UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

PDR
016

MAR 15 1985

Brian B. Smith, Esquire
Stark and Gordon
1600 Ford Building
Detroit, MI 48226

IN RESPONSE REFER
TO FOIA-85-140

Dear Mr. Smith:

This is in partial response to your letter dated February 28, 1985, in which you requested, pursuant to the Freedom of Information Act (FOIA), three categories of documents related to an NRC inspection of clinics run by Dr. Ramasami Gunabalan in the Detroit, Michigan, area.

We are enclosing copies of the three documents listed on the enclosed Appendix A which respond to categories one and two of your request.

The NRC has not completed its search for and review of any additional documents which may be subject to your request. We will respond again as soon as search and review are completed.

Sincerely,

J. M. Felton, Director
Division of Rules and Records
Office of Administration

Enclosures: As stated

PDR 016

APPENDIX A

FOIA 85- 140

12/11/84 Letter to Gunabalan from Axelson on safety inspection (16 pages)

1/10/85 Letter to Simmons from Gunabalan on Notice of Violation (3 pages)

2/8/85 Letter to Gunabalan from Axelson on noncompliance steps (1 page)

Wed

DEC 1 1 1984

30-18190

Radiological Imaging Consultants
ATTN: Ram Gunabalan, M.D.
5339 Kellen Lane
Bloomfield Hills, MI 48913

License No. 21-20279-01

Gentlemen:

This refers to the special safety inspection conducted by Ms. T. L. Simmons of this office on August 8 and 17 and November 19, 20, and 27, 1984, of activities authorized by NRC Byproduct Material License No. 21-20279-01 and to the discussion of our findings with you by telephone and with Mr. M. Slugaj at the conclusion of the inspection.

This inspection was conducted to determine whether or not allegations received by the NRC from an anonymous individual could be substantiated.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel.

During this inspection, certain of your activities appeared to be in noncompliance with NRC requirements, as specified in the enclosed Appendix. A written response is required.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC's Public Document Room. If this report contains any information that you (or your contractors) believe to be exempt from disclosure under 10 CFR 9.5(a)(4), it is necessary that you (a) notify this office by telephone within ten (10) days from the date of this letter of your intention to file a request for withholding; and (b) submit within twenty-five (25) days from the date of this letter a written application to this office to withhold such information. If your receipt of this letter has been delayed such that less than seven (7) days are available for your review, please notify this office promptly so that a new due date may be established. Consistent with Section 2.790(b)(1), any such application must be accompanied by an affidavit executed by the owner of the information which identifies the document or part sought to be withheld, and which contains a full statement of the reasons which are the bases for the claim that the information should be withheld from public disclosure. This section further requires the statement to address with specificity the considerations listed in 10 CFR 2.790(b)(4). The information sought to be withheld shall be incorporated as far as possible into a separate part of the affidavit. If we do not hear from you in this regard within the

8501170777

2pp

specified periods noted above, a copy of this letter, the enclosures, and your response to this letter will be placed in the Public Document Room.

The responses directed by this letter (and the accompanying Notice) are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

W. L. Axelson, Chief
Nuclear Materials Safety and
Safeguards Branch

Enclosures:
1. Appendix, Notice of Violation
2. Inspection Report No. 30-18190/84-02(DRSS)

cc w/encls:
DMB/Document Control Desk (RIDS)

RIII
Simmons/
12/07/84

RIII
Sreniawski
12/10

RIII
Weil

RIII
Axelson

Appendix

NOTICE OF VIOLATION

Radiological Imaging Consultants License No. 21-20279-01

August 8 and 17 and November 19, 20, and 27, 1984 violations were:

1. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

   Contrary to the above, no evaluation was made to show compliance with 10 CFR 20.104, which specifies dose limits for minors. Specifically, no dose determination has been made of your driver who is a minor.

   This is a Severity Level IV Violation (Supplement IV).

