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July 29, 2016

SUBJECT: WESTINGHOUSE RENEWAL APPLICATION MANAGEMENT MEASURES
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION (COST ACCOUNTING CODE
NUMBER L33337)

Westinghouse Electric Company LLC (Westinghouse) is pleased to provide the enclosed response to your Request for Additional Information dated May 18, 2016, regarding Management Measures described in our license renewal application.

If you have any questions regarding this information, please contact me at (803) 647-3338.

Sincerely,

A handwritten signature in blue ink that reads 'Nancy Blair Parr'.

Nancy Blair Parr, Manager
Licensing
Westinghouse Columbia Fuel Fabrication Facility
Docket 70-1151 License SNM-1107

Enclosure: Response to Request for Additional Information – 16 pages

cc:

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Attn: Mr. Thomas Vukovinsky

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Attn: Mr. Christopher Ryder, Mail Stop T-4A60

Enclosure

Westinghouse Columbia Fuel Fabrication Facility (CFFF) Management Measures RAI Responses

REQUEST FOR ADDITIONAL INFORMATION	REG BASIS	WESTINGHOUSE RESPONSE
<p>RAI 1 Describe how management measures are applied to ensure that procurement, surveillance, and maintenance documents incorporate relevant design requirements.</p> <p>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.</p>	<p>10CFR70.62(d) 10CFR70.64(a)(1) 10CFR70.64(a)(8)</p>	<p>When a modification is designed per the CFFF Configuration Management Program, the “change” is reviewed by the various safety disciplines to assure that 10CFR70.72 requirements are met. When a “change” potentially has an impact on existing IROFS or requires new IROFS, the revised or new maintenance and surveillance procedures for those IROFS must be approved and issued prior to implementation and start-up of the “change.” This includes functional verification of any other IROFS potentially affected by the “change.” For modifications affecting IROFS that require procurement controls, the procurement controls are identified in the specifications and documentation requirements for the “change,” and plant procedures are in place to assure that the purchased items conform to specified requirements.</p>
<p>RAI 2 Elaborate on the discussion of document control.</p> <p>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,</p>	<p>10CFR70.22(a)(8) 10CFR70.64(a)(1)</p>	<p>2.1 The CFFF Configuration Management Program assures that the CFFF maintains current necessary records associated with the design and safe operation of the facility. All changes to manufacturing and inspection systems, facilities and utilities require multi-disciplinary review and approval to make sure that systems continue to meet their specification requirements and comply with all applicable regulations. Additionally on an annual</p>

<p>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.</p> <p>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.</p>		<p>basis, the CFFF submits a report of changes to the facility that did not require NRC pre-approval and also submits a revised Integrated Safety Analysis (ISA) Summary incorporating these changes.</p> <p>2.2 In addition to the current design requirement records specified through the CFFF Configuration Management Program, other documents and records related to IROFS and their management measures include as-built drawings; operating, maintenance and surveillance procedures; administrative procedures describing each management measure program; Integrated Safety Analyses and ISA Summary including identification and specifications for IROFS; software controls. In addition, the License Application, the Fundamental Nuclear Material and Control Plan, the Site Emergency Plan and the Physical Security Plan are revised as needed to reflect current conditions.</p>
<p>RAI 3 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.</p>	<p>10CFR70.62(d) 10CFR70.61(e)</p>	<p>At the CFFF, IROFS that are purely administrative controls are implemented through procedures, e.g., a designated procedure action. Periodic review of these procedures is performed at least every two years to make sure that they are accurate and can be performed as written. In addition, periodic refresher training for personnel performing administrative IROFS is also performed. The periodic review and periodic refresher training for administrative IROFS is equivalent to “maintenance” of engineered controls. This periodic review and refresher training assures the availability and reliability of administrative IROFS and is considered part</p>

