



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

DMB

NOV 26 1985

Docket No. 50-346

Toledo Edison Company
ATTN: Mr. Joe Williams, Jr.
Vice President
Nuclear
Edison Plaza
300 Madison Avenue
Toledo, OH 43652

Gentlemen:

On May 28-31, 1985, an inspection of the implementation of Exo Sensors, Inc. Quality Assurance program (QA) was conducted by the Vendor Program Branch of the Office of Inspection and Enforcement. Exo Sensors, Inc., is a supplier of hydrogen sensors, analyzers, and other instrumentation. It is our understanding that Exo Sensors, Inc. products were supplied to and may be in use at your facility. A copy of the Inspection Report (99901015/85-01) is enclosed.

The inspection was conducted to investigate allegations that Exo Sensors, Inc. had failed to report a deficiency under 10 CFR Part 21 and that there existed a complete breakdown of their QA Program. During the inspection, it was determined that significant deficiencies exist in the implementation of the Exo Sensors QA Program and that the allegations were, for the most part, substantiated.

The deficiencies identified in the enclosed report should have been identified during QA audits and source inspections of the Exo Sensors facility. The results of the NRC inspection, while focused on the deficiencies within the Exo Sensors QA Program, nevertheless, may be indicative of potential weaknesses within your own QA organizations.

The enclosed report is sent to you to facilitate your review of this matter. We expect that through your review, you will confirm the acceptability of items at your facility, if any, which were procured from Exo Sensors, Inc.

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Toledo Edison Company

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You are requested to submit a written reply to this letter, within thirty (30) days, identifying the results of your review and the actions you have taken or plan to undertake.

We will gladly discuss any questions you have concerning this matter.

Sincerely,

"Original Signed by E.G. Greenman"

Charles E. Norelius, Director
Division of Reactor Projects

Enclosure: Vendor Report
No. 99901015/85-01 dtd 08/26/85

cc w/enclosure:
L. Storz, Plant Manager
DCS/RSB (RIDS)
Licensing Fee Management Branch
Resident Inspector, RIII
Harold W. Kohn, Ohio EPA
James W. Harris, State of Ohio
Robert H. Quillin, Ohio
Department of Health

RIII
RNY
Gardner/jp
11/25/85

RIII
Weil
11/25

RIII
Chrisotimos

RIII
Greenman

RIII
Norelius



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 26, 1985

Docket No. 99901015/85-01

Exo Sensors, Inc.
ATTN: Mr. Don Stevens
President
1220-B Simon Circle
Anahiem, California 92806

Gentlemen:

This refers to the inspection conducted by E. T. Baker of this office on May 28-31, 1985, of your facility in Anahiem, California and to the discussions of our findings with you and members of your staff at the conclusion of the inspection.

This inspection was conducted as a result of allegations that Exo Sensors, Inc. had not implemented a quality assurance program which met the requirements of Appendix B to 10 Part CFR 50. Areas examined during the inspection and our findings are discussed in the enclosed report. Within these areas, the inspection consisted of an examination of procedures and representative records, interviews with personnel, and observations by the inspector.

During the inspection it was determined that significant deficiencies exist in the implementation of the Exo Sensors QA program and that the allegations were, for the most part, substantiated. Deficiencies identified included the following: Exo Sensors has failed to train and qualify their inspectors; annual eye examinations were not performed; there were no controls on the origination of, modifications to, or issuance of shop travellers; rework and repairs were performed without documented procedures; design changes were implemented prior to approval; purchases were made from suppliers not on the approved vendor list; and nonconforming material was shipped to customers. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

The enclosed Notice of Violation is sent to you pursuant to the provisions of Section 206 of the Energy Reorganization Act of 1974. You are required to submit to this office within 30 days from the date of this letter a written statement containing: (1) a description of steps that have been or will be taken to correct these items; (2) a description of steps that have been or will be taken to prevent recurrence; and (3) the dates your corrective actions and preventive measures were or will be completed. Consideration may be given to extending your response time for good cause shown.

