections include follow-up for events through supplemental inspections, special inspection teams, augmented inspection teams, and incident investigation teams. A graded approach to reactive inspections is taken depending on the actual or potential risk-significance of an event or conditions. The plant specific supplemental inspections provide more diagnostic inspections of identified problems and issues beyond the core inspections. Supplemental inspections are performed as a result of performance issues that are identified by core inspections, event analysis, or during the licensee performance reviews. The licensee performance review is designed to provide an assessment of licensee performance to NRC management, while minimizing staff effort beyond that required for routine fuel cycle facility licensing and inspection activities. The information is also provided to the licensee's senior management and to interested members of the public, to apprise them of licensee performance.

3.2.9.3 Results of Assessment

A well-documented and structured oversight and operational monitoring program has been developed, based on DOE's considerable experience in performing these type of functions. Based on a review of pertinent documents and discussions with DOE personnel, DOE's operational oversight program for the WTP will likely be comparable to methods employed by NRC to inspect licensee programs and evaluate licensee operational performance. DOE's program will also incorporate oversight functions, comparable to those required of NRC licensees, through DOE's management measures and QA commitments.

3.2.10 Enforcement

3.2.10.1 Scope

NRC reviewed DOE's requirements and programs for regulatory enforcement, or the equivalent, which are applicable to the WTP, and compared them to the NRC requirements for similar licensed facilities. NRC conducted interviews with ORP staff responsible for regulatory oversight of the WTP enforcement program implementation. The reviewers evaluated and discussed with ORP staff the 2006 and 2007 enforcement actions (DOE, 2008d, 2008e) and a 2008 notice of investigation letter issued to BNI under the Price-Anderson Act Amendments (PAAA). The assessment includes additional information NRC obtained from DOE during a public meeting on the factual accuracy of the draft report (see Section 1.3).

3.2.10.2 Assessment

DOE has an enforcement process that is implemented by the Office of Enforcement, within the DOE's Office of Health, Safety and Security. The Office of Enforcement is responsible for implementing the enforcement program for nuclear- and worker-safety for all DOE nuclear activities, including the WTP, under the "General Statements of Enforcement Policy" in Part 820, Appendix A, and in Part 851, Appendix B. This process is generally referred to as the PAAA enforcement process. The Office of Enforcement has guidance and implementing procedures for the PAAA process, as do ORP and BNI.

For the WTP, events, issues, non-conformances, etc., are entered or reported through a variety of mechanisms and databases, including the DOE-wide National Tracking System (NTS). The BNI contractor is encouraged, but not required (by contract or regulation) to self-indentify and enter items into the NTS. Items entered into NTS and information obtained by other mechanisms is reviewed by the Office of Enforcement for potential significance and enforcement action. In most cases, a series of events or non-conformances are grouped together to reach a threshold to result in an enforcement action. The threshold appears to be consistently high.

ORP works with the Office of Enforcement through an assigned, trained, PAAA coordinator. This coordinator provides the first analysis of: (1) events; (2) DOE assessment issues; (3) contractor issues; and (4) contractor self-reported events, for potential PAAA applicability. The PAAA coordinator works as a liaison between Office of Enforcement and senior ORP leadership to make recommendations and provide support for potential regulatory activities. The regulatory activities can take the form of: (1) enforcement letters; (2) consent orders;

(3) potential notices of violation; (4) special report orders; and (5) compliance orders. The regulatory requirements, guidance, and procedures contain many features that appear similar to the NRC enforcement process.

Management tools to deal with QA or safety program deficiencies or violations during construction also include contract and owner-type options, within the requirements of the current contract. These tools include: (1) assessment reports that direct an identified issue be addressed; (2) show cause letters; (3) stop work; (4) conditional payment of fee; and (5) contract termination.

The review team discussed the contract provisions with the ORP QA and contracts personnel. The current DOE contract with BNI for the WTP activities does not have an active or pertinent fee incentive and no safety-performance fee clause. In practice, ORP construction and procurement inspection personnel are limited to the issuance of findings that require corrective action and a written response from the contractor; in extreme cases ORP may use stop-work authority.

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act and the Energy Reorganization Act. Subpart B of 10 CFR Part 2 of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. The NRC developed the Enforcement Policy document to describe the policy and procedures the NRC intends to follow in initiating and reviewing enforcement actions in response to violations of NRC requirements.

NRC uses inspector findings together with objective performance indicators to assess the performance of nuclear facilities. The assessment process allows the NRC to integrate various information sources relevant to licensee safety performance, make objective conclusions regarding their significance, take actions based on these conclusions in a predictable manner, and effectively communicate these results to the licensees and to the public.

As part of its oversight process, NRC issues sanctions called enforcement actions, to licensees that violate its regulations. Enforcement actions are used: (1) as a deterrent to emphasize the importance of compliance with regulatory requirements; and (2) to encourage prompt identification and prompt, comprehensive correction of violations. In assessing the significance of a noncompliance, the NRC considers four specific issues: (1) actual safety consequences; (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the NRC's ability to perform its regulatory function; and (4) any willful aspects of the violation.

The NRC considers the safety implications of non-compliances that may impact the NRC's ability to carry out it statutory mission. Non-compliances may be significant because they may challenge the regulatory envelope upon which certain activities were licensed. These types of violations include failures such as: (1) failures to provide complete and accurate information; (2) failures to receive prior NRC approval for changes in licensed activities; (3) failures to notify NRC of changes in licensed activities; and (4) reporting failures. Even inadvertent reporting failures are important because many of the surveillance, quality control, and auditing systems on which both the NRC and its licensees rely in order to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting.

The NRC emphasizes the importance of the licensee identifying issues and implementing effective and complete corrective action. The NRC enforcement process is usually initiated by NRC inspectors (see discussion in Section 3.2.9.2) during a planned routine inspection or a

special reactive inspection as a result of an incident. The potential violation(s) are normally noted, and discussed with the licensee at that time, or shortly thereafter. These actions initiate the enforcement process, including notification to the licensee at that point. A single violation of regulatory commitments may be processed as an enforcement action or grouped with others if related or appropriate. The enforcement action threshold is low and the enforcement action is determined based on the significance of the event, as described above.

3.2.10.3 Results of Assessment

The NRC and DOE enforcement processes are structurally similar in terms of documentation and enforcement letters. However, the results of implementation, and the practical effect, of the DOE oversight process may be much different from the NRC enforcement process. The function of the Office of Enforcement is at a separate and relatively distant organization from ORP and its parent Office of Environmental Management. The Office of Enforcement does not conduct routine inspections of specific facilities nor programs, but the WTP could be the subject of a program review, or inspected as a part of some larger general program inspection, more likely when it is in operation. In identifying and screening of potential non-conformances that may lead to an enforcement action and/or fine, the Office of Enforcement uses a variety of DOE and contractor sources, including the DOE-wide voluntary NTS, internal and external assessments, nonconformance reports, deficiency reports, safety reports, and employee concerns.

The NRC review and discussion with site staff indicate that the issues that led to the two enforcement actions and the 2008 notice of investigation, as discussed in Section 3.2.7.8 Quality Assurance Elements, had similarities and could be indicative of WTP program implementation that had started in 2003 or 2004, and are not fully addressed and resolved as of 2008.

As presented to NRC staff, by the interviewees, the PAAA enforcement action investigation is so extensive and detailed that the contractor is left with the impression that no additional "extent-of-condition" review is necessary. The interviewees indicated that the DOE enforcement process takes so long that, by the time the report is issued and any fine levied, the issue is old news, and, in most cases, the contractor has taken corrective actions and the project has moved on. For instance, issues addressed in the 2006 enforcement action (DOE, 2008d) began in 2002. However, the PAAA actions and the underlying issues indicate that significant safety program and QA functions, such as nonconformance control and corrective action, were not effective over an extended period of time. The BNI and ORP QA programs apparently were not effective in identifying these issues in a timely manner, determining the extent of condition, and resolving them.

The enforcement options available to DOE are similar to the options that NRC might apply to a licensee/owner of an NRC-licensed facility. Regulatory enforcement options available to DOE include enforcement letters, consent orders, potential notice of violation, special report orders, and compliance orders. In addition to the regulatory activities listed, which are similar to NRC options, the DOE also has available contract management tools which include assessment reports, show cause letters, stop work orders, conditional payment of fee, and contract termination. Of these, the contractual payment options available to DOE are, of course, not available to NRC. NRC uses civil penalties for significant license infractions. Currently, there are no additional enforcement options, such as an active or pertinent fee incentive or safety-performance fee clause, available to ORP in its role as an owner.

The NRC inspection and enforcement processes use a range of enforcement options and tools to effect and verify adequate assurance of safety by the licensee. The current regulatory and contractual requirements and processes, as implemented by DOE, do not provide equivalent options for ORP oversight of the WTP.

3.2.11 Allegations

3.2.11.1 Scope

NRC reviewed DOE's requirements and programs for allegations, or the equivalent, which are applicable to the WTP, and compared them to the NRC requirements for similar licensed facilities.

3.2.11.2 Assessment

DOE addresses allegations through an employee-concerns program approach. The DOE ORP employee concerns program requirements are established by DOE Order 442.1A (DOE, 2001f). The requirements identify criteria for the program and its implementation. The order (DOE, 2001f) identifies requirements for processing and closing employee concerns, and for documentation and record-keeping associated with the employee concerns program. DOE describes the requirements for training and qualification, and management assessment of the program (DOE, 2001f).

There are four criteria for the DOE employee concerns program (DOE, 2001f). First, there is a requirement for interfacing with appropriate organizations within DOE, and including the contractor's employee concerns program and external regulatory bodies that require employee concerns program. Second, there is a requirement for establishing documented program plans describing methods and processes used to implement program requirements. The third criterion is informing DOE and DOE contractor employees: (1) of the employee concerns process; (2) that employees are encouraged to first seek resolution with first-line supervisors or through existing complaint- or dispute-resolution systems, but that they have the right to report concerns through the DOE employee concerns program; and (3) that management does not tolerate reprisals against, or intimidation of, employees who have reported concerns. The fourth requirement is providing and publicizing a 24-hour hot-line (e.g., voice mail or e-mail system).

