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PRAIRIE ISLAND NUCLEAR GENERATING PLANT  
Docket Nos. 50-42 License Nos. DPR-282  
50-60 DPR-306

Deficiencies in Exo-Sensor, Inc Quality Assurance Program

This letter is written in response to your letter of November 26, 1985 which was concerned with the results of an inspection by E. T. Baker on May 28-31, 1985 on the implementation of the Exo-Sensor, Inc quality assurance program. The inspection was conducted to investigate allegations that there existed a breakdown in the Exo-Sensors Inc quality assurance program.

Our response addresses the following topics:

- A. Incompetent Auditor Allegation noted on Page 8 of NRC report 99901015/85-01
- B. Chronological Summary of surveillances, audits, and evaluations of Exo-Sensors Inc.
- C. Maintenance History of Exo-Sensors Inc Hydrogen Analyzers
- D. Analysis of allegations versus NSP's January 1985 audit of Exo-Sensors Inc

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A. Incompetent Auditor Allegation

One of the most serious allegations was that a recent audit by Northern States Power Company was performed by an incompetent auditor. The following is a brief resume of the NSP auditor's experience which shows the auditor has had a responsible career in quality assurance and is a very competent Lead Auditor.

1972                      Bachelor of Science Degree  
Earth Sciences - University of North Dakota

Jun 1975 - Dec 1978      °Tennessee Valley Authority  
Sequoyah Nuclear Plant  
°Instrumentation Engineering Unit and  
Materials Expediting Unit  
°Associate Engineer (various grades)

Responsibilities: reviewing material  
requisitions for proper technical and  
quality requirements, handling  
nonconforming material, other purchasing  
activities, and instrument status programs.

Dec 1978 - Jul 1979      °Thiokol/Wasatch Division  
Manufacturers of Solid Rocket Propellant  
°Quality Assurance Department  
°Material Records & Review and  
Quality Planning and Audit  
°Assistant Engineer/Systems Analyst

Responsibilities: compiling data for  
missiles, ensuring proper implementation of  
quality procedures, writing and revising  
quality control procedures.

Jul 1979 - Jun 1980      °Commonwealth Electric Company  
Electrical Contractor for Marble Hill  
Nuclear Generating Plant  
°Quality Assurance Engineer

Responsibilities: procedure writing, auditing,  
and overseeing quality inspectors; performing  
pre-award surveys, source inspections, and  
vendor audits; records turnover and inspection.

Jun 1980 - Jan 1981

°Northern States Power Company  
Power Production Nuclear Quality Assurance Dept  
°Quality Assurance Specialist

Responsibilities: writing quality  
administrative documents, corporate level  
auditing, department level auditing, and vendor  
auditing.

January 1981

Northern States Power Company  
Power Production Nuclear Quality Assurance Dept  
°Supplier QA Section  
°Senior QA Specialist

Responsibilities: conducting vendor audits,  
performing audits of nuclear fuel suppliers,  
conducting reevaluations of suppliers, conduct-  
ing source surveillance of vendors, and  
coordinating vendor audit activities with NSP  
consultants.

The auditor performed 11 vendor audits in 1985, 14 in 1984, 5 in 1983, 9 in 1982, and 6 in 1980. Beginning in 1982, the auditor has also performed 41 surveillances and audits of nuclear fuel suppliers' quality assurance programs. The auditor has been certified by NSP as a Lead Auditor since 1980.

The auditor has completed courses in the following subjects:

Lead Auditor Training	General Atomic
QA Codes and Standards	General Atomic
LWR Fuel Technology	General Atomic
Regulatory Codes & Stds	General Physics

Contrary to the allegations, NSP claims that the auditor is very competent and qualified to perform vendor audits as a Lead Auditor for Northern States Power Company. The allegation as stated in the inspection report could not be substantiated.