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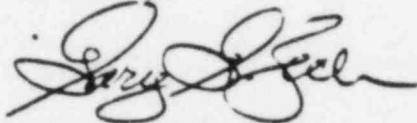
cc 5 1985

August 26, 1985

You are also requested to submit a similar written statement for each item which appears in the enclosed Notice of Nonconformance. Please reference the report number in all correspondence.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,



Gary G. Zech, Chief
Vendor Program Branch
Division of Quality Assurance, Vendor,
and Technical Training Center Programs
Office of Inspection and Enforcement

Enclosures:

1. Appendix A - Notice of Violation
2. Appendix B - Notice of Nonconformance
3. Appendix C - Inspection Report No. 99901015/85-01
4. Appendix D - Inspection Data Sheets

cc w/enclosures:

All Affected Plants
All Regions w/affected Plants
P. Fredrickson, RII

APPENDIX A

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

NOTICE OF VIOLATION

As a result of the inspection conducted on May 28-31, 1985, and in accordance with Section 206 of the Energy Reorganization Act of 1974 and its implementing regulation 10 CFR Part 21, the following violation was identified and categorized in accordance with the NRC Enforcement Policy (10 CFR Part 2, Appendix C), 49 FR 8583 (March 8, 1984):

Section 21.21 of 10 CFR Part 21, dated January 1, 1985 states, in part:
"Each individual, corporation ... subject to the regulations in this part shall adopt procedures to: (1) Provide for: (i) Evaluating deviations or (ii) informing the licensee or purchaser of the deviation..."

Contrary to the above, Exo Sensors did not have any Part 21 procedures at the time of the inspection. However, procedures were developed during the inspection and reviewed and found acceptable by the inspector.

This is a Severity Level V violation (Supplement VII).

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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.

~~99901015/85-01~~ 7pp.

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.

ORGANIZATION: EXO SENSORS, INC.
ANAHEIM, CALIFORNIA

REPORT NO.: 99901015/85-01	INSPECTION DATE(S): May 28-31, 1985	INSPECTION ON-SITE HOURS: 62
CORRESPONDENCE ADDRESS: Exo Sensors, Inc. 1220-B Simon Circle Anahiem, California 92806		
ORGANIZATIONAL CONTACT: Don W. Stevens, President TELEPHONE NUMBER: 714-632-8289		
PRINCIPAL PRODUCT: Hydrogen Sensors and Analyzers and other instrumentation. NUCLEAR INDUSTRY ACTIVITY: 60-70%.		
ASSIGNED INSPECTOR: <u>E. T. Baker</u> E. T. Baker, Reactive Inspection Section (RIS)		<u>8/5/85</u> Date
OTHER INSPECTOR(S): J. C. Harper, RIS		
APPROVED BY: <u>E. W. Merschoff</u> E. W. Merschoff, Chief, RIS, Vendor Program Branch		<u>8/7/85</u> Date
INSPECTION BASES AND SCOPE: A. <u>BASES</u> : 10 CFR Part 50 Appendix B and 10 CFR Part 21. B. <u>SCOPE</u> : The inspection was conducted to investigate an allegation that Exo Sensors, Inc. had failed to report a deficiency under 10 CFR Part 21 and that a complete breakdown of their Quality Assurance program existed.		
PLANT SITE APPLICABILITY: Prairie Island 1 and 2 (50-282/306), San Onofre 1 (50-206), Salem 1 and 2 (50-272/311), Comanche Peak 1 and 2 (50-445/446), Point Beach 1 and 2 (50-266/301), Beaver Valley 1 and 2 (50-334/412), Shearon Harris 1 and 2 (50-400/401), Millstone 3 (50-423), James A. FitzPatrick		

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ORGANIZATION: EXO SENSORS, INC.
ANAHEIM, CALIFORNIA

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PLANT SITE APPLICABILITY: (continued)

(50-333), Fermi 2 (50-341), Arkansas 1 (50-313), Davis-Besse (50-460), Brunswick 1 and 2 (50-325/324), LaSalle (50-373/374), Browns Ferry (unit not known), WNP-2 (50-397), Grand Gulf (50-416/417), Crystal River 3 (50-302).

A. INSPECTION ISSUES

The NRC had received allegations that a breakdown of the Quality Assurance Program existed at Exo Sensors, Inc. and that Exo Sensors, Inc. knowingly and willingly violated 10 CFR Part 21 reporting requirements.

B. INSPECTION FINDINGS

1. Violations:

Contrary to 10 CFR Part 21, Exo Sensors, Inc. did not have any procedures for evaluating deficiencies for reportability under 10 CFR Part 21 or reporting the deficiencies to their customers for evaluation. A Severity Level V violation was issued in this area.

