

Discussion Topics

**Supplemental Information Needs:
Westinghouse 40-Year License Renewal**

**NRC/Westinghouse Meeting
November 7, 2014**

**Supplemental Information Needs:
License Application, Chapter 3,
“Conduction of Operations” (Management Measures)**

Configuration Management

10 CFR 70.62(d) requires an applicant to establish management measures for engineered or administrative control or control system that are identified as items relied on for safety pursuant to 10 CFR 70.61(e) so that they are available and reliable to perform their function when needed.

10 CFR 70.4 defines configuration management (CM) 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 items relied on for safety to perform their functions when needed.

Section 3.1, “Configuration Management,” describes the CM program structures and implementation. During the acceptance review, the NRC staff found that Section 3.1 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the CM Program, as listed below:

1. Describe the translation of design basis information into drawings and other statements of requirements for IROFS.
2. Describe the process used to create and control documents that are relied on for safety and provide a list of document types to which these controls apply. Describe the extent to which the controls identified are applied to these documents.
3. Describe the process that will be followed to implement changes to affected onsite documentation as part of 10 CFR 70.72 changes.
4. Describe the characteristics of the CM program that will be graded in accordance with the quality levels identified in Section 3.3.2, or if the elements of CM are applied consistently to all Items Relied on For Safety (IROFS). Describe how the CM elements are applied to IROFS.

Maintenance

10 CFR 70.62(d) states, in part, that engineered and administrative controls and control systems that are identified as IROFS pursuant to 10 CFR 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed.

10 CFR 70.64(a)(8) requires that IROFS for new facilities or new processes at existing facilities receive adequate inspection, testing, and maintenance to ensure their availability and reliability when needed.

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Section 3.2, "Maintenance," states that the maintenance program is implemented in accordance with written procedures and work orders. During the acceptance review, the NRC staff found that Section 3.2 lacks sufficient information to proceed with a detailed technical review in the following areas. Provide supplemental information describing the key elements and attributes, or information requested for the Maintenance Program, as listed below:

1. Describe the process for corrective maintenance of IROFS.
2. Describe how the maintenance function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS.
3. Describe the process for documenting the basis for determining the maintenance frequency for IROFS (i.e., where are the results of analyzing the factors identified in the application documented).
4. Figure 3.1 of the license application provides a typical Integrated Safety Analysis (ISA) Summary IROFS Table. Describe where the frequency of the relevant functions is specified.
5. Section 3.9, "Record Keeping and Reporting," states that the Records Flow Schedule identifies the records to be retained, retention locations, and retention time limits. Describe the elements and attributes of the retention requirements applied to the surveillance schedules, performance criteria, and test results associated with IROFS, including the preventative maintenance and functional test schedule and results.
6. Describe the use of compensatory measures for surveillance tests that can be done only while IROFS are out of service.
7. Section 3.2.2.2 of the license application states that unsatisfactory maintenance, calibration, inspection, periodic functional testing, or post repair/replacement testing performance, is identified using the Incident Investigation and/or Corrective Active Process, described in Sections 3.7 and 3.8. Discuss the mechanisms (e.g., Incident Investigation Process or Corrective Action Process) to initiate repairs on IROFS in the event of the IROFS failure, or if an alternate approach such as the initiation of a work order, is used.
8. Discuss if functional testing will be applied to confirm the availability and reliability of IROFS in new processes.
9. Describe the process of verifying that the administrative controls identified as IROFS are available and reliable to perform their intended safety function over extended periods of operation.

