U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 30-19752/87-02
30-20466/87-01
30-08985/87-01

Docket Nos. 30-19752
30-20466
30-08985

License Nos. 29-19769-02 Priority 1 Category E3
29-19769-03
29-15364-01

Licensee: Isomedix Inc.
80 South Jefferson Road
Whippany, New Jersey

Facility Name: Isomedix Inc.

Inspection At: Parsippany and Whippany, New Jersey
and Northboro, Massachusetts

Inspection Conducted: August 19, 20 and 25, 1987

Inspectors: John J. Miller — 10/19/87
John J. Miller, Health Physicist — date signed

John J. Miller — 10/19/87
for John T. Jensen, Health Physicist — date signed

Marlene J. Taylor — 10/19/87
Marlene J. Taylor, Health Physicist — date signed

Francis M. Costello — 10/19/87
Francis M. Costello, — date signed
Senior Health Physicist

Approved by: John R. White — 10/20/87
John R. White, Chief — date signed
Nuclear Materials Safety Section C

Inspection Summary: Routine unannounced inspection of the irradiator at the Parsippany facility followed by reactive inspections at the irradiators at the Parsippany, Whippany, and Northboro facilities. Inspections conducted on August 19, 20 and 25, 1987. Inspection Report Nos. 30-19752/87-02, 30-20466/87-01, and 30-08985/87-01.

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29-19769-02

Areas Inspected: Control of High Radiation Area; training and instructions to employees; materials, facilities, and instruments; maintenance and inspection; personnel protection-external; receipt and transfer of materials; and corrective actions.

Results: Four apparent violations were identified:

Operating the irradiator facility without a radiation monitor and associated interlock (Parsippany); bypassing the air flow switch in the ventilation system in order to operate the irradiator (Northboro); failure to perform weekly and monthly maintenance checks (Parsippany); and failure to record safety interlock test results (Parsippany).

## DETAILS

1. Persons Contacted

*George Dietz, Vice President
*Jonathan Young, Radiation Protection Officer
*Tom Gamache, Facility Manager (Parsippany)
Patrick McEvoy, Operator (Parsippany)
John Wieczorek, Operator (Parsippany)
Wayne Lecher, Operator/Maintenance Manager (Parsippany)
*Frank Yacino, Production Manager (Northborough)
James Cookman, Maintenance Manager (Northborough)
John Schmidt, Operator (Northborough)
Tim Frankie, Quality Assurance (Northborough)

*Present at exit interviews

2. License No. 29-15364-01 (Parsippany Facility)

On August 19, 1987, the inspectors toured the licensee's facilities in Parsippany, NJ, and inspected the interlock system associated with the irradiator. The inspectors noted a sheet of paper posted on the entry door leading into the irradiator that directed all operators to use two survey meters whenever entering the cell. The directive posted on the door was dated May 29, 1987 and signed by the Facility and Production Managers of the Parsippany facility. The Facility Manager informed the inspectors during their tour that the radiation monitor was not present because it had been sent out for calibration and therefore the licensee had initiated the "two survey meter" entry requirement. The Facility Manager identified the space next to the console where the radiation monitor normally was situated and the plate on the labyrinth wall where the probe was normally located.

The Facility Manager stated that on May 29, 1987, upon his arrival at the facility, the radiation monitor was indicating high radiation in the cell when the source was supposed to be in the shielded position. After the radiation monitor was reset it indicated normal radiation levels for the shielded source. To verify the indication, the Facility Manager surveyed the deionizer system and the area adjacent to the door entering the irradiator with two different survey meters. No significant radiation levels were detected. A survey performed when the irradiator door was opened approximately 6 inches did not indicate any significant radiation levels.

The Facility Manager stated that he next entered the labyrinth with the two survey meters and checked the pool water level indicator located under a plate in the floor. He stated that the water level appeared to be normal. The Facility Manager then entered the cell with two survey meters and confirmed that the source was in the fully safe/shielded position.

