** Revision 1

U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR INSPECTION AND LICENSEE PERFORMANCE

ORGANIZATION:	Rosemount Nuclear Instruments, Incorporated Eagan, Minnesota	** **
REPORT NO.:	99900271/93-01	
ORGANIZATIONAL CONTACT:	Mr. Kenneth E. Ewald, Business Unit Manager (612) 681-5814	 **
CORRESPONDENCE ADDRESS:	1256 Trapp Road Eagan, Minnesota 55121-1282	** **
NUCLEAR INDUSTRY ACTIVITY:	Designer, manufacturer, and supplier of pressure and differential pressure transmitters and temperature detectors used extensively in nuclear safety-related applications.	
INSPECTION CONDUCTED:	February 1-4, and March 8-12, 1993	
INSPECTION TEAM LEADER:	Original proprietary version signed on March 1, 1994, by Joseph J. Petrosino, Team Leader Reactive Inspection Section 2 (RIS-2) Vendor Inspection Branch (VIB)	Date
OTHER INSPECTORS:	Kamalakar R. Naidu, RIS-2: VIB S.D. Alexander, RIS-2: VIB C. Paulk, NRC Region IV: Division of Reactor Safety K. Sullivan, Brookhaven National Laboratory T.L. Tinkel, Brookhaven National Laboratory	
APPROVED:	Original proprietary version signed on March 3, 1994, by Gregory C. Cwalina, Chief, RIS-2: VIB Division of Reactor Inspection and Licensee Performance Office of Nuclear Reactor Regulation	Date
INSPECTION BASES:	10 CFR Part 21 and 10 CFR Part 50, Appendix B	
INSPECTION SCOPE:	The implementation of the Rosemount 10 CFR Part 50, Appendix B QA program and its procedures adopted pursuant to 10 CFR Part 21 were evaluated.	
PLANT SITE APPLICABILITY:	Numerous	

** Changes were made to page 1 only, as indicated.

1 INSPECTION SUMMARY

1.1 Apparent Violation

Contrary to Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of the version of 10 CFR Part 21 (Part 21) in effect at the time, Rosemount, Incorporated, Measurement Division (Rosemount) did not ensure that all affected customers were appropriately informed of identified deviations. Specifically, from approximately August 1984 until December 1988, Rosemount did not inform all its customers of deviations involving sensor cell oil-loss that could cause degraded operation in its 1150 series of nuclear safety-related pressure transmitters. Degraded transmitter operation as a result of sensor cell oil-loss was identified mainly in Model 1153 and 1154 pressure transmitters that had been returned for analysis by NRC licensees or found by Rosemount field service personnel. Rosemount documents cited in this report showed that Rosemount had identified potential deficiencies in the transmitter's design and its manufacturing and testing processes and had implemented changes to the processes to correct the deficiencies.

In a March 25, 1988, letter, Northeast Utilities (NU) notified the NRC pursuant to Part 21 of a substantial safety hazard in Unit 3 of its Millstone facility as a result of failed Model 1153HD5PC Rosemount transmitters. NU's letter to the NRC stated, in part, that "the manufacturer [Rosemount] had indicated to us [NU, that] the failures are random and there is no generic problem."

Through an examination of various Rosemount documents it was determined that Rosemount was aware of numerous transmitter failures prior to March 1988, the cause of the failures, and the symptoms exhibited by the failed transmitters. However, Rosemount did not begin to inform affected nuclear licensee customers until December 1988, and formally informed its customers in accordance with its 10 CFR Part 21 procedure in February and May 1989. Consequently, as much as four years elapsed before all applicable NRC licensees were made aware of potentially suspect transmitters that may have been installed in applications where sometimes undetectable degraded operation could have caused safety limits to be exceeded or caused "substantial safety hazards."

1.2 Violations

1.2.1 Contrary to Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of 10 CFR Part 21, Rosemount failed to establish or implement a procedure to ensure that the provisions of 10 CFR Part 21 were executed at its Chanhassen facility. (93-01-01)

1.2.2 Contrary to Section 21.6,"Posting requirements," the 10 CFR Part 21 posting at Rosemount's Eden Prairie and Chanhassen facilities did not adequately describe the 10 CFR Part 21 regulation or the procedure adopted to implement 10 CFR Part 21. In addition, the postings were found to contain outdated names and telephone numbers of personnel to whom reports were to be made. (93-01-02)

1.2.3 Contrary to Section 21.51, "Maintenance and inspection of records," of 10 CFR Part 21, Rosemount records regarding a review of suspect resistors used in Rosemount 710 DU products did not contain adequate information to enable the team to determine whether Rosemount customers were appropriately informed of the deviation. (93-01-03)

1.3 Non-cited Violation

Contrary to Section 21.31, "Procurement documents," of 10 CFR Part 21, Rosemount did not invoke 10 CFR Part 21 before 1990 on most of its purchase orders for certain basic components, specifically, metal o-rings used in Model 1153 and 1154 transmitters. Purchase orders since then have invoked 10 CFR Part 21. This violation is not being cited because the enforcement criteria specified in Section VII.B of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions," were satisfied.

1.4 Nonconformances

1.4.1 Contrary to Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 and Section 5, "Instructions, Procedures, and Drawings," of Rosemount's Nuclear Quality Manual (NQM), Rosemount did not establish adequate procedures, or instructions to control activities affecting quality, such as, analyzing and determining the root cause of problems with safety-related pressure transmitters in its Failure Analysis (FA) Laboratory. (93-01-04)

1.4.2 Contrary to Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, Rosemount did not have an adequate Appendix B QA program for the control of "basic components" manufactured in its Chanhassen facility. Although Rosemount provided Chanhassen with its Nuclear Department-approved drawings and procedures for certain of its activities affecting quality, some QA functions were not appropriately controlled or performed. (93-01-05)

1.4.3 Contrary to Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, Rosemount did not implement the receipt inspection requirements delineated in Section 2.5, "Dedication," of NDP N-0730, "Dedication of Subassemblies from Chanhassen," for the sensor cells used in all of its safety-related nuclear transmitters. (93-01-06)

1.4.4 Contrary to Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, and Section 3, "Design Control," of Rosemount's NQM, as of March 12, 1993, the NRC inspection team identified the following nonconformances:

- Rosemount did not perform an adequate verification of the design change authorized by Engineering Change Order (ECO) 601919, dated May 23, 1983, and no evidence was found to indicate that the design change was compared to or met the existing Rosemount Model 1153 Equipment Qualification Report. Additionally, Rosemount did not perform an adequate verification of the design changes authorized by ECO 603675, dated February 1, 1984. Although these design changes were later superseded by subsequent changes, the team was concerned that Rosemount was making design changes without an adequate engineering evaluation to assure that previous equipment qualifications remain valid. (93-01-07)

- Rosemount did not adequately justify the use of fluids in its transmitters having an expired shelf life and did not state its basis for the operating temperature limits of the fluid used in sensor cells of nuclear-qualified transmitters. (93-01-08)

1.4.5 Contrary to Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, Section 18.3.3, "Internal Audits," of Rosemount's NQM, and Section 3.0, "Responsibilities," of NDP N-0730, Rosemount failed to schedule or conduct any internal audits in 1989. Additionally, since December 1991, Rosemount has failed to audit quality-related activities at its Chanhassen facility to determine compliance with applicable portions of Appendix B to 10 CFR 50 and 10 CFR Part 21. (93-01-09)

1.5 Inspector Follow-Up Items

Inspector Follow-Up Items are items that were identified during the inspection team activities that are perceived by the team to either need additional inspection time or to be of interest for future inspection follow-up.

1.5.1 The NRC inspectors started a review of how Rosemount handles incoming NRC licensee telephone calls regarding potential deviations. However, the NRC inspectors did not complete their review. In accordance with the provisions of Rosemount's Nuclear Department Procedure N-1697, "Returned Products From a Nuclear Facility," Revision A, Rosemount's marketing personnel enter the content of conversations with their customers in a log book. The team's review of incoming telephone calls that were entered in the 1989 log book showed that as of March 12, 1993, some calls did not appear to have been completely dispositioned. Since licensee related problems could potentially affect other customers or products the team was interested in further reviewing the manner in which Rosemount dispositions these telephone calls. (93-01-10)

1.5.2 The team conducted a design change review of changes to the metal o-ring drawing. The drawing revision history record that the team reviewed indicated that Rosemount made a number of changes to the metal o-ring drawing. However, contrary to what the drawing revision history indicated, the Rosemount Engineering staff stated that the actual o-ring configuration never physically changed, and that the drawing changes were administrative attempts to correct the drawing rather than physically change the o-ring. The Rosemount o-ring drawing revisions, particularly around the period of Revision E, December 13, 1981, and Revision F, February 6, 1984, will be reviewed during a future inspection. (93-01-11)

1.5.3 The team had questions based on its review and observations of the HP/Aging 1 (HP1) tests and associated activities. The team noted that sensor cells used in Model 1153 and 1154 transmitters undergo testing to ensure leak-tightness of the sensor cell over time. Rosemount determined that these time and pressure test values are sufficient to identify excessive leakage over the qualified life of the sensor. The team asked for the Rosemount basis related to the amount of oil that may leak before being detected by visual inspection. Rosemount presented a document entitled "Rosemount Sensor Life Calculations Based on Oil Loss in Model 1153 and 1154 Pressure Transmitters."

