

**REPORTING OF DEFECTS AND NONCOMPLIANCE OF SERVICES
TO NUCLEAR BASIC COMPONENTS
10CFR21**

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Rev No.	Preparer	Reviewer	Approver
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REVISION SUMMARY

Rev No.	Description of Revision	Date
05	Complete rewrite	12/12/2024
04	Addressed timelines and requirements in the regulation	09/15/2011
Previous Revisions on File		

1. PURPOSE

This procedure provides guidance for identifying and reporting defects and failures to comply that could create a substantial safety hazard were it to remain uncorrected, as required Title 10 of the Code of Federal Regulations, Part 21 (Part 21).

2. SCOPE

This procedure applies to items and services provided by Sonic Systems International, LLC (SSI) when imposed by a customer's procurement document.

3. GENERAL

3.1. References

- 3.1.1. Section 206 of Energy Reorganization Act of 1974
- 3.1.2. 10CFR21, "Reporting of Defects and Noncompliance"
- 3.1.3. NRC Regulatory Guide 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10CFR Part 21"
- 3.1.4. NEI 14-09, "Guidelines for Implementation of 10CFR Part 21 Reporting of Defects and Noncompliance", Revision 1
- 3.1.5. SSI-A-015, "Corrective Action"
- 3.1.6. SSI-A-016, "Nonconforming Materials, Parts, or Components"
- 3.1.7. SSI-A-017, "Procurement Control Procedure"
- 3.1.8. SSI-A-018, "Quality Records"

3.2. Responsibilities

- 3.2.1. The CEO is the "Responsible Officer" who is vested with executive authority over activities subject to Part 21.
- 3.2.2. The Director, Quality or designee shall determine if any corrective action or nonconformance requires evaluation under Part 21.
- 3.2.3. All employees are responsible for bringing suspected deviations to the Director, Quality's attention immediately upon discovery.

3.3. Definitions

- 3.3.1. Basic Component – when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents which could result in potential off-site exposure.
- 3.3.2. Commission – the Nuclear Regulatory Commission or its duly authorized representatives.
- 3.3.3. Constructing or Construction – the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in Part 21 and consulting services related to the facility or activity that are important to safety.
- 3.3.4. Defect:
 - a. A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in 10CFR21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

- b. the installation, use, or operation of basic component containing a defect; or
 - c. deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of 10CFR50 provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or
 - d. condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to 10CFR50.
- 3.3.5. Deviation – a departure from the technical requirements included in a procurement document.
- 3.3.6. Discovery – the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in 10CFR21.21(a).
- 3.3.7. Evaluation –the process of determining whether a particular deviation could create a substantial safety hazard or whether a failure to comply is associated with a substantial safety hazard.
- 3.3.8. Noncompliance – failure to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard.
- 3.3.9. Notification – Telephone communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.
- 3.3.10. Operating or Operation – the operation of a facility or the conduct of a licensed activity which is subject to Part 21 and consulting services related to operations that are safety-related.
- 3.3.11. Procurement Document – a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.
- 3.3.12. Responsible Officer – the president, vice-president, or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to Part 21.
- 3.3.13. Substantial Safety Hazard (SSH) – a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 70 and 71.
- 3.3.14. Supplying or Supplies – contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in Part 21.

4. REQUIREMENTS

4.1. Awareness and Posting

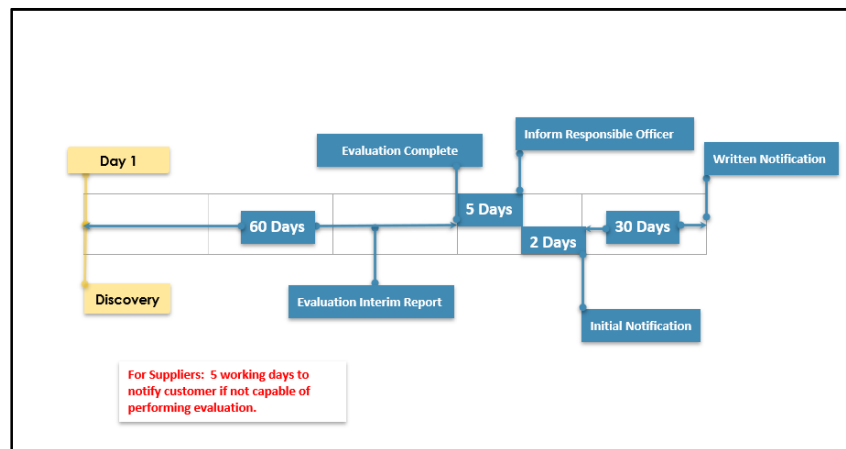
- 4.1.1. A general overview will be provided for all new hires, outlining how Part 21 applies to SSI work, the need for prompt notification, posting location and reporting/notification responsibilities.
- 4.1.2. The following documents are available to all employees by posting them in a conspicuous area in the SSI offices, the intranet or sonicsystems.com. (from Section 21.6)
 - Section 206 of the Energy Reorganization Act of 1974, and
 - 10 CFR21 "Reporting of Defects and Noncompliance", and
 - SSI-A-012, current revision

