



April 30, 2008
U.S. Nuclear Regulatory Commission,
Attn: Document Control Desk,
Washington, DC 20555

SUBJECT: "REPLY TO A NOTICE OF VIOLATION"

REFERENCE: NRC INSPECTION REPORT 71-0062/2008-201 AND NOTICE OF VIOLATION

Document Control Desk,

Industrial Nuclear Company, Inc has reviewed the NRC Inspection Report 71-0062/ 2008-201 and offer attached response to the "Notice of Violations.

All items listed in the "Notice of Violation" have been addressed in the Reply to Notice of Violation.

If you have any questions or need additional information, please contact Jerry Tucker, Quality Assurance Manager at (510) 352-6767

Sincerely,

Irene Dunn/for
Fenshya Chang
President
Industrial Nuclear Company, Inc.

Jerry A. Tucker
Quality Assurance Manager
Industrial Nuclear Company, Inc.

cc. David W. Pstrak, Chief
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NRC Report 71-0062/2008-201

April 2, 2008

"Reply to Notices of Violation"

NOTICE OF VIOLATION

- A. 10 CFR 71.111, "Instructions, procedures, and drawings," which states, in part, "The certificate holder shall prescribe activities affecting quality by documented procedures, and shall require that these procedures be followed."

Contrary to the above, the following instances were identified by the NRC where activities affecting quality were not prescribed in documented procedures, or where procedures for activities affecting quality were not followed:

- 1) INC Quality Procedure 15.1, "Control of Nonconformances," step 6.6 states "For nonconformances that are dispositioned Use-As-Is or Repair, the EM (Engineering Manager) shall provide documented justification that the items performance will comply with design and regulatory requirements and to justify why additional qualification testing is not required." The NRC identified several Nonconformance Reports (NCRs) that had been dispositioned Use-As-Is or Repair and that did not have the required justification documentation required of the EM attached.

INC RESPONSE

- A.1 INC's QAM and quality consultant performed a review of all nonconformance reports (NCRs) issued since the 1998 re-start of fabrication. INC has issued a total of 24 NCRs in this time period: a total of 19 NCRs had reject dispositions; one had a rework disposition; two had repair dispositions; and, three had use-as-is dispositions. Of the two NCRs that were dispositioned as repair, one included the required engineering evaluation (NCR 0006).

The other NCR dispositioned as repair was NCR 0015. A review of this NCR found that the repair disposition should have been indicated as rework. A damaged customer-owned IR-100 was restored to design condition as specified on approved design drawing IR-100-B, Revision 2 using approved welding procedure 17-98-001. Compliance with IR-100-B was verified by the QA Manager. The selection of the repair disposition was likely caused by the disposition category being selected by a delegate for the engineering manager. The NCR 0015 disposition has been revised to reflect the actual disposition condition of rework.

The use-as-is disposition for NCR 0023 was reviewed and found to be misleading. This NCR identified a storage condition for argon gas bottles used in the manufacture of sources, not cameras. This condition did not constitute a material deficiency but a programmatic issue unrelated to IR-100 fabrication. The correct vehicle for this condition should have been a Corrective Action Report. A note will be placed with this NCR indicating the use of the wrong vehicle to address this problem.

The use-as-is disposition for NCR 0024 identified depleted uranium shields that were tested at receipt and found to exceed allowable radiation levels. The orientation of these shields was changed and retests were performed and the shields were found to be acceptable. Although this appears to be a use-as-is condition, the re-orientation of the shields conformed to INC acceptance criteria. In light of the change in orientation of the shield, an engineering evaluation will be performed.

The EM position is currently vacant; however, INC is training a consultant engineer and has designated this individual to fulfill the assigned responsibilities of the EM. Training should be completed by the end of April and the evaluation should be complete by the end of May 2008.

INC has established a completion date of June 30, 2008 for completion of the EM review and documented justification for NCR 0024.

NOTICE OF VIOLATION

- 2) INC Quality Procedure 3.1 "Design Control," steps 5.4.4, 5.4.5, and 5.4.6 state, in part, "The original DCN (Design Change Notice) shall be attached to the original affected design document," that "DCNs shall be incorporated into the affected design document when three DCNs have been issued against a design document," and that "Once the DCN is incorporated into the design document, the file copy of the previous design document and DCN(s) shall be marked as Superseded." The NRC identified that when a DCN is generated by INC, it is immediately incorporated into the affected design document, rather than waiting for three DCNs to be issued. Further, the NRC identified that once the DCN is incorporated into the design document, it is maintained in the same file as the affected design document, and the DCN is not stamped as Superseded.