Training and Qualification

10 CFR 70.22(a)(6) requires the technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations.

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Section 3.4, "Procedures, Training, and Qualification," states information on the structure of the Training and Qualification program. During the acceptance review, the NRC staff found that Section 3.4 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the Training and Qualification, as listed below:

1. Describe measures beyond the periodic procedure review frequencies in Section 3.4.1.3 that are implemented to ensure that training is maintained up to date with facility design changes and configuration.
2. Describe both the content and maintenance of training records. Describe how the Records Management Program, as described in Section 3.9, maintains programmatic and individual training records.
3. Describe the position requirements for process operators that are included as part of the regulatory or safety function engineering position described in Section 2.1.1.3(e); alternately, identify the minimum qualifications for process operators.
4. Discuss the following training program attributes:
 - a. Training objectives states the knowledge, skills, and abilities that the trainee should acquire; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.
 - b. Lesson plans and other training guides provide guidance to ensure the consistent conduct of training activities and should be based on required learning objectives derived from specific job performance requirements.
 - c. Use of lesson plans or guides for all training, and these lesson plans or guides should include standards for evaluating acceptable trainee performance.
 - d. Establishment of review and approval requirements for all lesson plans or guides and other training materials before their issue and use.
5. Describe the use of on-the-job training for activities relied on for safety and how any such training satisfies the elements described in items (a) through (d) above.
6. Describe the provisions for continuing assurance of personnel training and qualification, including periodic requalification of personnel performing activities relied on for safety.
7. Describe the process used to evaluate training effectiveness and to correct training deficiencies and performance problems.

Procedures

10 CFR 70.22 (a)(8) requires an application to contain proposed procedures to protect health and minimize danger to life or property (such as procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures, etc.)

Section 3.4, "Procedures, Training, and Qualification," gives information on Procedures (e.g., issuance, approval, and communication of procedure content, and review frequencies). During

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the acceptance review, the NRC staff found that Section 3.4 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the Procedures, as listed below:

1. Section 3.4.1 of the license application states that “Operations to assure safe, compliant activities involving nuclear material are conducted in accordance with approved procedures.” Describe if procedures are used for both the operation of IROFS and for all management measures supporting those IROFS.
2. Describe if disciplines to direct certain activities such as design, procurement, and radiation safety, are addressed by the procedures described in Section 3.4.1.
3. Discuss the implementation of procedures or written guidance for operator actions necessary to prevent or mitigate accidents identified in the ISA Summary. For example, written procedures should cover activities such as management control; maintenance activities that address system repair, calibration, surveillance, and functional testing; emergency; and operation.
4. Describe the relationship between the ISA and procedure development; description of the use of field test to validate procedures; and identification of how procedures address the items described below:
 - a. Specify operating limits and IROFS;
 - b. Include required actions for off-normal conditions of operation, as well as normal operations;
 - c. Identify safety checkpoints, as appropriate; and
 - d. Include the following elements:
 - i. title and identifying information, such as number, revision, and date
 - ii. statement of applicability and purpose prerequisites
 - iii. precautions (including warnings, cautions, and notes)
 - iv. important human actions
 - v. limitations and actions
 - vi. acceptance criteria
 - vii. check off lists
 - viii. reference material
5. Describe the content and use of maintenance procedures to address the elements identified below:
 - (a) Pre-maintenance activities involve reviews of the work to be performed, including procedure reviews for accuracy and completeness.
 - (b) Procedure steps require notification of all affected parties (operators and supervisors) before performance of work and on completion of maintenance work, including discussion of potential degradation of IROFS during the planned maintenance.
 - (c) Maintenance procedures are reviewed by various safety disciplines, including criticality, fire, radiation, industrial, and chemical process safety, as applicable.
 - (d) Maintenance procedures describe the following:
 - qualifications of personnel authorized to perform the maintenance or surveillance;

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- controls on and specification of any replacement components or materials to be used (should be controlled by the configuration management function to ensure like-kind replacement and adherence to 10 CFR Part 21, "Reporting of Defects and Noncompliance");
 - records management of maintenance activities; and
 - safe work practices (e.g., moderation control or exclusion area; radiation hot work permits; and criticality, fire, chemical, and environmental issues)
6. Describe the use of temporary procedures.
7. Describe the procedure review measures for unusual events that occur between the periodic reviews described in Section 3.4.1.3.

Audits and Assessments

10 CFR 70.62(d) requires an applicant to establish management measures for engineered or administrative control or control system that are identified as items relied on for safety pursuant to § 70.61(e) so that they are available and reliable to perform their function when needed.