DOE ORP guidance for the employee concerns program details the processes and definitions involved in the employee concerns program and provides the forms for implementing the program. An employee concern is defined as "…a good-faith expression, by an employee, of a policy or practice which should be improved, modified, or terminated." Further, "…concerns can address issues such as health, safety, the environment, management practices, fraud, waste, or reprisal for raising a concern," and "…concerns may address an ORP, contractor or subcontractor policy or practice," are part of the definition of an employee concern. This definition is in contrast to the NRC definition of an allegation, "A declaration, statement, or assertion of impropriety or inadequacy associated with NRC-regulated activities, the validity of which has not been established. This term includes all concerns identified by sources such as individuals or organizations, and technical audit efforts from Federal, State, or local government offices regarding activities at a licensee's site." NRC's allegation program is not limited to licensee employees, but is available to all individuals and deals with concerns associated with NRC requirements, and wrongdoing by individuals or organizations that are licensed by NRC, applicants for licenses, licensee contractors or vendors, and employees of any of the above.

DOE Order 442.1A (DOE, 2001f) requires that the order be applied to DOE contractors, and thus the WTP contractor also has an employee concerns program. Under this order, the contractor is required to : (1) assist DOE in the resolution of employee concerns in a manner that protects the health and safety of both employees and the public and ensures effective and efficient operation of DOE-related activities under its jurisdiction; (2) ensure that contractor and subcontractor employees are advised that they have the right and responsibility to report concerns relating to the environment, safety, health, or management of DOE-related activities; and (3) cooperate with assessments used to verify that the contractor has acted to minimize, correct, or prevent recurrence of the situation that precipitated a valid concern.

DOE's program, as well as NRC's allegation program, encourages workers at nuclear facilities to take technical safety concerns to their own management first, but allow workers to bring safety concerns directly to the Federal agency, at any time. DOE's Order 442.1A (DOE, 2001f) states it is the Department's responsibility to respond to those concerns in a timely manner and to protect the identity of the individual to the degree possible. The ORP program implements the timeliness responsibility via time requirements, to provide the concern, once received, to the appropriate investigatory organization, but not necessarily to closure of the concern. How fast a concern is provided to the investigating organization depends on a severity-priority ranking system (e.g., imminent danger as compared to routine). Similarly, NRC actions to resolve concerns are prioritized, based on their safety or regulatory significance. If the concern requires immediate action to protect health and safety of the public, NRC immediately contacts the licensee and requests that it investigate the matter and take prompt corrective action. The NRC's allegation program also provides for confidentiality of allegers to the degree possible. In addition NRC has established timeliness goals for closing technical, non-wrongdoing allegations that do not require immediate action.

3.2.11.3 Results of Assessment

DOE ORP and its contractor implement separate employee concerns program. Although there are broad similarities between the DOE ORP employee concerns program and the NRC allegations program, there are some notable differences. First, the DOE employee concerns program does not focus solely on impropriety or inadequacy associated with DOE-regulated activities, but focuses more broadly on policies or practices that should be improved, modified, or terminated. Second, DOE has timeliness metrics for investigating employee concerns, but does not have goals for closing the concerns raised. Finally, the DOE and contractor employee concerns programs appears to only apply to DOE or contractor employees, whereas the NRC allegation program allows any individual to report a safety or security concern.

3.2.12 Probabilistic Safety Assessment and Safety Goals

3.2.12.1 Scope

This section reports results of NRC staff's review of the DOE process for performing and using probabilistic risk assessment in the context of the WTP program; then compares this DOE process to that which NRC would apply to this type of project. NRC staff has reviewed, and reports here, on DOE guidance regarding use of probabilistic risk assessment, on operational experience with probabilistic risk assessment in the WTP, and on how it supports decisions regarding construction and operating authorizations.

3.2.12.2 Assessment

3.2.12.2.1 NRC Probabilistic-Risk-Assessment Process

There is no explicit requirement, in Part 70, that a probabilistic risk assessment be performed for any major facility such as the WTP. In Subpart H of the regulation there is, however, a requirement that a licensee perform an integrated safety analysis, to identify all accidents that could lead to high or intermediate consequences -- high being greater than 1 Sv (100 rem) to a worker, or 0.25 Sv (25 rem) to a member of the public. Then it is required that controls be applied such that high-consequence events are "highly unlikely" and intermediate-consequence events are "unlikely". In Chapter 3 of NUREG-1520 (NRC, 2002) guidance is given on acceptable methods of performing an integrated safety analysis. One such acceptable method is a quantitative probabilistic risk assessment. Thus, under this existing regulation, there are two ways that a probabilistic risk assessment might be used: 1) the applicant may choose probabilistic risk assessment as its integrated safety analysis; or 2) NRC might require the applicant to perform a probabilistic risk assessment to achieve the required precision for the integrated safety analysis. This latter probabilistic risk assessment could be for purposes such as risk insights or design optimization, not for compliance.

In the first case, the quantitative guidance given in NUREG-1520 (NRC, 2002), as to what constitutes "highly unlikely" and "unlikely," is not a requirement. The guidance values of 10^{-4} for highly unlikely, and 10^{-5} for unlikely, are applied to individual accident sequences, not to the sum total over all sequences, as is being done for the operations risk assessment. These values are much higher than DOE ORP risk goals, because they are regarded as limits to support keeping risk out of the unacceptable range.

In the second case, probabilistic risk assessment would be performed, not for a determination of compliance with regulations, but to gain safety insights. NRC has guidance that describes how risk information can be used to support regulatory decisions (NRC, 2005b). Included in this guidance are six Quantitative Health Guidelines (QHGs), for nuclear material and waste. These QHGs are:

- QHG 1: probability of acute fatality to public
- QHG 2: expectation value of sub-lethal dose to public
- QHG 3: probability of serious injury to public
- QHG 4: probability of acute fatality to worker
- QHG 5: expectation value of sub-lethal dose to worker
- QHG 6: probability of serious injury to worker

3.2.12.2.2 DOE Probabilistic Risk Assessment Process

Secretary of Energy Notice SEN-35-91 (DOE, 1991) states that DOE has adopted two quantitative safety goals that "…should be viewed as aiming points for performance." These goals are the same as the NRC reactor safety goals; and are stated as being equal to 0.1 percent of corresponding U. S. average accident and cancer fatality risks. SEN-35-91 (DOE, 1991) further states that these goals are not a substitute for compliance with DOE directives and rules; and that these goals shall not be construed as a requirement to conduct probabilistic risk assessments.

DOE/RL-96-0006 (DOE, 2004) states three risk goals, summarized as follows:

- Operations Risk Goal: Less than 0.1 percent of U. S. cancer fatality risks to public and workers in the area of the facility.
- Accident Risk Goal: Less than 0.1 percent of U. S. fatal accident risk to average individual in the vicinity of the facility.
- Worker Accident Risk Goal: Risk to workers in the vicinity from radiological exposure should not be a significant contributor to overall occupational risk.

ORP has a guidance document (RL/REG-2000-08; DOE, 2002e) on conformance to risk goals. RL/REG-2000-08 interprets the meaning and quantitative value of these goals; and provides direction as to how they are to be used in the context of construction authorization and operations authorization approvals. For Operations Risk, the goal is stated quantitatively as $2x10^{-6}$ per year latent cancer fatality risk. This is for a hypothetical location of a person at the Hanford Site boundary. It also states that risks from normal operations shall be included with those from accidents. NRC probabilistic risk assessments do not consider releases resulting from normal operations, since these are limited and minimized by the Part 20 regulation. The DOE Accident Risk Goal is given as $4x10^{-7}$ per year prompt fatality risk to individuals outside the facility controlled area. The Worker Accident Risk Goal is given as $1x10^{-5}$ per year risk of a fatal accident to a site worker.

ORP's position in RL/REG-2000-08 (DOE, 2002e) is that for the construction authorization, comparison of risk assessment results need only be order-of-magnitude comparison. However, at the design confirmation stage, failure to meet the risk goals is to be resolved. In other words, at the final operating authorization stage, the plant must meet the risk goals.

3.2.12.3 Results of Assessment

There are at least two potential uses of probabilistic risk assessment in the context of NRC regulation of a WTP facility. Each of these NRC uses differs from the use of probabilistic risk assessment in the WTP. Neither NRC use of probabilistic risk assessment is mandatory.

The first type of use of NRC probabilistic risk assessment would be applied to individual accident sequences, not total risk. It would use risk limits much higher than the NRC and DOE safety goals. The second use of probabilistic risk assessment by NRC, for general risk-informing purposes, would use safety goals that are the same as DOE ORP, for offsite operational and accident risk, but this use by the NRC would not require that the safety goals be met. Whereas for the Hanford WTP, DOE ORP, as stated in RL/REG-2000-08 (DOE, 2002e), requires that their safety goals be met

3.2.13 Staffing Levels

As part of NRC's review of DOE's programs and practice, the staffing level and technical expertise of DOE's WTP related programs were compared to a comparable NRC regulatory program. NRC staff interviewed WTP-related DOE employees at Hanford and in the metropolitan Washington, DC area, and reviewed the pertinent organizational charts. NRC determined, within the scope of the NRC study, that the technical expertise applied by DOE is appropriate, both in terms of the breadth of technical disciplines applied and in terms of the

quality of the expertise of the individuals involved. The level of staffing by DOE ORP on the WTP is broadly comparable to the number of employees NRC involved in the regulation of a similar facility. However, DOE employees have the dual responsibilities as regulators and owners, and for certain technical disciplines, individual technical job responsibilities extend beyond the WTP (e.g., fire protection safety). As a result, although the staffing numbers may be comparable, the effective number of FTEs that DOE applies to ensuring nuclear safety is certainly less, albeit not easily quantifiable, than NRC would apply for regulation of a similar facility.

CHAPTER 4 CONCLUSIONS AND RECOMMENDATIONS

Section 4.1 summarizes the U.S. Nuclear Regulatory Commission's (NRC's) conclusions based on the review of the U.S. Department of Energy's (DOE's) regulatory process (Chapter 2) and DOE's program and practices in specific topical areas (Chapter 3). Section 4.2 suggests follow-up actions.

4.1 Conclusions

NRC conducted a high-level review of DOE's regulatory process for the WTP, to assess whether DOE's regulatory approach is broadly comparable to NRC's process for nuclear safety regulation. The staff reviewed DOE's statutory authority, legal requirements and DOE's activities that corresponded to NRC's regulatory process. NRC's regulatory approach encompasses: (1) regulations and guidance; (2) licensing; (3) regulatory oversight of licensed activities; (4) evaluation of experience; and (5) programs used to support regulatory decisions. NRC also reviewed some of DOE's programs and practices that carry out DOE's regulatory process, to assess the comparability to similar NRC programs and practices for regulating nuclear safety. NRC's review of these programs and practices addressed DOE's approaches for: (1) safety analysis (including hazard analysis); (2) radiation safety; (3) nuclear criticality safety; (4) chemical process safety; (5) fire safety; (6) environmental protection; (7) management measures; (8) inspection during construction and during operations; (9) enforcement; (10) allegations; and (11) risk assessment.