B. Chronological Summary Of Surveillances, Audits, And Evaluations  
Of Exo-Sensors Inc

Northern States Power Company's first experience with Exo-Sensors Inc began on April 29, 1980 when a pre-award survey was made for NSP by our consultant, U. S. Testing. The recommendations as a result of the survey stated that a manufacturing flow chart should be obtained and sufficient hold points should be established to provide surveillance of fabrication, testing, and shipping cycles. At that time, Exo-Sensors Inc was placed on the NSP Approved Vendor List (AVL) as "conditionally approved" in that source surveillance would be required for any procurement activity. The following is a chronological listing of surveillances, audits, and other important review and evaluation dates of Exo-Sensors Inc:

April 19, 1980	U. S. Testing Pre-award Survey Recommended forwarding to NSP a manufacturing flow chart and the establishment of "hold points" during fabrication, testing, and shipping cycles.
June 10, 1980	Proposal from Exo-Sensors Inc
July 15, 1980	Request for schedule, manual, and procedures by NSP.
July 18, 1980	Issuance of NSP Purchase Order MQ 05344 for hydrogen analyzers.
December 9-11, 1980	Visit by NSP to review progress of design and fabrication activities.
January 14-15, 1981	Surveillance at Exo-Sensors Inc by NSP personnel to review qualification plan and quality assurance program.
February 2, 5, & 6, 1981	Surveillance visit to AETL (Approved Engineering Test Lab), subvendor to Exo-Sensors Inc to review seismic testing procedures performed by U. S. Testing personnel.

February 18-20, 1981	Surveillance visit to AETL to witness LOCA testing of hydrogen analyzer by U. S. Testing.
June 22, 1981	Surveillance visit to Exo-Sensors to witness acceptance testing of hydrogen analyzer by U. S. Testing.
July 7, 1981	Surveillance visit to Exo-Sensors to witness retesting of hydrogen analyzer by U. S. Testing.
July 13 & 14, 1981	Surveillance visit to National Technical Systems (NTS) (formerly AETL) to witness seismic testing of hydrogen analyzer by U. S. Testing and NSP.
July 20 and 21, 1981	Surveillance visit to NTS to witness LOCA testing of hydrogen analyzer by U. S. Testing and NSP.
July 27-29, 1981	Visit by NSP to examine problems experienced during environmental qualification testing.
August 7, 1981	Surveillance visit to witness final inspection and to issue quality release for 8 platform assemblies.
August 13, 1981	Surveillance visit to witness functional test of hydrogen analyzer by U. S. Testing and NSP.
July 28, 1981	Meeting at Exo-Sensors Inc to discuss failure during LOCA testing.
Sept 8, 1981	Surveillance of continuing post LOCA environmental testing of hydrogen analyzer.
November 11-13, 1981	Witness radiation response test of containment hydrogen analyzer.

May 11, 1982	Audit notification
November 5, 1982	Rescheduled audit notification
December 16, 1982	Audit of Exo-Sensors Inc
January 14, 1983	Audit report with one finding in the area of test records.
February 22, 1983	Finding closed
January 19, 1984	Reevaluation of Exo-Sensors Inc
January 24, 1985	Triennial audit of Exo-Sensors Inc resulting in 2 findings and one recommendation.

Fourteen surveillance visits were conducted at Exo-Sensors Inc during the fabrication and testing of the hydrogen analyzers. These surveillance visits provided assurance that Exo-Sensors Inc complied with the purchase document requirements.

C. Maintenance History Of Exo-Sensors Inc Hydrogen Analyzers

<u>Date</u>	<u>Work Performed</u>
12-28-81	Fill low and high calibration gas bottles Unit 1 per WR #H7431
11-30-82	Fill low and high calibration gas bottles Unit 2 per WR #F6288
2-6-83	Replace sensors and piston/cup assembly Unit 1 per #G0222
10-11-83	Replace sensors and piston/cup assembly Unit 2 per WR
1-9-85	Refill low and high calibration gas bottles Unit 1 per WR #H7173, H7174

<u>Date</u>	<u>Work Performed</u>
8-13-85	Replace U8 prom during performance of SP 1226
8-14-85	Refill low and high calibration gas bottles in Unit 1 per WR #J5461
10-21-85	Refill low and high calibration gas bottles in Unit 2 per SCP 2227
11-1-85	Replaced fluorescent display on Train "A" per WR #J7424

The maintenance history, to date, in conjunction with the receipt inspection, installation, and preoperational testing activities confirms that the eight hydrogen detectors met the purchase document requirements and are suitable for use at the Prairie Island Nuclear Generating Plant.

