

OFFICE OF SAFETY REGULATION POSITION ON NEW SAFETY INFORMATION AND BACK-FITS



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PREFACE

As directed by Congress in Section 3139 of the *Strom Thurmond National Defense Authorization Act for Fiscal Year 1999*, the U.S. Department of Energy (DOE) established the Office of River Protection (ORP) at the Hanford Site to manage the River Protection Project (RPP), formerly known as the Tank Waste Remediation System. ORP is responsible for the safe storage, retrieval, treatment, and disposal of the high level nuclear waste stored in the 177 underground tanks at Hanford.

The initial concept for treatment and disposal of the high level wastes at Hanford was to use private industry to design, construct, and operate a Waste Treatment Plant (WTP) to process the waste. The concept was for DOE to enter into a fixed-price contract for the Contractor to build and operate a facility to treat the waste according to DOE specifications. In 1996, DOE selected two contractors to begin design of a WTP to accomplish this mission. In 1998, one of the contractors was eliminated, and design of the WTP was continued. However, in May 2000, DOE chose to terminate the privatization contract and seek new bidders under a different contract strategy. In December 2000, a team led by Bechtel National, Inc. was selected to continue design of the WTP and to subsequently build and commission the WTP.

A key element of the River Protection Project Waste Treatment Plant (RPP-WTP) is DOE regulation of safety through a specifically chartered, dedicated Office of Safety Regulation (OSR). The OSR reports directly to the ORP Manager. The regulation by the OSR is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor* (DOE/RL-96-25) (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, Process Safety Regulation of the RPP-WTP Contractor* (DOE/RL-96-26) (referred to as the MOA). These two documents provide the basis for the safety regulation of the RPP-WTP at Hanford.

The foundation of both the Policy and the MOA is that the mission of removal and immobilization of the existing large quantities of tank waste by the RPP-WTP Contractor must be accomplished safely, effectively, and efficiently.

The Policy maintains the essential elements of the regulatory program established by DOE in 1996 for the privatization contracts. The MOA clarifies the DOE organizational relationships and responsibilities for safety regulation of the RPP-WTP. The MOA provides a basis for key DOE officials to commit to teamwork in implementing the policy and achieve adequate safety of RPP-WTP activities.

The Policy, the MOA, the RPP-WTP Contract and the four documents incorporated in the Contract define the essential elements of the regulatory program being executed by the OSR. The four documents incorporated into the Contract (and also in the MOA) are as follows:

Concept of the DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE-96-0005,

DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor, DOE/RL-96-0003,

Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0006, and

Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor, DOE/RL-96-0004.

DOE patterned its safety regulation of the RPP-WTP Contractor to be consistent with the concepts and principles of good regulation (stability, clarity, openness, efficiency, and independence) used by the Nuclear Regulatory Commission (NRC). In addition, the DOE principles of integrated safety management were built into the regulatory program for design, construction, operation, and deactivation of the facility. The regulatory program for nuclear safety permits waste treatment services to occur on a timely, predictable, and stable basis, with attention to safety consistent with that which would occur from safety regulation by an external agency. DOE established OSR as a dedicated regulatory organization to be a single point of DOE contact for nuclear safety oversight and approvals for the WTP Contractor. The OSR performs nuclear safety review, approval, inspection, and verification activities for ORP using the NRC principles of good regulation while defining how the Contractor shall implement the principles of standards-based integrated safety management.

A key feature of this regulatory process is its definition of how the standards-based integrated safety management principles are implemented to develop a necessary and sufficient set of standards and requirements for the design, construction, operation, and deactivation of the RPP-WTP facility. This process closely parallels the DOE necessary and sufficient closure process (subsequently renamed Work Smart Standards process) in DOE Policy 450.3, *Authority for the Use of the Necessary and Sufficient Process for Standards-based Environment, Safety and Health Management*, and is intended to be a DOE approved process under DOE Acquisition Regulations, DEAR 970.5204-78, *Laws, Regulations and DOE Orders*, Section (c). DOE approval of the contractor-derived standards is assigned to the OSR.

The RPP-WTP Contractor has direct responsibility for WTP safety. DOE requires the Contractor to integrate safety into work planning and execution. This integrated safety management process emphasizes that the Contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. DOE, through its safety regulation and management program, verifies that the Contractor achieves adequate safety by complying with approved safety requirements.