The Facility Manager stated that after entering the cell to ensure the source was in the safe position he immediately informed the Radiation Protection Officer (RPO) that the radiation monitor was malfunctioning. He added that he and the RPO decided to send the radiation monitor out for calibration or repair. Subsequently, the monitor and detector were removed from the system on May 29, 1987, by the Facility Manager and a member of the Maintenance Department. After removal of the radiation monitor, a procedure was implemented to require two persons with survey meters to verify radiation levels prior to permitting personnel access to the cell.

The inspectors asked the RPO if he was aware that the facility had been operating since May 29, 1987 without a functioning radiation monitor. The RPO stated that he was aware and he stated that "although the letter of the law was not being followed," he believed the source drive piston-door interlock in conjunction with the "two survey meter" entry requirement provided adequate protection for the operators. The inspectors asked the RPO if the facility had ever been operated without an operable radiation monitor in place prior to May 29, 1987. The RPO stated that every time the radiation monitor was sent out for calibration, the "two survey meter" entry procedure was implemented as a substitute. He further stated that a replacement monitor was never installed in the interim. The RPO added that the monitor and probe were sent out for calibration almost annually and the equipment was in transit and at the manufacturers for a 2-4 week duration. Calibration records indicated that the Eberline Monitor RM-16 and Eberline Probe RD-17A had been calibrated on April 14, 1986, February 11, 1985, September 2, 1983, July 2, 1982, August 21, 1981, and December 1, 1978.

The inspectors asked the RPO why the radiation monitor and detector had not been replaced for 2½ months. The RPO stated that a representative for Eberline, the manufacturer of the equipment, had informed him that the probe was damaged beyond repair. The RPO stated that he ordered a new monitor and probe from Atomic Energy of Canada, Limited (AECL) on June 9, 1987. According to the RPO, AECL later informed him that the monitor and probe would not be available before September 1, 1987. On July 7, 1987, the order for the AECL equipment was cancelled. The RPO added that near the middle of July, 1987, he learned that the facility at Parsippany was scheduled to be decommissioned by October 1, 1987. The RPO stated that the news of the planned decommissioning of the Parsippany facility was the basis for not aggressively pursuing the purchase of a replacement radiation monitor.

In a telephone conversation with the inspector on August 15, 1987, the Vice President of the corporation stated that he was aware that the facility was being operated without the radiation monitor; and that the Radiation Safety Committee had approved continued operation of the irradiator without the monitor so long as two survey meters were used during cell entries and all other interlocks were operable.

10 CFR 20.203(c)(6)(i) requires that each entrance or access point, to an area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radioactive source, must be equipped with entry control devices which function automatically to prevent any individual from inadvertently entering the area when such radiation levels exit. Condition 20 of License No 29-15364-01 requires that the access door to the cell is controlled by an interlock activated by a signal from the radiation monitor such that access is only permitted when radiation levels are normal.

The finding that the licensee operated the irradiator without the cell monitor probe present is an apparent violation of 10 CFR 20.203(c)(6)(i) and Condition 20 of License No. 29-15364-01.

The inspectors tested the low water indicator alarm and the maze door interlock associated with the source drive piston. Both were fully functional. The interlock prevented entrance into the irradiator cell when the source was raised and lowered the source into the pool when the microswitch was tripped.

The inspectors also confirmed that the source was in the safe/shielded position when the licensee lowered the source in agreement with CAL 87-11 dated August 19, 1987. The time noted on the console clock was 374073.

No additional violations were identified.

3. Training and Instructions to Employees

The inspectors reviewed the training files for the two operators who were most recently qualified. Both individuals had successfully completed written examinations and the graded examinations were maintained in their respective files. Both operators when interviewed, were knowledgeable with regard to the licensee's operating and emergency procedures.

No violations were identified.

4. Materials, Facilities, and Instruments

The survey meters utilized by the operators to enter the cell were operable and had been calibrated within the last six months in accordance with License Condition 20.

The inspectors asked the Facility Manager if there had been any problems with the deionizer system. He indicated that there had been no problems with the system. A log of the daily conductivity readings was reviewed. The log indicated that readings were taken daily and that when conductivity levels reached 10 micromhos, the system was regenerated in accordance with License Condition 20.