[Deleted pursuant to 10 CFR 2.790 - Document discusses calculations, performance characteristics, and testing. Notes that testing should adequately identify transmitters with potential for failure.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses calculations, performance characteristics, and testing. Notes that testing should adequately identify transmitters with potential for failure.]

This area, including the synergistic effects of temperature and pressure on the physical characteristics (e.g. viscosity) of the sensor fill fluid will be reviewed during a future NRC inspection. (93-01-12)

1.5.4 Rosemount representatives stated that the current level of in-process testing that is performed by production personnel is sufficient to identify manufacturing deficiencies. For example, Rosemount stated that response time testing (performed after the sensor is mounted in its housing) is adequate to identify cells with low levels of fill oil.

The team subsequently identified that the ability of response time testing to accurately identify improperly filled cells may not be adequate in all cases because, depending on the transmitter range code, as much as 73 percent of the fill fluid may be lost before the response time test would reliably identify a sensor cell as having low-oil.

The team was in agreement with the Rosemount staff that the response time test verified that a certain degree of oil-fill had taken place and the transmitters would operate under certain conditions. However, the team questioned the validity of the response time test to assure whether or not the nuclear transmitters that are passed will perform within their designed and tested spectrum of operating conditions. (93-01-13)

1.5.5 The team reviewed Rosemount Field Instruction Manual No. 4302, for Model 1153, Series B, transmitters. The NRC inspectors reviewed the sequence of steps that licensee staff would use when changing out a sensor cell at their facility. The team questioned whether the Rosemount field manual contained an appropriate assembly sequence to allow licensee staff to adequately perform a field change out of sensor cells on Rosemount transmitters that require using stainless steel o-rings in their process flange area, as discussed in Section 4.4 below. Therefore, the information that Rosemount provided to certain NRC licensees will be discussed further with Rosemount representatives. (93-01-14).

1.5.6 The NRC inspection team review included areas that were associated with the dedication of commercial grade items (CGI). However, the appropriateness of Rosemount's overall program for dedication of CGIs used in its products destined for use in nuclear power plant safety-related systems was not specifically reviewed during this inspection. Therefore, Rosemount's dedication of CGIs for use in products shipped for use in NRC licensee applications will be reviewed during a future NRC inspection. (93-01-15)

2 STATUS OF PREVIOUS INSPECTION FINDINGS

No previous NRC inspection findings were left open or unresolved from the previous NRC inspections at Rosemount.

3 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 Entrance and Exit Meetings

During the NRC entrance meeting on February 1, 1993, the inspectors explained the scope of the inspection to the Rosemount staff. During an interim exit meeting on February 4, 1993, the team leader explained to Rosemount management that the NRC inspection would be continued because the team was not able to make adequate progress toward completing its inspection goals. The NRC team leader conducted an inspection continuation entrance meeting on March 8, 1993, and reiterated the inspection scope to Rosemount management and staff. At the exit meeting on March 12, 1993, the team leader summarized the team's concerns and findings for Rosemount management and staff.

3.2 Background

In January 1956, the Rosemount Engineering Company was incorporated as Rosemount, Incorporated (Rosemount). In 1969, Rosemount started to market and supply its Model 1151 solid-state, capacitance, industrial differential pressure (DP) transmitter. In 1974, Rosemount qualified its Model 1152 to the Institute of Electrical and Electronics Engineers, Incorporated (IEEE) Standard 323-1974. In 1975, the Model 1152 was seismically qualified to IEEE Standard 344-1971. In 1976, Rosemount was acquired by the Emerson Electric Company as a wholly owned subsidiary. During the 1970s and 1980s, Rosemount developed and qualified its Model 1153 and 1154 transmitters to the NRC's harsh environment equipment qualification regulations.

At the time of this NRC inspection, the Nuclear Business Unit (NBU) of the Rosemount, Incorporated Measurement Division controlled the design, qualification, manufacture, supply and other aspects of the nuclear-qualified Model 1152, 1153, and 1154 transmitters. However, the majority of the Rosemount NBU activities were in the process of being transferred from the Rosemount, Incorporated Measurement Division to Rosemount Aerospace, Incorporated (RAI).

Since the early 1980s, the NRC staff has become aware of several problems with Rosemount's 1150 series transmitters. Rosemount considered these problems as isolated, and handled them as they believed to be appropriate. In 1987, the NRC conducted an inspection at Rosemount because of a potentially generic problem concerning degraded transmitter operation associated with contaminates in sensor cell oil, a condition referred to as "latch-up." Subsequently, another problem surfaced, regarding degraded transmitter operation associated with oil-loss in the sensor cell. The oil-loss problem was discussed in NRC Information Notice (IN) 89-42, "Failure of Rosemount Models 1153 and 1154 Transmitters." As noted in the IN, Rosemount indicated to the NRC staff that the failures appeared to be random and not related to any generic problem with Rosemount pressure transmitters. Further discussions were conducted between Rosemount and industry groups, and Rosemount initially informed its customers of a potentially generic problem on December 12, 1988, and February 9, 1989.

3.3 Review of 10 CFR Part 21 Program

The NRC inspection team reviewed the procedures that Rosemount identified as implementing the provisions of 10 CFR Part 21, and historical records of problems that appeared to be potential deviations. The objective of this review was to determine the effectiveness of Rosemount's established 10 CFR Part 21 program and

its implementation. The team reviewed the following Rosemount procedures: Quality Implementation Procedure (QIP) 126(N), "Potential Defect or Deviation in Products for Nuclear Application," issued March 18, 1981; Nuclear Department Procedure (NDP) N-1626, "Handling Potential Defects or Deviations in Nuclear Products per 10 CFR Part 21," Revision A, dated April 21, 1992, which superseded QIP 126(N); and NDP N-1697, "Returned Products From a Nuclear Facility," Revision A, dated May 8, 1992.

The team also assessed whether Rosemount had adequately implemented Section 3.2 of NDP N-0730, "Dedication of Subassemblies From Chanhassen," Revision A, dated May 8, 1992, which mandated that the "Supplier [Chanhassen] will implement a procedure for reporting defects or deviations per 10 CFR Part 21." The NRC team's evaluation of Rosemount's 10 CFR Part 21 program included:

- review of correspondence (dating back to 1979) concerning deviations and transmitter failure analysis data
- discussions with Rosemount staff members regarding their training in and knowledge of the requirements of 10 CFR Part 21 and its implementation
- observation of the location and adequacy of Rosemount's posting of the required 10 CFR Part 21 documents at the Chanhassen and Eden Prairie facilities.

3.3.1 Review of QIP 126(N) and Associated Rosemount Records of Problems. The team's review of QIP 126(N) identified that Rosemount's company position, as stated in Section 1.3, was

> Because a supplier of industrial instruments cannot control how they may be applied or misapplied, and because only the system design agency can determine the effect any "defect" or "deviation" may have on operational safety, a means of prompt review and communication has been elected. The position RMT [Rosemount] has taken regarding 10 CFR Part 21 is detailed in the letter attached. This letter is sent to all customers regarding products destined for application in Nuclear facilities within the United States of America.

The team considered that the Rosemount Company Position in QIP 126(N) could be a strength if properly executed because the policy would tend to expeditiously transmit all deviations to NRC licensees as soon as they were identified and dispositioned by Rosemount. This would allow each NRC licensee to evaluate the deviation in accordance with 10 CFR Part 21 to determine whether or not a "substantial safety hazard" could exist. However, problems were identified by the inspectors with the adequacy and implementation of the procedure and Rosemount's execution of the Company Policy.