10 CFR 70.4 defines management measures the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

Section 3.6, "Audits and Assessments," describes the structure established by the licensee for audits and assessments and is defined as integrated activities intended to self-identify and self-correct issued such as process upsets and procedural inadequacies. During the acceptance review, the NRC staff found that Section 3.6 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the Audits and Assessments, as listed below:

1. Section 3.6 states that "Audits and Assessments are conducted to assure that operations important to environmental protection, health, safety, and safeguards are properly documented, are conducted in accordance with such documentation and meet management expectations with respect to effectiveness; Section 3.6.1.1 identifies that compliance audits are performed to assure that observed practices conform to approved implementation documentation (e.g., procedures, handbooks, plans). Describe how audits address compliance with regulatory requirements and license conditions and confirm which type of audits (e.g., compliance audits, program audits) address this element.
2. Section 3.6.2.3 provides commitment to ensure that qualified personnel without direct responsibility for the function and area being audited or assessed will perform the audits and assessments for the conduct of assessments. Discuss if similar commitments will also be applied to audit functions described in Sections 3.6.2.1 and 3.6.2.2, or describe how objectivity will be maintained in the conduct of audits.

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Incident Investigations

10 CFR 70.62(a)(3) states, in part, that a failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure. 10 CFR 70.74(a) and 70.74(b) requires incident investigation and reporting. Section 3.7, "Incident Investigations," describes the structure and implementation of the incident investigation program. During the acceptance review, the NRC staff found that Section 3.7 lacks sufficient information to proceed with a detailed technical review.

Describe the records retention requirements for abnormal events, including the manner in which incident investigation documentation will be retained to enable use for continuous improvement of affected operations.

Records Management

10 CFR 70.62(a)(3) states that each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure.

10 CFR 70.64(a), Quality standards and records, requires, in part that, for new facilities or new processes at existing facilities ..., the design must be developed and implemented in accordance with management measures, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

Section 3.9, "Record Keeping and Reporting," states the structure of licensee's record keeping and reporting program. During the acceptance review, the NRC staff found that Section 3.9 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the Records Management.

Describe the measures implemented to ensure legibility of records and to ensure the ability to read and use computer codes and data stores for the retention life of the record.

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Other Quality Assurance Elements

10 CFR 70.62(d) requires an applicant to establish management measures for engineered or administrative control or control system that are identified as items relied on for safety pursuant to 10 CFR 70.61(e) so that they are available and reliable to perform their function when needed.

10 CFR 70.4 defines management measures to include other Quality Assurance (QA) elements as part of the management measures.

Section 3.3, "Quality Assurance," provides a description of Westinghouse's Regulatory Component QA Program including the structure, implementation, and graded approach for the program. During the acceptance review, the NRC staff found that Section 3.3 lacks sufficient information to proceed with a detailed technical review. Provide supplemental information describing the key elements and attributes, or information requested for the Other Quality Assurance Elements, as listed below:

1. Section 3.3.1 of the license application states that the Regulatory Component quality program is structured to address the aforementioned QA criteria, namely:
 - (a) Organization;
 - (b) Regulatory Component Quality and Training Programs;
 - (c) Design Control;
 - (d) Procurement Document Control;
 - (e) Policies, Procedures, and Drawings;
 - (f) Document Control;
 - (g) Control of Purchased Material, Equipment and Services;
 - (h) Identification and Control of Materials, Parts and Components;
 - (i) Control of Special Processes;
 - (j) Inspection;
 - (k) Test Control;
 - (l) Control of Measuring and Test Equipment;
 - (m) Shipping/Receiving, Handling and Storage;
 - (n) Inspection, Test and Operating Status;
 - (o) Nonconforming Materials, Parts or Components;
 - (p) Corrective Action;
 - (q) EH&S Records; and
 - (r) Audits and Assessments.

