



December 11, 1992  
696-1998

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555

Subject: **Reply to a Notice of Violation**

Reference: MacDonald, Charles E., Letter to General Atomics, ATTN: Dr. K. E. Asmussen, "NRC Inspection Report No. 71003/92-07/Notice of Violation, Notice of Non conformance," dated November 12, 1992

Gentlemen:

Enclosed is General Atomics' (GA's) response to the Notice of Violation issued on November 12, 1992 (Reference). This response was prepared pursuant to the provisions of 10 CFR 2.201.

GA trusts you will find its corrective action measures to be appropriate and satisfactory. If you should have any questions concerning this response, please contact me at (619) 455-2823.

Very truly yours,

A handwritten signature in cursive script that reads "Keith E. Asmussen".

Keith E. Asmussen, Director  
Licensing, Safety, and Nuclear Compliance

KEA:shs

Enclosures - as above

cc: Mr. Charles E. MacDonald, Branch Chief,  
Transportation Branch, NMSS, U.S. NRC

Mr. John B. Martin, Regional Administrator,  
U.S. NRC Region V

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**General Atomics' Response to the  
Notice of Violation / NRC Inspection Report No. 71003/92-07**

During an inspection of General Atomics' implementation of its Quality Assurance Program, which was conducted on September 23-24, 1992, a violation of NRC requirements was identified. The violation is restated below followed by General Atomics' (GA's) response.

**VIOLATION:**

10 CFR § 21.31, "Procurement documents," requires the licensee to assure that each procurement document for a basic component specify that the provisions of 10 CFR Part 21 apply.

Contrary to the above, 10 CFR Part 21 was not identified on applicable purchase orders reviewed by the NRC inspection team.

For example, Purchase Order 799074 to Micron Machine Company, dated 06/14/82, for upper shield rings on the Model No. FSV-1 packaging did not indicate that the provisions of 10 CFR Part 21 apply.

This violation has been categorized as Severity Level IV (Supplement VII).

**GA's RESPONSE:**

1. Admission or Denial of the Alleged Violation:

GA admits the stated violation.

2. Reason for the Violation:

Quality Division Instructions (QDI) 4-1 Issue D dated 3/14/80 was in effect at the time Purchase Order (PO) 79907 was issued in 1982. QDI 4-1 provided a standard clause (#B-1-K) to invoke 10 CFR 21. Due to a lack of understanding on the part of GA personnel who prepared and reviewed procurement documents, 10 CFR 21 reporting requirements were not imposed on each supplier of FSV-1 cask safety-related components as the regulation was intended.

This misunderstanding was due in part to procedures such as QDI 4-1 that at that time did not provide specific instructions for imposing 10 CFR 21. In the 1982 period, GA's interpretation of 10 CFR 21 applicability was that for suppliers who provided non-complex basic components, quality could be

assured by GA via source or receiving inspection and the responsibility for 10 CFR 21 reporting would be GA's, not the supplier's. Consequently, 10 CFR 21 was not specified was not specified in every FSV-1 cask safety-related procurement document.

3. Corrective Steps Taken and Results Achieved:

Action to correct the subject PO is not necessary. The specific example called out by NRC, PO-799074 to Micron Machine is for a QAL II (non-safety-related) item, and therefore is not a valid example. However, the NRC violation is valid since three other PO's (in the 1982 period) for QAL I (safety-related) items were identified as not containing the 10 CFR 21 clause: PO 799068 to Micron Machine Co. for the 1501-058 Bottom Plug, PO 812051 to NL Industries for the 1501-15 depleted uranium, and PO 812053 to EM Jorgensen for the 1501-13 closure head forging.

The following action will be taken in regards to the three PO's identified above:

- 1) GA will contact each of the suppliers and determine whether any 10 CFR 21 reportable deficiencies have been identified for the procured components since GA's procurement in 1982 until the present time.

If a supplier has had a 10 CFR 21 reportable deficiency on a component procured by GA, GA will evaluate the status of the component and the need for any further reporting.

- 2) GA verified that all applicable quality characteristics of these components were evaluated and documented via receiving inspection, review of certifications, gamma scans and other documentation, and determined the items met design requirements and that they functioned as required.
- 3) GA will insert a document into the FSV-1 Cask Modification Project records acknowledging the 10 CFR 21 reporting deficiency for the three identified Po's. The document will record the results of the conversations with the suppliers in Item (1) and the results of the verifications in Item (2). The document will also indicate that GA will assume future 10 CFR 21 reporting responsibility based on the results of (1) and (2).

Additionally, GA will review all FSV-1 Cask Project PO's issued to date to determine if there are any additional QAL I (safety-related) PO's in which 10 CFR 21 was not imposed, but should have been.

For each PO identified, if any, GA will perform Items (1), (2), and (3) above. If all applicable quality characteristics can not be verified, GA will attempt to locate the components and remove them from service and/or notify the user of the components that the quality characteristics of the component have not been verified. GA will also notify the NRC per 10 CFR 21 reporting requirements.

4. Corrective Actions that will be Taken to Avoid Further Violations:

To prevent further violations, the following actions will be taken:

- 1) To reinforce the importance of specifying 10 CFR 21 reporting requirements on safety-related procurement documents, all Quality Assurance personnel will be provided refresher training.
- 2) General Atomics will review its Quality Assurance procedures related to procurement and determine if the criteria for imposing 10 CFR 21 reporting requirements are clear and concise. Procedures will be revised as necessary to assure the proper interpretation of when it is necessary to invoke 10 CFR 21 in a procurement document.
- 3) General Atomics will evaluate the practicality of developing a Commercial Item Upgrade Program to be used for off-the-shelf and catalog items that may be purchased in the future from vendors who cannot or will not comply with 10 CFR 21 reporting requirements.

5. Date When Compliance will be Achieved:

GA believes it is currently performing in compliance with NRC regulations. The above mentioned corrective actions are scheduled for completion by March 31, 1993.