The procedure required that any employee who detected or was notified of a potential defect or deviation immediately notify a Nuclear Review Committee member. The Committee member then was to gather all pertinent information and arrange a Committee meeting within one day. After the Committee completed their review (which may have taken several meetings), a recommendation was to be made to the Rosemount officer accountable for nuclear products. That officer was then to determine if customer notification was needed. If so, the officer was to prepare and issue a letter within two working days. Based upon a review of the procedure and the sample letter that was attached to QIP 126(N), the team

concluded that the Nuclear Review Committee should have reviewed all problems to determine if they constituted a deviation in accordance with Part 21. (Note: as stated above, Rosemount's company position was, and still is, that they cannot evaluate deviations to determine if they constitute a defect.)

The team reviewed Rosemount's intracompany memoranda and other correspondence written mainly before 1988, to determine how effectively the procedure had been implemented and whether identified problems were adequately reviewed to determine whether deviations existed and whether the Nuclear Review Committee was convened to review the deviations. Section 3.3.7.1 below also discusses other examples of Rosemount's implementation of its 10 CFR Part 21 program. Examples of correspondence that was reviewed by the team are as follows:

A Rosemount Intracompany Memorandum (RIM), dated August 27, 1984, that was copied to Rosemount staff and management in several departments including nuclear QA, manufacturing, and contracts, stated, in part, that:

> *...of greatest concern are four failures of model 1153 HA5*, all measuring Reactor Coolant Flow...*determined failure mode in 3 units to be loss of oil*, but could not determine cause. [emphasis added].

An RIM, dated April 23, 1986, stated, in part:

> [Deleted pursuant to 10 CFR 2.790 - Document discusses oil leaks, leakage paths, leakage testing, testing criteria and results.]

An RIM, "Nuclear Sensor Oil Leaks," dated May 7, 1986, stated, in part:

> [Deleted pursuant to 10 CFR 2.790 - Document discusses testing, loss of oil failures, and failure analysis and results. Document notes that leakage rate is so slow that detection may require long test periods.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses testing, loss of oil failures, and failure analysis and results. Document notes that leakage rate is so slow that detection may require long test periods.]

A Rosemount letter to [a customer's] Nuclear Power Plant [name deleted] staff, dated September 17, 1986, stated, in part:

[Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that Rosemount considers failures to be unique to customer facility.]

A letter from the [customer] staff to Rosemount, dated September 25, 1986, stated, in part:

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process and design characteristics. Document also discusses potential testing method shortcomings.]

An RIM, dated March 19, 1987, from a Rosemount manager to Rosemount staff stated, in part, that:

> *One of our larger field failure problems is the loss of sensor fill fluid in nuclear pressure transmitters.* It's important that we be able to identify the cause of these failures in order to take corrective action in production. *A transmitter which has lost oil exhibits unique performance characteristics, typically as slow response to input pressure or no response at all.* Effective immediately, the module from any returned transmitter which you suspect has failed due to loss of oil must be submitted for failure analysis [emphasis added].

Another RIM, "Meeting on Nuclear Sensor Oil Leaks," dated March 25, 1987, stated, in part, that:

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process, and testing and acceptance criteria.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses manufacturing process, and testing and acceptance criteria.]

Another RIM, "Oil Leakage Status Report," dated July 14, 1987, stated, in part, that:

[Deleted pursuant to 10 CFR 2.790 - Document discusses design characteristics, testing and acceptance criteria and experiments. The document identifies that transmitters with visually detectable leaks will ultimately fail.]

The team examined another RIM, dated August 5, 1981, from Rosemount's Houston office which identified operational problems in 47 industrial Model 1151 transmitters and requested that the Rosemount Eden Prairie staff investigate the various causes. An associated RIM, dated April 22, 1982, to Rosemount management from the failure analysis laboratory, indicated that approximately half of the 47 modules that were sent to Eden Prairie for investigation exhibited oil-loss (some were damaged). Additionally, the team reviewed a Rosemount Failure Analysis Request/Report (FAR) package, FAR 497, dated July 9, 1985, that analyzed 5 Model 1151 transmitter modules that were from [an off-shore (foreign) nuclear power station] [Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that transmitter modules lost oil.] The transmitters were supplied to the [nuclear power] station between May 1981 and August 1984. The Rosemount FAR was found to state, [Deleted pursuant to 10 CFR 2.790 - Document identifies customer and sales volume. Document also states that transmitter modules lost oil.] The team found that, at those times, the nuclear sensor cells went through the same process and manufacturing controls that were used for the industrial units. According to Rosemount QA staff, during this time period, "***except for traceability requirements, the industrial sensor cell was identical to the nuclear sensor cell*** [emphasis added]." The inspection team considers this staff knowledge of Model 1151 sensor cell problems relevant because Rosemount should have been aware that an industrial sensor cell oil-loss problem was a potentially generic problem that could also affect its nuclear sensor cells since nuclear and industrial type sensor cells were controlled, manufactured and fabricated almost identically. However, it appears that Rosemount did not appropriately recognize or adequately address the potential nuclear sensor cell implications of the failed industrial sensor cell problem when it was first documented by Rosemount in 1981 nor several subsequent occasions when failed or degraded transmitters due to oil-loss were found, returned or reported to Rosemount by NRC licensees as discussed herein.

The NRC team also reviewed Rosemount records pertaining to the Nuclear Review Committee meetings from 1982 to 1991. The inspectors' review for the 1982-1987 time period appeared to indicate that the first Rosemount Nuclear Review Committee meeting regarding oil-loss was held in April 1986, and that subsequent meetings took place in July 1986 and February 1987 (further discussed in Section 3.3.6.1 below). An RIM announcing the February 1987 Nuclear Review Committee

meeting stated under "topic of concern" that, "low oil in nuclear transmitters [was the subject]... Please bring all information that you may possess. We will try to determine the nature and scope of the problem and if it is generic."

Further, the team also found that approximately 70 instances of failed or degraded nuclear transmitters (due to oil-loss) had been discussed with or identified to Rosemount personnel prior to the time that the oil-loss problem was first addressed in the 1986-1987 Nuclear Review Committee meetings. However, it appears that Rosemount did not compile nor maintain any type of all-encompassing list of these failures until sometime in the late 1986-1987 time period when the nuclear quality group commenced a review of the oil-loss problem. One Rosemount document that was reviewed and discussed with Rosemount QA staff represented one of the first attempts by the Nuclear quality group to compile all of the known transmitter oil-loss failures. The quality group was attempting to understand the scope of the oil-loss problem and to determine commonality. That list started with four Model 1153HA5 transmitter failures in 1984 at Surry due to oil-loss (those 1984 failures were documented by Rosemount in an August 1984 intracompany memorandum discussed above in this Section) and ended with two Model 1153DB5 transmitter failures at Nine Mile Point in 1986. This list contained approximately 92 individual nuclear transmitter failures, of which, about 70 were traced back by the team and found to have been reviewed by Nuclear Review Committee members.

The Rosemount staff also informed team members that in the early to mid-1980s, all of the nuclear transmitter failures or customer problems with degraded transmitter operations would not necessarily be handled by the same Rosemount group or department. Prior to the late 1980s, the Rosemount service center staff would not necessarily involve the nuclear quality or engineering staff when it was resolving customer problems that might involve degraded operation of nuclear transmitters. According to Rosemount staff, these customer service activities and service center activities regarding NRC licensees are presently coordinated through the Rosemount nuclear quality and engineering group.

The team reviewed Rosemount's failure data information that its Engineering Department had compiled. The NRC team reviewed Rosemount Nuclear Engineering staff records that related to oil-loss problems. These consisted of various documents and graphs containing manufacturing and field return data for the Rosemount Model 1152, 1153 and 1154 nuclear transmitters. This information covered a period from about 1979 through 1992. The records, which included Rosemount field return failure data, appeared to indicate that the major cause of oil-loss from the sensor cell was leakage through the sensor cell glass-to-metal (G-M) interface. The team also reviewed Rosemount graphical data for confirmed G-M failures of Model 1152, 1153, and 1154 nuclear transmitters sorted by sensor cell weld date. The weld date is the date that the sensor cell diaphragms were welded, and represents the approximate Rosemount manufacturing date for a transmitter. Rosemount used these dates to provide approximate estimates of the manufacturing time-frame of nuclear transmitters with confirmed G-M failures. The confirmed number of failures due to oil-loss by weld date were found to be lowest in 1980 (1), 1989 (0), and 1990 (0). The highest number of failure occurred in 1982 (22), 1983 (23), 1984 (64), 1985 (29), and 1986 (10). These dates only represent the year that the failed units were manufactured and not the dates when Rosemount became aware of the failures.

