

**REQUEST FOR ADDITIONAL INFORMATION:
MANAGEMENT MEASURES
Westinghouse Electric Company, LLC
License Renewal
(CAC L33317, Docket 70-1151)**

NOTE: Requests for Additional Information (RAIs) refer to the revised chapter (Ref. 1) submitted by letter dated February 29, 2016.

RAI1. Describe how management measures are applied to ensure that procurement, surveillance, and maintenance documents incorporate relevant design requirements.

Management measures ensure that items relied on for safety (IROFS) can perform their intended safety function. A description is needed to understand how the management measures ensure that designed requirements of IROFS are reflected in the procurement, surveillance, and maintenance of the IROFS. For example, when a system is designed, a component that is designated to be an IROFS may need to be designed and manufactured to tighter tolerances than would typically be done for the same component if it were not to be an IROFS. The component may also require periodic testing and maintenance to verify that its function meets the performance criteria to which it was designed.

Regulatory Basis

10 CFR 70.62(d) requires that IROFS be designed, implemented, and maintained to ensure that they are available and reliable when needed.

10 CFR 70.64(a)(1) states that new facilities or new processes at existing facilities must develop and implement designs, in accordance with management measures, to provide reasonable assurance that IROFS will be designed, implemented, and maintained to ensure that they are available and reliable to perform their safety function when needed.

10 CFR 70.64(a)(8) states that the design of IROFS must provide for inspection, testing, and maintenance adequate to ensure their availability and reliability to perform their function when needed.

RAI2. Elaborate on the discussion of document control.

- 2.1. Describe the process used to control documents that are relied on for safety (e.g., formal documentation governing the design and continued modification of the site, structures, processes, systems, components, computer programs, personnel activities, and supporting management measures). Describe systems used to monitor the status/revision level of documents. To the extent practical, controls from Section 3.4 may be referenced.
- 2.2. Provide a list of document types to which the controls discussed in RAI 2.1 apply. The documents may include design requirements, ISAs, as-built drawings, specifications, procedures designated as IROFS, procedures involving training, quality assurance (QA), maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant deems part of configuration management.

Over the course of a 40-year license, the staff at the Columbia Fuel Fabrication Facility (CFFF) will change. Much reliance will be placed on documents to maintain the knowledge of the

IROFS. Documents include, but are not limited to, design requirements, integrated safety analysis, as-built drawings, specifications, all procedures that are IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that are deemed part of configuration management.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property. 10 CFR 70.64(a) (1) states that the licensee must maintain or control appropriate records of IROFS throughout the life of the facility.

RAL3. The Integrated Safety Analysis has a table (see excerpted Table 1) that identifies the management measures applicable to each type of IROFS. The table indicates that maintenance does not apply to administrative controls. Section 3.2, Maintenance, states that periodic verification of IROFS will be performed. Clarify if these will be completed for purely Administrative Control IROFS.

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on an unambiguous license application.

Regulatory Basis

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

Table 1 Excerpt from ISA 01 (page 370)

RAL4. Section 3.3 identifies quality levels that will be applied to IROFS based on their risk significance. Specify where the quality level designation for each IROFS is located.

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on documents to maintain knowledge about the CFFF configuration and the importance of each IROFS to safety.

Regulatory Basis

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as

Management Measures	Type of Control			
	Passive	Active Engineered Control	Administrative Control with Computer Alarm Assist	Administrative
Configuration Management	YES	YES	YES	YES*
Maintenance	**	**	**	NO
Quality Assurance	**	**	**	**
Procedures, Training & Qualification	YES	YES	YES	YES
Human Performance	YES	YES	YES	YES
Compliance Audits	YES	YES	YES	YES
Program Audits/ Self-Assessments	YES	YES	YES	YES
Incident Investigations	YES	YES	YES	YES
Corrective Action Process	YES	YES	YES	YES
Record Keeping & Reporting	YES	YES	YES	YES

* The CFFF electronic procedure system incorporates document and change control requirements for procedure development, review & approval and revision.
 ** A graded approach is applied to the quality assurance and maintenance of IROFS. The IROFS table provides additional information with regard to (1) periodic maintenance/calibration/inspection, 2) periodic functional test, and 3) post repair/replacement testing.

Source: Integrated Safety Analysis, ISA 01, "Plant Ventilation System", Revision 8. Submitted January 24, 2014.

IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 5. Section 3.3, Other Quality Assurance, describes the management measures applied to IROFS to provide reasonable assurance that IROFS are available and reliable to perform their intended functions. Describe or elaborate on the measures implemented for the following quality assurance criteria for IROFS and Administrative control IROFS (if applicable).

