CHAPTER 3
CONDUCT OF OPERATIONS
Comments/Questions to be Discussed During Site Visit

1. Revise Section 3.1 add the words , Configuration Management is an integrated management measure that provides oversight and control, establishes consistency among design requirements, safety information, physical configuration, facility documentation, records of modification that might impact the ability of items relied on for safety to perform their functions when needed. Configuration Management is carried forward through the facility technical baseline established in design and operations and maintains this consistency throughout the life of the facility as changes occur. The CFFF CM Program consists of CM functions associated with the following program elements: Engineering Component, Regulatory Component, Product Assurance Component. ...

2. Revise Section 3.1.1 CM Program Structure to include a discussion of the CFFF processes to identify interfacing program requirements that are used to achieve effective configuration management. The following summarizes some important interfaces; the assignment of SSC grades based upon the most important design requirements, the process used to identify codes and standards and performance standards used for facility design, operation and evaluation of their adequacy. Revise this section to describe maintenance management activities that will be performed on equipment, including repairable or replaceable equipment and non-replaceable equipment, which should include the provisions for identifying preventive and predictive maintenance activities such as tests, inspections, diagnostics and trending.

3. SNM 1107 Section 3.1.2.b, "CM Program Implementation" - Change control provisions are not discussed in detail. Revise "Documentation Updates" to include a discussion on how computer software configuration is managed, to assure changes are documented and controlled. Include in discussion elements of software version control, software verification and validation, software error notifications and software configuration management. Clarify the methods employed to check configuration changes for drawings, specifications, and modifications to operating procedures including the necessary training and retraining. Revise this section to incorporate requirements of 10 CFR 70.72.

4. SNM 1107 Section 3.1.2.d, "Regulatory Reviews and Approvals" - Clarify the application of graded QA controls by describing the degree or rigor of regulatory review and approval commensurate with SSCs functional classification. Since change control and document control are continuous processes, describe how the regulatory review, approval, and grading processes are integrated into each safety and safeguards discipline based on the same degree of rigor linked to the ISA Summary table of SSCs designated as IROFS.

5. SNM 1107 "QA Program Implementation", Section 3.3.3.2 states, "The program is performance based. That is, quality assurance decisions are based, to the extent practicable, on safety system performance histories". Since QA decisions are based on safety system performance histories, revise Section 3.3.3.2 to elaborate on the factors used to determine when and how QA decisions, performance histories, and performance deficiencies are graded commensurate with their risk, the level of analysis

applied based on their relative importance to safety, safeguards, and security. Describe the quantitative standards e.g., (how often IROFS fail, how long do IROFS perform until failure, and quantified number of failures per year) used to measure their performance per 10 CFR 70.62.

6. SNM 1107 "QA Program Implementation", Section 3.3.3.7 states, "The program embraces issue identification, remedial actions, and management control elements to ensure that deficiencies, deviations and defective equipment and services are disclosed and corrected in a timely manner through the utilization of the CFFF Corrective Action Process. This section does not embrace regulatory requirements of 10 CFR Part 21 for Reporting of Defects and Noncompliance. Change Section 3.3.3.7 to also include requirements for reporting of defects and noncompliance, per 10 CFR Part 21

7. SNM 1107 Section 3.3.3.8, QA Program Implementation states "... Such systems are not back-fit except for system upgrade modification and/or actions arising from internal evaluations or external disclosures (such as NRC Information Notices, etc.). Add a statement in Section 3.3.3.8 to include requirements for reporting of defects and noncompliance, per 10 CFR Part 21