All documents issued by the Office of Safety Regulation are available to the public through the DOE Public Reading Room at the Consolidated Information Center, Washington State University, Room 101L, Richland, Washington. Copies may be purchased for a duplication fee.

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OSR POSITION ON NEW SAFETY INFORMATION AND BACK-FITS

1.0 INTRODUCTION

The River Protection Project Waste Treatment Plant (RPP-WTP) regulatory program is established by contract¹ and includes DOE/RL-96-0004, *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the River Protection Project Waste Treatment Plant Contractor*, a process for establishing the set of standards that if properly implemented, will result in adequate safety. The set of standards resulting from performance of the standards identification process is identified in the Safety Requirements Document (SRD), which is prepared by the Contractor. The standards identification process establishes a facility safety baseline resulting from the evaluation of facility work processes, the hazards associated with the work processes, and postulated events involving the identified hazards. The OSR approves the Contractor's SRD as part of the Standards Approval regulatory action based on information provided by the Contractor regarding the facility safety baseline. Consistent with the RPP-WTP regulatory reliability principle, DOE/RL-96-25, *Policy for Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor*,² the stability of the established set of standards in the SRD is maintained to the maximum extent consistent with the continuous achievement of adequate safety.

However, over the course of RPP-WTP design, construction, and operations, new information related to the safety of the facility may be identified that was not previously considered in the process of establishing the facility safety baseline. New safety information may come from many sources such as:

- Operating experience at the RPP-WTP or other industrial facility with related processes
- Safety evaluations and analyses performed in connection with ongoing RPP-WTP engineering, management, and regulatory oversight activities
- Research and development work related to RPP-WTP waste treatment processes
- Evaluation of information relevant to safety provided by the public and other interested parties.

Regardless of the source, new safety information that comes to the attention of the OSR is evaluated by the Contractor and the OSR to determine if there are issues that may affect the nuclear, radiological, or process safety of the RPP-WTP, and if such safety issues exist, the actions necessary to ensure the adequacy of the facility safety baseline.

¹ DOE Contract No. DE-AC27-01RV14136 between DOE and Bechtel National, Inc., dated December 11, 2000.

² DOE/RL-96-25, Section 4.0, Item 5

In the RPP-WTP regulatory program, the Contractor has direct responsibility for safety as stated in DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*.³ The Contractor's appropriate and timely response to new safety information is a fundamental element of meeting this responsibility. The Contractor's response to new safety information results from the implementation of safety management processes that are described in the Contractor's Integrated Safety Management Plan (ISMP). It is an expectation of the RPP-WTP regulatory program that the Contractor's safety management processes will result in timely and appropriate response to new safety information.⁴ This continuous process of responding to new information results in a natural maturing of the facility safety baseline.

Consistent with its regulatory authority and responsibility, the OSR performs oversight of the Contractor's response to new information relevant to nuclear, radiological, or process safety. This oversight is accomplished through the implementation of the RL/REG-98-06, *Corrective Action Program* and RL/REG-98-05, *Inspection Program Description for the Regulatory Oversight of the River Protection Project Waste Treatment Plant Contractor*. RL/REG-98-06 incorporates a Regulatory/Safety Concern Information (RSCI) process to document and track the evaluation of matters of concern to the OSR. Safety issues identified from the evaluation of new safety information are tracked as RSCI under the Corrective Action Program. If the Contractor's response is determined by the OSR to be timely and appropriate, the OSR documents the determination and takes no further action. Verification of Contractor actions taken in response to new safety information is accomplished under the OSR Inspection Program.

Timely and appropriate response to new safety information is expected to occur in the normal course of Contractor and OSR activities described above. However, the OSR evaluation of new safety information and findings from the oversight of the Contractor's response to this information may result in an OSR determination that actions must be taken to ensure adequate safety or compliance with existing requirements.⁵ When the OSR is unable to concur with the Contractor's response to new safety information or requires additional information to make this determination, the OSR issues a Corrective Action Notice (CAN).⁶ The CAN identifies the matters of concern to the OSR and requests specific actions and/or information from the Contractor.

