Enclosure 1

Consolidated May 18, 2016 RAI Responses for Management Measures

REQUEST FOR ADDITIONAL INFORMATION	REG BASIS	WESTINGHOUSE RESPONSE
RAI 1 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.	10CFR70.62(d) 10CFR70.64(a)(1) 10CFR70.64(a)(8)	A revised Chapter 3.0, "Management Measures" was submitted to the NRC on September 15, 2017 following an NRC license renewal visit to the CFFF. The revised chapter specifies how relevant design requirements are incorporated into procurement, surveillance and maintenance documents for IROFS.
RAI 2 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	10CFR70.22(a)(8) 10CFR70.64(a)(1)	2.1 A revised Chapter 3.0, "Management Measures" was submitted to the NRC on September 15, 2017 following an NRC license renewal visit to discuss management measures. Document control was discussed on-site. The revised chapter specifies the document control requirements for IROFS. 2.2 The application of document control requirements is specified in the revised Management Measures chapter.

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.		
RAI 3 The Integrated Safety Analysis summary 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.	10CFR70.62(d) 10CFR70.61(e)	Section 3.2 of the License Application was revised to add the following statement: "Maintenance" for administrative control IROFS is performed through the procedure review and approval process described in Section 3.4 of this Chapter. Periodic review of procedures is performed to assure their continued effectiveness and suitability for the IROFS to which they apply.
RAI 4 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.	10CFR70.62(d) 10CFR70.61(e)	This question is no longer applicable, as the "quality levels" were removed from the Management Measures chapter submitted per LTR-RAC-16-18 on February 29, 2016.
RAI 5 Section 3.3, Other Quality Assurance, describes	10CFR70.62(d)	A revised Chapter 3.0, "Management Measures" was

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	10CFR70.61(e)	submitted to the NRC on September 15, 2017 following an NRC license renewal visit to the CFFF. The revised Section 3.3 of the License Application specifies how "Other Quality Assurance" elements apply to IROFS.

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.		
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.	10CFR70.62(d) 10CFR70.61(e) 10CFR70.64(a)(8)	The use of compensatory measures was added to Section 3.2 of the License Application. Components associated with IROFS shall not be disconnected or removed from service, while the process continues to operate unless authorized in a written procedure specifically approved in advance by EH&S. Whenever components associated with IROFS are observed to be defective, the controlled operations shall be terminated until appropriate compensatory measures, approved by EH&S, can be temporarily instituted while the defective component is being replaced.
RAI 7 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.	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e	The minimum qualifications for a process operator were added to Section 3.4.2.2 of the License Application.
RAI 8 Describe the use of training objectives and	10CFR70.22(a)(8)	A revised Chapter 3.0, "Management Measures" was

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 address 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.	10CFR70.62(d) 10CFR70.61(e)	submitted to the NRC on September 15, 2017 following an NRC license renewal visit to the CFFF. The revised Section 3.4.2 of the License Application specifies how the training and qualification management measure is implemented. 8.1 A performance-based training and qualification program is implemented at the CFFF in accordance with approved procedures. The objective of this program is to ensure individuals performing activities relied on for safety have the proper knowledge, skills and abilities to perform work activities in a safe and compliant manner. For training at the CFFF, 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 are understood. Training objectives are derived from specific job performance requirements. 8.2. Materials are used to guide training to assure that the objectives are met and that there is consistent conduct of training. These materials may include but are not limited to lesson plans, instructor guides, student guides, learning activities, assessments, presentations, handouts, checklists, and videos. Training is guided by the behavior the learner must demonstrate, the conditions under which the action will take place and the standard of performance. 8.3. The review and approval requirements for training materials vary based on the type of training and the training objective. Different EH&S safety disciplines approve training materials based on the subject matter to assure that training materials are technically correct and accurate. These review and approval requirements are similar to those required for procedures. Individuals are trained to work to their