There are broad similarities between DOE's and NRC's regulatory processes for nuclear safety; but they differ in a few important ways. DOE has programs or activities corresponding to each part of NRC's regulatory process, except that DOE does not use an internal adjudicatory process for considering contentions filed by the operator or third parties, or otherwise formally involve stakeholders, including members of the public, in the construction authorization decision process. Because DOE is the owner and operator of the WTP, it is responsible for implementing regulations beyond those areas regulated by the NRC (e.g., non-radioactive hazardous waste, industrial safety, etc.). DOE is also responsible for meeting the milestone schedule of the Tri-Party Agreement. In addition, some of DOE's programs and practices vary noticeably from NRC's practices. The conclusions that follow focus on differences between the two agencies' approaches on both the regulatory framework (Chapter 2) and relevant programs and practices (Chapter 3). The conclusions for each of the three parts of the regulatory process are presented in the following three sections (Sections 4.1.1 through 4.1.3). NRC presents its conclusions regarding the level of staffing and technical expertise of the DOE WTP regulatory program in Section 4.1.4.

Although NRC makes a number of specific conclusions on both the regulatory framework and relevant program and practices, NRC did not attempt to assess the significance of these differences on safety of the WTP project. According to NRC's regulatory framework, an assessment of safety is conducted via a licensing review, which is beyond the scope of this report. While the NRC did not perform a detailed assessment of the safety significance of each difference identified in this report, the NRC's high-level review of DOE's regulatory process did not reveal any differences that would – on their face – jeopardize the protection of the public health and safety. In addition, this assessment is a snapshot in time (up to mid-March 2008) and did not attempt to assess comparable DOE programs, such as research activities, event

assessment, and performance assessment, that are part of NRC's regulatory framework. DOE addresses the status of DOE's disposition of NRC's previous significant issues (Appendix A of NRC, 2000a) in Appendix A of this report.

Table 4.1 below provides a list of the significant issues the NRC found that should be further considered by DOE. Table 4.1 also identifies topic areas where NRC and DOE approaches are not comparable.

Table 4.1. Significant Issues for Further Consideration

Review Topic	Area Not Comparable to NRC
Radiation Protection	Use of co-located worker
Nuclear Criticality Safety	Formal procedure for review of new or changed design
Chemical Process Safety	• Use of co-located worker • Deterministic chemical consequence criteria
Fire Protection	• Protection based on financial loss • Staffing levels
Management Measures	• Audit and assessment program • Quality assurance
Enforcement	• Incentives vs. Fines • Use of enforcement tools
Allegations	• Focused on improving policies and practices • Available only to DOE and its contractors

4.1.1 Policies, Regulations, and Guidance

Both DOE and NRC have a nuclear safety-related policy addressing safety goals, which define an acceptable level of radiological risk. The DOE goals are the same as the NRC reactor safety goals, which NRC does not apply to its fuel cycle facilities. DOE's additional responsibilities lead to differences between the regulations and guidance for the DOE and NRC regulatory process. DOE applies a broader nonradiological worker health and safety in the workplace regulation to its WTP program than NRC would under its regulatory program. As the owner of the WTP, DOE has responsibilities other than nuclear safety that include environmental compliance and industrial safety.

NRC's review of DOE's program and practices for the WTP also identified additional differences between DOE and NRC regulatory processes. There are differences between the agencies' event frequency definitions used in hazard analysis. DOE has guidance on the technical specifications information to present in a safety analysis, whereas NRC's guidance does not address that topic. Although similar to NRC's radiation protection regulation, there are minor elements of NRC's radiation protection program (e.g., respiratory protection) missing from DOE's radiation protection regulation. DOE's regulation uses a co-located worker approach for radiation protection and chemical safety. This use has the potential to produce differing classifications for systems, structures, and components required for risk reduction to workers and the public. DOE's regulatory requirements for criticality safety, while addressing the use of consensus standards similar to NRC, rely on previous versions of the standards. DOE identifies

specific chemical-consequence criteria that correspond to more deterministic effects, such as numbers of hospitalizations and deaths, whereas the NRC regulatory approach uses the likelihood, in the exposed population, of the onset of symptoms from exposure. The major differences in fire protection are in the design-build process, the focus on the level of protection based on financial loss, and in lower staffing levels. DOE ORP procedures and manuals address some areas in a general narrative manner, rather than with specific requirements and procedural directions. These procedures and manuals are not comparable to NRC's guidance for assessments. The WTP simulator training facility, as planned, exceeds the NRC requirements for similar licensed fuel cycle facilities. DOE's use of risk assessment is not comparable to NRC's use. DOE's guidance makes the risk goal a practicable requirement at the final authorization for operation. DOE's use of the co-located worker concept, compared with a member of the public, and application of the risk goals to normal operations, is also different from NRC's implementation of risk assessment practice.

Although DOE does not license the WTP, it documents its requirements (regulations, orders, guidance, and standards) for the WTP in a contract. The contract serves as the basis for safety and as the vehicle that DOE uses to ensure that its legislative and legal mandates for nuclear material processing activities are also met.

4.1.2 Licensing / Authorization

DOE's approach to authorization, although similar in some respects to NRC licensing, is substantially different from NRC's implementation of its licensing activities.

NRC issues an initial license before the start of construction, and this license is subsequently modified. DOE issues separate authorizations for construction and operation of the facility. There are five important differences between the licensing and authorization processes. First, DOE's authorization decisions address both the design for operability and production, as well as safety. Second, DOE's use of a design-build approach to the WTP leads to more significant changes in the authorization basis during the construction period. That approach makes the change-control process more important for ensuring safety under DOE regulation than it would under NRC regulation. DOE's approach allows a substantially less completely designed facility to be subject to construction authorization, whereas an applicant's substantially complete design, and design bases, is usually the focus of NRC's licensing decision. Third, the contract controls DOE's schedule for completing its review of authorization-basis amendment requests, which are contractor requests to deviate from the authorization basis. There are no contractual or regulatory requirements for NRC's licensing safety-review schedule, although NRC plans and conducts its licensing reviews in accordance with specific schedules. In general, NRC's safety review takes longer than the periods required in DOE's WTP contract. Fourth, NRC maintains the licensing basis as part of the publicly available licensing docket, whereas DOE allows the contractor to maintain, between DOE's biennial reviews, a document that incorporates all the authorization basis changes for the WTP. Finally, NRC has a program for adjudicating contentions as part of its licensing process, whereas DOE does not have a comparable program for authorizations.

NRC's review of DOE's authorization practices found there is less information in the DOE safety analysis on nuclear-criticality-safety technical practices than NRC would typically accept. NRC determined that the contractor's nuclear-criticality-safety staff involvement in the review of new or changed designs is not formalized in procedures, which could lead to a deficient safety basis for the facility, if it was not otherwise detected and corrected. For the WTP, DOE's nuclear criticality safety approach centers on the determination that a criticality accident is not credible.

If the contractor's approach to nuclear criticality safety changes and criticality accidents are considered credible, nuclear-criticality-safety controls would need to be established. This would be a major change for the DOE WTP nuclear-criticality-safety program. The DOE WTP decision-making process considers costs and schedule, whereas NRC does not directly include cost and schedule in the regulatory decision process. DOE fulfills the maintenance management-measure program differently than NRC. DOE used an Executive Order to ensure that a program was developed and implemented to preserve and maintain all structures, systems, and components bought for the WTP, during the time between receipt and commissioning the facility.

4.1.3 Oversight

Both DOE and NRC regulatory approaches include inspection, enforcement, allegation assessment, and investigations. DOE and NRC inspection are broadly comparable for nuclear safety; however DOE has added responsibility for operability and industrial safety inspection requirements. Both DOE and NRC address enforcement in a comparable manner -- at least for the regulatory requirements. DOE addresses allegations through an employee concerns program, which is partially comparable to the NRC allegation assessment program. The DOE Office of Inspector General carries out DOE's investigation-of-wrongdoing program. NRC has a separate Office of Investigations. DOE also has no separate investigation of wrongdoing requirements in the contract.

The DOE oversight program for the WTP has multiple layers of oversight, whereas NRC is the sole oversight authority for nuclear safety. DOE's approach includes direct ORP oversight of the WTP contractor, and line management oversight of ORP by the Office of Environmental Management. In addition internal independent oversight by the Chief of Nuclear Safety and the Office of Independent Oversight are applied to the contractor, ORP, and the Office of Environmental Management.

DOE has a process for addressing items identified by external oversight groups such as the Defense Nuclear Facilities Safety Board and the Hanford Advisory Board. DOE's process, which relies on a corrective action response system approach, was not used to address the significant issues identified in NRC's report on TWRS-P project (NRC, 2001a). Nevertheless, many of the 28 significant issues NRC documented in 2001, appear to have been addressed by DOE as the WTP project has progressed (see Appendix A).

The DOE construction-inspection program goes beyond the requirements of the programs and methods used by NRC. DOE inspects against more codes, stresses worker health and safety, and inspects suppliers of other than safety-related goods and services. The NRC review of DOE's audits and assessment program determined that DOE focuses its program on the ownership responsibilities, rather than its nuclear-safety requirements. Because of the dual roles and responsibilities and lack of independence of the DOE's Office of River Protection (ORP) oversight organizations and staff, the ORP assessment program is not equivalent to NRC staff audits and assessment program. NRC reviewed DOE ORP's configuration management, QA, and audits and assessment programs, and DOE's Office of Health, Safety and Security's enforcement program. NRC has four main conclusions. First, significant configuration-management functions and interfaces (e.g., assuring consistency of: (1) the safety basis; (2) design; (3) procured structures, systems, and components; and (4) construction) were not effective over an extended period of time. Second, significant safety program and QA functions and interfaces (e.g., (1) design control and verification; (2) procurement planning and verification; (3) receipt inspection; and (4) corrective action) were

not effective over an extended period of time. Third, the audit and assessment program was not effective in identifying these issues, determining the extent of condition, and resolving the issues. The NRC inspection and enforcement programs use enforcement options and tools to effect and verify adequate assurance of safety by the licensee. Fourth, the current regulatory and contractual requirements and processes, as carried out by DOE, do not provide equivalent oversight of the WTP. An effective enforcement program must result in timely enforcement action, identify the full extent of condition, and result in timely and complete corrective actions.