No violations were identified.

5. Maintenance and Inspection

The inspectors reviewed logs of safety interlock tests that are performed daily. The logs indicated that the interlocks had not been tested during the period from August 29, 1986, to February 1, 1987, and from May 27, 1987, to August 19, 1987. The Facility Manager informed the inspectors that the interlock tests had been performed daily but the staff had been remiss in recording the checks. The Facility Manager stated that he was responsible for ensuring the tests were performed and recorded daily.

10 CFR 20.203(c)(6)(vii) requires the entry control devices required in 10 CFR 20.203(c)(6)(i) to be tested for proper functioning prior to initial operation with the source of radiation on any day that operations are not uninterruptedly continued from the previous day or before resuming operations after any interruption; and records maintained of the date, time, and results of such tests.

The finding that the licensee failed to maintain records of the safety interlock system is an apparent violation of 10 CFR 20.203(c)(6)(vii).

The inspectors reviewed the daily, weekly, and monthly safety/maintenance check records. The records indicated that weekly and monthly maintenance checks had not been performed during the period from December 17, 1986, and March 24, 1987. The RPO stated that he was responsible for reviewing the maintenance records. Condition 20 of License No. 29-15364-01 requires that weekly and monthly maintenance checks be performed on various systems associated with the operation of the irradiator.

The finding that the licensee did not perform the monthly maintenance checks for January and February 1987 and the weekly checks during the period from December 17, 1986 to March 24, 1987 is an apparent violation of License Condition 20.

The inspectors reviewed records for the monthly maintenance checks covering the period when the radiation monitor was out of service. Monthly safety/maintenance checks require that the monitor and probe be tested with a check source to ensure that the alarm will sound and the monitor will lock out the access door in the presence of the radiation field produced by the check source. Records of the monthly checks, dated June 4, 1987, indicated that the item addressing the monitor was not applicable due to the fact that the monitor was out for calibration. The maintenance record dated July 2, 1987 indicated that the monitor check was "OK", and the record dated August 5, 1987 indicated that the monitor was "out for repair." The RPO and the Facility Manager informed the inspectors that no radiation monitor was installed from May 29, 1987 to the day of the inspection.

Prior to each cell entry, the licensee's procedures require operators to perform a seven item safety check. Item 4 of this safety check requires that the monitor be checked to ensure that the in-cell probe is detecting a radiation field of normal background. Results of these checks are logged in the Irradiator Log. Records of these checks are recorded with one "OK" attesting to the fact that the checks of all seven items were performed. The inspectors questioned the Facility Manager concerning the "OK" designation on the records during the period from May 29, 1987 to August 19, 1987, when in fact the monitor was not in place. The Facility Manager informed the inspectors that "OK" applied only to the other 6 attributes and obviously not to the monitor since it was not present.

No additional violations were identified.

6. Personnel Protection - External

The inspectors reviewed personnel dosimetry records that were maintained by the licensee. Records were maintained in accordance with 10 CFR 20.401 and there were no exposures in excess of the regulatory limits.

No violations were identified.

7. Receipt and Transfer of Materials

The licensee indicated that there had been no shipment or receipt of radioactive material since the last inspection.

No violations were identified.

8. License No. 29-19769-02 (Northboro Facility)

The inspectors conducted an inspection at the licensee's Northboro, Massachusetts facility on August 20, 1987. The inspection was limited to observations of interlock testing, discussions with licensee personnel regarding these interlocks, and a review of applicable records.

The inspectors observed that the following safety systems appeared to function properly:

a. Maze radiation monitor
b. Low-level water monitor and alarm
c. Emergency cable inside the cell
d. Startup warning signal
e. Startup delay switch

The inspectors were told by the production manager, the assistant production manager, the maintenance manager, and three other individuals who operate the irradiator that the irradiator was never operated with a malfunctioning radiation safety interlock. The inspector reviewed the licensee's records of daily interlock testing and weekly and monthly tests of the interlock systems and determined that the records indicated that these tests were being performed as required. While the records also indicated that there had been several instances when the maze radiation monitor failed to function properly, licensee records and discussions with licensee personnel indicated that the irradiator had always been shut down until repairs to the monitor had been completed.