New safety information may identify a potential opportunity to achieve a substantial increase in worker or public health and safety at a justifiable cost.⁷ These potential safety enhancements are investigated by the OSR through a formal regulatory analysis that includes consideration of the costs and benefits that are expected to accrue from imposing a new regulatory requirement or interpretation.⁸ Regulatory analysis requires the evaluation of detailed information regarding the facility, possible approaches to implementing a new requirement or interpretation, and the costs and other impacts associated with changes to the facility or its operation. This information is

³ DOE/RL-96-0006, Section 4.1.2, "Safety Responsibility."

⁴ DOE/RL-96-0006, Sections 4.1.2.4 and 4.3.1.8 describe top-level principles related to this regulatory expectation.

⁵ The specific criteria used by the OSR in making this determination is established in DOE/RL-96-0003, Section 4.8, "Back-fit," Items 1 through 4

⁶ Corrective Action Notices are described in RL/REG-98-06

⁷ DOE/RL-96-0003, Section 4.8, "Back-fit," Item 5

⁸ DOE/RL-96-26, *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of River Protection Project Waste Treatment Plant Contractor*, Enclosure C, Section 2.3, item 1.

obtained, in part, through assessments requested by the OSR and performed by the Contractor.⁹ If based on the regulatory analysis, the Safety Regulation Official (SRO) determines that a safety enhancement is justified, the SRO recommends to the Office of River Protection (ORP) Manager that a new regulatory requirement be established. Recommendations to establish new regulatory requirements or interpretations are subject to independent review.¹⁰ Final decisions to impose new requirements or interpretations are made by the ORP Manager. New requirements or interpretations are implemented through the development and issuance of a back-fit order issued through the RPP-WTP Contracting Officer.

In addition to responding to new safety information, back-fits may also result from the need to implement new nuclear safety rules promulgated by the DOE. The specific applicability and implementation requirements for new nuclear safety rules are established as part of the DOE process for establishing nuclear safety rules. Applicable new nuclear safety rules are reflected in changes to the SRD. Implementation of these new requirements are conducted in accordance with a back-fit process consistent with the positions described in this document and with the implementation requirements of the new rule.

A back-fit order issued to implement a safety enhancement or new nuclear safety requirement is a contractual change subject to the relevant terms and conditions of the Contract.¹¹

2.0 TERMINOLOGY

2.1 Back-fit

The addition, elimination, or modification of (1) structures, systems, or components of the facility; or (2) procedures or organizations required to operate the facility after the construction authorization has been issued.

2.2 Immediate Hazard

As used in this document, immediate hazard is an imminent source of danger with the potential to cause illness, injury, or death to the public or workers or damage to the environment.

⁹ DOE/RL-96-0003, Section 4.5.2, Item 9, "Contractor Input."

¹⁰ DOE/RL-96-0003, Section 4.8, "Back-fit."

¹¹ Contract No. DE-AC27-01RV14136, Section I, I.82, "Changes – Cost Reimbursement (AUG 1987) – Alternate III (APR 1984)."

2.3 New Regulatory Requirement

As used in this document, a new regulatory requirement means the establishment of a safety regulatory requirement not currently contained in an existing Contract, Authorization Agreement, or currently approved SRD.

2.4 New Regulatory Interpretation

As used in this document, a new interpretation of an existing requirement occurs when the OSR establishes a position that:

- Is a change to a position described in a document referenced in Standard 7 of the Contract; or
- Is a change to a position described in an OSR Safety Evaluation Report issued in connection with the RPP-WTP regulatory process; or
- Requires modification of information currently contained in the authorization basis.

2.5 New Safety Information

Information that may be important to the radiological, nuclear, or process safety of a RPP-WTP facility that was not available, identified, or adequately considered during the development of existing regulatory requirements or the safety baseline of the facility. New safety information includes, but is not limited to, information that indicates a potential inadequacy in previous safety analyses that is determined to result in an Unreviewed Safety Question.

2.6 Safety Baseline

As used in this document, safety baseline means the composite of information used or developed by the Contractor to determine that the facility and its operation are adequately safe.