The team also reviewed Rosemount graphical data on Model 1152, 1153, and 1154 nuclear transmitters with confirmed oil-loss failures sorted by return date. The return date is an indication of the time frame when Rosemount became aware of these nuclear transmitter oil-loss failures and when they were shipped back to Rosemount for analysis. The team notes that the basis for this data differs somewhat from that of the G-M failure data discussed above. There are two reasons for this according to the Rosemount Engineering staff. First, the confirmed oil-loss failure data include G-M failures as well as other types of failures that can also cause oil-loss (such as defective welds or broken fill tubes). Second, the oil-loss data do not include some confirmed failures that were known to Rosemount, but not actually returned to Rosemount for reasons such as radioactive contamination. Rosemount's documented oil-loss transmitter failures that were confirmed in their failure analysis laboratory ranged from a low in 1984 (1) and 1985 (2); to the highest in 1986 (17), 1987 (27), 1988 (23), 1989 (10), 1990 (14), and 1991 (10).

Some of the graphs reviewed by the team contained time-lines for various corrective actions in Rosemount process control and design parameters aimed at correcting the oil-loss problem. From its review of this graphical and engineering data, the team concluded that Rosemount was aware as early as 1986 (and perhaps even earlier) that the number of transmitters failing as a result of oil-loss had increased and was implementing corrective action. However, Rosemount did not formally inform its nuclear licensee customers about its transmitter oil-loss problem until December 12, 1988.

The inspectors concluded, based upon a review of the above records, procedures and discussions with Rosemount staff that:

- Rosemount did not adequately ensure that the Nuclear Review Committee was aware of deviations in the operation of Rosemount's products in safety-related applications at NRC licensed facilities.

- Rosemount did not ensure that identified problems from operating nuclear plants where Rosemount products were used in safety-related applications were appropriately reviewed to determine whether a deviation, as defined in Section 21.3(e) of the revision of 10 CFR Part 21 that was in effect at the time, existed. Such a deviation could include a change in the transmitter response time or in its qualified life. Since Rosemount failed to adequately review or disposition its Model 1150 series transmitter oil-loss problems that could cause degraded operation or premature failures, Rosemount failed to inform its customers pursuant to 10 CFR Part 21 so that affected customers could determine if the deviations could create a "substantial safety hazard."

- Rosemount was aware of several transmitter failures prior to December 1988, the cause of the failures, and the symptoms exhibited by the failed transmitters. The oil-loss problem was discussed in Rosemount Nuclear Review Committee meetings in April and July 1986, and generic considerations were identified as early as February 1987.

One common thread found by the team in many of the Rosemount records was an interest among Rosemount staff to determine the cause of the problem in the manufacturing process and to take corrective action. This interest was viewed as a strength by the team. However, the team's examination of the records and

10 CFR Part 21 procedures identified some weaknesses that the team considered important when performing an evaluation or review of a potential deviation or anomaly. These weaknesses were:

- The documents did not address the determination of whether or not the anomaly or problem was potentially generic.

- The documents did not address whether the anomaly applied to basic components that were previously shipped to customers.

- The documents did not address whether the Nuclear Review Committee was informed so that disposition of the anomaly pursuant to 10 CFR Part 21 was accomplished.

This information was used to characterize the apparent Violation.

3.3.2 Review of NDP N-1626. The same Rosemount Company Policy and letter required by QIP 126(N) was found to be required by Procedure N-1626. The team verified by a review of a sample of current incoming purchase order (PO) packages from NRC licensees that Rosemount had typically transmitted this subject letter to its customers and the intent of the Rosemount company policy was properly expressed. The inspectors identified several weaknesses in Rosemount Procedure N-1626. Rosemount did not incorporate the time limits for the evaluation of deviations and failures to comply, and other new requirements that were first specified in the July 31, 1991, revision of 10 CFR Part 21.

This has not been identified as a violation because Rosemount's Company Position stated that it would not attempt to evaluate deviations since it was not in a position to determine whether a substantial safety hazard existed. Rosemount stated that it would promptly inform its customers of any deviations that it identified. Therefore, Rosemount's Company Policy complied with the intent of Section 21.21 (b) of 10 CFR Part 21. Further, Rosemount performed corrective action immediately by revising the procedure to adequately address the time limits and other NRC staff concerns. Additionally, the team would consider it a strength if Rosemount's nuclear customer service activities regarding potential deviations are coordinated through Rosemount's nuclear quality and engineering groups.

3.3.3 10 CFR Part 21 Procedure at Chanhassen. The inspection team reviewed Rosemount's activities at the Chanhassen manufacturing facility. That facility manufactures Rosemount industrial (commercial grade) Model 1151 transmitters. The same facility also manufactures safety-related sensor cells up to the oil-fill step. Manufacturing activities for the safety-related sensor cells at Chanhassen are controlled by separate procedures issued and approved by the nuclear department. In conjunction with these procedures, different or specific manufacturing process controls and some traceability requirements are also employed that are not typically used for the commercial grade items. The team concluded, in consultation with Rosemount, that the Chanhassen manufacturing activities associated with sensor cells used in safety-related pressure transmitters have relied on unique nuclear requirements and, therefore, would be subject to 10 CFR Part 21 requirements. Additionally, the Chanhassen facility was specifically required by Paragraph 3.2 of Procedure N-0730 to establish a 10 CFR Part 21 procedure. However, the inspectors determined that Rosemount had not established or implemented such a procedure. Violation 93-01-01 was identified in this area.

The inspectors identified one other area of concern regarding some Rosemount personnel's view of the activities being conducted at the Chanhassen facility. On two different occasions, between February 1-4, 1993, different NRC team members asked one Rosemount QA auditor why the 10 CFR Part 21 posting was outdated at Chanhassen. The auditor informed the NRC team members that it did not matter that the posting was outdated because 10 CFR Part 21 was not applicable to the Chanhassen facility activities. Further, some Rosemount managers also stated to the team that Chanhassen was a commercial grade operation. However, as discussed above, the team determined that Chanhassen was manufacturing safety-related sensor cells and that Rosemount Procedure N-0730 stated that 10 CFR Part 21 was applicable (indicating Rosemount's corporate viewpoint). The team is concerned that all Rosemount personnel may not be aware of Chanhassen's involvement in manufacturing nuclear grade sensor cells and, therefore, may not recognize their duty to comply with Part 21 when they recognize potential deviations.

3.3.4 Posting Requirements. The NRC inspection team determined that safety-related activities were being conducted at both the Chanhassen and Eden Prairie facilities; therefore, the inspectors observed the location and reviewed the adequacy of the 10 CFR Part 21 posting at both facilities.

The posting is required by Section 21.6, "Posting requirements," of 10 CFR Part 21. Section 21.6 of 10 CFR Part 21, requires, in part, that each individual, corporation, partnership, or other entity post current copies of either:

- 10 CFR Part 21, Section 206 of the Energy Reorganization Act of 1974 (ERA), and procedures adopted pursuant to 10 CFR Part 21; or

- Section 206 of the ERA, and a notice which describes 10 CFR Part 21 and procedures adopted to implement 10 CFR Part 21, including the name of the individual to whom reports may be made and the location of where the procedures may be examined.

The NRC inspectors found that the 10 CFR Part 21 postings at Rosemount's Eden Prairie and Chanhassen facilities did not adequately describe the 10 CFR Part 21 regulation or the procedure that Rosemount adopted to implement 10 CFR Part 21. Specifically, the "Description of 10CFR21" was actually a description of Section 206 of the Energy Reorganization Act of 1974, the postings described 10 CFR Part 21 as being applicable only to NRC-licensed facilities or those conducting NRC-licensed activities, and under "Notifications," the postings listed the NRC Region III phone number and indicated that NRC regional offices would accept collect calls; however, the posting did not mention the NRC Headquarters Operations Center, nor its phone number, as specified in the current revision of 10 CFR Part 21. Also, the list of Rosemount contact personnel was out of date. In addition, the inspectors found that the 10 CFR Part 21 posting at the Chanhassen facility was an older, outdated, version of the one posted at the Eden Prairie facility. Violation 93-01-02 was identified in this area.

3.3.5 Procurement Documents. Section 21.31, "Procurement documents," of 10 CFR Part 21, requires, in part, that entities impose the provisions of Part 21 on purchase orders (POs) to suppliers of components. During a review of engineering change orders (ECOs) the NRC inspectors found that ECO 642650, that was dated July 22, 1991, contained a note stating that the provisions of 10 CFR Part 21 were applicable, and Rosemount staff stated that the purpose of that note was to

impose the regulation on the o-ring vendor. This drawing then became part of Rosemount's PO. Therefore, Rosemount imposed Part 21 to the supplier on the drawing which became part of the PO package documents.

