Cardinal Health
Radiation Management Services
6045 Cochran Road
Cleveland, OH 44139

Date: December 23, 2003

To: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555

From: Christine Castleberry
Regulatory and Quality Manager
Cardinal Health
Radiation Management Services
6045 Cochran Road
Solon, OH 44139

Re: 10CFR Part 21 Notification
(Initial Report)

In accordance with 10CFR21, please find the attached notification.

Should you have any questions or require further information, please contact me at (516) 870-0100 or via email at christine.castleberry@cardinal.com or Zisimos Giatis at (440) 498-2550 or via email at zisimos.giatis@cardinal.com.

Respectfully,

Christine Castleberry

IE19

1.0 Name and address of individual informing the Commission:

Christine Castleberry
Regulatory and Quality Manager
Cardinal Health, Radiation Management Services
6045 Cochran Rd.
Solon, OH. 44139

(Formerly Victoreen and Inovision)

2.0 Identification of the basic component supplied which fails to comply or contains a defect:

The potential exists for an incorrect radiation value to be displayed due to a non-catastrophic failure of the detector high voltage power supply in the Model 977-201 and 977-210 Wide Range Ion Chamber Area Monitors. This notification applies to units manufactured between 10/1/90 and 11/1/03, using the P/N 90497703, 94097704, and 94097705 EPROM.

Detectors manufactured prior to 10/1/90, which utilize the P/N 977-LNK, 99197700, or 99197701 EPROM are not affected by this notice.

3.0 Identification of the firm supplying the basic component which fails to comply or contains a defect:

Cardinal Health, Radiation Management Services
6045 Cochran Rd.
Solon, OH. 44139

(Formerly Victoreen and Inovision)

4.0 Nature of the defect or failure to comply and the Safety Hazard created:

Background: A High Voltage fail test anomaly was initially identified while re-performing Software Validation test procedure 94094600VTP, Test 41. An external DC power supply was used to supply the detector High Voltage. The anomaly observed was the lack of a Fail alarm actuation until the High Voltage value was reduced below 1.0 Vdc. The new anomaly was identified as Item B in 94094600VTP-AN008. Since then, the hardware and software related to the anomaly have been investigated both internally, and externally, to include the effect of a reduced High Voltage value on the radiation value displayed.

The firmware affected is identified as P/N 94097703, Rev. 2, and is the standard firmware used in the 977-201 and 977-210 Ion Chamber Preamplifiers since October 1990. Firmware identified as P/N 94097704 and 94097705 is also affected.

General Description: The Model 945A Wide Range Ion Chamber Area Monitor consists of a Model 946A-200 Control Room Readout and a Model 977-201 or Model 977-210 Digital Preamplifier/ Detector. Both the readout and preamplifier are microprocessor-controlled devices, and communicate via a modified RS232C protocol. The readout and detector operate together as a Wide Range Area Radiation monitor, designed to monitor the radiation levels in a specific area, and to warn personnel of an increase in radiation level above predetermined set points. The normal High Voltage value, required for 100% Collection Efficiency at full scale (i.e. 1.0E8 mR/h) is 500 Vdc. The high voltage is generated from a voltage doubler circuit. The calibration accuracy of the detector is +/- 15% of reading for Cs-137.

Every 256 seconds, the microprocessor in the Model 977-201 or 977-210 performs a self test to verify the integrity of the detector, detector signal cable, detector high voltage cable, the electrometer circuitry, and the detector high voltage. The firmware that controls the detector self-test resides in EPROM, P/N 94097703, Rev. 2, located in the Model 977-201 or 977-210 preamplifier. Although the detector self test is performed correctly and will report a failure in the detector, cable, or electrometer components, the criteria for the High Voltage failure is a catastrophic failure of the High Voltage power supply, resulting in an output voltage of less than 1.0 Vdc.

Nature of Defect or Failure to Comply: In the units subject to this notification, a failure in the high voltage power supply circuit may result in a detector high voltage bias that is less than the voltage required for 100% collection efficiency. With the reduced collection efficiency, the radiation value displayed at high radiation values will be inaccurate, and will read low. Table 1, below, summarizes the results that may be expected at reduced high voltage values, for various radiation levels.

Radiation Level:	High Voltage Value:	% Error:
34 mR/h	1.0 Vdc	18% Low
	2.5 Vdc	6% Low
	5.0 Vdc	0%
2.8 R/h	1.0 Vdc	99% Low
	2.5 Vdc	43% Low
	10.0 Vdc	4% Low
1.25 kR/h	1.0 Vdc	98% Low
	5.0 Vdc	88% Low
	10.0 Vdc	77% Low
	100.0 Vdc	10% Low
	200.0 Vdc	1% Low

Table 1

From the test data, it was shown that, for radiation fields less than 1.25 kR/h, with a collection voltage of only 100 Vdc, the output radiation value was reduced by only 10%. For higher radiation levels, the error increases. For lower radiation levels, the error decreases.