2.7 Unreviewed Safety Question

A situation where (1) the probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analyses could be increased; (2) the possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analyses could be created; (3) a margin of safety could be reduced; or (4) the documented safety analysis may not be bounding or may be otherwise inadequate.¹²

¹² Definition taken from DOE/RL-96-0003, Glossary

3.0 OBJECTIVES

- Respond to new safety information in a manner consistent with the regulatory reliability principle by maximizing regulatory stability to the extent consistent with achieving adequate safety.
- Ensure that OSR decisions taken in regard to new safety information and back-fits are supported by adequate information concerning the need for and consequences of proposed actions.
- Ensure appropriate alternative approaches to the resolution of safety issues are identified and considered.
- Make the regulatory process related to identifying, evaluating, and responding to new safety information open to the public and other interested parties.

4.0 POSITION

NOTE: An overview of the process described below is provided in Attachment A.

4.1 Contractor Evaluation of New Safety Information

New safety information will be evaluated by the Contractor in accordance with processes established in the Contractor's ISMP. The Contractor's evaluation shall include:

- Determination if the new safety information raises issues that adversely affect the Contractor's ability to achieve adequate safety including assessing the information to ensure (a) the continued completeness and validity of the Contractor's implementation of the standards selection process, (b) compliance with applicable laws and regulations, and (c) conformance to top-level safety standards and principles.
- Identification of the actions and changes that are appropriate to address any safety issues or potential safety enhancements.
- Updates to the authorization basis to reflect the new safety information and any changes necessary to address the information.

4.2 OSR Actions Upon Receipt Of New Safety Information

4.2.1 New safety information will be identified and tracked as RSCI under the Corrective Action Program.

4.2.2 If new safety information indicates that an Immediate Hazard exists, the OSR will take prompt action to cause the hazard to be relieved under the Corrective Action Program.

Such actions will proceed independently of actions taken by the OSR to conform with the positions described in this document.

4.2.3 The OSR will assess the adequacy of Contractor's response to new safety information as follows.

- (1) The OSR will evaluate the new safety information to determine if Contractor action is required to achieve adequate safety including:
 - An evaluation to determine if the current set of standards derived from the Contractor's implementation of the standards selection process is adequate in light of the new safety information
 - Compliance with applicable laws and regulations
 - Conformance to top-level safety standards and principles.
- (2) If the new safety information requires action by the Contractor, the OSR will determine if the Contractor has identified the actions necessary to:
 - Ensure adequate safety of worker or public health and safety
 - Bring the facility and its operation into compliance with the operating authorization and the conditions attached thereto
 - Bring the facility and its operation into compliance with current applicable laws and regulations
 - Bring the facility and its operation into compliance with any Compliance Orders issued under Subpart C of 10 CFR 820.¹³

4.2.4 If information from a Contractor is necessary to complete the OSR assessment, the OSR will issue formal correspondence via the ORP Contracting Officer requesting the information. The Contractor will support the assessment by promptly responding to OSR requests for information.¹⁴

4.2.5 If the OSR assessment determines that the Contractor's response to the new safety information is adequate, the OSR will record the assessment findings and verify completion of the following:

- (1) Any actions (e.g., changes to facility or administrative control features) as identified in the Contractor's evaluation
- (2) The revision of the Contractor's authorization basis to reflect the new safety information and any changes made to address the information.

¹³ DOE/RL-96-0003, Section 4.8, listed criteria items 1 through 4

¹⁴ DOE/RL-96-0003, Section 4.5.2, Item 9, "Contractor Input"

4.3 OSR Action to Address Inadequate Contractor Response

If the OSR assessment determines that Contractor's response to new safety information is inadequate with respect to the criteria identified in Section 4.2, the OSR will:

- 4.3.1 Issue a CAN under the Corrective Action Program. The CAN will describe the OSR assessment findings and the Contractor actions required to address the matters of concern to the OSR.
- 4.3.2 Apply the incentives of the Corrective Action Program as necessary to achieve an appropriate Contractor response to the new safety information.

4.4 Establishing a New Regulatory Requirement

4.4.1 If the OSR assessment of new safety information identifies a potential to achieve a substantial increase in overall safety of the worker or public at a justifiable cost,¹⁵ the OSR will propose a new regulatory requirement if a regulatory analysis is performed that:

- (1) Demonstrates the safety benefits of a new requirement are justified in terms of the costs associated with implementing the requirement.