However, Rosemount also stated that before July 22, 1991, it did not pass down the requirements of 10 CFR Part 21 to the vendor. The NRC inspectors requested a sample of pre-1991 POs to the o-ring supplier and confirmed that Rosemount failed to invoke the 10 CFR Part 21 requirements on the metal o-ring vendor prior to July 22, 1991. Examples of POs that did not invoke the regulation are as follows: EK 5737, dated July 19, 1990; EK 5620, dated May 16,1990; EK 0493, dated October 19, 1989; and EK 2169, dated November 4, 1988. This violation is not being cited because the enforcement criteria specified in Section VII.B of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions," were satisfied.

3.3.6 10 CFR Part 21 Evaluation Records. The team reviewed Rosemount records that were applicable to its review of identified potential deviations or failures to comply to determine whether Rosemount had performed the required review, and whether those reviews were adequate (this issue is also discussed in Section 3.3.1). The team examined records of Rosemount activities that were performed from approximately 1978 through 1992. Since July 1991, entities that are required to comply with 10 CFR Part 21 were only required to maintain records associated with evaluations for a maximum period of five years; however, Rosemount has maintained the majority of its evaluation records from as early as 1978. The team noted that, in addition to the requirements of Part 21, Rosemount had additional requirements stated in its Procedure QIP 12S(N) as discussed in Section 3.3.1 above.

Based on its review, the team concluded that the Rosemount records did not contain adequate information in all cases to enable the team to determine whether the review and disposition of Rosemount's deviation evaluation was adequately performed in accordance with the applicable requirements. Specifically, on August 15, 1989, Rosemount staff discovered a problem with wire-wound resistors (1 ohm to 10,000-ohm range) used in the assembly of its Model 510 and 710 DU Trip Calibration System instruments (TCSs). The manufacturing process required brazing leads to the resistors, which were wound with wire that had a diameter of 0.0004 inch or less. Until 1988, the manufacturer cleaned the brazed leads before coating the resistors. In 1988, the manufacturer revised the manufacturing process and required the brazed leads to be cleaned after the resistors were coated. When the revised process was implemented, remnants of the flux that had been used during the brazing process remained on the brazed joint and caused contamination. When combined with voltage, humidity, temperature, and time, this contamination resulted in discontinuity between the leads and the resistor, and subsequently in failures. The failure mode regarding Rosemount TCSs is a shift in resistance (either high or open). The concern was that, if left uncorrected or if it were undetected, this condition could cause a trip unit to lose the stability provided by the reset differential circuitry. Rosemount's corrective action was to rid the inventory of the resistors and request that the vendor rescind the change in manufacturing process. However, the team could not ascertain from the records whether Rosemount had determined if the suspect resistors had been used in products that had already been shipped and whether Rosemount had informed the affected customers. Violation 93-01-03 was identified in this area.

3.3.6.1 Nuclear Review Committee Meetings Regarding Oil-Loss Problems. The team's review of Rosemount documents indicates that the Rosemount Nuclear Review Committee convened at least on three different occasions during 1986-1987. The first meeting that took place appears to have been conducted on April 11, 1986. An RIM from the Rosemount QA Director, dated April 9, 1986, "Subject: Meeting Notice - Nuclear Review Committee," stated, in a hand-written note, that the topic of concern was oil leaks in transmitters. The RIM also stated that any transmitter found with loss of oil would go through failure analysis.

Another RIM from the QA Director, same subject as above, undated, indicated that a Nuclear Review Committee meeting would be conducted on Friday, July 11, 1986, and the topic of concern was, "low oil in cells of nuclear returned transmitters." The RIM also stated that the failures were random and that testing on-line would eliminate the problem.

Still another RIM from the QA Director, same subject, undated, indicated that a Nuclear Review Committee meeting was conducted on February 12, 1987. The hand-written note regarding the topic of concern on this RIM was "low oil in nuclear transmitters - Please bring all the information that you possess." The RIM simply stated that, "*We will try to define the nature and scope of the problem, and if it is generic* [emphasis added]."

The team noted that it would appear that Rosemount's Nuclear Review Committee was informed of the oil-loss transmitter problem and convened to discuss the problem as early as April 1986. This information was also considered in the characterization of the apparent Violation described herein.

3.4 Inspection for Compliance with Appendix B to 10 CFR Part 50

The NRC inspection team reviewed selected portions of the quality assurance (QA) program that Rosemount established and implemented to comply with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 (Appendix B). The team also inspected selected process control implementation aspects of Rosemount activities that could affect the reliability and quality of Rosemount transmitters supplied to NRC licensees. The team's review of the quality-related Rosemount activities included the Chanhassen failure analysis laboratory and sensor cell manufacturing and fabrication areas; and the Eden Prairie sensor cell degassing, oil fill and sensor module fabrication, assembly and testing activities. Additionally, the team conducted discussions with Rosemount staff regarding the printed circuit (PC) card manufacturing area at Chanhassen.

The team concluded from its inspection activities and reviews of records that the Rosemount Nuclear Quality Manual (NQM), Revision A, appeared to be comprehensively written and well suited to ensure compliance with the requirements of Appendix B. Nevertheless, as discussed below, the team also identified areas in which Rosemount has failed to adequately implement its established QA program procedures and instructions.

Rosemount's NQM, D9000115, Revision A, stated, in part:

> This Nuclear Quality Manual is a new manual structured and organized according to 10CFR50, Appendix B Criteria, and NQA-1-1986. The manual replaces Rosemount Quality Assurance Manual 1742 for Nuclear and corporate procedures pertaining to quality. The Nuclear Program this manual addresses does not change.

Despite this Corporate policy, the team identified three important areas in which the program did not meet Appendix B requirements. These three areas included the Failure Analysis (FA) Laboratory, Chanhassen manufacturing QA controls, and certain QA inspection activities at the Eden Prairie fabrication and testing areas and are discussed below.

3.4.1 Failure Analysis Laboratory. The inspection team evaluated the Rosemount FA Laboratory to determine whether the activities being performed complied with NRC regulations. The team observed in-process activities, conducted interviews with FA personnel, reviewed FA request/report forms, and reviewed the qualifications of personnel who performed the failure analyses on returned safety-related series 1150 pressure transmitters.

The team asked to review the procedures or instructions that were being used by FA staff to perform the analyses on transmitters that were returned by licensees. The team was informed that there were no formal procedures to address the root cause analyses activities performed by the FA staff but that there were some informal instructions and guidance that were being used. Nonconformance 93-01-04 was identified in this area.

The team examined FA personnel records that indicated that the FA staff were qualified in accordance with ANSI N45.2.6-1978. The FA personnel qualification and training documents indicated that the FA personnel were qualified and capable of performing root cause failure analysis. However, the FA laboratory supervisor stated that the FA staff had not received any formal training on root cause analysis and that they were only capable of identifying the proximate cause of transmitter failures. Additionally, the responsible Nuclear Product Group engineer stated that formal root cause analysis training had not been provided. The lack of adequate root cause analysis training is considered a weakness in the Rosemount corrective action program.

3.4.2 Activities Affecting Quality at Chanhassen. On February 1-4, 1993, the NRC inspection team was informed that all of Rosemount's activities that would come under an Appendix B to 10 CFR Part 50 program were located at the Eden Prairie facility. The team was also informed that Rosemount's Chanhassen facility manufactured the sensor cell units for both the industrial Model 1151 transmitter and the nuclear-qualified Model 1152, 1153 and 1154 transmitters under a quality assurance program prescribed by International Organization for Standardization (ISO) Standard 9001:1987, "Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation and Servicing." Rosemount stated that the activities at Chanhassen were commercial-grade activities; hence, Chanhassen was treated as a commercial-grade supplier by Rosemount's Nuclear Department of the Instrument Division (This issue is also discussed in Section 3.3.4).

The team was informed that Rosemount "dedicated" the CGIs upon receipt inspection at the Eden Prairie facility, in accordance with Rosemount Procedure NDP N-0730, "Dedication of Subassemblies from Chanhassen," Revision A, dated April 6, 1992. The team was provided with a copy of Procedure NDP N-0730. The team toured the Chanhassen facility to observe and evaluate the in-process manufacturing controls that were implemented for sensor cell fabrication activities. The team asked the Rosemount staff to demonstrate how they controlled the quality of commercial-grade items (CGIs) for nuclear use.

