0cs/0cs

MVH Miami Valley Hospital

One Wyoming Street
Dayton, Ohio 45409-2793

Telephone: 513-223-6192

March 28, 1994

Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Sir:

Please find attached to this document, Miami Valley Hospital's response to the NRC "Notice of Violation and Proposed Imposition of Civil Penalty." We thank you for the opportunity to provide feedback with regards to the corrective action steps taken by Miami Valley Hospital to rectify the violations identified by the NRC surveyor. Please refer to the request by Miami Valley Hospital to mitigate the civil penalty imposed as a result of these violations.

Sincerely,

Mark S. Shaker
Senior Vice-President
Hospital Operations

APR 1 1994

IE07
1/1

Reply to NRC "Notice of Violation
and
Proposed Imposition of Civil Penalty"

Miami Valley Hospital
Dayton, Ohio

Docket No. 030-02643
License No. 34-00341-06
EA 93-288

I. Violation Assessed a Civil Penalty

Condition 24. of License No. 34-00341-06 requires that licensed materials be used in accordance with statements, representations, and procedures contained in an application received Sept. 25, 1988.

Item 10.4 of the section of the referenced application entitled "Safe Use of Radiopharmaceuticals," requires that the licensee follow Appendix I to Regulatory Guide 10.8, Revision 2. Item 2 of Appendix I requires individuals to wear gloves at all times while handling radioactive materials.

Contrary to the above, on September 10, 1993, an individual handled radioactive material, strontium-89, without wearing gloves.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The root cause of this violation was neither malicious disregard nor ignorance of the requirements of the NRC license, but a concern for the safety of the staff member who would have been required to return for the gloves. An error of poor judgment, rather than willful violation was committed.

(3) The corrective steps that have been taken and the results achieved:
As of 8-16-93, an additional dosimetrist was hired to allow the RSO more time to attend to the Radiation Safety Program. A license amendment to appoint an assistant RSO was applied for on 12-21-93, and was approved on 3-15-94. As of January 1, 1994, NMA, an outside Physics consulting firm has been retained for the year to provide auditing for 2 days per quarter. These steps were taken not only to prevent a recurrance of the violation, but also to strengthen communications between the RSO and the Nuclear Medicine section employees.

Initial results are positive regarding each of these steps.

(4) The corrective steps that will be taken to avoid further violations:

Ongoing training on NRC license requirements will continue for the staff, physicians and management via the Annual Radiation Safety Reviews, and Radiation Safety Committee Meetings.We have already discussed this issue with the Nuclear medicine staff and authorized users, and have clearly stated that willful violations of any kind will not be tolerated. We believe that these measures as well as others enumerated in this reply will ensure that individuals involved in NRC licensed activities will, in the future, understand and comply with NRC requirements and will not commit willful violations.

(5) The date when full compliance will be achieved:

Full compliance with NRC license regulations was achieved by December 1, 1993, when all required responses to the violation were completed.

II. Other Violations Associated with the Contamination Event

A. 10 CFR 20.101 requires that the licensee limit the extremity radiation dose of an individual to 18 3/4 rems per calendar quarter.

Contrary to the above, the licensee did not limit the extremity dose of an individual to 18 3/4 rems per calendar quarter. Specifically, on September 10, 1993, an authorized physician user received an extremity dose of 52.9 rems.

(1) Admission or denial of the alleged violation:

The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:

Skin exposure to physician resulted from not wearing gloves during injection as described in Violation I.

(3) The corrective steps that have been taken and the results achieved:

Physician user has been counseled as to license requirements for all personnel to wear gloves when handling radioactive materials.

(4) The corrective steps that will be taken to avoid further violations:

None required.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

B. Condition 24. of the License No. 34-00341-06 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application received September 25, 1988.

Item 10.4 of the section of the referenced application entitled "Safe Use of Radiopharmaceuticals," requires that the licensee follow Appendix I to Regulatory Guide 10.8, Revision 2. Item 8 of Appendix I requires, in part, that individuals wear finger exposure monitor during the injection of radiopharmaceuticals.

Contrary to the above, on September 10, 1993, an authorized physician user of licensed material performed an injection of strontium-89 and was not wearing a finger exposure monitor.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician users have had body exposure badges since the inception of the license. However, ring badges have not been provided in the past due to oversight on the part of the licensee. Physician injection activity has been extremely limited, and they have always been gloved in the past.