2. Nonconformances:

- a. Contrary to Appendix B, Exo Sensors had not documented the authority and duties associated with the position of Vice President of Engineering and Quality Assurance which was established in August 1984.
- b. Contrary to Appendix B, ANSI N45.2.6, ASNT SNT-TC-1A, and Paragraph 1.3.3 of Exo Sensors' Quality Assurance Manual (QAM) Exo Sensors failed to establish and implement a training program which met Appendix B and failed to adequately train and qualify the production, inspection, and test personnel.
- c. Contrary to Appendix B, Paragraph 5.3.5 of the QAM and Quality Operating Procedure QOP-024, Exo Sensors failed to control the issuance and modification of shop travellers. used Engineering Change Notices (ECNs) rather than Procedure Change Notices (PCNs) to control changes to QOPs, and implemented ECNs prior to their approval.

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- d. Contrary to Appendix B, Paragraphs 4.4, 7.1, and 7.4 of the QAM, Exo Sensors placed a purchase order with Air Dimensions prior to approving them and placing them on the Approved Suppliers List, and failed to place any controls on distributors who supplied components for safety related equipment. In addition, paragraph 7.6 of the QAM conflicts with paragraphs 4.4, 7.1, and 7.4 of the QAM.
- e. Contrary to Appendix B, paragraphs 9.3, 10.9.1, and 10.9.2 of the QAM, and Ebasco purchase order (PO) NY-435288, unqualified personnel performed soldering operations, inspections of soldered joints, and other visual examinations. In addition, annual vision examinations for inspectors had never been performed and qualification records did not meet specified requirements.
- f. Contrary to Appendix B and paragraph V.2 of QOP-065, Exo Sensors failed to consistently establish inspection hold points or perform the inspections.
- g. Contrary to Appendix B and paragraph 12.18 of the QAM, Exo Sensors failed to include instrument calibration data recording requirements in some QOPs. In addition, QOP-064 does not require recording test results if the valves fail the test. Only if the valves pass the test are the results required to be recorded.
- h. Contrary to Appendix B and paragraph 5.1.1 of the QAM, production and inspection personnel were not signing off on the shop travellers when operations and inspections were completed. In addition, the QAM has no provisions for tracking "conditional release" material.
- i. Contrary to Appendix B and paragraph 15.2 of the QAM, Exo Sensors was performing repairs and rework without written procedures. In addition, the QAM does not address how nonconformances discovered as a result of Quality Surveys or Questionnaires are documented.
- j. Contrary to Appendix B and paragraph 16.2.8 of the QAM, most Defect Report (DR) forms had not been signed off upon completion of any required corrective action and on Defect Report DR-473 there was no indication that the rejected circuit boards covered by the DR were ever reworked or re-inspected although the boards were used in equipment supplied to Fermi 2 and Fitzpatrick plants.

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- k. Contrary to Appendix B and paragraphs 2.2, 18.1.1, and 18.1.5 of the QAM, Exo Sensors failed to perform periodic audits on an annual basis and also failed to close out audit findings for the audits that were performed.

3. Allegations

The following allegations were investigated during the inspection:

a. Allegation:

The corporate organizational chart is not up-to-date.

Observation:

The allegation was substantiated and nonconformance B.2.a was issued in this area. At the time of the inspection, the position of Vice President of Quality Assurance and Engineering, which was created in August 1984, had not been added to the organization chart, nor had the duties and authorities associated with the position been documented.

b. Allegation: *

There exists insufficient organizational freedom in that the Vice President of Engineering is also in charge of Quality Assurance. In addition, he is also the Chief Designer verifying his own work.

Observation:

The allegation was not substantiated. The organization's structure is sufficient to provide the necessary degree of organizational freedom and independence between Quality Assurance and other departments. Each division (Quality Assurance, Engineering, Manufacturing, and Marketing) has a separate manager. The Manager of QA and the Manager of Engineering both report to the Vice President of QA and Engineering who reports to the President. As with most small companies, there were instances where due to absences or position vacancies a single employee performed in more than one capacity. However, it was not evident that this had an adverse impact on product quality.

ORGANIZATION: EXO SENSORS, INC.
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c. Allegation:

The Quality Assurance Manual does not contain provisions for independent checking and verification of design; independent checking and verification of design is not being accomplished.

Observation:

The allegation was not substantiated. The Quality Assurance Manual (QAM) contains adequate provisions for independent checking and verification of design. The implementation of these requirements was not consistent for the reasons stated in b. above, employees performing in more than one capacity due to absences or vacancies. Again, it was not evident that this condition had an adverse impact on product quality.

d. Allegation:

There are few provisions in the Quality Assurance Manual requiring that procurement documents impose or require compliance with 10 CFR 21. The allegor indicates that these requirements are not being imposed on suppliers in the procurement process.