		of the “procedure” management measure described in Section 3.4 of the License Application.
<p>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.</p> <p>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.</p>	<p>10CFR70.62(d) 10CFR70.61(e)</p>	<p>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.</p>
<p>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).</p> <p>(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.</p> <p>(b) Design Control/Document Control - clarify how the process ensures that all documents are properly modified authoritatively approve and make them available to personnel</p>	<p>10CFR70.62(d) 10CFR70.61(e)</p>	<p>At the CFFF, most quality assurance elements to assure the availability and reliability of IROFS are implemented through the configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations and records management programs.</p> <p>(a) If "procurement document control" is required for an IROFS, then the appropriate specifications, codes, standards, tests, inspections, and/or associated records are identified as part of the Configuration Management Program. A formal Quality Assurance Program for this element would only apply to sole IROFS at the CFFF, and the CFFF does not have any sole IROFS.</p> <p>(b)The Configuration Management and Procedure management measures programs assure all designs and documents are properly modified, approved and implemented.</p> <p>(c) If procurement control is required for an IROFS, then</p>

<p>(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.</p> <p>(d) Control of special processes - clarify how these controls will be applied to IROFS (e.g. inspection, maintenance).</p> <p>(e) QA records (note that records are addressed by Section 3.9 with the exception of record preparation (generation and authentication), transmittal, and distribution).</p> <p>(f) Control of Measuring and Test Equipment - clarify how these CFFF procedures apply to IROFS.</p> <p>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.</p>		<p>the CFFF procedures ensure that the purchased items conform to specified requirements. Uninspected or unacceptable items are physically segregated from inspected and acceptable items when possible, and/or clearly marked or tagged as uninspected or unacceptable; so they cannot be mistaken for inspected and acceptable items. Inspection includes the resolution of any non-conformances. A formal Quality Assurance Program for this element would only apply to sole IROFS at the CFFF, and the CFFF does not have any sole IROFS.</p> <p>(d) Control of special processes is implemented through the CFFF Configuration management and Maintenance program which include facility specifications and standards, mechanical integrity, dye penetrant inspection and welding standards/program. A formal Quality Assurance Program for this element would only apply to sole IROFS at the CFFF, and the CFFF does not have any sole IROFS</p> <p>(e) Records for Management Measures are described in Section 3.9 of the License Application. The Records management Program specifies requirements for creation, protection, retention, retrieval and disposition of records. These provide a complete, authenticated document which furnishes evidence of compliance with applicable regulatory requirements.</p> <p>(f) Measuring and Test Equipment (MT&E) controls for tools, gauges, instruments, and other measuring and test equipment used for IROFS and activities affecting IROFS include the methods and calibration frequency of as well as any controls to maintain accuracy within</p>
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<p>RAI 6 Describe the use of compensatory measures.</p> <p>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.</p>	<p>10CFR70.62(d) 10CFR70.61(e) 10CFR70.64(a)(8)</p>	<p>specified limits.</p> <p>The process operations shall be terminated pending EH&S approvals if special conditions are not described in an applicable approved procedure.</p> <p>IROFS may never be defeated, bypassed, over-ridden, or forced Off, unless specifically approved in advance by EH&S. Procedures shall state the required conditions, time limit, and controls to be maintained while a control is in By-Pass Operations.</p> <p>IROFS may be forced On only when conducting operability tests in accordance with written procedures. Where possible, operability testing must be conducted while line operations are terminated (SNM processing has stopped). This is because the process of forcing interlocks On causes them to perform their intended function.</p> <p>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 controls, approved by EH&S, can be temporarily instituted while the defective component is being replaced.</p>
<p>RAI 7 Identify the minimum qualifications (i.e., education and experience) for process operators themselves.</p> <p>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</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>A high school diploma is the minimum qualification for a process operator. Process operators who perform work involving licensed material and/or IROFS are properly trained and qualified to perform these activities through a documented Training Delivery System to assure safe and compliant activities are conducted at the CFFF. Performance-based training programs are documented in approved procedures. These programs are structured such</p>

<p>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.</p>		<p>that specific training and qualification requirements are met prior to regulatory-significant positions being fully assumed or covered tasks being independently performed.</p> <p>The knowledge, skills and abilities required for a specific task are included on an Electronic Checklist (ECL). The ECL is used to document on-the-job (OJT) training has been completed.</p>
<p>RAI 8 Describe the use of training objectives and lesson plans at the CFFF. Address the following topics:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Unambiguous and documented training objectives ensure that, over the 40 years of a license, training</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Materials are used to guide training to assure that the</p>