- (a) Procurement document control - clarify how process translates design requirements into procurement documents to ensure technical required specifications or functional testing of the IROFS is requested base on applicability.
- (b) Design Control/Document Control - clarify how the process ensures that all documents are properly modified authoritatively approve and make them available to personnel
- (c) Control of purchased items and services - clarify how this process is applied to all IROFS. This includes controls of receiving inspection, supplier selection, and control of supplier.
- (d) Control of special processes - clarify how these controls will be applied to IROFS (e.g. inspection, maintenance).
- (e) QA records (note that records are addressed by Section 3.9 with the exception of record preparation (generation and authentication), transmittal, and distribution).
- (f) Control of Measuring and Test Equipment - clarify how these CFFF procedures apply to IROFS.

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on license documents to maintain knowledge of the IROFS and management measures that ensure the availability and reliability of those IROFS.

Regulatory Basis

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 6. Describe the use of compensatory measures.

Compensatory measures may be used to compensate for the unavailability of an IROFS that need to be taken out of service for surveillance testing. Such measures maintain the intended level of safety for the time that the IROFS is unavailable. Clarify how the unavailability of an IROFS is addressed in order to maintain the level of safety.

Regulatory Basis

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

10 CFR 70.64(a)(8) states that the design of IROFS must provide for inspection, testing, and maintenance adequate to ensure their availability and reliability to perform their function when needed.

RA17. Identify the minimum qualifications (i.e., education and experience) for process operators themselves.

Section 3.4.2.4 describes the training and qualification process for process operators. Qualifications ensure that a staff member has at least a minimum of knowledge necessary to safely operate a system, including sufficient education and experience to demonstrate an adequate level of proficiency to fulfill nuclear process operation responsibilities. Include activities that involve the administrative controls. Section 3.4.2, Training and Qualification, do not mention training and qualification requirements for these.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property. 10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RA18. Describe the use of training objectives and lesson plans at the CFFF. Address the following topics:

- 8.1. Confirm that training objectives will state 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.
- 8.2. Confirm that lesson plans or guides will be used for all training and that such guidance will be based on training objectives that include standards for evaluating trainee performance.
- 8.3. Describe the review and approval requirements for lesson plans and training guides. Clarify how problem identification and resolution are addressed on lesson plans and training guides.

Unambiguous and documented training objectives ensure that, over the 40 years of a license, training will remain focused on conveying the knowledge, skills, and abilities needed to safely operate equipment. Guides and lesson plans ensure consistent, structured implementation of training programs, and maintain knowledge of training, as CFFF staff change. Review and approval requirements for lesson plans and training guides ensure that ad hoc changes to training are prevented.

Regulatory Basis

10 CFR 70.22(a)(8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RA19. The license application describes on-the-job training only in relation to process operator qualification. Identify if on-the-job training will be used for other disciplines and, if so, describe the use of on-the-job training for such activities.

Safe operation of the CFFF necessitates all people performing licensed activities having current and thorough understanding of their roles and responsibilities. This can be achieved through an appropriate combination of personnel education, experience, and training, which can encompass classroom and on-the-job learning.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RA10. Section 3.4 states that “Training, qualification and requalification of individuals performing activities relied on for safety are performed in accordance with the requirements specified for the CFFF Electronic Training Check list (ECL).” Section 2.1.1.2 states that periodic refresher training is conducted in accordance with the applicable regulations and Westinghouse policies and procedures.

- 10.1. Clarify the controls that will be implemented by CFFF to provide assurance of continued personnel training and qualification over time. Clarify the areas in which ECL is applicable.
- 10.2. Describe the use of periodic requalification in a given job to provide reasonable assurance that personnel continue to understand, recognize the importance of, and be qualified to perform activities that are relied on for safety.

Refresher training and requalification ensure that CFFF staff have current knowledge to perform their activities in a safe manner.

Regulatory Basis

10 CFR 70.22(a)(8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property. 10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RA11. Describe the process used to evaluate training effectiveness and to correct both training deficiencies and performance problems. Identify the frequency of such reviews. Identify the qualifications of personnel performing reviews of training effectiveness. If the audit

and assessment process will be used to perform this function, identify how the process will apply feedback from trainee performance and trainees to evaluate training effectiveness.

Personnel must receive training that is sufficiently robust to ensure their capability to perform assigned work duties. In order to fulfill its objectives in establishing and maintaining employee proficiency, a system is needed to evaluate the effectiveness of training programs on a regular basis using qualified individuals. Assessment of the training function must also account for the views of licensee personnel in order to ensure the training is delivered in a manner that can be understood and is of sufficient breadth and depth. Such practices take on added importance during a 40-year renewal period.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 12. Section 3.4.1 states that “Procedures exist to direct operation of IROFS and for all management measures supporting those IROFS.” Identify where in the license application procedures for procurement are described, or add a description of these procedures.