Observation:

The allegation was not substantiated. The QAM does require passing Part 21 requirements down to suppliers of safety related parts. Purchase orders (POs) for safety related parts, which were reviewed, did pass Part 21 requirements down to subtier suppliers. However, the majority of materials and components purchased are commercial grade, to which Part 21 is not applicable.

e. Allegation:

No Approved Vendors List exists at Exo Sensors and there are no provisions implemented to determine whether vendors are qualified and that procurement is from appropriately qualified vendors.

ORGANIZATION: EXO SENSORS, INC.
ANAHEIM, CALIFORNIA

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Observation:

This allegation was partially substantiated and nonconformance B.2.d was issued in this area. An Approved Vendors List (AVL) does exist at Exo Sensors, however, the QAM allows unapproved vendors to be used. In addition, the QAM allows certain categories of vendors, i.e., distributors to be placed on the AVL without adequate justification.

f. Allegation:

The company does not have a design manual. Two engineers perform design as they feel necessary and this design is not documented. The design process is not controlled.

Observation:

This allegation was partially substantiated and nonconformance B.2.c was issued in this area. There are no requirements, either contractual or regulatory, that a company must have a design manual, only that the design process be controlled and the design documented. There were instances where the QAM requirements for control of design changes were not followed, i.e., the issuance of Engineering Change Notices prior to approval.

g. Allegation:

Procedures for document control and filing are non-existent and practices are not consistently implemented. There exists no formal system to maintain document control.

Observation:

This allegation was partially substantiated and nonconformance B.2.c was issued in this area. There are no procedures for controlling shop travellers. Work was started prior to generating shop travellers and changes were made to the travellers after initial approval without subsequent approval. In addition, Exo Sensors was using the incorrect form to document changes to Quality Operating Procedures (QOPs).

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h. Allegation:

No hold or QC witness points are used on shop travellers.

Observation:

This allegation was partially substantiated and nonconformance B.2.f was issued in this area. The QAM and QOPs have requirements for hold points, but the hold points are not consistently indicated on the shop travellers nor are they consistently complied with.

i. Allegation:

There was no program in place for nonconformance reporting prior to March of 1985. Further, many of the nonconformance reports initiated since March of 1985 are still open and corrective action has not been implemented.

Observation:

This allegation was partially substantiated and nonconformances B.2.i and B.2.j were issued in this area. A review of the QAM indicates that a program for documenting nonconformances did exist prior to March 1985. However, there were numerous Defect Reports that had never been closed out, including those initiated both prior to and after March 1985. An example of the Defect Reports not closed out is Defect Report DR-473. DR-473 was issued on 10/15/84 for 21 DAC Boards which were soldered by an unqualified individual. At the time of the inspection there was no indication on the DR that the boards had ever been corrected or reinspected. Nor had the President or Corrective Action Designator signed off that the DR was closed, as required. In addition, the QAM does not address how nonconformances discovered as a result of Quality Surveys or Questionnaires are documented.

j. Allegation:

There is no provision in the Quality Assurance Manual for quality assurance audits.

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Observation:

This allegation was not substantiated. The QAM does contain requirements for conducting audits. However, periodic audits of the complete quality program have never been performed, as required by the QAM. Nonconformance B.2.k was issued in this area.

k. Allegation:

The allegor indicates that equipment with "short support rails" was supplied on 'out of containment' racks. The rails do not conform to drawing requirements; further, the allegor indicated that one of these rails failed at FitzPatrick Station.

Observation:

This allegation was not substantiated. A review of the correspondence and the trip report written by the investigating engineer, including photographs, indicated that the failures discovered at FitzPatrick were due to shipping damage and not design deficiencies or nonconforming hardware.

i. Allegation:

General Electric's vendor audits of Exo Sensors have not identified any of these problems indicating to the allegor that either General Electric is not looking closely or that audits were performed by incompetent auditors. In fact, the allegor indicates a recent audit by Northern States Power was performed by an incompetent auditor.

Observation:

The inspectors reviewed the audits performed by General Electric and Northern States Power. None of these audits detected any nonconformances of significance. As such, the allegation was partially substantiated. Qualifications of the auditors were not examined during this inspection.

m. Allegation:

General Electric vendor surveillance representatives have allowed shipment of equipment before the paperwork is completed.