(3) The corrective steps that have been taken and the results achieved:
Ring badges have been provided for the physician users since December 1993. No further incidents have been encountered. The ring badges have been worn at all times when injecting has been required.

(4) The corrective steps that will be taken to avoid further violations:
Ring badges will be worn by all persons engaging in the administration of radioactive materials, as per license conditions.

(5) The date when full compliance will be achieved:
Full compliance has been achieved as of 12-1-93.

C. Item 3 of Appendix I requires, in part, that either after each procedure or before leaving the area, occupational workers monitor their hands for contamination.

Contrary to the above, on September 10, 1993, an authorized physician user of licensed material failed to monitor his hands either after a procedure involving the injection of strontium-89 or before leaving the area.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician user was off-site at the time of the administration of Sr 89 without a survey meter. The action was an inadvertent omission, due to the unusual nature of the situation.

(3) The corrective steps that have been taken and the results achieved:
No radioactive material will be administered off-site and without monitoring of hands after the procedure or before leaving the area.

(4) The corrective steps that will be taken to avoid further violations:
All employees are aware of their responsibilities in this regard.
In order to make it easier to comply with this license regulation, a radiation detection device will be placed near the employees' locker rooms in order to eliminate the need to return to the "hot lab" at the end of the day to survey hands for contamination.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

D. Condition 10. of the License No. 34-00341-06 requires that licensed material be used only at 1 Wyoming Street, Dayton, Ohio, or 7707 Paragon Rd., Suite 106, Centerville, Ohio.

Contrary to the above, on September 10, 1993, the licensee used licensed material at a private residence, a location not authorized by the license.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician believed that the patient was unable to come into the hospital for the therapy injection due to

his extremely debilitated condition. The patient was unable to come for the injection on two previous occasions due to intractable pain, and the physician felt that this might be the only way to provide treatment with the radioisotope before it decayed to an unusable level. In the urgency of the situation, the physician inadvertently neglected to consult with the RSO before proceeding with the treatment.

(3) The corrective steps that have been taken and the results achieved:
No radioactive material will be administered off-site.

(4) The corrective steps that will be taken to avoid further violations:
Ongoing training on NRC license requirements will continue for the staff, physicians and management via the Annual Radiation Safety Reviews and Radiation Safety Committee meetings.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

III. Other Violations

A. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Dept. of Transportation (DOT) in 49 CFR Parts 170 through189.

49 CFR 173.421, in part, excepts radioactive materials in certain limited quantities from the specification packaging, shipping paper and certification, marking and labeling requirements of subpart H, 49 CFR Part 173 if the radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.

Contrary to the above, on December 30, 1992, the licensee delivered to a carrier for transport a package of iodine-131 labeled as limited quantity exempt from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR 173, and the external surface radiation level of the package was greater than 0.5 millirem per hour. Subsequent survey of the package at its destination point found a radiation level of 10 millirem per hour.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The technologist failed to place the I-131 capsules in

lead pigs in the shipping case, and failed to perform a survey of the case before shipment as required under our policies.

(3) The corrective steps that have been taken and the results achieved:

The technologist was counseled and disciplined concerning this event according to our written hospital policies. The entire Nuclear Medicine Section has been given additional review on shipping radioactive packages during the Annual Radiation Safety Review.

(4) The corrective steps that will be taken to avoid further violations:

The technologist involved in this violation will be required to work in an environment where direct supervision is present. The supervision must be from a Nuclear Medicine Technologist Supervisor. The technologist will not be permitted to work completely alone for a period ending April 1, 1995.

(5) The date when full compliance will be achieved:

We are currently in full compliance.

B. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, from March 6, 1991 to October 27, 1993, the licensee did not survey with a radiation detection survey instrument Area Number 8, a room where radiopharmaceutical waste is stored, on a monthly basis.

(1) Admission or denial of the alleged violation:

The licensee admits to this violation, but disputes the dates mentioned in the letter. We began storing waste in Area number 8 only since July 1, 1993. This is when Syncor discontinued their waste return service. Therefore surveying did not occur in this area from July 1, 1993 through October 27, 1993.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:

Our Radiation Safety Officer was informed of the changes in our procedure for handling radioactive waste. However, regulatory audit of our procedure

had not revealed our oversight of the survey requirement until it was discovered during inspection.