8. SNM 1107 Section 3.2.1 "Maintenance Program " states, "To keep safety-related systems and components at the Columbia Fuel Fabrication Facility (CFFF) in a condition of readiness such that they are likely to perform their desired function when called upon to do so, a maintenance program is implemented in accordance with approved procedures. Maintenance is a management measure controlled by the quality program described in Section 3.3 of this License Application ." Since maintenance activities provide assurance that the physical configuration of the facility is maintained within design requirements, Section 3.3.3.2 states " The program is performance based." However, the maintenance program does not provide enough information regarding the involvement of engineering and technical support functions used to identify and evaluate potential degradation mechanisms ("performance basis") caused by environmental conditions and service over time (e.g. predictive maintenance activities) and the provisions utilized to reliably predict performance under normal operating conditions. Additionally, predictive maintenance consists of actions necessary to monitor, maintain, calibrated instruments, find trends, analyze process parameters, and performance characteristics. Revise SNM Section 3.2.1 to include a narrative discussion on engineering and technical support used to identify, evaluate, and predict failure of IROFS or SSCs. Revision should include the processes and procedures used to monitor performance characteristics important to safe reliable operation of items relied on for Safety (IROFS) and the measurements used to capture and forecast predictive maintenance and trending of maintenance activities .

9. SNM 1107 Section 3.2.2.4, The purchasing module should be revised. There is no correlation of the application of the graded approach to procurement of Safety Significant Components. How will the graded approach be applied during procurement? There is no evidence that the graded approach used to ensure that the level of analysis, documentation, resources, and actions used for procurement of items for High Consequence Systems or Intermediate Consequence Systems are applied commensurate with their relative importance to safety, safeguards and the environment. Revised this section to include a discussion on the processes used in the development of procurement specifications, audits and/or source inspections of vendors who supply QA Level A, or QA Level B materials and the QA grading and application of Safety

Significant Controls.

10. SNM 1107 Section 3.3.3 states, "The program's description is documented in a manual that specifies authority, responsibility, and accountability for all program elements." Revise this section to specify which manual specifies authority, responsibility, and accountability for all program elements.

11. SNM 1107 Section 3.4.1.1, Regulatory-Significant Procedure Structure states " CFFF procedures are classified into three general categories. Revise and change the word "general" to "specific".

12. SNM 1107 Section 3.4.1.1 (a) ...Examples of Category-1 procedures subcategories include; .... Revise to add subcategories Chemical Process; and Fire Safety.

13. SNM 1107 Section 3.4.1.2 "Issuance, Approval and Communication of Procedure Content". Revise to include the processes used to identify, verify, validated, control changes, review and resolve comments to procedures.

14. SNM 1107 Section 3.4.2 Training and Qualification Structure, In accordance with the requirements of 10 CFR Part 70, personnel who perform activities relied on for safety are required to be trained and tested as necessary. Section 3.4.2.2 and 3.4.2.3, "Training and Qualification of Regulatory Function Engineers" and "Training and Qualification of Regulatory Operation Technicians" respectively states ... "In addition to the general topical and refresher training requirements previously described, all Regulatory Function Engineers (and Regulatory Operation Technicians) receive training and documented qualification specific to their regulatory activities". Revise training and qualification to include the processes used for developing lesson plans and training guides, on-the-job training, testing, and qualification of personnel who perform activities relied on for safety.

15. SNM 1107 Section 3.7.1.1, Internal Reporting of Unusual, Safety-Related Occurrences states, "In accordance with approved procedures, a formal, computerized system is maintained by the Regulatory Component to enable all CFFF employees to report safety-related process upsets and procedure inadequacies to their First Level Managers for follow-up action. Such process upsets specifically include failures of Safety Significant Controls (SSCs) and/or Management Measures to execute their intended purpose. Procedural inadequacies include failure to have an approved procedure, inability to follow an approved procedure, and/or failure to follow an approved procedure". The terminology "procedure inadequacies" is undefined and does not denote that the item, activity or procedure is deficient. Contrary to the commitments stated in SNM 1107, QA Program Implementation, Section 3.3.3.7 which states, "The program embraces issue identification, remedial actions, and management control elements to ensure that deficiencies, deviations and defective equipment and services are disclosed and corrected in a timely manner through the utilization of the CFFF Corrective Action Process", therefore, "inadequacies" would be defined as "programmatic deficiencies or deviations" and defective equipment hardware affecting nonconformance". Revise the term "procedure inadequacies" or "inadequacies" used throughout Chapter 3 to "procedure deviation" which is defined in ASME NQA-1 as meaning (e.g., a departure from specified requirements), or "procedure deficiency or nonconformance" (e.g., a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate).