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<p><u>Observation:</u></p> <p>This allegation was partially substantiated. Equipment was shipped prior to completion of all paperwork. However, as long as GE controlled the equipment properly this would not necessarily create any quality problems. Correspondence to GE indicates that the paperwork was sent to GE shortly after the hardware was shipped.</p> <p>n. <u>Allegation:</u></p> <p>The alleged indicates that a Mill Certification was falsified in that information was removed from another certification and added to a different certification by hand.</p> <p><u>Observation:</u></p> <p>The allegation was not substantiated. The Mill Certification the alleged made reference to was reviewed by the inspectors. The addition to the Certified Material Test Report (CMTR) was hand written in ink and included the initials of the person who added the information and the date it was added. In addition, the CMTR from which the hand written information was taken was available to the inspectors and indicated that the handwritten information was accurate. Therefore, the CMTR had been altered, not falsified. There was no intent to defraud.</p> <p>o. <u>Allegation:</u></p> <p>Material on hold in the warehouse is used before accomplishment of receipt inspections. The alleged indicates that he wrote an NCR on this practice.</p> <p><u>Observation:</u></p> <p>The allegation was substantiated through a review of the NCRs and discussions with management personnel. The inspectors did not observe any further instances of this type of nonconformance during the inspection. However, there was insufficient time to determine to what extent this problem existed in prior production.</p>		

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p. Allegation:

Based on these examples of nonconformance the allegor stated that a breakdown of the Quality Assurance Program exists at Exo Sensors, Inc.

Observation:

This allegation was substantiated to the extent that significant deficiencies in the implementation of the Exo Sensors QA program were identified. In addition, based on record review, a Quality Assurance Program which complies with Appendix B to 10 CFR Part 50 has never existed at Exo Sensors, Inc.

q. Allegation:

The allegor was of the opinion that such a breakdown of the Quality Assurance Program was reportable under 10 CFR Part 21, that company officials were aware of the breakdown and Part 21 reporting requirements and were consciously not reporting as required.

Observation:

This allegation was not substantiated. A breakdown of a Quality Assurance program is not required to be reported under 10 CFR Part 21 due to the subjective nature of determining when a breakdown has occurred. However, in investigating this allegation it was determined that Exo Sensors did not have any Part 21 procedures and violation B.1 was written in this area.

C. Supplementary Information

In determining whether or not the allegations could be substantiated, the inspectors, (1) reviewed the QAM, some QOPs, Exo Sensors' POs to subtier suppliers, drawings, utility/utility agents audits of Exo Sensors, Carolina Power and Light (CP&L) PO to Exo Sensors, and associated production and quality records, and (2) performed an inspection of hardware on the shop floor. A description of the inspectors efforts and conclusions in each of these areas is summarized below.

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1. Organization

A review of Exo Sensors current operations indicates that the position of Vice President of Engineering and Quality Assurance was created in August 1984. However, at the time of the inspection the company organization chart had not been updated nor had the duties and authorities associated with the position been spelled out. Nonconformance 2.a was written covering this area.

2. Quality Assurance Program

Based on the numbers and significance of the nonconformances identified during the inspection it was determined that Exo Sensors does not have nor has it ever had a quality assurance program which complies with Appendix B to 10 CFR Part 50. Nonconformance 2.b was written covering this area.

3. Training

The inspectors reviewed the training forms for all production and inspection personnel. The review of production personnel training folders revealed well-organized and documented training and qualification records with the exception of one person performing soldering operations (see "Corrective Action" and "Nonconforming Material"). At the time of the inspection, Exo Sensor had no one in their employ with any Quality Assurance experience. The positions of QA Manager and Quality Engineer were vacant. The President and Vice President of the company were performing receiving and in-process inspections. There were no records of training or qualification which established their ability to perform adequately in the capacity of inspector. Nonconformance 2.b was written covering this area.

4. Design Control

The inspectors reviewed section 3.0 of the QAM on design control and various engineering change notices and shop travellers. The provisions of the QAM appeared sufficient for controlling design and personnel appeared to be complying with provisions to the extent possible in a small company. In certain instances the person who prepared the design or design change also signed off as the company official in another capacity, e.g., Quality Assurance or Manufacturing. However, in no instance among those documents reviewed did the same person sign off as the preparer and as the Engineering representative.

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5. Procurement Document Control

The inspectors reviewed the QAM in this area and found the QAM requirements acceptable. However, implementation of the QAM in this area was not checked due to time constraints.

6. Instructions, Procedures and Drawing

The review of instructions, procedures and drawings and the control thereof is covered under the applicable specific criteria.

