

APPENDIX B

Exo Sensors, Inc.
Docket No. 99901015/85-01

NOTICE OF NONCONFORMANCE

Based on the results of an NRC inspection conducted on May 28-31, 1985, it appears that certain of your activities were not conducted in accordance with NRC requirements. Nonconformances with these requirements are as follows:

- A. Criterion I, "Organization," of Appendix B to 10 CFR Part 50 states, in part: "The authority and duties of persons and organizations performing activities affecting the safety related functions of structures, systems, and components shall be clearly established and delineated in writing."

Contrary to the above, the position of Vice President of Engineering and Quality Assurance was created in August 1984, but the authority and duties of the position have not been documented nor has the position been added to the organization chart.

- B. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states, in part: "... shall establish ... a quality assurance program which complies with the requirements of this appendix. The program shall be documented by written policies, procedures, or instructions and ... shall be carried out ... in accordance with those policies, procedures, or instructions The quality assurance program shall provide control over activities affecting quality of the identified components The program shall take into account the need for special ... skills to attain the required quality The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Contrary to the above, Exo Sensors failed to establish and implement a quality assurance program to provide control over activities affecting quality as described below.

1. Paragraph 1.3.3 of Exo Sensors Quality Assurance Manual (QAM) states that the QA Manager: "Supervises all training of Exo Sensors, Inc. visual and mechanical inspectors."

A footnote to paragraph 20.1 of Exo Sensors' QAM states: "Evidence of training shall include, but not be limited to: lesson plans, course completion records, and employee training records."

Contrary to the above, a training program for Exo Sensors visual and mechanical inspectors had not been established nor was there any evidence of training or qualification of these inspectors.

2. Criterion VI, "Document Control" of Appendix B to 10 CFR Part 50 states: "Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval..."

Paragraph 5.3.1 of Exo Sensors' QAM states, in part: "Changes to released drawings will be initiated by Engineering Change Notice and will require approval by Engineering, Manufacturing, and Quality Assurance prior to implementation."

Quality Operating Procedure, QOP-024, requires that a Procedure Change Notice (PCN) be used to document changes to a QOP and that PCNs be recorded.

Contrary to the above,

- a. Exo Sensors has no controls on the revision of or approval of revisions to shop travellers. This resulted in travellers being modified after approval without subsequent approval of the changes. The modifications included addition of manufacturing steps and inspections and deletion of manufacturing steps and inspections. In addition, work was performed prior to travellers being approved and issued.
 - b. Exo Sensors was using Engineering Change Notices (ECNs) to document changes to procedures rather than PCNs. In addition, on ECN #2 to QOP-052, the ECN was implemented 4/3/84 but approval of the ECN by Engineering, Design, QA, and Manufacturing did not occur until 5/31/84.
3. Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part: "Measures shall be established to assure that purchased material, equipment, and services ... conform to the procurement documents. These measures shall include provisions as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products delivered."

Paragraph 4.4 of Exo Sensors' QAM states: "No order for safety related materials, goods, or services shall be issued to a source not referenced on the Exo Sensors, Inc. "Approved Supplier List"."

Paragraph 7.1 of Exo Sensors' QAM states: "All materials, goods, and services obtained by Exo Sensors, Inc. for incorporation into safety essential product designs shall be obtained from suppliers/agents identified on the Exo Sensors, Inc. "Approved Suppliers List"."

Paragraph 7.4 of Exo Sensors' QAM states, in part: "Initial approval and retention of sources, agents, or manufacturers for use on specialty safety related essential equipment shall be accomplished in one of the following ways by the QA Manager or his designated consultant or Exo Sensors, Inc. designee.

7.4.1 Acceptable

- A. Successful completion of a Quality Survey or Questionnaire ..."