NRC reviewed DOE's inspection program for operations. DOE has just begun developing the WTP operations inspection program, so NRC has no definitive conclusion on comparability between the two agencies' programs.

DOE's employee-concerns program is not similar to NRC's allegations assessment program. The DOE program does not focus solely on impropriety or inadequacy associated with DOE-regulated activities, but focuses more broadly on policies or practices that should be improved, modified, or terminated. Unlike the NRC allegations program, which allows any individual inside or outside of NRC, to raise safety and security concerns, the DOE employee concerns program appears to be only available to employees of DOE and its contractors.

4.1.4 Staffing Levels

NRC compared the staffing level and technical expertise of DOE's WTP programs to a comparable NRC regulatory program. NRC staff interviewed WTP-related DOE employees at Hanford and in the metropolitan Washington, DC area, and reviewed the relevant organizational charts. NRC determined, within the scope of the NRC study, that the technical expertise applied by DOE is comparable to NRC's program. The breadth of technical disciplines applied and the quality of the expertise of the individuals involved are appropriate. The DOE ORP staffing level of the WTP is broadly comparable to the staffing level NRC would use for regulation of a similar facility. However, most all DOE employees have the dual responsibilities, as both regulators and owners. For certain technical disciplines, individual technical job responsibilities extend beyond the WTP (e.g., fire protection safety). As a result, although the staffing numbers may be comparable, the effective staff review time that DOE applies to ensuring nuclear safety is less (but not easily quantifiable) than NRC would apply for regulating a similar facility.

4.2 Recommendations

The regulations and requirements that DOE has in place, in most cases, are similar to the NRC's. Despite the issues identified in the report, the NRC believes that the DOE program, if properly implemented, is adequate to ensure protection of public health and safety. Therefore, the NRC makes no specific recommendations within the scope of this review.

Nevertheless, based on the review, NRC makes several suggestions for DOE's consideration. NRC suggests that DOE evaluate how these requirements are being implemented and how the transparency of its decisions and actions regarding the WTP could be improved. NRC also suggests that DOE consider the list of significant issues identified in Table 4.1 and the specific safety and regulatory issues in Table B.1 of this report. In addition, NRC suggests that DOE explore ways to gain and maintain more independence between regulatory oversight and project management functions.

CHAPTER 5 REFERENCES

Administrative Procedures Act, as Amended, P. L. 89-554, 80 Stat. 381 (1966).

American Concrete Institute (ACI), "Code Requirements for Nuclear Safety-Related Concrete Structures," ACI-349-01, Farmington Hills, Michigan, 2001.

American National Standards Institute, American Nuclear Society (ANSI/ANS), "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," ANSI/ANS-8.1-1983, La Grange Park, Illinois, 1983.

American National Standards Institute, Electronic Industries Alliance (ANSI/EIA), "National Consensus Standard for Configuration Management," ANSI/EIA-649, La Grange Park, Illinois, 1998.

American Society of Mechanical Engineers (ASME), "Quality Assurance Program Requirements for Nuclear Facilities/with Addenda," NQA–1–1994, New York, New York, 1994.

– – – 1996. "Process Piping," ASME B31.3, New York, New York, 1994.

Atomic Energy Act of 1954, as Amended, P.L. 83-703, 68 Stat. 919 (1954).

Bechtel National, Inc. (BNI), 2001. SRD 24590-WTP-RPP-ESH-01-001, Revision 0, "Radiation Protection Program for Design and Construction." BNI: Richland, Washington. December 2001.

– – – 2006. 24590-WTP-RPT-NS-01-001, Revision 5, "Preliminary Criticality Safety Evaluation Report for the WTP." BNI: Richland, Washington. December 2006.

– – – 2007a. 24590-WTP-SRD-ESH-01-001-02, Revision 4k, "Safety Requirements Document." BNI: Richland, Washington. October 2007.

– – – 2007b. 24590-WTP-QAM-QA-01-001, Revision 7b, "Quality Assurance Manual." BNI: Richland, Washington. October 2007.

Clean Air Act, as Amended, P.L. 88-206, 77 Stat. 392 (1963).

Clean Water Act, as Amended, P.L. 95-217, 91 Stat. 1566 (1977).

Code of Federal Regulations, *Title 10, Energy,* Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders."

Code of Federal Regulations, *Title 10, Energy,* Part 20, "Standards for Protection against Radiation."

Code of Federal Regulations, *Title 10, Energy,* Part 50, "Domestic Licensing of Production and Utilization Facilities."

Code of Federal Regulations, *Title 10, Energy,* Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.”

Code of Federal Regulations, *Title 10, Energy,* Part 70, “Domestic Licensing of Special Nuclear Material.”

Code of Federal Regulations, *Title 10, Energy,* Part 820, “Procedural Rules for DOE Nuclear Activities.”

Code of Federal Regulations, *Title 10, Energy,* Part 830, “Nuclear Safety Management.”

Code of Federal Regulations, *Title 10, Energy,* Part 835, “Occupational Radiation Protection.”

Code of Federal Regulations, *Title 10, Energy,* Part 851, “Worker Safety and Health Program.”

Code of Federal Regulations, *Title 10, Energy,* Part 1021, “National Environmental Policy Act Implementing Procedures.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1500, “Purpose, Policy, and Mandate.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1501, “NEPA and Agency Planning.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1502, “Environmental Impact Statement.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1503, “Commenting.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1504, “Predecision Referrals to the Council of Proposed Federal Actions Determined to be Environmentally Unsatisfactory.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1505, “NEPA and Agency Decision-making.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1506, “Other Requirements of NEPA.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1507, “Agency Compliance.”

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 1508, “Terminology and Index.”

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), P. L. 96-510, 42 U.S.C 9601 et seq., (1980).

Department of Energy (U.S.) (DOE). SEN-35-91, “Nuclear Safety Policy.” DOE: Washington, D.C. September 1991.

– – – 1993. DOE-STD-1073-93-Pt.2, “Guide for Operational Configuration Management Program.” DOE: Washington, D.C. November 1993.

– – – 1994. DOE/EH-0256T, Revision 1, “Radiological Control Manual.” DOE: Washington, D.C. April 1994.

– – – 1996a. DOE Policy 450.4, “Safety Management System Policy.” DOE: Washington, D.C. October 1996.

– – – 1996b. DOE/EIS-0189, “Tank Waste Remediation System, Hanford Site, Richland, Washington, Final Environmental Impact Statement.” DOE: Washington, D.C. August, 1996.

– – – 1996c. DOE Guide 1324.5B, “Implementation Guide for 36 CFR Chapter XII - Subchapter B.” DOE: Washington, D.C. July 1996.

– – – 1996d. DOE/RW-0333P, Revision 18, “Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program (QARD)” DOE: Washington, D.C. June 1996.

– – – 1999a. DOE Order 252.1, “Technical Standards Program.” DOE: Washington, D.C. November 1999.

– – – 1999b. DOE-STD-1066-99, “Fire Protection Design Criteria.” DOE: Washington, D.C. July 1999.

– – – 2000a. DE-AC27-01RV14136, “Bechtel National, Inc., Design, Construction, and Commissioning of the Hanford Tank Waste Treatment and Immobilization Plant.” DOE: Richland, Washington. 2000.

– – – 2000b. DOE-TSPP-3, Revision 4, “Use of Voluntary Consensus Standards and Interaction with Standards Development Organizations.” DOE: Washington, D.C. August 2000.

– – – 2000c. DOE-STD-1063-2000, “Facility Representatives.” DOE: Washington, D.C. March 2000.

– – – 2001a. DOE/RL-96-0005, Revision 2, “Concept of the DOE Regulatory Process for Radiological, Nuclear and Process Safety.” DOE: Richland, Washington. November 2001.

– – – 2001b. DOE/RL-96-0003, Revision 2, “DOE Regulatory Process for Radiological, Nuclear and Process Safety.” DOE: Richland, Washington. November 2001.

– – – 2001c. DOE/RL-96-0004, Revision 2, “Process for Establishing a Set of Radiological, Nuclear and Process Safety Standards and Requirements.” DOE: Richland, Washington. November 2001.

– – – 2001d. RL/REG-98-14, Revision 3, “Office of Safety Regulation Position on New Safety Information and Backfits.” DOE: Richland, Washington. March 2001.

– – – 2001e. RL/REG-98-17, Revision 2, “Office of Safety Regulation Position on Tailoring for Safety.” DOE: Richland, Washington. September 2001.

– – – 2001f. DOE Order 442.1A, “Department of Energy Employee Concerns Program.” DOE: Washington, D.C. June 2001.

– – – 2001g. RL/REG-99-05, “Review Guidance for the Construction Authorization Request (CAR)” Rev. 3.” DOE: Washington D.C. July 2001.

– – – 2001h. DOE Order 5480.19, Change 2, “Conduct of Operations Requirements for DOE Facilities.” DOE: Washington, D.C. October 2001.

– – – 2002a. DOE STD-3009-94, Change Notice 2, “Preparation Guide for U. S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analysis.” DOE: Washington, D.C. April 2002.

– – – 2002b. RL/REG-98-06, Revision 4, “Corrective Action Program Description.” DOE: Richland, Washington. 2002.

– – – 2002c. DOE Order 420.1A, “Facility Safety.” DOE: Washington D.C. May 2002.

– – – 2002d. DOE Order 451.1B, “National Environmental Policy Act Compliance Program.” DOE: Washington D.C. October 2002.

– – – 2002e. RL/REG-2008-08, Revision 2, “Office of Safety Regulation Position on Conformance with Risk Goals in DOE/RL-96-0006.” DOE: Richland, Washington. April 2002.

– – – 2003. DOE Policy 141.2, “Public Participation and Community Relations.” DOE: Washington, D.C. May 2003.

– – – 2004. DOE/RL-96-0006, Revision 3, “Top-Level Radiological, Nuclear and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor.” DOE: Richland, Washington. February 2004.

– – – 2005a. DOE Order 420.1B, “Facility Safety.” DOE: Washington, D.C. December 2005.

– – – 2005b. RL/REG-97-13, Revision 11, “Office of River Protection Position on Contractor-Initiated Changes to the Authorization Basis.” DOE: Richland, Washington. March 2005.

– – – 2005c. DOE Order 450.1, “Environmental Protection Program.” DOE: Washington, D.C. January 2005.

– – – 2005d. DOE Order 414.C, “Quality Assurance.” DOE: Washington, D.C. June 2005.