(3) The corrective steps that have been taken and the results achieved:

We have revised our weekly wipe and survey forms, so that Area Number 8 is now a part of our routine procedure. Application to amend the license to include this area as a radioactive waste storage area was made on 12-21-93. The amendment was approved on 3-15-94.

(4) The corrective steps that will be taken to avoid further violations:

All weekly wipes and surveys continue to be audited to assure compliance of license conditions. The "Weekly Wipes and Survey" form will be used to methodically record each required area. If at any time an additional area is required for waste storage, approval will be requested prior to using that additional area.

(5) The date when full compliance will be achieved:

Full compliance with our new form has been achieved since December 15, 1993.

Answer to a Notice of Violation Dated 3-1-94

Miami Valley Hospital
Dayton, Ohio

Docket No. 030-02643
License No. 34-00341-06
EA 93-288

We request that the proposed civil penalty discussed in Part-I of the above Notice of Violation be fully mitigated for the following reasons:

1. The apparent willful nature of the violation was not deliberate or capricious. The authorized user was acting out of what he considered to be the needs of the patient and the safety of the technclogist. Initially, they forgot to bring gloves, not deliberately refusing to bring them. While walking to the patient's house, the technologist remembered that they had not brought gloves with them. The authorized user then considered many conflicting requirements, including the safety of the technologist, his schedule for the rest of the day, the condition of the terminally ill patient, and the small risk of a spill. It was the result of considering these factors that led the authorized user to continue to the patient's house for the injection, not a flagrant disregard for NRC License regulations. This authorized user has been named on the license for many years, and is not a deliberate violator of NRC regulations.

2. The authorized user was completely candid with me, our consultant from NMA who investigated the incident, and the NRC inspector, concerning the details of the inspection.

3. The authorized user was fully cooperative with all corrective action that was taken concerning this violation.

4. The authorized user has an excellent record of performance with NRC License requirements. This is the first violation of any kind with which he has been involved.

5. This violation is the isolated action of the authorized user and did not result from a lack of management oversight of its employees.

6. Substantial corrective action has already been taken concerning this violation as documented in the Reply to NRC Notice of Violation, demonstrating the seriousness of the violation and our commitment to fulfilling the requirements of our License.

MVH Miami Valley Hospital

One Wyoming Street
Dayton, Ohio 45409-2793

Telephone 513-223-6192

March 28, 1994

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Dear Sir:

Please find attached to this document, Miami Valley Hospital's response to the NRC "Notice of Violation and Proposed Imposition of Civil Penalty." We thank you for the opportunity to provide feedback with regards to the corrective action steps taken by Miami Valley Hospital to rectify the violations identified by the NRC surveyor. Please refer to the request by Miami Valley Hospital to mitigate the civil penalty imposed as a result of these violations.

Sincerely,

Mark S. Shaker
Senior Vice-President
Hospital Operations

Reply to NRC "Notice of Violation
and
Proposed Imposition of Civil Penalty"

Miami Valley Hospital
Dayton, Ohio

Docket No. 030-02643
License No. 34-00341-06
EA 93-288

I. Violation Assessed a Civil Penalty

Condition 24. of License No. 34-00341-06 requires that licensed materials be used in accordance with statements, representations, and procedures contained in an application received Sept. 25, 1988.

Item 10.4 of the section of the referenced application entitled "Safe Use of Radiopharmaceuticals," requires that the licensee follow Appendix I to Regulatory Guide 10.8, Revision 2. Item 2 of Appendix I requires individuals to wear gloves at all times while handling radioactive materials.

Contrary to the above, on September 10, 1993, an individual handled radioactive material, strontium-89, without wearing gloves.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The root cause of this violation was neither malicious disregard nor ignorance of the requirements of the NRC license, but a concern for the safety of the staff member who would have been required to return for the gloves. An error of poor judgment, rather than willful violation was committed.

(3) The corrective steps that have been taken and the results achieved:
As of 8-16-93, an additional dosimetrist was hired to allow the RSO more time to attend to the Radiation Safety Program. A license amendment to appoint an assistant RSO was applied for on 12-21-93, and was approved on 3-15-94. As of January 1, 1994, NMA, an outside Physics consulting firm has been retained for the year to provide auditing for 2 days per quarter. These steps were taken not only to prevent a recurrance of the violation, but also to strengthen communications between the RSO and the Nuclear Medicine section employees.

Initial results are positive regarding each of these steps.