The inspectors also observed the licensee test the interlock between the operations of the ventilation system and the irradiator. Section 4.6.1 of the license application dated May 24, 1982 requires that the proper operation of the ventilation fan be monitored by an air flow switch installed in the filter body such that, if no air flow is indicated, the source is returned to the fully shielded position. The inspectors noted that, when the licensee shut off the ventilation system, the irradiator failed to shut down and the source was not returned to the fully shielded position.

Licensee representatives stated that jumper cables had been installed on the previous day, to by-pass the interlock, to permit operation of the irradiator while the ventilation system was shut down to replace filters. The individual responsible for maintenance at the facility stated that he had forgotten to remove these cables when the task was completed. He added that he had previously bypassed the interlock between the ventilation system and the irradiator when water, resulting from heavy rainfall, entered the ventilation system and interfered with its operation. He said that it was normal practice to install the bypass, in such conditions, until the water was pumped out of the ventilation system.

The bypassing of the air flow switch in the ventilation system represents an apparent violation of Condition 19 of License No. 29-19769-02 which requires compliance with the statements, representation, and procedures contained in the licensee's application dated May 24, 1982.

In addition, the inspectors took a sample of the licensee's pool water and had it analyzed for radioactivity in the NRC Regional Laboratory. No measurable radioactivity was detected in the sample which is consistent with the licensee's most recent analysis of pool water radioactivity. The minimum detectable concentration of the NRC measurement was 1 E-7 microcurie per milliliter.

9. License No. 29-19769-03 (Whippany Facility)

The inspectors inspected the irradiator facility at the Whippany site on August 19, 1987. The door interlocks were tested and found to be operational.

The low water alarm was also tested and was found to function properly. The cell radiation monitor was tested with the source in the raised position. The monitor alarmed immediately.

The inspectors reviewed a representative sample of the irradiator logs and all of the maintenance records dating back to the previous inspection. There was no evidence that the irradiator had ever been operated when the interlock system was not functioning properly.

No violations were identified.

10. Corrective Actions

On August 25, 1987, the inspectors returned to the Parsippany facility to evaluate the radiation monitor and probe that had been installed in the irradiator cell. The Eberline equipment had been replaced by an AECL Model L118 monitor coupled with an AECL Model 110 probe. This monitoring system is the same as the systems installed at the Whippany and Northboro facilities. The radiation monitor was set to alarm and lock out the access door to the cell at 0.5 milliroengtgen per hour. The inspectors tested the monitor with a 10 microcurie cesium-137 check source. The test source tripped the alarm and the monitor interlock precluded entry into the cell in accordance with 10 CFR 20.203(c)(6)(i). The inspectors asked the licensee representative test the monitor with the source in the raised position and verified that it properly functioned. Following, the licensee representative tested every interlock and warning signal on the console. All of the features functioned as required by License Condition 20.

The inspectors interviewed an operator concerning the new radiation monitor and the modified interlock system. The operator demonstrated a working knowledge of the system and appeared well versed in the licensee's operating procedures.

No violations were identified.

11. Exit Interview

The inspectors met with the individuals identified in Section 1 at the conclusion of the inspection and discussed the scope and findings of this inspection.

CASE No.1-87-019

United States
Nuclear Regulatory Commission

# Report of Investigation

## Isomedix, Incorporated:

## Willful Violations of License Conditions and NRC Regulations

Office of Investigations

Reported by OI: RI

Title: ISOMEDIX, INCORPORATED:

WILLFUL VIOLATIONS OF LICENSE CONDITIONS AND NRC REGULATIONS

Licensee:

Isomedix, Incorporated
80 South Jefferson Road
Whippany, New Jersey 07901

Docket Nos.: 30-19752
30-08985

Case Number: 1-87-019

Report Date: August 11, 1988

Control Office: OI:RI

Status: CLOSED

Reported By:

Edward A. Fitzgerald

Edward A. Fitzgerald, Investigator
Office of Investigations
Field Office, Region I

Reviewed By:

Chester W. White

Chester W. White, Director
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Field Office, Region I

Participating Personnel:

Approved By:

Ben B. Hayes

Ben B. Hayes, Director
Office of Investigations

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# SYNOPSIS

This investigation was initiated upon receipt of a written request, dated November 23, 1987, from the Regional Administrator, U.S. Nuclear Regulatory Commission (NRC), Region I. The Office of Investigations (OI) was asked to determine if the licensee was operating its Parsippany, New Jersey facility without the required radiation monitoring interlock system (RMIS), and if management knowingly directed personnel to violate NRC regulations.