During discussions with Rosemount staff while inspecting the Chanhassen facility, the team evaluated the differences between the industrial Model 1151 sensor cells with Model 1151 type printed circuit (PC) cards and the nuclear Model 1152, 1153, and 1154 sensor cells with the nuclear type PC cards. The main programmatic difference in the process controls between the Model 1151 and the Model 1152, 1153, and 1154 transmitters was the procedures used. The Nuclear Department supplied its approved drawings and procedures for the Model 1152-1154 transmitters, while the industrial procedures were used for the Model 1151 transmitters. Based upon the technical discussions and tour of the Chanhassen facility, the team concluded that it did not appear that all of the Model 1152-1154 transmitter parts manufactured at Chanhassen were CGIs. By their nature, the sensor cell and certain PC cards made at Chanhassen cannot legitimately be considered CGIs because they do not fit the definition of CGIs in Part 21. Rosemount has applied to those parts requirements that are unique to nuclear facilities, such as the use of radiation-resistant parts in the PC cards and additional controls on the glassing process. The team asked the Rosemount staff why they characterized the Chanhassen facility Model 1152-1154 transmitter sensor cell and PC card manufacturing activities as commercial grade activities. The Rosemount staff explained that the company had made a business-driven decision to treat the Chanhassen facility as a CGI supplier and then perform what they described as a dedication on these parts because this arrangement was deemed more acceptable by their customers.

The team observed some NRC licensee orders for safety-related transmitters being processed, evaluated some of the differences in the processes and process controls and conducted discussions with several technicians that were performing the activities. For example, while observing the operations involved in fabricating the cell cups for a batch of Model 1153 transmitter sensor cells, the NRC inspectors examined the traveller package for the group of cell cups undergoing one of the machining operations and noted that the control sheet (the traveller itself) called for the machining instruction (Manufacturing Instruction 1153-3063) to be in the package and in use; instead, the inspectors found the glassing procedure (Manufacturing Instruction 1153-3064). Not only had the wrong procedure been included by Production and Inventory Control (P&IC) when making up the traveller package for this assembly level of this batch, but the instrument builder performing the operations apparently had not discovered the error. Although the inspectors concluded that the instrument builder had not been actually referring to the procedure, no hardware problems were found by the team.

This was observed and acknowledged by the Rosemount representative escorting the inspectors who said that the instrument builder should have caught the error. The representative brought this to the attention of the instrument builder and the supervisor who took action to correct the situation. This type of error was pointed out to Rosemount as an example of the type of discrepancy that could be minimized by instituting a program of an appropriate level of some type of independent, random, periodic monitoring or other QA oversight.

The team generally found the Chanhassen facility to be a modern manufacturing facility with knowledgeable staff and management. However, the team found that "basic components" were being manufactured without the benefit of some of the elements of an Appendix B QA program. Rosemount indicated that certain sensor cell and PC card manufacturing areas were previously controlled under a QA program that was in compliance with Appendix B but, in 1991, Rosemount decided to control all of its Chanhassen activities under an ISO 9001 QA program, and abolished the majority of its Appendix B controls for the Chanhassen facility activities. Based on the team's understanding of Rosemount's actions, the only aspects of Rosemount's Appendix B QA program at Chanhassen that was retained were design, document, and procedure controls. The team found that there was no independent oversight or verification of the Chanhassen activities. Rosemount stated that there was in-process verification of many process control aspects, but confirmed that no independent QA/QC type of monitoring or oversight activities were performed. The team found that, because Rosemount considered the Chanhassen facility to be a commercial grade manufacturing facility, no planned or periodic audits were performed to verify compliance with necessary aspects of the quality assurance program and verify its effectiveness. Nevertheless, many of the Chanhassen activities were relied upon to "dedicate" the sensor cells at Eden Prairie yet were not verified even by a commercial grade survey. The team recommended Rosemount review the Chanhassen QA program in light of Appendix B and augment the program as necessary to comply with Appendix B for their nuclear grade transmitters. This was identified as Nonconformance 93-01-05 by the team and was discussed with Rosemount personnel.

3.4.3 Activities Affecting Quality at Eden Prairie. The scope of inspection at the Eden Prairie facility consisted of an inspection for adequacy of selected aspects of Rosemount's implementation of its Appendix B QA program. Generally, the review encompassed an inspection of the majority of the Eden Prairie fabrication activities and some engineering activities. Eden Prairie receives sensor cells and sensor module subassemblies with installed PC cards. The team evaluated activities such as: sensor cell receipt inspection controls, sensor cell de-gassing, oil-fill, and the suitability of engineering design change and manufacturing process and test controls related to pressure transmitters that are manufactured for use in safety-related (Class 1E) systems at nuclear power stations.

3.4.3.1 Lack of QA Oversight at Eden Prairie. The team noted that, as a given lot of sensor cells is routed through the Eden Prairie production area, it is accompanied by a Production and Inventory Control document known as a "traveller." In addition to identifying the serial number of each cell in the specific lot being processed, the traveller specifies the sequence of activities performed, the applicable procedure to be followed for each operation, and the person responsible for performing each task. The team's review of the applicable Rosemount procedure, No. T01153-0218, "Traveller, Cell, Sensor Oil Fill," found that it indicated that a quality control (QC) inspection was performed following completion of the cell oil-fill and fill-tube welding operations. The team requested several travellers for its review that would be representative of previous production lots of various range code sensors. Each traveller was found to be signed in the appropriate section by the person performing the activity, and QA inspection points were found to be appropriately stamped by a member of the QA organization. From a review of these documents alone, it appeared that QA had verified the acceptable performance of operations preceding the inspection point, such as verification of proper oil fill.

The team reviewed the travellers in conjunction with the applicable QA inspection procedure, 01153-3321, Revision J, dated January 29, 1992. The team found that only range code 9 and 10 sensor cells were actually verified or over-inspected by QA/QC for proper oil fill level. The team voiced the concern to Rosemount that a traveller may be misleading if viewed as a stand-alone document. If NRC licensees reviewed the Rosemount travellers without the benefit of the associated procedure, they could conclude that QA/QC involvement was required and was present for all range codes, when, in fact, it was not.

As a result of finding this problem, the team focused on inspecting required QA involvement for other activities affecting quality at the Eden Prairie facility. The team found that few activities affecting quality are verified by members of the QA organization. Discussions with responsible Rosemount representatives revealed that, in previous years, the Rosemount QA organization had played a more active role in verifying the quality of work performed by production personnel. However, approximately three years ago, this philosophy was changed to place greater reliance on the ability of the individual operator to perform high-quality work and to identify and report discrepancies observed during production. This change eliminated the majority of the QA independent verification activities. Rosemount representatives stated that the principal factors for initiating this change were an excessively high scrap rate and a perception by production personnel that the QA verification process was overly "police-like." The team discussed this matter with Rosemount to assure them that a "police-like" QA organization was not intended, but that some degree of QA oversight is needed. Further, an excessively high scrap rate is insufficient justification for eliminating QA independent verification activities.

3.4.3.2 Required Receipt Inspection of Chanhassen Sub-Assemblies. During the initial inspection on February 1-4, 1993, the team toured the Eden Prairie receipt inspection area to observe work in progress and assess the implementation of Rosemount's procedures and policies for the receipt of components procured for use in nuclear-qualified Model 1152, 1153, and 1154 transmitters. In general, the receipt inspection area appeared to be well organized with parts received for nuclear orders categorized by unique Rosemount order numbers. An N prefix is used to identify "catalog," commercial-grade, items used in a nuclear product. The team also found that the receipt inspection area based its determination of sample size (number of components to be inspected from a given lot) on the U.S. Department of Defense, Military Standard (MIL-STD) 105D, "Sampling Procedures and Tables for Inspection by Attributes." In addition, for each part or sub-component that is manufactured by others and used in nuclear transmitters, Rosemount had developed receipt inspection procedures. The team found that Rosemount maintained these procedures in a separate file cabinet designated specifically for nuclear applications. A review of a random sample of procedures did not identify any concerns. The procedures and attached drawings appeared to adequately identify critical characteristics of each purchased part and appeared to provide suitable instructions for determining both the sample lot size and acceptance/rejection criteria.

Subsequently, during further inspection of this area on March 8-12, 1993, the team discovered that sensor cells manufactured at the Rosemount Chanhassen facility and used in nuclear-qualified pressure transmitters did not go through the Eden Prairie receipt inspection area and were not receipt inspected as required by Procedure N-0730. Instead, it was determined that these devices were shipped directly from Chanhassen to the Eden Prairie nuclear process manufacturing area without the benefit of the required receipt inspection.