– – – 2006a. DOE/CF-0010, “U.S. Department of Energy Strategic Plan.” DOE: Washington, D.C. 2006.

– – – 2006b. “Notice of Intent to Prepare the Tank Closure and Waste Management Environmental Impact Statement for the Hanford Site, Richland, WA.” *Federal Register*, Vol. 71, No. 22, pp. 5655 – 5660. February 2, 2006.

– – – 2006c. Department of Energy (U.S.) and State of Washington, Civil No. 2:03-cv-05018-AAM, “Settlement Agreement re: Washington v. Bodman.” January 6, 2006.

– – – 2006d. Department of Energy (U.S.) and Washington State Department of Ecology, "Memorandum of Understanding Between the United States Department of Energy, and the Washington State Department of Ecology, for the Development of the Hanford Site Tank Closure and Waste Management EIS." January 6, 2006.

– – – 2006e. "Report of the Review of the Hanford Tank Closure & Waste Management Environmental Impact Statement (EIS)." DOE: Richland, Washington. October 2006.

– – – 2006f. DOE Order 413.3A, "Project Management for the Acquisition of Capital Assets." DOE: Washington D.C. July 2006.

– – – 2007a. DOE Order 226.1, "Implementation of Department of Energy Oversight Policy." DOE: Washington, D.C. July 2007.

– – – 2007b. DOE Order 433.1A, "Maintenance Management Program for DOE Nuclear Facilities." DOE: Washington D.C. February 2007.

– – – 2008a. Design Oversight Report Number D-08-Design-058, "Criticality Safety Program Assessment for the Waste Treatment and Immobilization Plant (WTP)." DOE: Richland, Washington. January 2008.

– – – 2008b. "Office of River Protection ORP Organization." <http://www.hanford.gov/orp/?page=8&parent=0> (22 April 2008).

– – – 2008c. ORP/OSR-2003-01, Revision 3, "Construction Authorization Agreement between the U.S. Department of Energy, Office of River Protection and Bechtel National, Inc." <http://www.hanford.gov/orp/uploadfiles/OSR-2003-01%20CAA%20Rev%20%203.pdf> (22 April 2008).

– – – 2008d. EA-2006-03, "Preliminary Notice of Violation and Proposed Civil Penalty - $198,000 (March 16, 2006)." <http://www.hss.energy.gov/enforce/eas/EA-2006-03.pdf> (20 May 2008).

– – – 2008e. EA-2007-05, "Preliminary Notice of Violation (October 4, 2007)." <http://www.hss.energy.gov/enforce/eas/EA-2007-05.pdf> (20 May 2008).

– – – 2008f. DOE Order 430.1B, Change 1, "Real Property Asset Management." DOE: Washington D.C. February 2008.

Washington State Department of Ecology (Ecology) 2002. Publication Number 01-05-006, "Fact Sheet for the Hanford Facility Resource Conservation and Recovery Act Draft Permit for the Treatment, Storage, and Disposal of Dangerous Waste." Ecology: Olympia, Washington. September 18, 2002.

– – – 2007. "Dangerous Waste Portion of the Resource Conservation and Recovery Act Permit for the Treatment, Storage, and Disposal of Dangerous Waste, Part III, Operating Unit 10 (WA7890008967), Waste Treatment and Immobilization Plant." Ecology: Olympia, Washington. October 29, 2007.

Ecology, et al. "The Hanford Federal Facility Agreement and Consent Order, as amended." Washington State Department of Ecology, U.S. Environmental Protection Agency, and U.S. Department of Energy: Olympia, Washington. 1989.

Energy Reorganization Act of 1974, P.L. 93-438, 88 Stat. 1233 (1974).

Hobson, D. and P. Visclosky (Committee on Appropriations, Subcommittee on Energy and Water Development, U. S. House of Representatives) 2008. Letter to: D.E. Klein (Chairman, U. S. Nuclear Regulatory Commission). May 2, 2008. Located at: Agencywide Documents Access and Management System (ADAMS), ML081410077.

International Organization for Standardization (ISO), "Quality Management – Guidelines for Configuration Management," ISO 10007:1995, Geneva, Switzerland, 1995.

Klein, D.E., U.S. Nuclear Regulatory Commission, letter to Honorable B. Boxer, U.S. Senate, ADAMS ML080440470, March 21, 2008.

National Environmental Policy Act of 1969, as Amended, P.L. 91-190, 83 Stat. 852 (1970).

National Technology Transfer and Advancement Act of 1995, P.L. 104-113, 110 Stat. 776 (1995).

National Fire Protection Association (NFPA). NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Material." NFPA: Quincy, Massachusetts. 2003.

– – – 2007. NFPA 13, "Standard for the Installation of Sprinkler Systems." NFPA: Quincy, Massachusetts. 2007.

U. S. Nuclear Regulatory Commission/Occupational Safety and Health Administration, (NRC/OSHA) 1988. "Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, Worker Protection at NRC-Licensed Facilities." *Federal Register* No. 53, October 31, 1988.

Nuclear Regulatory Commission (U.S.) (NRC) 1998a. SECY-98-038, "Hanford Tank Waste Remediation System Privatization Co-located Worker Standards." NRC: Washington, D.C. March 1998.

– – – 1998b. SRM-SECY-98-038, "Staff Requirements – SECY-98-038 – Hanford Tank Waste Remediation System Privatization Co-located Worker Standards." NRC: Washington, D.C. April 1998.

– – – 1999. Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards." NRC: Washington, D.C. November 1999.

– – – 2000a. NUREG-1702, Final Report, "Standard Review Plan for the Review of a License Application for the Tank Waste Remediation System Privatization (TWRS-P) Project." NRC: Washington, D.C. March 2000.

– – – 2000b. NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed-Oxide (MOX) Fuel Fabrication Facility." NRC: Washington, D.C. August 2000.

– – – 2001a. NUREG–1747, “Overview and Summary of NRC Involvement with DOE in the Tank Waste Remediation System-Privatization (TWRS-P) Program.” NRC: Washington, D.C. June 2001.

– – – 2001b. NUREG-1513, “Integrated Safety Analysis Guidance Document.” NRC: Washington, D.C. May 2001.

– – – 2002. NUREG–1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.” NRC: Washington, D.C. March 2002.

– – – 2005a. Regulatory Guide 3.71, Revision 1, “Nuclear Criticality Safety Standards for Fuels and Material Facilities.” NRC: Washington, D.C. July 2005.
– – – 2005b. “Risk-Informed Decision-Making for Nuclear Material and Waste Applications.” (ADAMS ML042730524). NRC: Washington, D.C. May 11, 2005.

– – – 2008a. NUREG-1614, Vol. 4, “Strategic Plan Fiscal Years 2008–2013.” NRC: Washington, D.C. February 2008.

– – – 2008b. “How We Regulate.” <http://www.nrc.gov/about-nrc/regulatory.html> (4 April 2008).

– – – 2008c. “Safety Goals for the Operation of Nuclear Power Plants (51 FR 28044; August 4, 1986, as corrected and republished at 51 FR 30028; August 21, 1986).” <http://www.nrc.gov/reading-rm/doc-collections/commission/policy/#power> (11 April 2008).

Office of Management and Budget (OMB). Circular A-119, Revised, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.” OMB: Washington, D.C. February 1998.

President, The. Executive Order 13327, “Federal Real Property Asset Management.” *Federal Register*, Vol. 69, No. 25, pp. 5897 – 5900. February 6, 2004.

Resource Conservation and Recovery Act of 1976, P. L. 94-580, 90 Stat. 2796., as amended (1976).

Toxic Substances Control Act, P. L. 94-469, 80 Stat. 381, 90 Stat. 2003, as amended (1976).

U.S. Congress, House Committee on Appropriations, “Committee Print, Consolidated Appropriations Act, 2008, H.R. 2764; Public Law 110–161,” January 2008.

THIS PAGE INTENTIONALLY LEFT BLANK

APPENDIX A

STATUS OF SIGNIFICANT NRC ISSUES IDENTIFIED IN NRC'S 2001 CLOSEOUT REPORT

THIS PAGE INTENTIONALLY LEFT BLANK

ABBREVIATIONS

ASME	American Society of Mechanical Engineers
BNI	Bechtel National, Inc.
CFR	Code of Federal Regulations
DBE	Design Basis Event
DOE	U.S. Department of Energy
HLW	High-Level Waste
LAW	Low Activity Waste
NRC	U.S. Nuclear Regulatory Commission
ORP	Office of River Protection, DOE
PSAR	Preliminary Safety Analysis Reports
QAM	Quality Assurance Manual
SER	Safety Evaluation Report
SRD	Safety Requirements Document
TWRS-P	Tank Waste Remediation System-Privatization
WTP	Waste Treatment Plant

THIS PAGE INTENTIONALLY LEFT BLANK

INTRODUCTION

In response to a letter from Chairman Visclosky and Representative Hobson of the House Appropriations Subcommittee (Hobson and Visclosky, 2008), dated May 2, 2008, the U.S. Nuclear Regulatory Commission (NRC) staff reviewed the U.S. Department of Energy's (DOE's) efforts to address the significant issues NRC raised during its involvement in the Tank Waste Remediation System-Privatization (TWRS-P) project (Appendix A in NRC, 2001). NRC described DOE's process for addressing items provided to DOE as the result of external oversight in Section 2.2.2.3.1.

An update on DOE's resolution of the significant issues is included in Table A.1. Due to the scope of NRC's review, the NRC did not assess or inspect the resolution status of the over fifty specific topics in the Hanford Waste Treatment Plant (WTP) design and approach that required further efforts and analysis (NRC, 2001). The status of DOE's disposition, as presented in the following table, reflects a short, but significant, effort to be responsive to NRC's request for information on the status of each of the items. NRC has not attempted to assess whether DOE's information in Table A.1 is responsive to the issues raised by NRC. An effort to assess whether DOE's information provided in Table A.1 is responsive and resolves the significant issues raised in NRC's report (2001) would require substantially more time and funded resources than used in this study.