D. Analysis Of Allegations Versus NSP's January 1985 Audit Of Exo-Sensors Inc

The following is a point by point analysis of allegations investigated by the NRC as listed in Report 99901015/85-01 versus findings of the NSP audit of Exo-Sensors Inc in January of 1985. Each item follows the numbering of the NRC report under Section B, Inspection Findings, No. 3, Allegations.

- a. During the NSP 1985 audit, the auditor observed the position of QA Manager was vacant at the time and was told the President and Vice President were acting for the QA Manager and QA Engineer but that the positions listed in the May 11, 1984 revision of the QA Manual were current. At the time, Exo-Sensors Inc was advertising for the QA positions.

Since it appeared Exo-Sensors Inc realized the need for full time QA personnel, NSP's concern was documented but no finding was issued.

- b. At the time of the NSP audit, the auditor was aware of the Vice President also acting as the QA Manager. Although this was expressed as a concern, the overall organization established was determined to be acceptable.



No finding was issued because it appeared adequate independence was maintained in the areas reviewed. A concern was expressed, however, because QA responsibilities in some areas were not up to date due to the lack of a full time QA person to fulfill those obligations.

- c. The NSP audit determined the QA Manual to contain provisions for independent checking and verification of design. However, the concern of dual responsibility as identified in a and b above was expressed.
- d. Purchase orders for safety-related parts which were reviewed were found satisfactory.
- e. The Approved Supplier List (ASL) was reviewed in conjunction with the purchase orders reviewed in d above. Supplier data and documentation for approval was available but 2 suppliers reviewed were not on the ASL.

Also, the required review of the ASL was not being performed. Therefore, a finding in this area was issued.

- f. NSP reviewed the area of design by review of control of qualification reports and a sampling of ECN control. The reports and drawings with revisions which were reviewed were all found to be satisfactory.
- g. Document control was verified throughout the audit by review of drawing files, purchase orders, etc.

Document control of products was maintained through Configuration Control Records which were verified for 2 jobs. Also, the QA Manual Log was reviewed.

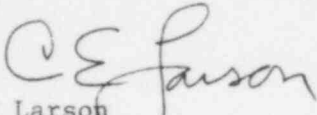
The area was determined satisfactory. Although no specific procedures were available, documents requested during the audit were filed and effectively maintained.



- h. While NSP was auditing, Job 8437 was in process in the shop. The Traveler for this job and its associated subassembly travelers were reviewed for completeness and found satisfactory.
- i. The QA Manual appeared to address the area of nonconforming material control adequately. However, implementation of the system to control Defect Reports was determined deficient and was addressed as a recommendation by NSP.
- j. The NSP audit reviewed the April 10, 1984 audit of Exo-Sensors by an external auditor. The audit was found satisfactory and lead auditor certifications were on file.
- k. Not observed
- l. See Section A of this response (Incompetent Auditor Allegation).
- m. Not observed
- n. Not observed
- o. Receipt inspection activities were audited on the shop floor. Segregated items on hold were observed to be in a cabinet. The log reflecting items on hold was reviewed and found current. Nothing in the cabinet was released and was on hold.  
  
Purchase Order Completion Slips were prepared to indicate completion of orders.  
  
The person performing receipt inspection was not certified. The deficiency was addressed as a finding and the recommendation was to review certifications for inspectors and keep them current.
- p. NSP found the Exo-Sensors, Inc QA Program to have numerous deficiencies. Therefore, continuous surveillance took place during the fabrication of products for NSP. NSP has always kept Exo-Sensors Inc on our AVL as a conditionally approved supplier with the following conditions applicable to new purchase orders:

1. Any test procedures require NSP approval.
  2. Production schedule must be submitted to NSP for the establishment of source surveillance hold points.
- q. The NSP auditor verified posting of 10CFR Part 21 and noted the responsibility for reporting Part 21 deficiencies was delegated to the QA Manager in the QA Manual. Due to the continuous interfacing and contact among the small group of employees at Exo-Sensors Inc, the auditor determined the posting and delegation of responsibility in the QA Manual comply with the basic requirements of 10CFR21.

As a result of the review, Northern States Power Company is confident that the product quality of the Exo-Sensors Inc hydrogen analyzers complies with the requirements of the purchase documents. Furthermore, NSP believes that all audits and surveillances were performed by qualified personnel. Northern States Power Company intends to provide similar controls on any future procurement activities with Exo-Sensors Inc.



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