INC RESPONSE

- A.2 The cause of this failure to implement the programmatic requirements appears to be inadequate training of the responsible individual. Corrective action for this issue includes a revision to INC Quality Procedure 3.1 and training of the individual responsible for implementing the requirements. INC Quality Procedure 3.1 was revised effective April 30, 2008 to reflect

INC's actual practice of incorporating each DCN after approval into affected design documents. No change has been made to the requirement to stamp all incorporated DCNs as superseded. The INC QAM has reviewed all DCNs and stamped them superseded as required by INC's program. The preparer of the revised procedure, INC's quality consultant, has provided training in the new procedural requirements.

All actions for A.2 are complete.

NOTICE OF VIOLATION

- 3) INC Quality Procedure 3.1 "Design Control," steps 5.3.4 and 5.3.5, state, in part, "The Document Control Clerk shall distribute new and revised documents in accordance with the Controlled Document Master Distribution Log," and "The Document Control Clerk shall remove superseded documents from the controlled locations and replace documents with the revised documents and shall discard all superseded copies." Contrary to the requirements of INC Quality Procedure 3.1, the NRC reviewed controlled drawings issued to the fabrication shop areas against the Controlled Document Master Distribution Log and identified that: 1) drawing IR-100-1B, Rev. 2, was located at the welding booth but was not indicated as being at that location in the Controlled Document Master Distribution Log; 2) the Controlled Document Master Distribution Log indicated that drawing OP-100-1, Rev. 4, was located in the plywood assembly area, however, Rev. 3 of the drawing was actually located there, and Rev. 5 is the actual current revision of the drawing; and 3) drawing IR-100-C14A, Rev. 0, was shown on the Controlled Document Master Distribution Log as being in the plywood assembly area, however, the drawing could not be located in any of the fabrication shop areas.

INC RESPONSE

- A.3 The cause of this issue appears to be a failure to perform oversight of the implementation of INC's program to assure compliance with these requirements.

INC has corrected the Controlled Document Distribution Master Log and issued the correct drawing revisions to all shop locations for those items noted above. The INC QAM has also performed a complete review of the Controlled Document Distribution Master Log to verify reflection of the correct revisions of all documents listed. The QAM has verified that the correct revisions have been distributed to all locations as required.

Oversight via internal audit of the implementation of all aspects of the quality program has been scheduled for 2008 and partially implemented to date.

All actions for A.3 are complete.

NOTICE OF VIOLATION

- 4) INC Quality Procedure 18.1, Rev. 2, "Audits and Commercial Grade Surveys," step 7.4.4, states, in part, "The QAM shall also verify and document on the Maintenance of Lead Auditor Proficiency record, Attachment 18.1.D, that the Lead Auditor has maintained his proficiency." Contrary to the above requirement, the NRC identified that the contract Lead Auditor, used by INC for the required annual QA program audits since at least 1999, did not have any Attachment 18.1.D forms on file attesting to his having maintained proficiency for conducting audits on INC's behalf.

INC RESPONSE

- A.4 The cause of this problem appears to be inadequate training of responsible personnel on new program requirements established in revision 2 of QP 18.1
It should be noted that all the information concerning maintenance of auditor proficiency contained on Form 18.1.D is also found on Form 18.1.C, "Record of Lead Auditor Qualification," and that Form 18.1.C has been issued triennially for the contract Lead Auditor.

In light of the fact that there is no regulatory basis nor Quality Assurance Program Manual commitment to retain this information, INC has revised QP 18.1 to no longer require the use of Form 18.D but will continue the use of Form 18.C on a triennial basis.

QP 18.1, Revision 3 has an effectivity date of April 28, 2008. All actions for A.4 are complete.

NOTICE OF VIOLATION

- B. 10 CFR 71.137, "Audits," states, in part, "The certificate holder shall carry out a comprehensive system of planned audits to verify compliance with all aspects of the quality assurance program." INC's Quality Assurance Program document, Rev. 10, Section 18.0.1, states, in part, that "These audits shall verify compliance with all aspects of the QA Program on an annual basis to determine its effectiveness." Further, INC Quality Procedure 18.1, "Audits and Commercial Grade Surveys," step 6.1.1, states, in part, that "All elements of the QA Program shall be audited within a 12 month period."

Contrary to the above, the NRC identified that INC did not perform annual audits for the calendar years 2006 and 2007.

This is a Severity Level IV violation (Supplement VI).

INC RESPONSE

- B. There are several causes for the suspension of the internal audit program in 2006 and 2007. INC did not have a supplier of a critical part of the IR-100 licensed shipping package during this time so none were being manufactured. INC management erred in believing that INC was not implementing the quality program in this time frame thus suspending the internal audit program. INC was also burdened with unforeseen financial investments required to meet new post 9/11 security requirements. This financial burden coupled with the lack of income from not having IR-100 cameras to sell lead to the decision to suspend the internal audit program. INC management believed that not implementing the internal audit program carried little risk under the circumstances.

Prior to the NRC inspection in April 2008 INC issued an internal and supplier audit schedule for 2008 and commenced implementation of the audit program. INC has completed one of three scheduled internal audits and one of three scheduled supplier audits. INC is committed to implement these requirements in the future.