Contrary to the above,

- a. Paragraph 7.6 of Exo Sensors' QAM conflicts with the above requirements in that it allows purchases of materials/goods for use in safety related equipment from companies not on Exo Sensors' "Approved Suppliers List".
 - b. Exo Sensors placed an order with Air Dimensions Inc. on 8/25/83, PO E-002, for a Class 1E containment suction pump although Air Dimensions was not approved and placed on Exo Sensors' "Approved Suppliers List" until 12/1/83.
 - c. Exo Sensors failed to place any quality controls on electrical equipment purchased from distributors for use in safety related equipment. Distributors are placed on Exo Sensors "Approved Suppliers List" without a Quality Survey or Questionnaire being completed and Exo Sensor does not perform any kind of verification testing upon receipt of the equipment.
4. Criterion IX "Control of Special Processes", of Appendix B to 10 CFR Part 50 states: "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

Paragraph 9.3 of Exo Sensors' QAM states: "Special processes shall be accomplished under controlled conditions in accordance with applicable codes, standards, specifications, criteria and other special requirements using qualified personnel and approved procedures."

Paragraph 10.9.1 of Exo Sensors' QAM states: "Authorization to perform inspections, examinations and testing shall be granted only to those personnel meeting the requirements of ANSI/ASME N45.2.6."

Paragraph 10.9.2 of Exo Sensors' QAM states: "Personnel qualification records shall be maintained."

Ebasco PO NY-435288 requires that structural welding be performed in accordance with AWS D1.1 and tubing and fittings be welded in accordance with Section IX of the ASME Boiler and Pressure Vessel Code and ANSI B31.1. AWS D1.1 and ANSI B31.1 require that personnel performing nondestructive examinations be qualified to ASNT SNT-TC-1A.

Contrary to the above,

- a. Unqualified personnel were used to perform soldering operations on equipment supplied to Fermi 2 and Fitzpatrick nuclear plants.
 - b. At the time of the inspection Exo Sensor did not have any inspectors qualified to either SNT-TC-1A or ANSI/ASME N45.2.6.
 - c. Personnel qualification records did not meet the requirements of either SNT-TC-1A or N45.2.6.
 - d. Annual vision tests required by SNT-TC-1A had never been performed nor were they required by Exo Sensors' procedures.
5. Criterion X, "Inspection", of Appendix B to 10 CFR Part 50 states, in part: "A program for inspection of activities affecting quality shall be established and executed ... to verify conformance with the documented instructions, procedures, and drawing for accomplishing the activity If mandatory inspection hold points, which require witnessing or inspecting ... beyond which work shall not proceed ... are required, the specific hold points shall be indicated in appropriate documents."

Paragraph V.2 of QOP-065, "Insulation Test Procedure," states: "Prior to removal of jumpers, Quality Engineer will verify that all circuits subject to test were connected. Verification will be initialed on shop traveller."

Contrary to the above, Exo Sensors was not consistent in indicating inspection hold points for the insulation test. On shop travellers for assembly of hydrogen analyzer cabinets 4004 and 4005, Operation 23, Insulation Test, was not denoted as being an inspection hold point.

6. Criterion XI, "Test Control", of Appendix B to 10 CFR Part 50 states, in part: "Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used Test results shall be documented and evaluated to assure that test requirements have been satisfied".

Paragraph 12.18 of Exo Sensors' QAM states: "All QOP and Acceptance Test Procedures requiring the use of test equipment and gauges shall include provisions to record the type of instrument, serial number, and calibration due date."

Contrary to the above,

- a. QOPs 012, 023, 063, 064 and 066 do not require or have provisions for recording type of instrument, serial number, and calibration due date. In addition, completed data sheets for instrument valve seat closure test (QOP-064) for valves SV-7 and SV-8 on hydrogen analyzers 4004 and 4005 did not include the required data.
 - b. QOP-064 only requires documenting of test data if the valve passes the test. The procedure does not address documenting the failure of a valve to pass the valve seat closure test.
7. Criterion XIV, "Inspection, Test, and Operating Status," of Appendix B to 10 CFR Part 50 states, in part: "Measures shall be established to indicate, by use of markings such as ... routing cards ... the status of inspections and tests performed upon individual items These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests"

Paragraph 5.1.1 of Exo Sensors' QAM states: "All Exo Sensors, Inc. Production and Inspection personnel are responsible for completing the required sign-offs entries provided for each shop operation. All sign-offs require initials and dating."