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on documents to maintain the knowledge of the IROFS and the management measures supporting the IROFS.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 13. Section 3.4.1.1 states that “Administrative procedures include applicable instructions on the purpose, policy and scope, terms and definitions, responsibilities, regulatory requirements, procedure requirements and references.” Expand the description of procedure content to explain how the following procedure elements are applied to all regulatory-significant procedures:

- (a) Prerequisites and precautions
- (b) Acceptance criteria

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on an unambiguous license application because the authors of the application will be unavailable to reconcile what is documented and what was intended to be documented. Having

a commitment to include basic structural elements in regulatory-significant procedures will ensure that necessary controls and guidance is included in CFFF procedures.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 14. Describe how the conduct of maintenance activities includes the following:

- 14.1. Reviews of the work to be performed, including procedure reviews for accuracy and completeness, as part of pre-maintenance activities.
- 14.2. Procedure steps requiring notification of all affected parties (operators and supervisors) before performance of work and on completion of maintenance work.

The scope of work needs to be understood so that other CFFF staff know when reliance can be placed on a system, and the ramifications of making changes, which may include unintended consequences. Affected personnel need to know when work begins and when work is completed to ensure the availability and reliability of IROFS.

RAI 15. Section 3.6 states, “An annual formal audit and assessment schedule is planned, documented, revised (as necessary), and implemented.” Discuss threshold to determine how often these need to be performed.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

RAI 16. Section 3.7 states that “Records of abnormal events are maintained in accordance with the retention requirements specified in Section 3.9 of this License Application.” Section 3.9 states that “Records of IROFS and management measures failures required by 10 CFR 70.62(a) (3) are maintained as described in Section 3.7 of this Chapter in the License Application.”

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

- 88.3 Describe how more significant abnormal occurrences that required a formal investigation and correction are handled. Section 3.7 Incident Investigation does not describe neither 3.8 Corrective Action.
- 88.4 Based on Section 3.7 the retention requirements for abnormal events is a minimal of 3 years. How does trend is expected to be identified in components with lower failure rates. Is this applicable to IROFs as well?

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on documents to maintain knowledge of the abnormal events for the life of the CFFF so that the "lessons learned" may be applied by future generations of staff to ensure that past mistakes are not repeated.

Regulatory Basis

10 CFR 70.64(a) (1) states that the licensee must maintain or control appropriate records of IROFS throughout the life of the facility.

RAI 17. Section 3.8 discusses CFFF policy and procedures for 10 CFR Part 21. Describe the following:

- 17.1. Expand on the basis for the procedure applicable to the evaluation of conditions associated with a substantial safety hazard and elaborate on the reporting requirements in case there is a conditions that is a substantial safety hazard.
- 17.2. Elaborate on the retention record requirements for evaluations perform on conditions identified as substantial safety hazards.

RAI 18. Section 3.9, "Records Management," states that the Records Flow Schedule identifies the records to be retained, retention locations, and retention time limits. Identify the retention requirements applied to surveillance schedules, performance criteria, and test results associated with IROFS. Describe the retention of the preventative maintenance and functional test schedule and results.

Over the course of a 40-year license, the CFFF staff will change. Much reliance will be placed on documents to maintain the knowledge of the IROFS. Such documents must be maintained (updated, located) in a manner that ensures that they are preserved and accessible for an adequate period.

Regulatory Basis

10 CFR 70.64(a) (1) states that the licensee must maintain or control appropriate records of IROFS throughout the life of the facility.

RAI 19. Describe the measures implemented to ensure the ability to read and use computer codes and data stores for the retention life of the record.

Over the course of a 40-year license, information media will change. Software, and hardware to use the software, will change and potentially no longer be sold. Parts of hardware will become obsolete. Having a planned, systematic mechanism to retrieve records as time progresses is

necessary to ensure that documents are accessible, can be readily modified, and are readily transferrable.

Regulatory Basis

10 CFR 70.64(a) (1) states that the licensee must maintain or control appropriate records of IROFS throughout the life of the facility.

RAI 20. Section 3.9 identifies that “Responsibilities for a records coordinator are defined to assure that the records management system is successfully implemented. This records coordinator develops and maintains a Records Flow Schedule (RFS).”

- 92.1 Clarify the use of procedures for records verification, transmittal, and distribution.
- 92.2 Confirm that procedures identify authority for records retention and disposal, describe controlled access of records, and control records management during emergency conditions.
- 92.3 Clarify how the CFFF organizational structure take part on the responsibility of records.

Over the course of a 40-year license, CFFF staff will change. Established and documented procedures need to specify the requirements and responsibilities for maintaining records to ensure that appropriate processes exist for current and future record creation, management, and disposal activities.

Regulatory Basis

10 CFR 70.22(a) (8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property. 10 CFR 70.64(a)(1) states that the licensee must maintain or control appropriate records of IROFS throughout the life of the facility.

RAI 21. Discuss how the CFFF organizational structure enables authority, access, and independence for quality-affecting functions.

Organizational responsible for ensuring that appropriate QA has been established should have sufficient authority, access to work areas, and organizational independence to perform its responsibilities.

Regulatory Basis

10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

REFERENCE

1. Letter from N. Parr, Westinghouse Electric Company LLC, "Westinghouse License Renewal Application Revised Management Measures Chapter (TAC #: L33317)", February 29, 2016. ADAMS accession number ML16060A464.