7. Document Control

In reviewing production and quality records associated with CP&L PO NY-435288 the following problems were identified:

- a. Exo Sensors has no controls on the revision of or the approval of revisions to shop travellers. In reviewing shop travellers for Hydrogen Analyzer Cabinet Assemblies 4004 and 4005, Remote Control Cabinets 4006 and 4007, Relay Tray Assemblies 3007 and 3009, and Microprocessor Assemblies 3008 and 3010, the following deficiencies were observed:
 - (1) work and inspections being performed prior to approval of the Shop Traveller
 - (2) revisions to drawings and procedures listed on the travellers were being made after approval of shop travellers and performance of inspections with no evidence of subsequent re-approvals of shop travellers or re-inspections of hardware.
 - (3) deletion of operations and inspections, including inspection hold points, after shop traveller approval without subsequent re-approval of the shop traveller.
 - (4) addition of operations and inspections, including inspection hold points, after approval of shop traveller without subsequent re-approval of the shop traveller.

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- b. Engineering Change Notice (ECN) #2 to QOP 052 was added to travellers 3008 and 3010 on 4/3/84, but the ECN was not approved by Engineering, QA, and Manufacturing until 5/31/84. In addition, according to QOP-024 a Procedure Change Notice (PCN) form should have been used rather than an ECN. It was determined by discussions with the Vice President of Engineering and Quality Assurance that PCNs had never been used. QOP-024 had been forgotten or ignored since its origination on 12/8/81.

Nonconformance 2.c was written covering this area.

8. Control of Purchased Material, Equipment, and Services

The inspectors reviewed sections 4.0 and 7.0 of the QAM, QOP-040, the Approved Suppliers List, and POs for safety related parts issued by Exo Sensor to Air Dimensions, General Electric, Control Specialist, and Amerae Corporation.

The review of the QAM revealed conflicting requirements. Paragraph 7.5 and 7.6 allow purchases of material, goods, and services for use in safety related equipment from companies which do not have quality programs and are not on Exo Sensors Approved Suppliers List (ASL). In addition, QOP-040 allows distributors to be placed on the ASL without a questionnaire or a survey by Exo Sensor and Exo Sensor does not perform any verification testing upon receipt. A review of the Exo Sensors PO to Air Dimensions revealed that the PO was placed on 8/25/83, but Air Dimensions was not placed on the AVL until 12/1/83. Nonconformance 2.d was written covering this area.

9. Identification and Control of Material, Parts, and Components

The inspectors reviewed section 8.0 of the QAM and the requirements appear sufficient. There was insufficient time to review the implementation of these provisions, however, there were several Defect Reports written in this area which had not been closed at the time of the inspection.

10. Control of Special Processes

The inspectors reviewed sections 9.0 and 10.0 of the QAM, AWS D1.1, ANSI/ASME N45.2.6, SNT-TC-1A, Ebasco PO NY-435288 and related documents, Welding Procedures 101, 103, 200, 201, 203, Weld Procedure Qualifications, Welder Qualifications, Soldering

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Personnel Qualifications, and Soldering and Welding Inspector Qualifications.

-- In addition, a visual examination of welded joints on production units on the shop floor was conducted.

As a result of this review it was determined that the annual eye examinations required for visual inspectors had never been performed and there was no documentation for soldering and welding inspector qualification. The visual examination of the structural and piping welds revealed no deficiencies.

During the review of Defect Reports it was discovered that an unqualified person had performed soldering on 21 circuit boards (see 16 and 17 below). This issue was not pursued to determine if the unqualified person had performed other soldering operations due to time constraints. Nonconformance 2.e was written covering this area.

11. Inspection

The inspectors reviewed Section 10 of the QAM and found the provisions sufficient to comply with Appendix B. Shop travellers were reviewed to determine compliance with the provisions of the QAM. During the review it was noted that Exo Sensors was not consistent in indicating when Inspection Hold Points were necessary nor in signing off the traveller indicating that the inspections were performed. Nonconformance 2.f was written covering this area.

12. Test Control

-- The inspectors reviewed Section 11 of the QAM and various QOPs. QOPs 012, 023, 063 and 064 did not have the required provisions for recording the type, serial number, and calibration due date of any instrumentation used. In addition, QOP-064 only required recording the results of the valve seat closure test if the valves passed, not if they failed. Nonconformance 2.g was written covering this area.

13. Control of Measuring and Test Equipment

The inspectors reviewed Section 12 of the QAM and found that the provisions met the requirements of Appendix B. Implementation of the provisions was not reviewed due to time constraints.

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14. Handling, Storage and Shipping

This area was not reviewed during the inspection.