(4) The corrective steps that will be taken to avoid further violations:

Ongoing training on NRC license requirements will continue for the staff, physicians and management via the Annual Radiation Safety Reviews, and Radiation Safety Committee Meetings.We have already discussed this issue with the Nuclear medicine staff and authorized users, and have clearly stated that willful violations of any kind will not be tolerated. We believe that these measures as well as others enumerated in this reply will ensure that individuals involved in NRC licensed activities will, in the future, understand and comply with NRC requirements and will not commit willful violations.

(5) The date when full compliance will be achieved:

Full compliance with NRC license regulations was achieved by December 1, 1993, when all required responses to the violation were completed.

II. Other Violations Associated with the Contamination Event

A. 10 CFR 20.101 requires that the licensee limit the extremity radiation dose of an individual to 18 3/4 rems per calendar quarter.

Contrary to the above, the licensee did not limit the extremity dose of an individual to 18 3/4 rems per calendar quarter. Specifically, on September 10, 1993, an authorized physician user received an extremity dose of 52.9 rems.

(1) Admission or denial of the alleged violation:

The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:

Skin exposure to physician resulted from not wearing gloves during injection as described in Violation I.

(3) The corrective steps that have been taken and the results achieved:

Physician user has been counseled as to license requirements for all personnel to wear gloves when handling radioactive materials.

(4) The corrective steps that will be taken to avoid further violations:

None required.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

B. Condition 24. of the License No. 34-00341-06 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application received September 25, 1988.

Item 10.4 of the section of the referenced application entitled "Safe Use of Radiopharmaceuticals," requires that the licensee follow Appendix I to Regulatory Guide 10.8, Revision 2. Item 8 of Appendix I requires, in part, that individuals wear finger exposure monitor during the injection of radiopharmaceuticals.

Contrary to the above, on September 10, 1993, an authorized physician user of licensed material performed an injection of strontium-89 and was not wearing a finger exposure monitor.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician users have had body exposure badges since the inception of the license. However, ring badges have not been provided in the past due to oversight on the part of the licensee. Physician injection activity has been extremely limited, and they have always been gloved in the past.

(3) The corrective steps that have been taken and the results achieved:
Ring badges have been provided for the physician users since December 1993. No further incidents have been encountered. The ring badges have been worn at all times when injecting has been required.

(4) The corrective steps that will be taken to avoid further violations:
Ring badges will be worn by all persons engaging in the administration of radioactive materials, as per license conditions.

(5) The date when full compliance will be achieved:
Full compliance has been achieved as of 12-1-93.

C. Item 3 of Appendix I requires, in part, that either after each procedure or before leaving the area, occupational workers monitor their hands for contamination.

Contrary to the above, on September 10, 1993, an authorized physician user of licensed material failed to monitor his hands either after a procedure involving the injection of strontium-89 or before leaving the area.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician user was off-site at the time of the administration of Sr 89 without a survey meter. The action was an inadvertent omission, due to the unusual nature of the situation.

(3) The corrective steps that have been taken and the results achieved:
No radioactive material will be administered off-site and without monitoring of hands after the procedure or before leaving the area.

(4) The corrective steps that will be taken to avoid further violations:
All employees are aware of their responsibilities in this regard.
In order to make it easier to comply with this license regulation, a radiation detection device will be placed near the employees' locker rooms in order to eliminate the need to return to the "hot lab" at the end of the day to survey hands for contamination.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

D. Condition 10. of the License No. 34-00341-06 requires that licensed material be used only at 1 Wyoming Street, Dayton, Ohio, or 7707 Paragon Rd., Suite 106, Centerville, Ohio.

Contrary to the above, on September 10, 1993, the licensee used licensed material at a private residence, a location not authorized by the license.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The physician believed that the patient was unable to come into the hospital for the therapy injection due to

his extremely debilitated condition. The patient was unable to come for the injection on two previous occasions due to intractable pain, and the physician felt that this might be the only way to provide treatment with the radioisotope before it decayed to an unusable level. In the urgency of the situation, the physician inadvertently neglected to consult with the RSO before proceeding with the treatment.

(3) The corrective steps that have been taken and the results achieved:
No radioactive material will be administered off-site.

(4) The corrective steps that will be taken to avoid further violations:
Ongoing training on NRC license requirements will continue for the staff, physicians and management via the Annual Radiation Safety Reviews and Radiation Safety Committee meetings.

(5) The date when full compliance will be achieved:
We are currently in full compliance.