<p>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.</p>		<p>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.</p> <p><i>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.</i></p> <p>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 Process for resolution.</p>
<p>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.</p> <p>Safe operation of the CFFF necessitates all people</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>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.</p>

<p>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.</p>		
<p>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.</p> <p>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.</p> <p>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.</p> <p>Refresher training and requalification ensure that CFFF staff have current knowledge to perform their</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p><i>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.</i></p> <p>In the license application, the use of ECL’s is required for operator training. Where Process Operation Qualification Interlocks are in use, then 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 accordance with CFFF specifications.</p> <p><i>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.</i></p> <p>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:</p> <ul style="list-style-type: none"> • Asking questions about the process procedure(s). • Observing the person demonstrate the ECL tasks per the procedure. • Observing/asking questions while the person

<p>activities in a safe manner.</p>		<p>simulates/verbalizes the tasks, if equipment is not available or the process is down.</p> <p>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.</p>
<p>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.</p> <p>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.</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>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.</p> <p>Evaluation of training effectiveness is performed on a continuing basis, and when training deficiencies or performance issues are identified, they are corrected immediately.</p>
<p>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</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>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</p>

<p>for procurement are described, or add a description of these procedures.</p> <p>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.</p>		<p>Application states that identification 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.</p>
<p>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:</p> <p>(a) Prerequisites and precautions (b) Acceptance criteria</p> <p>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.</p>	<p>10CFR70.22(a)(8) 10CFR70.62(d) 10CFR70.61(e)</p>	<p>CFFF procedures shall clearly identify specific regulatory requirements, special precautions, or warnings prior to the action to which they apply. Prerequisites elements, while not titled as such in the standard plant procedure format, are required to be included as activities specified in the procedure. Acceptance criteria elements, while not titled as such in the standard plant procedure format, are also specified in procedures, i.e., criteria needed to confirm the availability and reliability of IROFS are documented in the procedure.</p>
<p>RAI 14 Describe how the conduct of maintenance activities includes the following:</p>	<p>None provided.</p>	<p>The Work Management process establishes and defines the process utilized to identify, prepare and complete maintenance activities and engineering projects which</p>

<p>14.1. Reviews of the work to be performed, including procedure reviews for accuracy and completeness, as part of pre-maintenance activities.</p> <p>14.2. Procedure steps requiring notification of all affected parties (operators and supervisors) before performance of work and on completion of maintenance work.</p> <p>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.</p>		<p>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.</p> <p>14.1. Prior to performing maintenance work activities, the craftsman must be current on the associated electronic 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.</p> <p>A "Safety Checklist" found on all 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, operations signs the work order as "ok to start," indicating that it is safe for the work to begin.</p> <p>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" and the owner of the equipment, typically operations, will sign the work order indicated that the work has been completed and accepted.</p> <p>Any post maintenance testing and functional verification of IROFS will be performed prior to the work being completed and accepted.</p>
<p>RAI 15 Section 3.6 states, "An annual formal audit</p>	<p>10CFR70.22(a)(8)</p>	<p>The CFFF audit and assessment program specifies the</p>

<p>and assessment schedule is planned, documented, revised (as necessary), and implemented.” Discuss threshold to determine how often these need to be performed.</p>	<p>10CFR70.62(d) 10CFR70.61(e)</p>	<p>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 or assessments 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 (severity and frequency of programmatic or compliance issue).</p>
<p>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.”</p> <p>88.1 Describe the records retention requirements for abnormal events.</p> <p>88.2 Clarify the manner in which incident investigation documentation will be retained to enable use for continuous improvement of affected operations.</p> <p>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.</p>	<p>10CFR70.64(a)(1)</p>	<p>88.1 Describe the records retention requirements for abnormal events. 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. Section 3.7 states that records for abnormal occurrences are maintained for a minimum of three years. The statement in Section 3.7 will be removed from the License Application.</p> <p>88.2 Clarify the manner in which incident investigation documentation will be retained to enable use for continuous improvement of affected operations. As described in Section 3.9, records of abnormal occurrences are maintained for a minimum of three years or as otherwise required by federal regulation or other license condition. As described in Section 3.7, abnormal occurrences are periodically trended and summarized 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. It is customary that operating experience from abnormal occurrences is incorporated into the ISA.</p>

