





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

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Rev. No. Date	Quality Assurance Manager Approval	SSI President Approval Responsible Officer of Corporation
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Revision History: Addressed timelines and requirements in the regulation.		
Previous Revisions on File		



1. **PURPOSE**

The purpose of this procedure is to control the implementation of the Nuclear Regulatory Commission's (NRC) Rules and Regulations Title 10 of the Code of Federal Regulations, Part 21 (Part21) for identifying, evaluating potential defects and reporting defects that could create a substantial safety hazard.

2. **SCOPE**

This procedure shall apply to Sonic Systems International, Inc. (SSI) supplied items and/or services when imposed by a customer's procurement document.

3. **GENERAL**

3.1. References

- Section 206 of "Energy Reorganization Act of 1974"
- 10 CFR21 "Reporting Of Defects And Noncompliance"
- SSI-A-015 "Corrective Action"
- SSI-A-016 "Nonconforming Materials, Parts, or Components"
- SSI-A-017, "Procurement Document Control"

3.2. Responsibilities

- The President of SSI is the "Responsible Officer" who is vested with executive authority over activities subject to Part21.
- The Quality Assurance Manager shall determine if any corrective action or nonconformance requires evaluation under Part21.
- All managers, supervisors, and employees are responsible for bringing suspected deviations to the Quality Assurance Manager's attention immediately upon discovery.

4. **IMPLEMENTATION OBJECTIVES**

4.1. The following documents shall be available to all employees by posting in a conspicuous area in SSI's offices and/or on the intranet.

- Section 206 of the Energy Reorganization Act of 1974, and
- 10 CFR21 "Reporting Of Defects And Noncompliance"
- SSI-A-012, current revision

4.2. Procurement documents issued by SSI for safety related items/services shall specify the provisions of 10CFR21 in accordance with SSI-A-017.

4.3. The Quality Assurance Manager shall review Nonconformance Reports (SSI-A-016) and Corrective Action Reports (SSI-A-015) for evaluation and reportability under the requirements of this procedure.



- 4.4. A general overview will be discussed with new hires, outlining how 10CFR21 applies to SSI work, the need from prompt notification, posting location and who to report problems to.
- 4.5. Suspected deviations or noncompliance may be identified by any source. Any employee identifying a deviation that may require evaluation to 10CFR21 shall notify the QA Manager immediately.
- 4.6. The Quality Assurance Manager is required to notify the responsible officer in writing that a potential SSH exists within 48 hours of identification.
- 4.7. Disposition of suspected deviations or noncompliance by the Quality Assurance Manager shall require consultation with responsible departments or agencies.
  - The responsible manager or NDT Level III for certification of individual employees shall be contacted for matters regarding certifications or qualifications of applicable employees.
  - The supplier of instrumentation or repairs to said equipment, where applicable.
  - The supplier of consumable items such as couplant, liquid penetrant products or other inspection items such as gauges or test and measuring equipment.
- 4.8. An evaluation of the suspected defect is started 'Immediately, and completed within 60 days of discovering the suspected defect. If the evaluation cannot be completed in 60 days, then an interim report to the NRC shall be filed as required and in accordance with 10CFR21.
- 4.9. The evaluation shall consist of:
  - Identifying and locating the affected item/service
  - Validating the defect (i.e. reviewing certification package and background info, etc)
  - Evaluate the results to determine if a substantial safety hazard exists.
- 4.10. The President shall be notified within 5 days after the completion of the evaluation.
- 4.11. If the evaluation conclude that defect exists: the NRC shall be initially notified within **2 days** of the determination. Initial notification to the NRC Operations Center may be made by phone or facsimile (facsimile is the preferred method). The phone numbers for initial notification may be found in Section 21.21 of 10CFR21. If facsimile notification is used, verification that the facsimile has been received should be made by calling the NRC Operations Center. Notifications to the NRC shall be made by the QA Manager and/or President. A written report within five days containing all information required by Part 21, Section 21.21 (B) (3).
- 4.12. 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 of 10CFR21. The written report shall include the following as a minimum:
  - 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 of the defect was obtained.
  - The number and location of all such basic component in use or supplied to facilities subject to this regulation.
  - The corrective action including name of the individual responsible for the action, and length of time taken to complete the action.
  - Advice given to purchasers related to the defect.



- 4.13. 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. Any such report should contain complete details as specified in Part 21, Section 21.21 (B) describing both the possible "defect" of "failure to comply" and the extent of SSI's examination which led to the conclusion that the item may be reportable under the provisions of 10 CFR Part 21.
- 4.14. If SSI makes a report to the NRC in connection with services provided through any purchase order, a copy of such report shall be mailed concurrently to the client issuing said purchase order.
5. **DOCUMENTATION**  
Records required to comply with this procedure shall be retained and accessible for audit by client, licensee, or Nuclear Regulatory Commission.
6. **ATTACHMENTS**  
Attachment A - Definitions.



## ATTACHMENT A

### DEFINITIONS

- a) "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.

"Basic Component" when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70, or 71 of 10CFR means a component structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in 10CFR21 and in which a defect [see 3.0 (d)] or failure to comply with any applicable regulation in 10 CFR, order or license issued by the Commission could create a substantial safety hazard [see 3.0 (k)].

- b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.
- c) "Constructing" or "Construction" means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in 10CFR21 and consulting services related to the facility or activity that are important to safety.
- d) "Defect" means:
- 1) deviation [see 3.10(e)] in 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 [see 3.0 (f)] the deviation could create a substantial safety hazard; or
  - 2) the installation, use, or operation of basic component containing a defect as defined in paragraph 3.10 (d) (1); or
  - 3) deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 of 10 CFR 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;
  - 4) 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 Part50 of 10CFR.
- e) "Deviation" means a departure from the technical requirements included in a procurement document [see 3.0 (l)].
- f) "Evaluation" means the process accomplished by or for a license to determine whether a particular deviation could create a substantial safety hazard.
- g) "Operating" or "Operation" means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in 10 CFR 21 and consulting services related to operations that are important to safety.



- h) "Noncompliance" means 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.
- i) "Procurement Document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.
- j) "Responsible Officer" means 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 10 CFR 21.
- k) "Substantial Safety Hazard" means 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.
- l) "Supplying" or "Supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in 10 CFR 21.