III. Other Violations

A. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Dept. of Transportation (DOT) in 49 CFR Parts 170 through189.

49 CFR 173.421, in part, excepts radioactive materials in certain limited quantities from the specification packaging, shipping paper and certification, marking and labeling requirements of subpart H, 49 CFR Part 173 if the radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.

Contrary to the above, on December 30, 1992, the licensee delivered to a carrier for transport a package of iodine-131 labeled as limited quantity exempt from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR 173, and the external surface radiation level of the package was greater than 0.5 millirem per hour. Subsequent survey of the package at its destination point found a radiation level of 10 millirem per hour.

(1) Admission or denial of the alleged violation:
The licensee admits to this violation.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:
The technologist failed to place the I-131 capsules in

lead pigs in the shipping case, and failed to perform a survey of the case before shipment as required under our policies.

(3) The corrective steps that have been taken and the results achieved:

The technologist was counseled and disciplined concerning this event according to our written hospital policies. The entire Nuclear Medicine Section has been given additional review on shipping radioactive packages during the Annual Radiation Safety Review.

(4) The corrective steps that will be taken to avoid further violations:

The technologist involved in this violation will be required to work in an environment where direct supervision is present. The supervision must be from a Nuclear Medicine Technologist Supervisor. The technologist will not be permitted to work completely alone for a period ending April 1, 1995.

(5) The date when full compliance will be achieved:

We are currently in full compliance.

B. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, from March 6, 1991 to October 27, 1993, the licensee did not survey with a radiation detection survey instrument Area Number 8, a room where radiopharmaceutical waste is stored, on a monthly basis.

(1) Admission or denial of the alleged violation:

The licensee admits to this violation, but disputes the dates mentioned in the letter. We began storing waste in Area number 8 only since July 1, 1993. This is when Syncor discontinued their waste return service. Therefore surveying did not occur in this area from July 1, 1993 through October 27, 1993.

(2) The reasons for the violation, if admitted, and if denied, the reasons why:

Our Radiation Safety Officer was informed of the changes in our procedure for handling radioactive waste. However, regulatory audit of our procedure

had not revealed our oversight of the survey requirement until it was discovered during inspection.

(3) The corrective steps that have been taken and the results achieved:

We have revised our weekly wipe and survey forms, so that Area Number 8 is now a part of our routine procedure. Application to amend the license to include this area as a radioactive waste storage area was made on 12-21-93. The amendment was approved on 3-15-94.

(4) The corrective steps that will be taken to avoid further violations:

All weekly wipes and surveys continue to be audited to assure compliance of license conditions. The "Weekly Wipes and Survey" form will be used to methodically record each required area. If at any time an additional area is required for waste storage, approval will be requested prior to using that additional area.

(5) The date when full compliance will be achieved:

Full compliance with our new form has been achieved since December 15, 1993.

Answer to a Notice of Violation Dated 3-1-94

Miami Valley Hospital
Dayton, Ohio

Docket No. 030-02643
License No. 34-00341-06
EA 93-288

We request that the proposed civil penalty discussed in Part-I of the above Notice of Violation be fully mitigated for the following reasons:

1. The apparent willful nature of the violation was not deliberate or capricious. The authorized user was acting out of what he considered to be the needs of the patient and the safety of the technologist. Initially, they forgot to bring gloves, not deliberately refusing to bring them. While walking to the patient's house, the technologist remembered that they had not brought gloves with them. The authorized user then considered many conflicting requirements, including the safety of the technologist, his schedule for the rest of the day, the condition of the terminally ill patient, and the small risk of a spill. It was the result of considering these factors that led the authorized user to continue to the patient's house for the injection, not a flagrant disregard for NRC License regulations. This authorized user has been named on the license for many years, and is not a deliberate violator of NRC regulations.

2. The authorized user was completely candid with me, our consultant from NMA who investigated the incident, and the NRC inspector, concerning the details of the inspection.

3. The authorized user was fully cooperative with all corrective action that was taken concerning this violation.

4. The authorized user has an excellent record of performance with NRC License requirements. This is the first violation of any kind with which he has been involved.

5. This violation is the isolated action of the authorized user and did not result from a lack of management oversight of its employees.

6. Substantial corrective action has already been taken concerning this violation as documented in the Reply to NRC Notice of Violation, demonstrating the seriousness of the violation and our commitment to fulfilling the requirements of our License.