As shown in Table 1, an error of +/- 10%, in radiation fields up to 1 kR/h, with the high voltage reduced to 100 Vdc, may be expected. Because less collection voltage is required for 100% collection efficiency at lower dose rates, the impact of a reduction in the high voltage value is less at lower dose rates (i.e. below 1kR/h). The high voltage required for 100% collection efficiency at full scale (1.0E8 mR/h) is 500 Vdc. The high voltage is derived from a voltage doubler circuit. Because there are a number of failure mechanisms in the power supply circuit, high quality, conservatively derated components are used in the high voltage power supply. The most likely cause of a partial failure in this type of circuit is a failure of one of the diodes used to create the high voltage. For this reason, the voltage doubling diodes, which will carry a maximum current of 0.8 microamps, are rated to carry a maximum current of 1 amp at 1,000 Vdc. The derating of these diodes significantly reduces the potential for a partial failure of these critical components. Note that in the event of a catastrophic failure of the high voltage power supply, a Fail alarm is generated.

Looking at the overall preamplifier, the electrometer and the supporting electronics are located on 2 separate printed circuit boards. From an MTBF standpoint, the 977-210-10 Interface board, that contains the high voltage power supply, has an overall MTBF of 3.88 years at 120^0F. The high voltage power supply components in the 977-200-15 Interface board have an MTBF of 19.92 years, at 120^0F. The low voltage dc power supply, P/N 942A-100-50, has an MTBF of 19.86 years at 120^0F. This suggests that a failure of the high voltage power, from a MTBF viewpoint, is about as likely to occur as a failure of the low voltage dc power supply. The MTBF for the voltage doubling diodes themselves is even greater, over 6,000 years at 120^0F.

From a repair history perspective, approximately 40% of the units shipped since 1986 have been returned for repair or recalibration. The most common repairs experienced were related to electrical leakage in the ion chamber, interconnecting cables, and electrometer circuit. Less than 1% of the voltage doubler circuit units returned were found to have high voltage power supply failure.

Based on the above, the high voltage power supply has been shown to be highly reliable, and not prone to failure. This is also the reason why this anomaly was not identified earlier in the product's life.

The anomaly has no impact on the seismic or environmental qualification of the device.

SAFETY IMPACT: It is noted that the detector integrity test performed by the preamplifier is not affected by this anomaly, and will produce a Fail alarm when a degraded detector test signal is received. Should a catastrophic failure of the high voltage power supply occur (i.e. high voltage output drops below 1.0 Vdc), the Fail alarm will actuate as intended. Further, it has been our experience that the most common failure mode of the ion chamber is electrical leakage in the ion chamber, interconnecting cables, or the electrometer input circuitry.

Should a catastrophic failure of the high voltage power supply occur (i.e. high voltage output drops below 1.0 Vdc), the Fail alarm will actuate as intended. Should a partial loss of the high voltage output occur, the radiation value used for display and alarm may be lower than the actual radiation value. Based on the set point, the radiation value, and degree of high voltage loss, the unit may not issue a high radiation alarm when required.

The impact of the anomaly is that at high radiation levels, above 500 R/h, sufficient collection voltage may not be available to collect all of the ions generated. This would result is a reduction of the radiation value displayed. The magnitude of the reduction would be based on the actual high voltage available to the detector, and the actual radiation field. In some cases, where the radiation value is low, the reduced reading may be within +/-10% of the actual value. For high radiation fields, above 500 R/h, the error may be significant. Refer to Table 1 above for a description of the error, as a function of radiation value and high voltage.

For operation in low radiation fields below, 50 mR/h, the radiation display value anomaly may not represent a significant hazard to the public or the plant. This would also apply to power plant workers, who are normally equipped with independent personal radiation dosimetry.

Because the unit may be operated in radiation fields above 500 R/h, the reduced radiation display value anomaly may represent a significant hazard to the public or the plant.
Notification of a 10CFR21 notice of non-Compliance, therefore, is required

5.0 The date on which the information of such defect or failure to comply was obtained:

A High Voltage fail test anomaly was initially identified on August 18, 2003 while re-performing Software Validation test procedure 94094600VTP, Test 41. The anomaly observed was the lack of a Fail alarm actuation until the High Voltage value was reduced below 1.0 Vdc. The new anomaly was identified as Item B in 94094600VTP-AN008. Since then, the hardware and software related to the anomaly have been investigated both internally, and externally, to include the effect of a reduced High Voltage value on the radiation value displayed. The anomaly was deemed 10CFR21 reportable December 9, 2003.

6.0 Affected facilities:

Based on the information available to date, the product is used in Safety-Related applications by the following NRC licensed users, who are affected by this failure to comply:

Owner/Plant:

First Energy / Davis-Besse (4)

Other utilities have purchased similar units that are not used in safety-related applications, but are subject to notification as a result of augmented quality requirements specified in their respective Purchase Orders. We are currently reviewing our sales records and will provide a listing of these customers by January 16, 2003.

A complete list of user's is also being prepared.