		procedures. This ensures individuals performing activities relied on for safety have the proper knowledge, skills and abilities to perform work activities in a safe and compliant manner. Deficiencies identified with training materials are entered into the Corrective Action Program for resolution.
RAI 9 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.	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	Salaried professionals receive on the-job-training (OJT) needed to meet minimum requirements to work in assigned areas. OJT is accomplished by working with an individual of the same position category and/or working with experienced engineers and/or managers who are knowledgeable of the position responsibilities. In addition, Regulatory Component personnel received training as specified in Section 3.4.2.2 of the License Application.
RAI 10 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	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	***10.1.*** In the license application, the use of ECL's is required for operator training. Where process operation qualification interlocks are in use, an operator cannot perform a task until he/she is current on procedure, training and qualification requirements. Procedures, training and qualification requirements assure that activities related to IROFS and management measures are properly performed. In addition, audits are performed to assure ongoing effectiveness. ***10.2.*** Periodic requalification for operators performing activities relied on for safety requires that an OJT Trainer determines if a re-qualifying person can continue to successfully and safely perform the process per the procedure(s) by performing the following: • Asking questions about the process procedure(s). • Observing the person demonstrate the ECL tasks per

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.		the procedure. • Observing/asking questions while the person simulates/verbalizes the tasks, if equipment is not available or the process is down. For all personnel with unescorted access at the CFFF, annual refresher training is required to assure those individuals maintain a current knowledge of the safety and safeguards requirements for the site.
RAI 11 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.	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	A performance-based training and qualification program is implemented at the CFFF in accordance with approved procedures. The objective of this program is to ensure individuals performing activities relied on for safety have the proper knowledge, skills and abilities to perform work activities in a safe and compliant manner. Component Managers are responsible for assuring their personnel are properly trained and qualified or do not work independently until training and qualification requirements are met. Evaluation of training effectiveness is performed on a continuing basis, and when training deficiencies or performance issues are identified, they are corrected immediately or entered into the Corrective Action Program for resolution.
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	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	The Configuration Management Program described in Section 3.1 of the License Application would identify any special provisions required for the procurement of IROFS. In addition, Section 3.3 of the License Application states that identification

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.		and control of material, parts and components for procured IROFS is performed in accordance with written procedures to assure that only correct items are used and installed.
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.	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	Administrative procedures assign responsibilities and provide requirements for activities that do not involve manipulation, operation, modification, maintenance, testing, or calibration of plant equipment or real-time computer systems. These procedures provide the administrative and general CFFF regulatory requirements. Administrative IROFS are typically implemented in Operating procedures. Operating procedures give step-by-step process instructions and specify operator actions necessary to prevent or mitigate accidents identified in the ISA Summary. Operating procedures are required to include prerequisites and acceptance criteria. Special precautions or warnings are also included.
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.	None provided.	The Work Management process establishes and defines the process utilized to identify, prepare and complete maintenance activities and engineering projects which affect facilities and equipment at the CFFF. This process ensures maintenance work is executed with a level of rigor that is appropriate for any risk to personal or public safety.

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.		14.1. Prior to performing maintenance work activities, the craftsman must be current on the training and procedure requirements for the work activity. After that, a craftsman performs the maintenance work in accordance with the procedure and work order requirements. If the work cannot be performed as written, the craftsman is required to stop and contact the supervisor. Work is not allowed to proceed until the written instructions are corrected. A "Safety Checklist" found on work orders is completed as part of pre-maintenance activities. Safety considerations are indicated on the Safety Checklist prior to work beginning. Also, prior to starting work, the owner of the equipment (typically Operations) signs the work order as “ok to start,” indicating that it is released to maintenance for the work to begin. 14.2. Prior to beginning work directed by a maintenance work order, the owner of the equipment must approve the work order as “ok to start,” and after the work is completed, the craftsman signs the work order as "Completed By." The owner of the equipment, typically operations, then signs the work order indicated that the work has been completed and accepted. Any post maintenance testing and functional verification of IROFS will be performed prior to the work order being completed and accepted.
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.	10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)	The CFFF audit program specifies the required frequency for required program audits completed in accordance with the frequencies stated in our license application and associated regulatory requirements. Management may also direct audits to be completed more frequently or to be completed in areas other than what is required in the License Application based on any performance deficiencies.