Table A.1. Disposition of NRC's Significant Issues

Issue Number, Topic, and Status of DOE's Disposition
1 Level of Detail The current WTP design is 76 percent complete [versus 14 per cent when NUREG 1747 (NRC, 2001) was written]. The latest Preliminary Safety Analysis Report (PSAR) submitted by the WTP Contractor, Bechtel National, Inc. (BNI), provides extensive system descriptions and references, including classifications of safety systems, and detailed commitments to integrated safety management processes. The PSAR is in six volumes and is dated March 31, 2008. This revision is currently under review by the DOE Office of River Protection (ORP), with a Safety Evaluation Report (SER) scheduled to be issued June 30, 2008. SERs for earlier revisions of the PSAR, and the earlier DOE approved revisions were issued beginning in 2003, 2004, and 2006.
2 Reasonable Conservatism and Adequate Assurance of Safety The hazard analyses referenced in the PSAR use very conservative estimates of the quality and quantity of hazardous substances that could hypothetically be released due to operation under any credible circumstance. This is consistent with the requirements of 10 CFR 830 that hazard analyses start with a so-called "unmitigated scenario" that determines the consequences of release of hazardous substances that are present, without any assumption that safety systems mitigate or prevent this release. Then, based on the severity of these unmitigated consequences, a succession of safety controls are required to ensure that credible hypothetical events are either prevented, or have very low consequences. When NUREG-1747 (NRC, 2001) was issued in 2001, the Contractor had not completed these unmitigated scenario calculations to meet DOE's requirements. Since then, with the issuance of the PSARs described in Issue # 1, the analyzed hazards of the WTP have been adequately described and controlled, subject to verification by DOE of the final description of controls by the Contractor in the

Table A.1. Disposition of NRC's Significant Issues, Cont.
2 Reasonable Conservatism and Adequate Assurance of Safety, Cont. Documented Safety Analysis, to be submitted approximately one year before the start of cold (non-radioactive) testing of the facility.
3 Risk Based Design Approach The design approach for the facility is not primarily "risk based." The design approach, as discussed in Issue # 2 above, starts with a non probabilistic assessment of the worst consequences that could occur at the facility, then requires development of safety controls to ensure the expected consequences with controls are low. These controls are applied using DOE O 420.1 (DOE, 2002a) and DOE STD 3009 (DOE, 2002b), as required by Part 830. In addition, the Contract (DOE, 2000) has required one method of verification of the adequacy of the design to be an assessment of the total risk of the facility, using the risk objectives assigned by the Secretary of Energy in Secretarial Energy Notice, SEN 35-91 (DOE, 1991). This verification is a secondary objective. Rigorous estimation of risk using a probabilistic risk assessment is subject to many uncertainties for a one of a kind facility. This is one of the reasons DOE does not rely on this technique for its primary method of assuring adequate safety from nuclear, radiological and process safety hazards to the public and workers at the WTP, as pointed out in the NUREG 1747 (NRC, 2001) statement of this issue.
4 Redundancy and Defense in Depth The defense in depth concept applied to this project ensures that safety will be maintained. Defense in depth provides safety margins. Redundancy is a requirement for certain systems. Defense in depth is described for every design basis event (DBE) in the PSAR in Sections 3.34.x.x.x.6, "Requirements for Selected Control Strategy." In addition, redundancy and defense in depth is required by the Safety Requirements Document (SRD; BNI, 2007a). Appendix B, "Implementing Standards for Defense in Depth" is dedicated to detailing the requirements for defense in depth. Redundancy is addressed in many places in the SRD, for example, in Safety Criteria 4.3-2, 4.3-3, 4.3-5, 4.4-3, 4.4-4, 4.5-1, and in Appendices A and B.
5 Design/Authorization Bases, Concept Evolution, Design Changes and Integration In the eight years since NUREG 1747 (NRC, 2001) was written, the control of the authorization basis has evolved. The Contractor is required to perform safety evaluations for all changes affecting safety. Changes that are significant have to be submitted to DOE for review and approval prior to implementation. The Contractor has developed implementing procedures that institutionalize the safety evaluation process. For those changes submitted to DOE for review, DOE issues a SER assessing the change for safety and conformance with requirements. In addition, DOE performs a periodic review of the PSAR to ensure that all safety evaluations are properly reflected in it. This ensures that the PSAR accurately describes plant design.
6 Safety Emphasis The management of the WTP by DOE necessarily includes frequent consideration of cost and schedule. Given the large cost of the facility, and the limitations in the cleanup budget allocated by Congress to this project, this is one of DOE's responsibilities. However, from the outset, DOE has provided dedicated staffing and resources to conduct the safety reviews and inspections required to ensure the WTP is adequately

Table A.1. Disposition of NRC's Significant Issues, Cont.
6 Safety Emphasis, Cont. safe when it operates. Most importantly, within DOE, from the Secretary of Energy, to the Project Manager for the WTP, all of the direct line managers for the WTP recognize that adequate nuclear, radiological, and process safety of the WTP is essential and must be achieved. To that end, initially, in the privatization phase, a dedicated, large Regulatory Unit with the single purpose of nuclear and radiological safety oversight was chartered and staffed. With the end of privatization, this Regulatory Unit was reorganized into an independent Office of Safety Regulation within ORP in 2001-02. The DOE charter and resources for the Office of Safety Regulation were comparable to those provided by the Regulatory Unit. This organization conducted the initial construction authorization reviews of the PSAR in 2002-03. These reviews were very extensive. Subsequently, as the preliminary design has matured, fewer resources have been required to review and approve evolutionary changes to the original design, and dedicated resources have slowly been reduced as the work necessary to conduct these reviews has diminished. Throughout, DOE has ensured selected personnel are only tasked with ensuring adequately safety of the design of the facility. In addition, DOE has assigned significant numbers of field inspectors and Facility Representatives who have assurance of construction safety as one of their principal responsibilities, with neither cost nor schedule a principal responsibility. Finally, other project personnel consider cost, schedule, and safety in their assignments.
7 Dose Assessment Methodology including Data Sources In the eight years since NUREG 1747 (NRC, 2001) was written, the methodology for dose assessment, including the development of source terms, has been developed by the Contractor. The source terms are generally conservative as well as the credit given for preventive and mitigative safety functions. The methodologies that are used are industry consensus methods which are consistent with NRC recommendations. For example, methods for calculating radiation dose rates in the facility prescribes the Microshield code and the Monte Carlo N-Particle code which are industry consensus approaches for radiation doing dose rate calculations. Regarding the selection and use of source data, the source data are explained in every DBE in the PSAR, typically in the Sections 3.4.x.x.x.1, "Accident Scenario," and 3.4.x.x.x.2, "Evaluation of Source Term."
8 Optimistic Design Assumptions Impact on Operations and Maintenance As discussed above, the safety analysis is much more mature now than it was in 2001, when NUREG 1747 (NRC, 2001) was published. The safety analysis relies on very conservative estimates of the radioactive source terms postulated to credibly occur during off-normal events. During normal operations, the facility will be required to keep radioactive exposures to personnel as low as is reasonably achievable. All operations of the facility with radioactivity or hazardous chemicals will be required to meet the rigorous limitations on personnel exposure of 10 CFR 835 and of the Technical Safety Requirements for the facility (once the final design is approved). As experience with facility operations is gained, DOE expects the WTP will improve its reliability and performance, as is typical. To improve both the initial and life cycle performance of WTP, DOE is continuing process testing to identify and correct weaknesses in the design that could reduce its reliability or throughput. Extensive melter and ion exchange testing has been completed. Work is currently underway evaluating mixing, erosion, solid/liquid separation, caustic leaching, and oxidative leaching. An effort to identify process limits and conditions requiring further testing is also in progress. Extensive operations

Table A.1. Disposition of NRC's Significant Issues, Cont.
8 Optimistic Design Assumptions Impact on Operations and Maintenance, Cont. research modeling to evaluate the impact of component failures and repair times on plant availability is being conducted, as well. These process improvements will be based on a test program using an engineering scale prototype that is under construction.
9 Uncertainties Uncertainties are addressed for every DBE in the PSAR, typically in the Sections 3.4.x.x.x.7. Assumptions supporting conservative selections of parameters are presented, and explained. For example, in the waste drum drop accident, Section 3.4.1.6.1.7, explains that no credit is taken for the energy absorbed by the container or drum. For the case where a loaded high efficiency particulate air filter, known as HEPA filter, is crushed, in Sections 3.4.1.6.1.7 and 3.4.1.6.4.7, the conservatisms in the leak-path factor, meteorological-dispersion factor, inhalation-unit-liter dose, material at risk, damage ratio, the air-release fraction and respirable fraction are discussed. While uncertainty bounds are not carried through the calculations, the calculations are based on conservative selection of parameters. DOE considers the project is being implemented consistent with industry accepted practice for the use of conservative parameters and assumptions that would be expected to envelope uncertainties by a wide margin.
10 Lack of Methodology and "Reasonable" Criteria" for Selecting Approaches and Input Values The methodology and calculations used by the Contractor in the design and analyses supporting that analysis are described in the PSAR, and have been reviewed by DOE in the associated SERs for the PSAR. Insofar as establishing safety controls, this methodology and calculations are deterministic, using the guidance required by Part 830 in DOE O 420.1 (DOE, 2002a) and DOE STD 3009 (DOE, 2002b). As discussed above, relative to DOE's safety goal, probabilistic safety methodology for the WTP is still under development, but is not a primary element in the development of safety control strategies. DOE expects the probabilistic assessment of WTP by the Contractor to continue to mature, as the design is finalized, so that it eventually may become a useful component of risk informed operational decision making, similar to what has occurred with commercial nuclear power reactors regulated by the NRC.
11 Definition of Unmitigated Events DOE agrees that at the time of the NRC assessment (NRC, 2001), Contractor safety assessments did not consistently assess the consequences of unmitigated events properly, as defined by Part 830, and DOE STD 3009 (DOE, 2002b). As the Contractor design and safety analysis has matured since 2001 when NUREG 1747 (NRC, 2001) was issued, this weakness has generally been eliminated. Occasional isolated repetitions of this weakness reoccur. In its reviews of Contractor PSAR Updates, and authorization-basis-amendment requests (which are incremental design and standards change proposals from the Contractor), DOE rigorously enforces the requirements for unmitigated hazard analyses to determine required safety controls. Consequently, DOE is confident that the current approved safety basis for the preliminary design will provide adequate safety to workers and the public.