The cost-benefit analysis should be quantitative to the maximum extent practical. However, depending on the specific circumstances of proposed requirement and the availability of suitable quantitative information, the analysis may, in whole or in part, be qualitative. In any event, the cost-benefit analysis will be sufficient to support a DOE decision regarding the proposed requirement. Implementing costs will include consideration of the continuing costs of compliance in addition to the initial implementation costs.

- (2) Evaluates the potential for any adverse safety impacts that might arise from the implementation of the new requirement or position (e.g., increased complexity in facility operations).
- (3) Identifies and evaluates reasonable alternatives to the new requirement that would achieve the same objective.

4.4.2 The Contractor shall provide information and assessments¹⁶ in support of regulatory analysis, as requested by the OSR.

4.4.3 Documentation of the regulatory analysis will be made publicly available.

4.4.4 A new requirement will be proposed by the SRO if an independent review concurs with the OSR determination or regulatory analysis described in Section 4.4.1. This review will normally be performed by the Office of Environment, Safety and Health (EH).

¹⁵ DOE/RL-96-0003, Section 4.8, item 5

¹⁶ DOE/RL-96-0003, Section 4.5.2, Item 9, "Contractor Input."

However, the SRO may assign this review to another DOE organization or constitute a special independent review group. The ORP Manager will approve new radiological, nuclear, and process safety requirements.

4.5 Establishing a New Regulatory Interpretation

The OSR may establish a new regulatory interpretation by either:

- Obtaining concurrence from the Contractor that the interpretation will not adversely impact cost or schedule; or
- Evaluating and implementing the new interpretation as described in Section 4.4 and Section 4.6.

4.6. Back-fit Implementation

4.6.1 Back-fits will be required by the OSR as necessary to implement the following:

- (1) New regulatory requirements or interpretations as established in Section 4.4 or Section 4.5.
- (2) Applicable DOE nuclear safety requirements¹⁷ that become effective, but are not currently included in the Contractor's authorization basis.

4.6.2 The OSR will develop a draft back-fit order containing the following information:

- (1) Description of the back-fit.
- (2) Objective of the back-fit
- (3) Documentation of the regulatory analysis completed in accordance with Section 4.4.
- (4) Specific actions required by the Contractor to complete the back-fit. The specific actions will include:
 - The changes to the Contractor's SRD incorporating the new regulatory requirement or interpretation.
 - A description of the changes to the Contractor's facility or administrative control features that are necessary to implement the new regulatory requirement or interpretation.

¹⁷ The reference to "DOE nuclear safety requirements" are those regulatory requirements that are enforceable under 10 CFR 820.

- Acceptable alternatives to meeting the objectives of the back-fit, if applicable.

(5) Implementation schedule for the back-fit.

NOTE: If the draft back-fit order is related to a newly effective DOE nuclear safety requirement, the order shall conform to the implementation requirements of the rule.

- 4.6.3 The Contractor shall provide information and assessments¹⁸ in support of back-fit order development, as requested by the OSR.
- 4.6.4 The draft back-fit order will be made available for comment by the Contractor, public, and other interested parties. The SRO will make the comment period between 7 and 30 days consistent with the urgency of back-fit and the significance of the regulatory action.
- 4.6.5 Following consideration and resolution of comments on the draft back-fit order by the OSR, the SRO will determine whether to issue, modify, or rescind the order. Verification of back-fit implementation will be performed under the OSR Inspection Program.

5.0 IMPLEMENTATION

The positions described in this document will be implemented following the issuance of Construction Authorization.

6.0 REFERENCES

DOE/RL-96-25, *Policy for Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RL-96-26, *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the River Protection Project Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RL-96-0003, *DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RL-96-0004, *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

¹⁸ DOE/RL-96-0003, Section 4.5.2, Item 9, "Contractor Input"

DOE/RL-96-0005, *Concept of the DOE Process for Radiological, Nuclear, and Process Safety Regulation of the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