Contrary to the above,

- a. In reviewing shop travellers for Hydrogen Analyzer Cabinets 4004 and 4005, Remote Control Cabinets 4006 and 4007, Relay Tray Assemblies 3007 and 3009, and Microprocessor Assemblies 3008 and 3010 there were four instances where tests requiring inspections prior to continuation of work were not signed off and four instances where manufacturing operations were not signed off.
 - b. In addition, the QAM has no provisions for tracking "Conditional Release" material.
8. Criterion XV, "Nonconforming Materials, Parts, or Components", of Appendix B to 10 CFR Part 50 states, in part: "Measures shall be established to control materials, parts or components which do not conform to requirements in order to prevent their inadvertent use or installation Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

Paragraph 15.2 of Exo Sensors' QAM states: "Said notice when discrepant materials, parts, or service reports are concerned, will be documented within Exo Sensors, Inc. by the use and completion of a nonconformance report or defect report which is logged and tracked for completion of corrective action. Repaired or re-worked items shall be re-inspected with results documented."

Contrary to the above,

- a. Exo Sensors was performing repairs and rework but did not have any procedures covering these activities.
 - b. Exo Sensors' QAM does not address how nonconformances discovered as a result of Quality Surveys or Questionnaires are documented.
 - c. On defect report DR-473, there was no indication that the 21 circuit boards rejected were re-inspected after the rework was performed.
9. Criterion XVI, "Corrective Action", of Appendix B to 10 CFR Part 50 states, in part: "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Paragraph 16.2.8 of Exo Sensors' QAM states: "All Exo Sensors, Inc. DR and NCR Forms calling for Corrective Action on the part of Shop Personnel, Suppliers, Agents or others, must also include a reference date for completion of the recommended action."

Contrary to the above,

- a. Exo Sensors' QAM does not address how corrective action is achieved for nonconformances discovered as a result of Quality Surveys or Questionnaires.
 - b. On defect report DR-473, 21 circuit boards were rejected because the soldering was performed by an unqualified person. Disposition was to rework the boards. However, there was no indication that the boards were ever reworked on the Defect Report, yet the boards were used in analyzers shipped to Fermi 2 and Fitzpatrick nuclear plants.
 - c. Most Defect Report forms had not been signed off by the company president or the corrective action designator upon completion of corrective action as required.
10. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 states, in part: "A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the

program Audits shall be documented and reviewed by management having responsibilities in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated."

Paragraph 2.2 of Exo Sensors' QAM states: "The program described in the Exo Sensors, Inc. Quality Assurance Manual will be periodically reviewed for compliance with any of the specifications that might be invoked by Exo Sensors, Inc. clients, contract proposals, code regulations, or national standards requirements. As a minimum, this review shall be conducted on an annual basis."

Paragraph 18.1.1 of Exo Sensors' QAM states: "The purpose of periodic audits performed within Exo Sensors, Inc. is to provide an assessment by audit review into the effectiveness of the Quality Assurance System described, initiated, and governed by this manual."

Paragraph 18.1.5 of Exo Sensors' QAM states: "Outside Consultant firms or auditors shall be appointed to conduct an overall audit of the Quality Assurance program at Exo Sensors, Inc."

Contrary to the above,

- a. Exo Sensors never established a schedule for performing periodic audits until March 1985. No audits were performed in 1980 and 1981. Audits of engineering and procurement were performed in 1982 and a periodic audit was performed on special processes in 1983. No periodic audits were performed in 1984.
- b. The December 10, 1982 audit of engineering revealed a number of significant nonconformances, yet the QA Audit Notice forms were not completed. The cause of the nonconformance had not been listed, the required completion date was not given, no followup action had been taken, acceptability of corrective action was not indicated, and none of the findings had been closed out as of May 31, 1985.