Table A.1. Disposition of NRC's Significant Issues, Cont.
12 Criticality Analysis The WTP criticality design and safety analyses have been modified and extensively revised since NUREG 1747 (NRC, 2001) was issued. DOE will ensure that the final approved design meets Part 830 and DOE O 420.1 (DOE, 2002a), as required. Based on the current criticality analysis referenced in the PSAR, DOE expects that existing open review issues should be resolved without requiring significant rework of the facility design or safety controls by the Contractor, by improving the current criticality analyses. Final confirmation of the design and safety management systems will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
13 Future Site Conditions DOE agrees that the potential effects of reducing the site boundary to a position closer to the facility boundary have not been considered in the design of the facility. If DOE were directed to make such a reduction to meet other important national priorities, it is possible that refinement of the safety analysis would still permit such a reduction, given the large safety margins that exist in the current assumed source term for the facility. However, at this point, such reductions are not planned, so no detailed analysis of the impacts of such a reduction has been performed.
14 Process Technology DOE agrees that when NUREG 1747 (NRC, 2001) was issued in 2001, technology development and testing for the WTP was incomplete. Since that time, an extensive research and technology program has been implemented. Testing has been performed on Low Activity Waste (LAW) and High-Level Waste (HLW) melters, offgas systems, evaporators, ion exchange systems (including development of a superior cesium ion exchange resin), mixing systems, sampling systems, and other processes. Testing is continuing and includes an engineering scale (1:4.5) pretreatment system that will demonstrate the WTP Pretreatment Facility process (excluding evaporators and cesium ion exchange that were previously tested). Integrated testing will begin in late calendar year 2008. This testing will confirm design assumptions and provide improved estimates of system capacity. Since facility safety controls require the achievement of specified process inventories, any failure to achieve assumed constituent inventories at a step in the process will result in delay or inoperability of the process until the deficiency is corrected, but not increased hazard to the workers or public. These process corrections will occur as a result of operator adherence to the Technical Specification Requirements, regardless of production goals, as well as adherence to required safety management programs (for example, quality assurance, maintenance, surveillance, training). Final confirmation of the design and safety management systems related to process technology will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
15 Consequences of Extremely Unlikely Seismic Events DOE requirements for nuclear facilities [Part 830 and DOE Order 420.1 (DOE,2002a), specifically] require that a nuclear facility such as the WTP be designed to withstand a 2500 year earthquake, using the seismic requirements delineated in DOE STD 1020 (DOE, 2002c), DOE STD 1021 (DOE, 1993), and DOE STD 1023 (DOE, 1995). Since the issuance of NUREG 1747 (NRC, 2001), the facility seismic design has advanced

Table A.1. Disposition of NRC's Significant Issues, Cont.
15 Consequences of Extremely Unlikely Seismic Events, Cont. such that its seismic design has been completed, to these requirements. In addition, in 2005-2007, DOE requested Pacific Northwest National Laboratory to conduct an extensive, $18 million borehole drilling project at the site to characterize the basalt-interbed structures that underlie the site. With the completion of this work, the site response to an earthquake is very well understood. The results of this project have been documented (Rohay and Brouns, 2007). In addition, as described in the "DOE Position" in NUREG 1747 (NRC, 2001), DOE required the Contractor to complete a seismic fragility study to ensure that the WTP facility did not have vulnerabilities to a seismic event that exceeded the required 2500 year design basis earthquake. Preliminary DOE analyses using rudimentary models of the design were performed in 1999 and 2000. The Contractor follow-up study was completed and concluded that the risk of beyond design basis seismic events was within the project risk goals.
16 Seismic Probabilistic Risk Analysis A limited seismic probabilistic fragility analysis was done in 2003 and is summarized in Section 3.7 of Volume 1 of the March 2008 PSAR. As noted above, assurance of seismic safety is primarily provided by compliance with the seismic standards cited in Issue # 15. The additional seismic fragility analysis that was performed is an additional measure to assure that the overall facility risk goal in SEN 35-91 (DOE, 1991) can be attained. This probabilistic fragility analysis is inherently subject to many uncertainties, given the one-of-a-kind nature of the facility. Contractor evaluation of changes in the design indicates that conclusion of the seismic probabilistic risk analysis remain valid. Final confirmation will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
17 Fire Protection Since the issuance of NUREG 1747 (NRC, 2001) in 2001, the fire protection hazard analysis and design has advanced considerably. The current analysis is provided in six volumes that address: (1) general information; (2) balance of facilities; (3) analytical laboratory; (4) LAW building; (5) pretreatment building; and (6) HLW building. DOE approved this analysis in the SER for the 2006 PSAR. Final confirmation of the design and safety management systems related to fire protection will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
18 Explosive Hazards NUREG 1747 (NRC, 2001) relates the status of investigation of explosive hazards at the time of NRC involvement in 2001. The concerns identified by the NRC were also identified by DOE as needing resolution. This topic was thoroughly explored in the review by DOE of the initial PSAR in 2003 and in the review of subsequent PSAR updates in 2004, 2006, and 2008 and was, and will be, documented in the respective SERs. Although most issues related to explosive hazards (in particular, steam explosions, nitrate-organic reactions, and sugar dust explosions) have been resolved, resolution of credible hydrogen explosions due to radiolysis and thermolysis is still incomplete. An extensive review and subsequent series of design changes to reduce

Table A.1. Disposition of NRC's Significant Issues, Cont.
18 Explosive Hazards, Cont. this hazard has occurred. Extensive changes to the design were proposed by the Contractor to ensure adequate mixing of the process waste in vessels, and to ensure removal of evolved explosive gases (mainly hydrogen) from the vessels. In addition, significant work is in progress to address the "hydrogen in piping and ancillary vessels (HPAV)" hazard. As a result of these design changes and new operational administrative requirements, explosions in vessels are prevented, but, in a few instances, rare explosions in small diameter piping are not planned to be prevented, but will be mitigated by design features (such as thicker, stronger piping). Such explosions are considered extremely unlikely, but may still occur once or twice in a stagnant section of piping in the plant, using conservative assumptions. To ensure adequate safety in such cases, ORP has established criteria that any hydrogen explosions not produce inelastic deformation of piping. The Defense Nuclear Facilities Safety Board has been briefed on these criteria by DOE. Prediction of the loading in hydrogen explosions is based on the loading information determined by new research at the Caltech Explosion Dynamics Laboratory, on deflagration to detonation transition shocks in piping (Liang, et al., 2006). Currently, DOE is sponsoring additional further research at Caltech and the Southwest Research Institute to predict loads from hydrogen explosions on pipe supports in representative piping systems. Final confirmation of the design and safety management systems for explosive hazards will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
19 Compliance with NQA-1 Since the issuance of NUREG 1747 (NRC, 2001) in 2001, ORP has approved the initial Quality Assurance Manual (QAM) for the Contractor, after a review to ensure it met the DOE requirements of Part 830, Subpart A, and the American Society of Mechanical Engineers (ASME) NQA-1 standard (ASME, 1989). This QAM is updated annually by the contractor, and all revisions are reviewed and approved (if acceptable) by ORP. In its latest revision (BNI, 2007b), the QAM implements the requirements of NQA-1 2000 (ASME, 2000) and the safety software criteria in DOE Order 414.1C (DOE, 2005). As required by Part 830 and the approved QAM, the Contractor has a suite of implementing procedures and administrative processes to detail the implementation of quality assurance at WTP.
20 Quality Assurance Program Implementation Since the issuance of NUREG 1747 (NRC, 2001) in 2001, the Contractor has implemented an extensive quality assurance program. This program includes oversight to verify the implementation of sub-tier quality assurance programs by its subcontractors. DOE periodically performs oversight of the Contractor's and subcontractor implementation of quality assurance program requirements, as required by NQA-1.
21 Safety Classification of Structures, Systems, and Components and Graded Quality Assurance The complete safety classification of structures, systems and components has now been developed by the Contractor for the WTP project. It follows the guidance of DOE Standard 3009 (DOE, 2002b). This approach is very similar to that used by NRC in nuclear power plant application and graded appropriately for the hazards associated with

Table A.1. Disposition of NRC's Significant Issues, Cont.
21 Safety Classification of Structures, Systems, and Components and Graded Quality Assurance, Cont. the WTP project. The most robust classification is "Safety Class," the next is "Safety Significant" and the last is "Additional Protection Class." Each class carries their own design standards. The class that applies depends on the severity level for the event. The severity level is determined based on the unmitigated calculation of exposure to the public, to co-located workers or to workers.
22 Chemicals and Their Safety Since the issuance of NUREG 1747 (NRC, 2001) in 2001, an extensive hazard analysis of chemical safety issues has been completed. As noted in Issue # 1 above, the facility design has progressed from 14 percent to 76 percent. The current design and hazard analyses are summarized in the PSAR, and its updates, that were issued beginning in 2003, continuing to the latest submittal in 2008. DOE's review and acceptance of these analyses has been documented in the corresponding SERs. Final confirmation of the design and safety management systems for chemicals will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
23 Iodine Removal Since the issuance of NUREG 1747 (NRC, 2001) in 2001, an extensive hazard analysis of iodine removal safety issues has been completed. The current design and hazard analyses are summarized in the PSAR, and its updates, that were issued beginning in 2003, continuing to the latest submittal in 2008. The design also incorporates silver mordenite columns in the HLW Facility, and activated charcoal beds in the LAW Facility portions of the WTP, which should provide additional iodine removal (to the extent that iodine is found in the processed waste). DOE's review and acceptance of these analyses has been documented in the corresponding SERs. DOE will require the caustic scrubber system depended on for iodine removal to be operable. If, in the future, DOE should move the Hanford site boundary closer to the WTP facility, further safety analysis, and, potentially, additional iodine control technology, would be added to the facility to ensure adequate safety for the workers and public, if needed to meet the nuclear safety regulatory requirements of Part 830. Final confirmation of the design and safety management systems for iodine removal will occur with the review and approval of the Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
24 Increased Tankage and Inventories Since the issuance of NUREG 1747 (NRC, 2001) in 2001, the design of the feed receipt tankage has changed from six large receipt tanks to four. The hazards of this inventory are analyzed in the PSAR, and its updates, that were issued beginning in 2003, continuing to the latest submittal in 2008. DOE's review and acceptance of these analyses has been documented in the corresponding SERs. DOE considers the hazards of the feed receipt tankage to be well understood and has concluded that the Contractor's design and safety management systems should provide adequate safety to the public and workers. Final confirmation of the design and safety management systems for hazardous tankage will occur with the review and approval of the