<p>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?</p> <p>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.</p>		<p>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.</p> <p>Section 3.7 states that more significant abnormal occurrences are handled in accordance with the requirements in Section 3.8 "Corrective Action Process." The CAP specifies criteria to determine the issue significance and the associated level of investigation required. The rigor required for the causal analysis investigation increases is based on the significance of the issue.</p> <p>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? See the responses to 88.1 and 88.2 above.</p>
<p>RAI 17 Section 3.8 discusses CFFF policy and procedures for 10 CFR Part 21. Describe the following:</p> <p>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.</p> <p>17.2. Elaborate on the retention record requirements for evaluations perform on</p>	<p>None provided.</p>	<p>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.</p> <p>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.</p> <p>17.2. Elaborate on the retention record requirements for evaluations perform on conditions identified as</p>

<p>conditions identified as substantial safety hazards.</p>		<p>substantial safety hazards. Part 21 evaluations are performed in accordance with written procedures associated with the CFFF Corrective Action Process. As described in Section 3.9, records of abnormal occurrences are maintained for a minimum of three years or as otherwise required by federal regulation or other license condition. 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.</p>
<p>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.</p> <p>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.</p>	<p>10CFR70.64(a)(1)</p>	<p>The regulatory reference stated for this RAI is 10CFR70.64(a)(1). This specifies the quality standards and records for meeting the Baseline Design Criteria for new facilities or new processes at existing facilities. As stated in Section 3.9 of the License application, records specifically required for new facilities or new processes at existing facilities as required by 10CFR70.64(a) are maintained in accordance with those regulations. Any CFFF License Application for a new facility or process would describe how the Baseline Design Criteria are met, and this License Application would require NRC pre-approval prior to commissioning or start-up of the new facility or process.</p> <p>For existing maintenance activities related to IROFS (including surveillance schedules, performance criteria, test results and preventing maintenance), records are maintained for the life of the process as stated in Section 3.2 of the License Application.</p>
<p>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.</p>	<p>10CFR70.64(a)(1)</p>	<p>The regulatory reference stated for this RAI is 10CFR70.64(a)(1). This specifies the quality standards and records for meeting the Baseline Design Criteria for new facilities or new processes at existing facilities. As</p>

<p>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.</p>		<p>stated in Section 3.9 of the License Application, records specifically required for new facilities or new processes at existing facilities as required by 10CFR70.64(a) are maintained in accordance with those regulations. Any CFFF License Application for a new facility or process at would describe how the Baseline Design Criteria are met, and this License Application would require NRC pre-approval prior to commissioning or start-up of the new facility or process.</p> <p>At the CFFF, there is a requirement to preserve and maintain the 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 hardware become unavailable. This mechanism will assure that a readable and usable copy of the record is maintained.</p>
<p>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).”</p> <p>92.1 Clarify the use of procedures for records verification, transmittal, and distribution.</p> <p>92.2 Confirm that procedures identify authority for records retention and disposal, describe controlled access of records, and control records management during emergency conditions.</p> <p>92.3 Clarify how the CFFF organizational</p>	<p>10CFR70.22(a)(8) 10CFR70.64(a)(1)</p>	<p>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.</p>

<p>structure take part on the responsibility of records.</p> <p>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.</p>		
<p>RAI 21 Discuss how the CFFF organizational structure enables authority, access, and independence for quality-affecting functions.</p> <p>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.</p>	<p>10CFR70.62(d) 10CFR70.61(e)</p>	<p>Chapter 2.0 of the License Application states that the CFFF Plant Manager is ultimately responsible for ensuring that CFFF operations are conducted in a safe and compliant manner. The CFFF Plant manager is responsible to establish an 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.</p>