According to Rosemount QA staff, Rosemount only performed a formal receipt inspection on parts and materials procured from outside Rosemount. Rosemount staff stated that sensor cells were manufactured as commercial-grade units at the Chanhassen facility in accordance with an ISO 9001 QA program. These units were then shipped directly to the Eden Prairie nuclear manufacturing and fabrication area, where they were filled with fluid and "dedicated for use in nuclear applications" by in-process testing that was performed in that area. It appeared to the team that pressure testing alone did not verify that all critical characteristics are adequate, such as materials and radiation resistant properties of printed circuit cards. Additionally, the team noted that sample size and acceptance/rejection criteria such as those promulgated in MIL-STD 105D were not applicable to the sensor cells; instead, the acceptance/rejection criteria was only applicable to components produced by non-Rosemount manufacturers.

Following the walk-through of the Eden Prairie receipt inspection area, the NRC inspectors reviewed Rosemount Procedure N-0730, and determined that Section 2.5 of this procedure required receiving inspection to verify that subassemblies conform to the applicable drawings, bills of material, and other defined nuclear requirements. This document went on to state that every lot must be inspected and found acceptable before it was released to production. Contrary to the documented procedural requirements, however, as discussed above, sensor cells manufactured at the Chanhassen facility for use in safety-related nuclear transmitters were not verified for conformance to design documents by the Eden Prairie receipt inspection area. Nonconformance 93-01-06 was identified in this area.

3.4.4 Engineering Design Review. During the early to mid-1980s, various nuclear licensees began to report that some Rosemount Model 1153 and 1154 transmitters were not performing properly in their safety-related service applications. Subsequently, it was found by the industry that many of the reported problems were related to oil-loss from the transmitters' sensor cells. Due to the Rosemount transmitter design, oil leakage from the sensor cell is internal and cannot be detected by an external, visual inspection of the transmitter. As discussed in Section 3.3.2 above, Rosemount had compiled failure data that encompassed returned transmitters from approximately 1980-1992. The team reviewed the time frame during which oil-loss problems were reported to determine whether the problems were related to sensor cell and module design issues. During this design review, the team evaluated several selected areas and noted three different problems; one concerning the translation of design parameters and the other two related to design change control, as follows:

- Engineering Change Order (ECO) 601919, May 1983.

  [Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

The team was concerned that Rosemount may be making design changes without an adequate engineering evaluation to assure that previous equipment qualifications remain valid. The team discussed this concern with the Rosemount Nuclear Engineering Supervisor and concluded that Rosemount failed to perform an adequate verification of the design change. Nonconformance 93-01-07 was identified in this area.

- ECO 603675, February 1984.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

Therefore, the team disagreed with Rosemount's conclusion, and discussed this concern with the Rosemount Nuclear Engineering Supervisor, and concluded that Rosemount failed to perform an adequate verification of this design change. This is another example of Nonconformance 93-01-07.

- ECO 630229, July 1989.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

- ECO 630618, August 1989.

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

[Deleted pursuant to 10 CFR 2.790 - Document discusses specific design characteristics.]

- ECO 649042, September 1992. During an inspection of the Eden Prairie safety-related activities, the team discovered that the viscosity test date recorded on a container of [Manufacturer] sensor fill fluid, located in the nuclear production sensor oil fill area, identified the contents as being beyond the manufacturer's certified shelf life. The team noted that, upon receipt of this material, Rosemount Receipt Inspection verified its viscosity value and wrote that value and the date of test on the outside of each container.

  The applicable [manufacturer] product specification data sheet states, "when stored in the original, sealed container, at or below 77 degrees F, [manufacturer]... fluids have a shelf life of 12 months from the date of shipment, although no inherent limitations on the useful life of this product are known to exist." The team discussed this issue with Rosemount engineers, who stated that, as a result of product liability concerns, [manufacturer] changed the certified shelf life of the fluid in 1992 from "indefinite" to 12 months. Rosemount, however, still considers the shelf life to be indefinite. On September 9, 1992, Rosemount issued ECO 649042 to modify its procurement drawings (N10485 and N11981) to reflect this position.

  The concern about the specified shelf life versus usable life of the [manufacturer] fluid was the topic of two letters received by Rosemount from [manufacturer]. With regard to one of the [manufacturer] fluids used by Rosemount, a letter dated April 14, 1992, from [manufacturer] to Rosemount stated, in part, that:

  > [Manufacturer] certifies that [Manufacturer] [type A] fluid will meet the sales specification requirements for 12 months from date of shipment when properly stored in the original unopened container ... Because the sensor is completely sealed and free from contaminates and air it shouldn't change chemically over a long period of time... It is the responsibility of our customers to test and evaluate our products in their specific applications ... the usable life of the [manufacturer] fluid is up to our customers to determine.

  The team also reviewed a letter from [manufacturer] to Rosemount, dated August 31, 1992, regarding the useable life of [manufacturer] [type B] fluid. Although this letter stated that no inherent limitations on useful

life of the product are known to exist, it also clearly stated that, "It is the responsibility of Rosemount to test and evaluate our products in your specific application to determine compatibility...."

Model 1153 and 1154 transmitters use [manufacturer] [type B] fluid. Based on environmental qualification testing of these transmitters, the team concluded that it appears that Rosemount has demonstrated the usefulness of this fluid when placed in a sealed sensor cell (at a certain point in time). However, the technical justification for assigning an indefinite shelf life to unused fluid, as stated on ECO 649042, does not appear to be sufficiently supported by the information supplied by the manufacturer. Although the manufacturer stated that it is Rosemount's responsibility to test and evaluate the fluid for specific applications Rosemount did not perform additional testing of the product. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, requires that a review for suitability of the application of materials and processes that are essential to the safety-related functions of components be performed.

The team also noted that Rosemount ECO 649042 attributed the company's justification for indefinite shelf life to a lack of experience with any adverse effects either in the field or in the manufacturing process. The technical basis for Rosemount's justification for the use of fluids having an expired shelf life does not appear to be well demonstrated without performing periodic verifications of unused fluid (such as verification of chemical properties) to ensure that the fluid has not changed from the date of Rosemount qualification and without a review for suitability of application. Nonconformance 93-01-08 was identified in this area.

The team related these inconsistencies in the Rosemount performed activities that affect the quality of safety-related components in part to the lack of monitoring, surveillance or other type of independent QA verification activities which has been discussed earlier.

3.4.5 Internal Audits. The NRC inspection team reviewed several Rosemount activities to determine whether adequate internal audits were performed. Section 18, "Audits," of the Rosemount NQM, dated February 1, 1991, stated, in part, that:

> Internal audits of selected aspects of activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all activities within the scope of the Nuclear Quality Program will be completed annually.

The team also noted that paragraph 4.21.4 of the 1988 Rosemount QAM-M, required that all quality-related activities be audited at some time in each calendar year and that audit frequency will not exceed 14 months. Paragraph 4.21 of QAM-M also required that the implementation of the controlling documents be audited to verify compliance with the QA program, and to verify that corrective action requests are complete. The team reviewed the audit schedule from 1989 to the present, and found that the audits had been performed as scheduled since 1990; however, there were no audits scheduled or performed for the entire year of 1989. Additionally, the quality related activities used to manufacture "basic components" at the Chanhassen facility had not been audited under Appendix B since December 1991. Nonconformance 93-01-09 was identified in this area.

4 OTHER ISSUES AND COMMENTS

4.1 Review to Correlate Observed Failure Trends with Transmitter Design Features and Design Changes

The NRC team attempted to determine whether observed failure data trends correlated with any particular transmitter design features or design changes after reviewing Rosemount failure data, design similarities, and differences between transmitter models. Because the team decided that the most significant problem identified to them was the loss of oil from the transmitter sensor cell, the review focused primarily on the sensor cell module assembly. Various drawings for the sensor cell and its module assembly were reviewed to identify design features as well as design changes that were made by Rosemount. Parts and drawings reviewed by the team included fill tubes, elastomer o-rings, and metal o-rings. The team made the following observations:

- The drawing revision history showed that Rosemount made a number of changes to the metal o-ring drawing. However, contrary to what the drawing revision history indicated, the Rosemount Engineering staff stated that the actual o-ring configuration never physically changed, and that the drawing changes were administrative attempts to correct the drawing rather than physically change the o-ring. As a result of the disparity between the Rosemount records and staff recollections, the Rosemount o-ring drawing revisions, particularly around the period of Revision E, December 13, 1981, and Revision F, February 6, 1984, will be reviewed during a future inspection to resolve the disparity. See Inspector Follow-up Item 93-01-11.

- The team concluded that the metal o-ring drawing appeared to be inadequately controlled. This matter was discussed with the Rosemount Engineering staff. Rosemount staff stated that the latest drawing change corrects the dimensional discrepancies that previously existed between the part and the drawing.