15. Inspection, Test, and Operating Status

The inspectors reviewed Section 14 of the QAM and found the provisions acceptable with the exception of how material released under a "Conditional Release," paragraph 7.16, will be tracked. Provisions for tracking "Conditional Release" material were lacking. Implementation of QAM provisions was reviewed during the review of the shop travellers for the CP&L job. On shop travellers 4004, 4005, 4006, 4007, 3007, 3008, 3009, and 3010 there were four instances where tests/inspections required prior to continuation of work were not signed off and four instances where manufacturing operations were not signed off. Nonconformance 2.h was issued covering this area.

16. Nonconforming Materials, Parts, or Components

The inspectors reviewed Section 15 of the QAM, Defect Reports issued for 1983, 1984, and 1985, and the Defect Report Log. The review indicated that Exo Sensors was not closing Defect Reports in a timely manner, that Exo Sensors was performing repairs and rework without documented procedures, and that the QAM does not address how nonconformances discovered as a result of Quality Surveys or Questionnaires are to be documented. Nonconformance 2.i was issued covering this area.

17. Corrective Action

The inspectors reviewed Section 16 of the QAM, Defect Reports for 1983, 1984, and 1985, and Audit Reports for 1982, 1983, and 1984. The review revealed that the QAM does not address how corrective action is achieved for nonconformances discovered as a result of Quality Surveys or Questionnaires; nor does the QAM require that prior production be reviewed to determine if additional corrective action is necessary. As an example, on DR-473, 21 circuit boards were rejected because they were soldered by an unqualified person. However, there was no indication what corrective action had been taken or that the boards had been reinspected. Yet the boards were used in units shipped to Fermi and FitzPatrick Nuclear Plants. Additional prior production boards may have been soldered by the same person but there was

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no evidence that Exo Sensors had investigated prior work performed by the employee. In addition, most Defect Report forms have not been signed off by the company President or the Corrective Action Designator as required by the form. Nonconformance 2.j was issued covering this area.

18. Audits

The inspectors reviewed Section 18 of the QAM and found the provisions acceptable except that the QAM did not require a schedule be established for internal audits until March 1985. A review of the audits conducted revealed that no periodic audits were performed in 1980 and 1981, two areas were audited in 1982, one area was audited in 1983 and no periodic audits were conducted in 1984.

The audits of engineering in 1982 revealed a number of significant deficiencies, but to date there was no evidence that any action has been taken to correct them or close out the audit findings. An external auditor was brought in in 1983 and 1984 to perform an overall audit of the QA program in addition to the internal periodic audits. The audits lasted two days each and had no significant findings. The audits were of questionable quality because they did not detect that internal audits were not being performed, that travellers were not controlled or that Defect Reports were not being closed out in a timely manner. Nonconformance 2.k was issued covering this area.

INSPECTOR E. T. Baker

SCOPE _____

DOCUMENTS EXAMINED

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ITEM NO.	TYPE OF DOCUMENT	DOCUMENT NO.	REV.	DATE	TITLE / SUBJECT
1	QAM		6	5/1/84	Exo Sensors, Inc. Quality Assurance Manual
2	QCD			11/84	Exo Sensors, Inc. Users List
3	PO	NY-435288			Carolina Power & Light / Ebasco PO to Exo Sensors
4	SPEC				Ebasco Specification CAR-SH-N-45
5	SPEC				ASME Code, Section IX, Welding Requirements
6	SPEC				AWS-D1.1 Structural Welding Requirements
7	SPEC				SMN-TC-1A NDE Personnel Qualification Requirements
8	SPEC				ANSI B31.1 Piping Requirements
9	SPEC				Ebasco Welding Spec. CAR-SH-ME 15
10	SPEC				Ebasco QA Spec. 860-75
11	QCD				Shop Travellers 4004, 4005, 4006, 4007, 3007, 3009, 3008, 3010
12	PRO				Quality Operating Procedures - 012, 023, 037, 024, 048, 052, 064, 065, 066, 068
13	QCD				Log of Defect Reports

TYPE OF DOC:

DWG - DRAWING
SPEC - SPECIFICATION
PRO - PROCEDURE
QAM - QA MANUAL
QCD - QC DOCUMENT
PO - PURCHASE ORDER

LTR - LETTER

INSPECTOR E. T. Baker

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ITEM NO.	TYPE OF DOCUMENT	DOCUMENT NO.	REV.	DATE	TITLE / SUBJECT
14	QCD				Defect Reports from 1983 to May 1985.
15	QCD			5/3/85	Trip Report on Damaged Equipment at Fitzpatrick Plant
16	QCD			10/27/83	Internal Audit Report on Special Processes
17	QCD			12/10/82	Internal Audit Report on Engineering
18	QCD			5/31/84	Engineering Change Notice #2 for QOP-052
19	DWG			4/9/84	Drawing 117D050 w/ECN #2
20	QCD			1/25/85	Wisconsin Public Service Corp. Audit of Exo Sensors
21	QCD				Personnel Qualification Records (Production and Inspection)
22	QCD				Shop Travellers and Data Accumulation Sheets for
					Hydrogen Sensors - Serial Numbers 957, 958, 959, 960, 961, 962, 966, 967, 946
23	QCD			9/24/82	General Electric Report on Review of Exo Sensors QA Manual
24	QCD			1/21/83	" " " " " "
25	QCD			10/1/82	G.E. Audit of Exo Sensors' QA Program Implementation.

TYPE OF DOC:

DWG - DRAWING
SPEC - SPECIFICATION
PRO - PROCEDURE
QAI - QA MANUAL
QCD - QC DOCUMENT
P.O. - PURCHASE ORDER
TIT - TITLING

LTR - LETTER

INSPECTOR J.C. HARPER
SCOPE Exo - Sensors

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ITEM NO.	TYPE OF DOCUMENT	DOCUMENT NO.	REV.	DATE	TITLE / SUBJECT
1	QAM	20	6	5/11/84	Exo Sensors, Inc. - Quality Assurance Manual
2	"	Section 7	4	3/15/84	Control of Purchased Material, Equipment / Services
3	"	Section 8	4	3/15/84	Identification & Control of Material, Parts & Components
4	"	Section 12	5	5/11/84	Control of Measuring & Test Equipment
5	PRO	QOP-055	1	2/2/84	Quality Operating Procedure Visual Inspection of Welds
6	"	# 103	1	10/28/81	WPS GTAW - Manual, PAR, QW
7	"	# 101	2	10/6/81	WPS GTAW - Manual, PAR
8	"	# 202	2	1/16/85	WPS GTAW - Manual, PAR
9	"	# 200	3	2/28/84	" "
10	"	# 201	3	2/28/84	" "
11	PO.	8401		7/16/84	Northeast Utilities/PO # 829010/EX-CONTAINMENT H ₂ MANAGING SYSTEM
12	QUALIFICATION RECORDS	5.4			Employee Qualification Records
13	TRAINING RECORDS	5.3			Employee Training Records
14	DWG	111D007		2-7-84	DRAIN RESERVOIR
15	"	1140003		7-15-84	DETECTION CHAMBER DETAILS

TYPE OF DOC:

DWG - DRAWING	LTR - LETTER
SPEC - SPECIFICATION	_____
PROC - PROCEDURE	_____
QAM - QA MANUAL	_____
QCD - QC DOCUMENT	_____
P.O. - PURCHASE ORDER	_____
IMM - INTERNAL MEMO	_____

INSPECTOR J.C. HARPER
 SCOPE EXP - SENSORS

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ITEM NO.	TYPE OF DOCUMENT	DOCUMENT NO.	REV.	DATE	TITLE / SUBJECT
16	DWG	116D121		10-13-83	#1 Rempts Enclosure FAB.
17	"	"		"	#2 " " "
18	"	116D131		9-15-83	CABINET FAB
19	"	116D021		8-26-83	FAB Enclosure
20	QOP-267		0	5-28-85	SUBSTANTIAL SPEEDY HAZARD REPORTING PURCH
21	PO	E0062		8/25/83	AIR DIMENSION Inc / CLASS I E CONTAINMENT PUMP
22				6/6/84	Quincy Controls Vendor Surveillance Report.
23	PO	E0386		5/7/84	GENERAL ELECTRIC - MOTOR STARTER
24				12/1/83	Supplier Quality Survey - A.R. Dimension, Inc
25	PO	E0429		5/21/84	AMERINE CORP. Control Products Div - Buchanan Terminal Bldg
26	PO	E0816		12/27/84	CONTROL SPECIALIST - ASCO Solenoid Valve
27	PO	E0816		12/27/84	
28	Audit Report			5/21/84	STONE + Webster Engineering Co. of Exo Sensors, Inc
29	Audit Report			5/6/83	EBA SCO SERVICES Incorporated

TYPE OF DOC:

- DWG - DRAWING
- SPEC - SPECIFICATION
- PRO - PROCEDURE
- QA1 - QA MANUAL
- QCD - QC DOCUMENT
- P.O. - PURCHASE ORDER
- INH - INTERNAL MEMO

LTR - LETTER

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