The licensee, Isomedix, Incorporated (Isomedix), has corporate headquarters at Whippany, New Jersey, and operates ten (10) plants located in the United States, Canada, and Puerto Rico. Isomedix is one of the largest contract gamma sterilization firms in the industry.

On August 19, 1987, two NRC Inspectors conducted an inspection at Isomedix's Parsippany facility. The Inspectors observed that the RMIS was removed and that the circuitry was bypassed while the facility continued to operate. The Inspectors reported that a notice, dated May 29, 1987, was posted on the irradiator cell entry door depicting an alternate safety procedure to be used for entry while the RMIS was removed. The alternate safety procedure did not meet the requirements of 10 CFR 20.203, and operations ceased on August 19, 1987, on the advice of NRC. The matter was subsequently referred to OI.

OI's investigation included the examination of pertinent records and interviews of involved personnel. The Vice President for Operations (VPO) was interviewed and said that Isomedix has a Radiation Safety Committee (RSC), and in May 1987, it consisted of himself, a former Vice President for Technical Matters (presently a consultant to Isomedix), and the former Director of Operations who was laid off during corporate restructuring in July 1987. The RSC met several times a week and during a meeting in May 1987, discussed the removal of the Parsippany RMIS for the annual calibration. The RSC recommended that alternate safety procedures be utilized during the period of removal even though they knew that alternate safety procedures did not meet the NRC regulatory requirements. The recommendations were approved by the RSC and implemented under the direction of the VPO. The VPO further stated that the practice of the alternate safety procedures was used almost each year since 1978 for a two to four week period while the RMIS was removed for calibration. The VPO said that he approved and implemented the recommendations of the RSC and that he is solely responsible for the violations. The VPO stated that the RSC did not formalize recommendations in writing or keep written minutes of meetings held.

The Radiation Protection Officer (RPO) was interviewed and stated that he supervised removal of the RMIS on May 29, 1987, and implementation of the alternate safety procedure recommended by the RSC under the direction of the Director of Operations. The RPO said that he knew that the procedure followed by Isomedix did not "meet the letter of the law." The RPO also said that the RMIS was removed almost annually and the same alternate safety procedure was used.

This investigation corroborated the findings of the NRC Inspectors that Isomedix knowingly violated 10 CFR 20.203(c)(6)(e) by the removal of the RMIS specifically during the period from May 29, 1987, to the NRC inspection on August 19, 1987, while continuing to operate the irradiator, and in addition, for a two to four week period in December 1978, August 1981, July 1982, September 1983, February 1985, and April 1986.

CASE No. 1-88-005

**United States**
**Nuclear Regulatory Commission**

# Report of Investigation

Isomedix, Incorporated:

Bypassing of Interlocks

**Office of Investigations**

Reported by OI: RI

Title: ISOMEDIX, INCORPORATED:

BYPASSING OF INTERLOCKS

Licensee:

Isomedix, Incorporated
80 South Jefferson Road
Whippany, New Jersey 07901

Docket Nos.: 30-19752
30-08985

Case No.: 1-88-005

Report Date: October 20, 1988

Control Office: OI:RI

Status: CLOSED

Reported by:

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Approved by:

for Ben B. Hayes

Ben B. Hayes, Director
Office of Investigations

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## SYNOPSIS

This investigation was initiated upon receipt of a written request, dated November 23, 1987, from the Regional Administrator, U.S. Nuclear Regulatory Commission (NRC), Region I. The Office of Investigations (OI) was asked to determine if the licensee was operating its Northborough, Massachusetts facility without a required air flow switch (AFS) of the irradiator ventilation system by the use of a bypass, and if the licensee attempted to conceal the use of this bypass during an NRC inspection.