Describe, or reference existing requirements, the implementation of the following elements:

- (a) Design Control - Describe measures for design control, including the specification and translation of design inputs to design documents and the control of design changes.
- (b) Procurement Document Control - Describe how documents associated with the procurement of items and services include or reference the design-bases information and other documentation necessary to ensure adequate quality and that, to the extent necessary, suppliers must have a QA program commensurate with the quality level of the item or service to be procured.
- (c) Instructions, Procedures, and Drawing Control - Describe controls for ensuring that activities affecting the quality of IROFS are prescribed by and

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performed in accordance with documented instructions, procedures, or drawings appropriate for the circumstances and reference appropriate quantitative or qualitative acceptance criteria. Section 3.4 identifies that “Operations to assure safe, compliant activities involving nuclear material are conducted in accordance with approved procedures.” Describe the elements and attributes of the controls for ensuring that appropriate instructions and drawings are used and that work-controlling documents reference or include required acceptance criteria.

- (d) Document Control – Describe controls for the preparation, review, approval, issuance, and modification of documents that specify quality requirements or prescribe activities affecting quality.
- (e) Control of Purchased Items - Describe CFFF controls for the procurement of items and services (e.g., supplier selection, receiving inspection, mechanisms for control of changes in items or services).
- (f) Identification and Control of Items - Describe CFFF controls for ensuring that only the correct items are used or installed; include processes for item identification and traceability as appropriate.
- (g) Control of Processes - Describe controls for special processes affecting the safety of IROFS or related services such as welding, heat treating, and nondestructive examination.
- (h) Inspection - Describe controls for inspections used to verify conformance of an IROFS item or activity. Include that (1) inspection processes will specify the characteristics to be inspected, inspection methods to be used, and controls for the planning and execution of the inspection; (2) inspection results will be documented; and (3) inspections will be performed by qualified personnel other than those who performed or directly supervised the work being inspected.
- (i) Test Control - Describe controls for tests performed to verify conformance of an IROFS or computer program to specified requirements and to demonstrate availability and reliability of performance. Include the test processes will specify the characteristics to be tested, the test methods to be used, and that test results will be documented and evaluated against the test requirements and acceptance criteria.
- (j) Control of Measuring and Test Equipment - Describe controls for controlling tools, gauges, instruments, and other measuring and test equipment used for IROFS and activities affecting IROFS to ensure required calibration and accuracy are maintained.
- (k) Handling, Storage, and Shipping - Describe controls for the handling, storage, cleaning, packaging, shipping, and preservation of IROFS to prevent damage or loss and to minimize deterioration.
- (l) Inspection, Test, and Operating Status - Describe controls for identifying the status of inspection and test activities for IROFS, ensuring that required inspections and tests are performed, and ensuring that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.
- (m) Control of Nonconforming Items - Describe provisions for preventing the inadvertent installation or use of nonconforming material, parts, equipment, or services designated as IROFS (i.e., identification, documentation, evaluation, segregation, and disposition of nonconforming items and notification to affected organizations).

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- (n) Audits - Describe the applicability of the audit and assessment process to the review of the QA Program /quality management system. Address the planning and scheduling of audits and assessments to verify compliance with, and to determine the effectiveness of, QA elements, and responsibilities and procedures for assessing, auditing, documenting, and reviewing results.
2. Section 2.1.1.3 states that “Administrative and managerial controls are in effect at all times to assure that decisions related to the operation are made at the designated level of accountability by individuals meeting the necessary authority and technical requirements.” Describe how the organizational structure enables authority, access, and independence for quality-affecting functions.
 3. Section 3.3.2.2 of the license application states that “Important safety systems receive selective application of the Regulatory Component QA program requirements to assure failure of their availability and reliability is unlikely. That is, only the criteria that the Regulatory Component determines should apply are specifically addressed.” Describe the factors considered and process used by the Regulatory Component in determining the application of QA program requirements to important to safety components (quality level B).