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." • Describe the records retention requirements for abnormal events. • Clarify the manner in which incident investigation documentation will be retained to enable use for continuous improvement of affected operations. • 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. • 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.	10CFR70.64(a)(1)	Section 3.9 of the License Application states that records of abnormal requirements involving IROFS are maintained for a minimum of three years or as otherwise required by federal regulation or other license condition. The statement in Section 3.7 has been removed. Abnormal events involving degraded or failed IROFS/management measures are also entered into the CAP. The CAP retains incident investigation documentation for degraded or failed IROFS/management measures. Formal investigation of abnormal occurrences is performed in accordance with the CAP. The CAP has criteria to determine the issue significance and the associated level of investigation required. The rigor required for the causal analysis investigation increases based on the significance of the issue. The information is retained in the CAP. Also, abnormal occurrences are periodically trended and summarized (at least annually) to identify repetitive failures and generic issues. Additional evaluation, corrective actions and continuous improvement activities may be initiated as a result of this trend analysis. The ISA may be revised based on this information.

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.	None provided.	A revised Chapter 3.0, "Management Measures" was submitted to the NRC on September 15, 2017 following an NRC license renewal visit to the CFFF. The revised Section 3.8 removed this information from the License Application. The criteria for a substantial safety hazard at the CFFF is based on the NRC guidance in NUREG-0302 as it pertains to a 10CFR70 licensed facility. The reporting of Conditions Adverse to Nuclear Safety is as stated in the 10CFR21 regulation. Part 21 evaluations are performed in accordance with written procedures. The CAP is used to document Part 21 issues. Part 21 requires these records to be retained for 5 years. However, the CFFF retains these records as "permanent," i.e., the lifetime of the facility.
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.	10CFR70.64(a)(1)	A revised Chapter 3.0, "Management Measures" was submitted to the NRC on September 15, 2017 following an NRC license renewal visit to the CFFF. The revised chapter clarified the records management practices in Section 3.9.
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.	10CFR70.64(a)(1)	At the CFFF, there is a requirement to preserve and maintain any record in accordance with the Records Flow Schedule. In the case of electronic records, provisions are made to maintain the required records should the software or

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.		hardware become unavailable. This mechanism assures that a readable and usable copy of the record is maintained.
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)." • Clarify the use of procedures for records verification, transmittal, and distribution. • Confirm that procedures identify authority for records retention and disposal, describe controlled access of records, and control records management during emergency conditions. • 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.	10CFR70.22(a)(8) 10CFR70.64(a)(1)	The CFFF EH&S Department Manager has the overall responsibility for the management of records required to meet license commitments. The EH&S Records Coordinator implements this records management system in accordance with plant procedures to assure compliance with these commitments. In addition, the system describes the records requirements for other applicable regulatory requirements. Procedures define the requirements for verification, transmittal and distribution; specify the authority needed for records retention or disposal; describe access controls; provide for the protection of records from loss, damage, tampering, and theft or during an emergency; and assure that the records management system remains effective.
RAI 21 Discuss how the CFFF organizational structure enables authority, access, and independence for quality-	10CFR70.62(d) 10CFR70.61(e)	Chapter 2.0 of the License Application states that the CFFF Plant Manager is ultimately responsible for ensuring that CFFF

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.		operations are conducted in a safe and compliant manner. The CFFF Plant manager is responsible for establishing organization with defined accountabilities. To the extent practicable, the Regulatory Component is administratively independent of the Manufacturing, Engineering, and Quality Components to prevent conflicts of interest. Similarly, the Quality function is administratively independent of the Manufacturing, Engineering, and Regulatory Components.