The licensee, Isomedix, Incorporated (Isomedix), has corporate headquarters in Whippany, New Jersey, and operates ten plants located throughout the United States, Canada, and Puerto Rico. Isomedix is one of the largest contract gamma sterilization firms in the industry.

On May 19, 1987, an alleger notified an NRC Inspector, who was on a site visitation with senior NRC headquarters staff, that the Isomedix, Northborough facility periodically bypassed a required AFS, and that there were some efforts to conceal it from the NRC during a previous inspection in February 1987.

In response to the aforementioned allegation, two NRC Inspectors conducted an inspection at Isomedix on August 20, 1987. During the course of the inspection, the licensee was requested to turn off the AFS as a test to ascertain if the source would return to a fully shielded position as required. The AFS failed the test. The NRC Inspectors determined that the AFS had been bypassed by using a "jumper cable." The licensee representative explained that the Maintenance Mechanic (MM) had installed the bypass to change filters on the air shafts and forgot to remove the device. Further inquiries by the Inspectors revealed that the AFS was also bypassed to pump water from air shafts when rain drainoff filled the shafts of the ventilation system. The bypass of the AFS is a violation of an NRC license condition issued to Isomedix for this facility. The matter was subsequently referred to OI.

OI's investigation included the examination of pertinent records and interviews of involved personnel. The Plant Manager (PM), who also serves as site Radiation Safety Officer (RSO), was interviewed and said that the AFS was routinely bypassed following some heavy rainstorms when air shafts took in water. He also said that on rare occasions, a bypass was used to change filters but because of adequate "down time" of the irradiator, it was not routine. The PM said that in his opinion, the use of the bypass never posed a safety problem to the public or plant personnel. He said that he did not know that it was a violation of conditions of the NRC issued license until the facility was inspected on August 20, 1987. The PM admitted that as PM and site RSO, it was his responsibility to know, and he should have known, that in bypassing the AFS, Isomedix was violating the conditions of the license, and thus, violating NRC regulations. The PM further stated that immediate corrective action has been taken at the site.

The MM was interviewed and stated that he applied the bypass to the AFS that was discovered by NRC Inspectors. He stated that he did so to change filters on the air shafts of the system, and forgot to remove it when the task was complete. The MM said that it is normal for him to change the filter during "down time" of the irradiator as they are changed once a month, but said that he bypassed the AFS on an average of once a year. He said that following several heavy rainstorms when the air shafts take in ground water, he installed a bypass to facilitate pumping out the water which would take approximately one hour. The bypass was removed after the pump out was complete. Following the NRC inspection, a high speed pump was installed which does not require the bypass and only requires one to two minutes to complete a pump out. The MM further stated that he did not know that bypassing the AFS was a violation but felt it was a safe short-term procedure. He stated that at no time did he attempt to conceal the use of the bypass from the NRC or anyone else, the bypass was always removed following the purpose of its use.

The Vice President for Corporate Operations (VPO) was interviewed and said that he did not authorize or have knowledge that the Northborough site was using a "jumper cable" to bypass the AFS for pumping water from air shafts and changing of filters. The VPO said that he was aware of the water leaking into air shafts and that it had to be pumped out, but the bypassing was not an authorized method. He said that the PM, who is also the RSO for the site, should have been fully aware of the conditions of the NRC license, and that the bypassing of the AFS was a violation of the conditions of the license.

The alleger was interviewed and said that he has no specific information concerning an attempt to conceal the use of a bypass from NRC Inspectors. His purpose in approaching the NRC Inspector was to air his concerns about operations that he thought were in violation of NRC regulations.

This investigation corroborated the finding that Isomedix willfully violated Condition 19 of License No. 29-19769-02 and 10 CFR 30.3 on a routine basis following some heavy rainstorms and on occasions when changing filters. There was insufficient evidence to substantiate that attempts were made to conceal the use of the bypass of the AFS from the NRC Inspectors.