7.0 Corrective Action:

7.1 As a result of the initial anomaly identification, Test 41 was re-run to determine the voltage level that would actuate the Fail alarm. Further testing was then performed on older versions of the firmware to determine the voltage level that would actuate the Fail alarm. The older versions were found to fail at a high voltage level of 250Vdc.

7.2 An analysis of the 94097703 firmware was made to determine the source of the anomaly. From the review, the anomaly was traced to a modification made to a subroutine in the LIBRA module that controls the High voltage check. A review of the firmware design history of the LIBRA module was made and it was determined that the anomaly was first introduced into the system in October 1990. It was further determined that the original 977-LNK firmware provided a High Voltage Fail alarm when the High Voltage decreased below approximately 250 Vdc.

7.3 A summary of the firmware design history was performed. Based on the design history, the Model 977-201 or 977-210 preamplifiers, and modifications, supplied with the 94097703, 94097704, and 94097705 EPROM's were determined to be subject to the High Voltage failure anomaly

7.4 Further testing was performed to determine the effect of reduced ion chamber collection voltage on the radiation reading. From the test data, it was shown that, for radiation fields less than 1.25 kR/h, with a collection voltage of only 100 Vdc, the output radiation value was reduced by only 10%. For higher radiation levels, the error increases. For lower radiation levels, the error decreases. Table I above summarizes the results of the collection efficiency tests. From the above data, the following affect of reduced collection efficiency on the radiation value displayed may be determined:

- For radiation values in the mR/h range, the collection voltage error is negligible for collection voltages down to 2.5 Vdc.
- For radiation values in the R/h range, the collection voltage error is negligible for collection voltages down to 10 Vdc.
- For radiation values in the kR/h range, the collection voltage error is negligible for collection voltages down to 100 Vdc.

7.5 A Risk Analysis (Attachment 2) and a safety impact analysis have been completed.

7.6 Engineering Change Notice (ECN) 4204 has been initiated to revise the subject firmware, firmware validation documents and hardware test procedures to include a partially degraded high voltage power supply test.

7.7 Notification letters will be sent to all affected utilities, advising them of the potential for reduced radiation value display as a result of a partially degraded high voltage power supply, and advising the availability of a replacement EPROM.

8.0 Advice related to the defect or failure to comply about the basic component that has been, is being, or will be given to purchasers:

Based on the above, we believe the probability of a partial high voltage failure is low, and it is not necessary to remove the unit from service. When using the 94097703, 94097704, or 94097705 EPROM, the following User Actions are recommended:

8.1 Trend the output of the detector over time and look for a reduction in the normal radiation value expected.

8.2 Monitor the output of the detector for positive or negative spikes in the radiation value. This may be an indicator of high voltage transients, resulting from instability in the high voltage power supply output, and may indicate a high voltage power supply failure.

8.3 Perform a high voltage value check as a part of the monitor's complete surveillance test. The complete electrical test should be performed at intervals of two years or less.

8.4 ECN 4204 is scheduled to be completed by March 31, 2004. At that time, a revised EPROM and Installation Instruction will be available for shipment to your facility. When the revised EPROM is received, install the replacement EPROM provided. If the unit is returned for repair, calibration or electrical alignment, the replacement EPROM will be installed as a part of the service performed.

For further information please contact:

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Attachment 1 – List of 977-201 or 977-210 Safety-Related Users with 94097703, 94097704, 0r 94097705 EPROM

Customer:	Plant:	Purchase Order:	Sales Order No.:	Ship Date:	Serial Nos.:
First Energy	Davis-Besse	7085975	174014	4/29/2002 and 7/29/2002	107417 – 107423 (Note, only 4 units are Safety Related)
Non- US Installations:					

Note: Although not required under 10CFR21, a replacement EPROM will be made available to all users of the 94097703, 94097704, and 94097705 EPROM, since October 1990.

ATTACHMENT 2 - RISK ANALYSIS PROCEDURE

SYSTEM RISK ANALYSIS TABLE **Cardinal Health Radiation Management Services**

Model 977 Collection Voltage Failure

Hazard *(6.2.1)*	**Cause** *(6.2.2)*	**Effect** *(6.2.3)*	**Severity** *(6.2.4)*	**Probability/ Frequency** *(6.2.5)*	**Detectability** *(6.2.6)*	**Risk Index** *(6.2.7)*	**Method of Management** *(6.2.8)*
Compromised Safety net	Partial failure of high voltage power supply	Understated radiation value display, below 500R/h	d Note 1	A	3	3	Acceptable with management approval See Note 2
	Partial failure of high voltage power supply	Understated radiation value display, above 500R/h	e Note 1	A	3	4	Unacceptable See Note 2
Compromised Safety net	Complete failure of high voltage power supply	No radiation value display and Fail alarm initiated	b	B	1	1	Acceptable as Implemented; Tested in LT946/977
Note 1: Assumes no secondary or back-up radiological protection measures are utilized							
Note 2: Compromised Safety net with upgraded firmware per ECN 4204	Partial failure of high voltage power supply	Understated radiation value and Fail alarm initiated	b	A	1	1	Acceptable as Implemented; Tested in TP977-201/210