Additionally, the scope of discussion detailed SNM 1107 Section 3.7.1.2, identifies the Structure used for evaluating Unusual, Safety-Related Occurrences. Revise Section 3.7.1.2, to clearly define how the "Redbook System" will ensure that when safety related process upsets, Management Measures and safety control systems have been identified to significantly impact the reliability of items relied on for safety they are properly evaluated, entered into the Corrective Action Process, corrected and trended.

Revise Section 3.7.1.2, to include how the "Redbook System" will ensure the provisions described in 10 CFR 70.62 (a)(3) will be implemented for documenting and tracking when an IROFS or management measures fail, which include affected processes, cause of failure, whether the failure was in the context of the performance requirements, or upon demand or both and any corrective or compensatory action that was taken as a result of the failed IROFS or management measure.

16. SNM 1107 Section 3.8, Corrective Action Process (CAPs) states the "The Columbia Fuel Fabrication Facility (CFFF) maintains a corrective action process that provides a structured, disciplined approach to detect and prevent recurrence of "undesirable issues." CFFF application for renewal and ASME NQA-1 Criterion 16 does not identify or define "undesirable issues". Revise Section 3.8, change the term "undesirable issues" to "conditions adverse to quality" or "significant conditions adverse to quality" and define the term's definition. Additionally, include in revision of Section 3.8 the processes used to report significant conditions adverse to quality and the provisions used to report them to appropriate levels of upper management.

17. SNM 1107 Section 3.8, Corrective Action Process, does not identify or include the integration of the structured disciplined approach used to identify, control, detect, document, evaluate, notify, disposition, and correct nonconforming hardware SSCs. Revise Section 3.8, to include the corrective action processes used for nonconforming hardware items.

18. SNM 1107 Section 3.9.1.2, "Reports" Change the term "procedural inadequacies" to "procedural deficiencies" for consistency with Section 3.3.3.7 by embracing the process of issue identification and management control elements to ensure that deficiencies, deviations and defective equipment and services are disclosed and corrected in a timely manner through the utilization of the CFFF Corrective Action Process.

19. SNM 1107 Section 3.9.2.1, "Record Keeping" states "The Records Flow Schedule contains detailed information of records types, separated into the following record names:" 10 CFR 70.62 (a)(2) states, "Each licensee or applicant shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section." Revise Section 3.9.2.1 to identify and incorporate the provisions for records attesting to IROFS or management measures, ISA hazard identification and assumptions and conditions under which IROFS support compliance to performance with performance requirements per 10 CFR 70.62.

    In addition, SNM 1107 Section 3.9 is silent in regards to the provisions made for authentication and validation of records, record changes and record custodian storage requirements. Revise Section 3.9 to include the above mentioned provisions.

20. SNM 1107 Section 3.9.2.2 "Reporting" states,... "In particular, the following reports are submitted in response to the revised 10 CFR 70 regulation: Revise and add the

requirements per 10 CFR 70.72. (3)(f) as follows:

(b) Safety-related records of changes will include a written evaluation that provides a basis for determination that changes initiated by CFFF do not require NRC approval and the attesting records will be maintained until termination of the CFFF license.

21. SNM 1107 Section 3.6.2.1 "Formal Inspections" Revise 3.6.2.1(b) to specify the frequency in conducting formal inspections of regulatory-significant performance. Revise Section 3.6.2.1 (b) to describe the provisions pertaining to how inspection results are shared with all managers, and how corrective actions and Lessons Learned are compiled and disseminated. Describe the provisions for certification and qualification of personnel who perform regulatory significant inspections.

22. SNM 1107 Section 3.6.2.2 "Program Audits" states in part, ... "program audits are led by appropriately qualified and certified individuals, and audit team membership may include personnel who have technical understanding of the program being audited". Section 3.4.2, "Training and Qualification Structure" does not discuss or identify provisions for training, qualification or certification of Lead Audit Personnel. Revise to include provisions for training, qualification and certification of individuals used to perform Program Audits. Provisions should be consistent with ASME NQA-1.

23. SNM 1107 Section 3.7.2.3 Notification of Regulatory Agencies. Revise this section to incorporate the provisions described in 10 CFR 21.21 "Notification of failure to comply or existence of a defect and its evaluation."