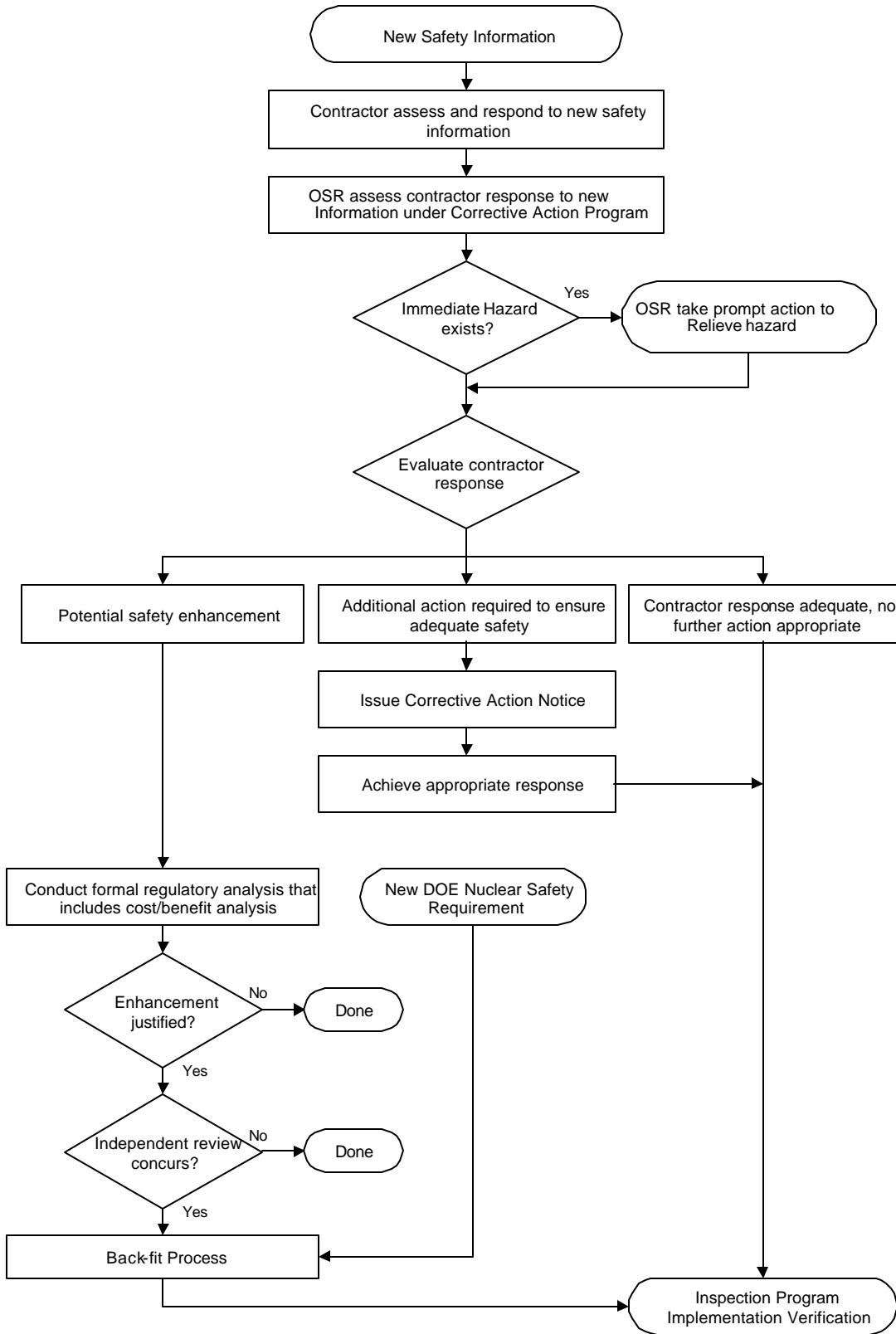
RL/REG-98-05, *Inspection Program Description for the Regulatory Oversight of the RPP-WTP Contractor*, Rev. 4, U.S. Department of Energy, Office of River Protection 2001.

RL/REG-98-06, *Corrective Action Program Description*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

7.0 LIST OF TERMS

CAN	Corrective Action Notice
DOE	U.S. Department of Energy
ISMP	Integrated Safety Management Plan
ORP	Office of River Protection
OSR	Office of Safety Regulation
RSCI	Regulatory/Safety Concern Information
SRD	Safety Requirements Document
SRO	Safety Regulation Official
RPP-WTP	River Protection Project Waste Treatment Plant

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