Table A.1. Disposition of NRC's Significant Issues, Cont.
24 Increased Tankage and Inventories, Cont. Documented Safety Analysis, which is required to be submitted one year before the start of cold testing.
25 Inspection Features Inspection features required in the design are developed in the Contractor hazard analysis process, and described in the PSAR. DOE subsequently reviews and approves the PSAR. Designs are reviewed in integrated safety management meetings (a broad cross-disciplinary review) to ensure that inspection features are established where appropriate. The plant is designed such that "black cells" -- those cells that cannot be entered after hot operation commences -- have only passive components in them that are designed to not require maintenance for the life of the facility. Other, normally inaccessible areas are designed with maintenance ports, cameras, manipulator ports, or viewing shield windows so that equipment in the cells requiring maintenance can be inspected and maintained. Equipment outside black cells is accessible for inspection and maintenance. Active components outside black cells have surveillance requirements associated with them as required by the SRD (BNI, 2007a).
26 Chemical versus Radiological Risk The DOE requirements for protection from chemical hazards are defined in the Safety Requirements Document Safety Criterion 2.0.2 (BNI, 2007a), and derive from the requirements in Part 830 and DOE STD 3009 (DOE, 2002b) to ensure adequate protection from radioactive and hazardous chemicals. To this end, consensus national standards for the protection of workers and the public from chemical hazards, as described by Emergency Response Planning Guideline limits established by the American Industrial Hygiene Association, are employed. In addition, the requirements of 40 CFR 68 related to hazardous chemical protection, and 29 CFR 1910 and 10 CFR 851 related to integrated safety management hazard analysis and worker industrial protections from hazardous chemicals, are invoked.
27 Reliance on the Operators Since the issuance of NUREG 1747 (NRC, 2001), the design of the LAW melter has evolved, but operator access for maintenance is still assumed. This does not indicate a preference for administrative controls and operator actions (including evacuation) over engineering and design controls. The opposite is correct, and required by the Safety Requirements Document (BNI, 2007a), and the nuclear safety regulation Part 830 [through its subordinate DOE Order 420.1 (DOE, 2002a)]. The fundamental engineering control that is required for operator protection in the LAW melter is a redundant safety significant interlock in the Pretreatment Facility feed piping to ensure that high activity feed is not inadvertently sent to the LAW melter. Another important control is redundant safety significant ventilation fans to ensure that in the event of loss of normal melter ventilation, evolved NOx gas does not asphyxiate operators working near the melters. Shielding is a design feature provided in the LAW facility for areas that will otherwise produce excessive exposure of operators. Administrative controls, including operator actions, are part of the defense in depth hierarchy of safety controls that ensure adequate safety for the public and operators.

Table A.1. Disposition of NRC's Significant Issues, Cont.
28 TWRS-P Site Specific Geophysical and Geotechnical Investigation Report Since the issuance of NUREG 1747 (NRC, 2001) extensive site specific geophysical and geotechnical investigations have been completed, and used to revise the seismic design basis for the facility. A discussion of the most recent of these activities is found in Rohay and Brouns (2007). The current seismic design basis for the facility is described in the Safety Requirements Document (BNI, 2007a), Safety Criterion 4.1-3 and Table 4-1. As a result of this additional geotechnical investigation, the peak horizontal ground acceleration is anchored at 0.30 g, significantly greater than the 0.26 g value assumed in the period when NUREG 1747 (NRC, 2001) was developed.

REFERENCES

American Society of Mechanical Engineers (ASME), "Quality Assurance Program Requirements for Nuclear Facilities/with Addenda," NQA–1–1989, New York, New York, 1989.

American Society of Mechanical Engineers (ASME), "Quality Assurance Program Requirements for Nuclear Facilities with Addenda," NQA–1–2000, New York, New York, 2000.

Bechtel National, Inc. (BNI), 2007a. 24590-WTP-SRD-ESH-01-001-02, Revision 4k, "Safety Requirements Document." BNI: Richland, Washington. October 2007.

– – – 2007b. 24590-WTP-QAM-QA-01-001, Revision 7b, "Quality Assurance Manual." BNI: Richland, Washington. October 2007.

Code of Federal Regulations, *Title 10, Energy,* Part 830, "Nuclear Safety Management."

Code of Federal Regulations, *Title 10, Energy,* Part 835, "Occupational Radiation Protection."

Code of Federal Regulations, *Title 10, Energy,* Part 851, "Worker Safety and Health Program."

Code of Federal Regulations, *Title 29, Labor,* Part 1910, "Occupational Safety and Health Standards."

Code of Federal Regulations, *Title 40, Protection of Environment,* Part 68, "Chemical Accident Prevention Provisions."

Department of Energy (U.S.) (DOE). SEN-35-91, "Nuclear Safety Policy." DOE: Washington, D.C. September 1991.

– – – 1993. DOE-STD-1021-93, "Natural Phenomena Hazards Performance Categorization Guidelines for Structures, Systems, and Components." DOE: Washington, D.C. July 1993.

– – – 1995. DOE-STD-1023-95, "Natural Phenomena Hazards Assessment Criteria." DOE: Washington, D.C. March 1995.

– – – 2000a. DE-AC27-01RV14136, "Bechtel National, Inc., Design, Construction, and Commissioning of the Hanford Tank Waste Treatment and Immobilization Plant." DOE: Richland, Washington. 2000.

– – – 2002a. DOE Order 420.1A, "Facility Safety." DOE: Washington D.C. May 2002.

– – – 2002b. DOE STD-3009-94, Change Notice 2, "Preparation Guide for U. S. Department of Energy Nonreactor Nuclear Facility Documented Safety Analysis." DOE: Washington, D.C. April 2002.

– – – 2002c. DOE-STD-1020-2002, "Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities." DOE: Washington, D.C. January 2002.

– – – 2005. DOE Order 414.C, "Quality Assurance." DOE: Washington, D.C. June 2005.

Hobson, D. and P. Visclosky, (Committee on Appropriations, Subcommittee on Energy and Water Development, U. S. House of Representatives) 2008. Letter to: D.E. Klein (Chairman, U. S. Nuclear Regulatory Commission). May 2, 2008. Located at: Agencywide Documents Access and Management System (ADAMS), ML081410077.

Liang, Z, J. Karnesky, and J.E. Shepherd, "Structural Response to Reflected Detonations and Deflagration –to-Detonation Transition in H_2-N_2O Mixtures," Explosion Dynamics Laboratory Report FM 2006.002, California Institute of Technology, Pasadena, California, 2006. <http://www.galcit.caltech.edu/EDL/publications/reprints/galcit-fm2006-003.pdf?bcsi_scan_B666A1DE717DB577=0&bcsi_scan_filename=galcit-fm2006-003.pdf> (May 30, 2008)

Nuclear Regulatory Commission (U.S.) (NRC) 2001. NUREG–1747, "Overview and Summary of NRC Involvement with DOE in the Tank Waste Remediation System-Privatization (TWRS-P) Program." NRC: Washington, D.C. June 2001.

Rohay, A.C. and T. M. Brouns. PNNL-16652, *Site Specific Velocity and Density Model for the Waste Treatment Project, Hanford*. Pacific Northwest National Laboratory: Richland, Washington. 2007 <http://www.pnl.gov/main/publications/external/technical_reports/PNNL-16652.pdf?bcsi_scan_B666A1DE717DB577=0&bcsi_scan_filename=PNNL-16652.pdf> (May 30, 2008).

APPENDIX B

SPECIFIC SAFETY AND REGULATORY ISSUES

THIS PAGE INTENTIONALLY LEFT BLANK

INTRODUCTION

Several specific safety and regulatory issues were identified during staff visits to the WTP site, discussions with DOE personnel, and reviews of WTP documentation. These issues are summarized in the table below. Although NRC staff considered these issues during their review, a detailed study was not performed because the issues fell outside the scope and intent of this review. As of the completion of this review, these issues had not yet been resolved. We believe our observations may assist the DOE in continued oversight of the WTP project.

Table B.1. Specific Safety and Regulatory Issues

Issue	Concern
Hydrogen Flammability and Explosion Concerns	The waste treatment process generates hydrogen as a result of radiolysis and other chemical reactions within the waste. The concern is the collection of hydrogen in system piping and providing a viable means of limiting the effects of a possible hydrogen explosion.
Inspection and Maintenance of Structures and Components in Black Cells	The Hanford WTP design makes use of "black cells." Black cells are equipment vaults that are sealed to prevent personnel access due the existence of very high radiation levels once radioactive processing begins. This inaccessibility appears to be contrary to DOE implementing standards that require the performance of periodic inspections and maintenance of equipment and structures, including those likely to be within black cells.
Materials Issues Regarding Corrosion and Erosion	Tank waste consists of chemicals and solid particles and the processing of waste introduces more chemicals that may exacerbate the effects of corrosion and erosion. The concern is that the waste treatment system and other systems relied on for safety need to be adequately designed, tested, and maintained to account for these effects.
Ammonia Related Accidents and Chemical Interactions	The waste treatment process utilizes anhydrous ammonia. The potential hazardous aspects of the storage and use of this material (e.g., flammability and explosive considerations, effects of storage tank failures, etc.) do not appear to have been included and evaluated in the documentation.

Carbon Dioxide Accidents and Hazards	The waste treatment process utilizes carbon dioxide. The potential hazardous aspects of the storage and use of this material (e.g., expanding liquid vapor cloud and asphyxiation hazards, effects of storage tank failures, etc.) do not appear to have been included and evaluated in the documentation.
Chemical Material at Risk (MAR) Estimates	The MAR estimates developed for the chemical event hazard and consequence analyses appear to be based on the assumption that the total quantity of chemicals present at any one time is that contained within the process lines. This would appear to understate the actual quantities that might be involved in potential events (i.e., does not consider the volume of chemicals that would continue to be fed into the system pending the shutdown of the chemical supply system).
Removal of the Technetium Ion Exchange Columns from the Design	The DOE and the contractor removed technetium ion extraction columns from the original system design based upon a waste performance assessment that indicated technetium removal was no longer necessary. However, the State of Washington (also a regulator of the WTP) has concluded technetium removal is still necessary and has reinforced their position by adding a requirement for technetium removal to the RCRA permit.
New Resin for Cesium Removal by Ion Exchange	The DOE replaced the original cesium ion exchange resin with a new type of resin with better production-related performance (including less swelling and attrition) and lower cost. However, a description of this change and potential safety implications do not appear to have been included in the documentation.
Operation, Maintenance, and Safety of Revised Melter Designs	The low activity waste facility was originally designed to use three vitrification melters. After facility construction had commenced, testing indicated that melter throughput could be increased by as much as 50% by using “bubblers.” This also supported a design change that reduced the number of

	melters to two. The potential operational, maintenance, and safety implications of reducing the number of melters does not appear to have been fully addressed.
Ultrafiltration (UF) Approach	The original UF design was changed from four parallel lines with separate filtration and washing operations to two parallel lines performing both solids filtration and solids washing in the same units. Although this design change will eventually be tested, the DOE regulatory process allows construction to continue despite the potential that design could impacted by the above test results.