- Rosemount has changed the dimension or tolerance (or both) on the sensor cell module assembly o-ring groove on a number of past occasions. This dimension affects the compression of the process flange o-ring. In general, the smaller the dimension, the greater the o-ring compression and the greater the force on the o-ring joint. Further, the greater the tolerance, the greater the variation in the o-ring compression and the greater the variation of the forces in the joint. The o-ring forces and joint compression directly affect the seal of the process fluid joint in the transmitter. Additionally, the joint forces contribute to the stress levels in the sensor cell. Further, the nonuniform geometry and dissimilar materials in the region where glass seals the fill tube holes create an additional stress concentration. Thus, higher o-ring joint forces may impair the bond between the glass and metal that contains the oil in the sensor cell.

- Because of the potential importance of the o-ring flange joint dimensions on the sensor cell G-M seal, potential for oil-loss, and subsequent transmitter performance, the June 1983 Model 1153 (ECO 601919 and Drawing No. 1153-0221, Revision E) and July 1984 Model 1154 (Drawing No. 01154-0004, Revision A) design changes that expanded the transmitter process

flange o-ring groove tolerance are considered to be potentially important in explaining at least some of the transmitter oil-loss failures that occurred in the mid-1980s.

4.2 Employee Awareness of 10 CFR Part 21

The NRC inspectors interviewed several employees at the Chanhassen facility regarding their understanding and knowledge of 10 CFR Part 21, with respect to the requirement in NDP N-0730, Paragraph 2.4.3, "Reporting of defects or deviations per 10 CFR Part 21 is required." The inspectors asked various employees what they knew about their responsibilities under 10 CFR Part 21.

Some employees stated that they had attended a training session on 10 CFR Part 21. Most knew of the posting regarding 10 CFR Part 21, and that the posting listed the names of personnel to be contacted regarding Part 21 matters. In general, the employees stated that it was their understanding that they were expected to bring to the attention of their immediate supervisors or persons listed on the Part 21 posting any unsatisfactory conditions of which they were aware in any nuclear sensor cells or parts that had gone through production or had been shipped, in which the condition remained uncorrected, or where they did not know that it had been corrected. Some also stated that it was their understanding that they could inform the NRC of such conditions if they felt it necessary.

4.3 Sensor Cell Oil-Fill Concern

Based upon the NRC inspection activities discussed in Section 3.4 above, the team identified a concern regarding the adequacy of the Rosemount transmitter sensor cell oil filling and verification. The Rosemount representatives who were interviewed stated that the current level of in-process testing (performed by the same personnel who perform the actual activity) is sufficient to identify manufacturing deficiencies. For example, when questioned on the apparent lack of conformance to Appendix B requirements regarding inspection for sensor cell oil-fill activities other than range codes 9 and 10, Rosemount representatives stated that independent verification is not necessary because subsequent response time testing (performed after the sensor is mounted in its housing) is adequate to identify cells with low levels of fill oil. However, the team was concerned whether or not the response time testing was an appropriate test that would accurately reflect the actual amount of oil in the sensor cell. Based upon discussions with Rosemount representatives and a review of associated records, the team appeared to have identified that the ability of response time testing to accurately identify improperly filled cells may not be adequate because, depending on the transmitter range code, as much as 73 percent of the fill fluid may be missing before the response time test would reliably identify a cell as having low oil.

The approximate percentage of oil that must be missing before the response time test identified that response time performance was not within the required specification for ranges 3 through 9, varied between 36-73 percent. Therefore, the team was concerned that it could be possible for a transmitter with a relatively low oil level to be determined to be acceptable by successful response time testing. It is not clear whether an initially low oil level could manifest itself in a manner similar to subsequent loss of oil resulting in degraded operation, but do so much earlier. This concern will be addressed during a future inspection. Inspector Follow-Up Item 93-01-13.

4.4 Field Instruction Manual No. 4302

The team's review of the transmitter process flange field assembly instructions, contained in Rosemount user instruction manuals for 1150 series transmitters, revealed that the assembly sequence appeared to be inappropriate for transmitters using stainless steel process flange O-rings. For example, the procedure in Rosemount Instruction Manual 4302 for Model 1153, Series B, pressure transmitters called for placing both stainless steel O-rings (when two are used, e.g., for a differential pressure unit) into the isolator wells of the sensor cell and then fitting the process flanges to the sensor module. This sequence appeared to be appropriate for elastomer o-rings because their outside diameters are slightly larger than the inside diameter of the isolator wells and the o-rings should remain in place under slight compression. However, new metal o-rings did not stay in place by themselves when the team attempted to perform the assembly process. Therefore, following the sequence of steps in the procedure as written would be impractical for one or more metal O-rings given the orientation of the sensor module in most installations or even if the sensor was held so that the isolator wells were oriented in a vertical position on a workbench.

Although the 1153 and 1154 manuals call for the stainless steel O-rings, the process flange assembly instructions were apparently not revised with an appropriate assembly sequence and technique, such as those given in the instructions used in Rosemount's Eden Prairie shop (and demonstrated to the team). In this procedure, one metal o-ring is placed in the well with the module on its side and its process flange is fitted and held in place by hand to retain the o-ring while the unit is inverted. The second o-ring is then installed, the second flange fitted and the flanges are bolted together.

Another perceived problem with the field instructions was that, although the description of the correct orientation of the metal o-ring was technically understandable, it is difficult to identify the correct orientation in practice without the technique demonstrated by an experienced instrument builder. Further, for fitting the process flange to the sensor module, the field instructions stated: "Evenly seat the flanges on the sensor housing, using a hand torque wrench." However, in observing this process in the Eden Prairie shop, the team learned that with metal o-rings, and with the variance in the dimensional tolerance stack-up of the rings and the isolator well depths, in many cases, the flanges never fully seat on the sensor housing even with the maximum specified torque applied. Attempting to evenly seat the flanges on the housing as required by the procedure might require exceeding the specified torque, if it were possible at all, and possibly result in putting excessive stress on the sensor cell. In a communication subsequent to the inspection, Rosemount informed the NRC of its position that these procedures were not intended necessarily to be followed verbatim, but stated that the procedures would nevertheless be revised appropriately. This will continue to be discussed with Rosemount until this matter is resolved. Inspector Follow-up Item 93-01-14.

4.5 Transformer Discrepancy

During the review of some Nuclear Review Committee files and records, the team noted that a Nuclear Review Committee meeting on May 28, 1991, discussed a problem with a transformer (Rosemount Part No. 01151-0163-0001) that is used in the electronic component package of the Model 1151, 10-50 milliampere (mA) transmitter. This same transformer is also used with a different part number on the Model 1153 and 1154 units. Rosemount Prccedure NDP N-1697, "Returned

Products from a Nuclear Facility," Revision A, provides guidance on tracking deficiencies and keeping historical records. This procedure requires nuclear marketing or contract personnel to initiate a returned material authorization (RMA) or an event report (ER) to document information received from a customer regarding impaired performance of a Rosemount product.

The team also reviewed Rosemount's Division Operating Procedure (DOP) 440, "Engineering Change Order," (ECO) Revision C, to determine if Rosemount's procedural controls were being implemented to preclude the use of products known to cause failures. This procedure requires the design engineer who initiates a change to identify the affected item and to contact the originator of the ECO to determine the impact of the proposed change, timing, and the next process step. If the item is used in more than one product, the engineer must route the ECO to the Nuclear Design Engineering Department so that engineers responsible for other products can review and approve or disapprove the change. In the case of the transformer ECO, the ECO was routed to the nuclear engineers and the engineers did not recommend the change.

The team inspected the review process and determined that the designated engineers from the Nuclear Design Engineering Department had reviewed the manufacturer's proposed design or manufacturing changes and had complied with the requirements of DOP 440.

4.6 PERSONNEL CONTACTED

Rosemount, Incorporated (Rosemount) and Rosemount Aerospace, Incorporated (RAI)

G. Anderson	1	Nuclear QA Supervisor, Rosemount
R. Ballintine	2	VP Government Relations, RAI
S. Brown	1	Nuclear Engineering Supervisor, Rosemount
K. Ewald	1	Nuclear Business Unit Manager, RAI
L. Halsne	2	VP Quality Assurance, RAI
D. Moffatt	2	President, Rosemount Aerospace, Inc.
P. Olson	1	Quality Auditor, Rosemount
J. Sandstrom	1	Product Marketing Manager, Rosemount
J. Valley	1	Nuclear QA Manager, RAI
M. Van Sloun	1	Director, Distribution, Rosemount
R. Volsted	1	Contract Supervisor, Rosemount

1 Attended all entrance and exit meetings.

2 Attended March 12, 1993 exit meeting only.