**Supplemental Information Needs:
License Application, Chapter 7,
“Chemical Safety Program”**

1. 10 CFR 70.22(a)(7)-(8) requires a description of equipment, facilities and proposed procedures that will be used to protect health and minimize danger to life or property. The information on the Chemical Safety Program provided in the license renewal application does not include the information required by §70.22 and §70.62 to support an assessment of the applicants program for managing chemical hazards of licensed material and hazardous chemicals produced from licensed material. Descriptions, details, procedures, and elements of individual safety programs such as the chemical safety must be described in sufficient detail as part of the license application which does not include the ISA.

Expand the discussion of the Chemical Safety Program to include equipment and facilities, and process descriptions (or reference to such descriptions).

Describe key elements and attributes of approved procedures, and policies.

2. 10 CFR 70.62(a) requires a licensee to establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. The safety program required by §70.62(a) is intended to adequately protect the worker, public health and safety, and the environment from chemical hazards of licensed material. Westinghouse states that it “essentially follows 29 CFR 1910.119” and states that this standard is the basis for the Chemical Safety Program. However, Westinghouse does not provide details on the elements of the safety program to demonstrate compliance with the applicable NRC requirements.

Expand the discussion of the Chemical Safety Program to include description of the 23 elements mentioned in Chapter 7 when they are relevant for complying with the requirements of 70.61 and 70.62.

3. 10 CFR 70.62(a)(1) requires that a chemical safety program be established and maintained that demonstrates compliance with the performance requirements of § 70.61. Information about the chemical hazards within the jurisdiction of NRC can be found in Chapter 7 and Chapter 4 of the license renewal application. However, Chapter 7 is about both OSHA and NRC, with little discussion about elements and attributes that support the management of NRC-regulated chemical hazards.

Describe (1) the process used to identify and evaluate the hazards of NRC-licensed materials and chemicals produced from NRC-licensed materials (2) the process used to select IROFS to manage chemical hazards and (3) the management measures that are used to maintain such IROFS.

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4. 10 CFR 70.62(c)(1) requires, in part, that an ISA be conducted and maintained that is of appropriate detail for the complexity of the process that identifies chemical hazards of licensed material and hazardous chemicals produced from licensed material. The ISA definition in §70.4 states that the ISA is limited to consideration of the effects of all relevant hazards of chemical hazards directly associated with NRC licensed radioactive material. It is unclear in the renewal application whether all relevant hazards including all exposure pathways are considered.

Discuss how all relevant chemical hazards are evaluated to include all exposure pathways.

**Supplemental Information Needs:
“Environmental Report”**

1. 10 CFR 51, requires that an environmental report discuss alternatives to the Proposed Action. The No-Action Alternative is not properly defined in the Environmental Report (ER). Section 1.2 of the ER defines the No-Action Alternative as “continued operations for the foreseeable future, without any significant changes in the existing facility. An operating period of up to 40 years is assumed.” The No-Action Alternative is the NRC’s denial of the license application request. The result of this denial would be that Westinghouse would continue to operate the Columbia Fuel Fabrication Facility (CFFF) until September 30, 2027, in accordance with its current license. Describe the No-Action Alternative and its impacts.
2. 10 CFR 51, requires that the cumulative impacts of the Proposed Action be stated. Discuss the reasonably foreseeable future actions that could occur within the affected environment during the 40 years of the Proposed Action. Describe the cumulative impacts to resources impacted by the CFFF. Although additional information regarding cumulative impacts is in Enclosure 3 to the license application, this information is limited in its consideration of reasonably foreseeable actions and in its consideration of cumulative impacts to each affected resource area. A thorough consideration of reasonably foreseeable actions is a significant aspect of an environmental review when the Proposed Action will take place over an extended period, as would be the case with a 40-year license.
3. 10 CFR 51, requires that the environmental report contain a description of the Proposed Action. The Proposed Action is the NRC’s granting the 40-year license extension request and modifying the license to include other changes identified in the license application. Westinghouse identifies changes from the currently approved license that are associated with this application, including a modification to the calcium fluoride release limit and the authorized possession limit for ²³⁵U. Discuss other proposed changes and their environmental impacts; if no other changes are anticipated, so state.