4.2. Identification of Potential Defects and Noncompliances

- 4.2.1. A suspected deviation or noncompliance may be identified by any source. Any employee identifying a deviation that may require evaluation to Part 21 shall notify the Director, Quality immediately.
- 4.2.2. The Director, Quality shall review Corrective Action Reports from SSI-A-015 and Nonconformance Reports from SSI-A-016 for suspected deviations.

4.3. Evaluation

- 4.3.1. An evaluation of the suspected defect is started upon discovery and completed within 60 days. (from Section 21.21(a)(1)).
- 4.3.2. The evaluation consists of:
 - a. Identifying and locating the affected item/service
 - b. Validating the defect or noncompliance (i.e. reviewing certification package and background info, etc.)
 - c. Evaluate the results to determine if a substantial safety hazard exists.
- 4.3.3. If the evaluation cannot be completed in 60 days from the date of discovery, then an interim report is submitted to the NRC. The interim report shall describe the deviation or failure to comply that is being evaluated and shall state when the expected evaluation completion date. (from Section 21.21(a)(2)).
- 4.3.4. Disposition of a suspected deviation or noncompliance by the Director, Quality may require consultation with responsible departments, Principal Level III or suppliers.
- 4.3.5. Should SSI not have the capability to perform the evaluation, the purchaser(s) of the basic component shall be notified within 5 days of identification of the suspected defect. Following this notification, all further responsibilities for notification to the NRC are the responsibility the purchaser(s) of the basic component. (from Section 21.21(b)).



4.4. Notification

- 4.4.1. The Responsible Officer shall be notified within 5 days after the completion of the evaluation whether a defect exists or not. (from Section 21.21(a)(3)).
- 4.4.2. If the evaluation concludes that a defect exists, the Responsible Officer shall notify the NRC. (from Section 21.21(d)(1)).

- 4.4.3. Initial notification – the Responsible Officer will notify the NRC within **2 days** of the determination by facsimile as directed in Section 21.21(d)(3). Verification that the facsimile has been received should be made by calling the NRC Operations Center. (from Section 21.21(d)(3)(i)).
- 4.4.4. Within 30 days of the determination that a defect exists, a written notification shall be sent to the NRC at the address identified in Section 21.5. (from Section 21.21(d)(3)(ii)).
- 4.4.5. The written report shall include the following as a minimum (from Section 21.21(d)(4)):
- Name and address of the entity informing the NRC
 - Identification of the basic component that contains the defect.
 - Identification of the firm supplying the basic component.
 - Nature of the defect and the substantial safety hazard that could be or was created by the defect.
 - The date that the information about the defect was obtained.
 - The number and location of all such basic components in use or supplied to facilities that are subject Part 21.
 - The corrective actions that have been, are being, or will be taken; the name of the individual responsible for the action; and the length of time taken to complete the action.
 - Advice given to purchasers related to the defect.
- 4.5. If SSI makes a report to the NRC in connection with services provided through any procurement document, a copy of the submitted evaluation report shall be mailed concurrently to the customer(s) who issued the procurement document.

5. RECORDS

Records required to comply with this procedure shall be retained and accessible for audit by customer, licensee, or Nuclear Regulatory Commission. (from Section 21.51(b))

- 5.1. Evaluation reports for deviations and failures to comply (from Section 21.51(a)(1))
- 5.2. Customer notification(s) (from Section 21.51(a)(2))
- 5.3. Customer purchase orders (from Section 21.51(a)(3))

6. ATTACHMENTS

None