2. License Condition No. 19 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in letter dated June 17, 1984.

   Item No. 3 of referenced letter states: "The exterior of the package will be labeled with the appropriate label (i.e., RADIOACTIVE WHITE-I label, RADIOACTIVE YELLOW-II label, or RADIOACTIVE YELLOW-III label) as required by 49 CFR, Sections 173.391 and 173.392. The exterior of the package will also be marked "USA DOT 7A TYPE A" as required by Section 178-350-3 (letters at least 1/2" high). In accordance with Section 172.312, packages containing liquids will also bear the label "THIS END UP" where appropriate."

   Contrary to the above, it was observed that none of several packages ("Samsonite" attache cases) in the licensee's possession were labeled as required and were used to transport licensed material.

   This is a Severity Level IV Violation (Supplement VI).

3. License Condition No. 19 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in letter dated June 17, 1983.

   Item No. 4 of the referenced letter states: "Drivers will be trained in all items specified in 10 CFR 19.12 and will be instructed in the handling of radioactive spills and other potential emergencies. Instruction will be at hire and annually thereafter."

~~8501240347~~

3pp

Contrary to the above, the driver has not been instructed as required. Specifically, your driver, who had been delivering unit doses for at least two weeks as of the date of this inspection, had not been instructed at hire.

This is a Severity Level IV Violation (Supplement VI).

4. License Condition No. 19 requires that all license material be possessed and used in accordance with statements, representations and procedures contained in letter dated June 17, 1983.

Item No. 3 of the referenced letter states the packaging will conform with 49 CFR Type A design requirements.

49 CFR 173.412 requires that certain tests be performed and packages that are to be classified as Type A.

Contrary to the above, the licensee has not tested packages as required by 49 CFR. Specifically, none of the licensee's Samsonite attache transport packages had been certified as Type A containers.

This is a Severity Level IV Violation (Supplement VI).

5. 10 CFR 19.11(b) requires that the license, license conditions, documents, incorporated into the license, license amendments, and operating procedures be posted, or that a notice describing these documents and where they may be examined, be posted.

Contrary to the above, these documents were not posted as required. Specifically, at Woodward Nuclear Laboratory only Amendment 5 of the license was posted.

This is a Severity Level V violation (Supplement VI).

6. License Condition 19 requires that all licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated June 17, 1983.

Item No. 6 of the referenced letter states that all activity will be removed each day from each location and returned to the "base station."

Contrary to the above, all activity has not been removed from each location and returned to the base station. Specifically, the following facilities store calibration sources on the premises:

Radiological Imaging
Consultants
43555 Dalcoma, Suite 2
Mt. Clemens, Michigan

Medical X-Ray
31500 Schoolcraft
Livonia, Michigan

Woodward Nuclear Laboratory P.C.
3800 Woodward Avenue
Suite 1202
Detroit, Michigan

Cardiac Diagnostic and
Rehabilitation Center
2370 Walton Blvd.
Rochester, Michigan

In addition, other activity such as unused doses, spent doses, and waste being decayed are left at the facilities at the end of the day.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

12/10/84
Dated

W. L. Axelson, Chief
Nuclear Materials Safety and
Safeguards Branch

U. S. NUCLEAR REGULATORY COMMISSION
REGION III

Report No. 30-18190/84-02(DRSS)

Docket No. 30-18190

Licensee: Radiological Imaging Consultants
5339 Kellen Lane
Bloomfield Hills, MI 48013

Inspection At: Shores Nuclear and Ultrasound Diagnostics
24025 Greater Mack Avenue
St. Clair Shores, MI

Radiological Imaging Consultants
43555 Dalcoma, Suite 2
Mt. Clemens, MI

Medical X-Ray
31500 Schoolcraft
Livonia, MI

Woodward Nuclear Laboratory
3800 Woodward Avenue
Detroit, MI

Cardiac Diagnostic and Rehabilitation Center
2370 Walton Blvd.
Rochester, MI

Inspection Conducted: August 8 and 17 and November 19, 20, and 27, 1984

Inspector: T. L. Simmons D J Sreniawski for 12/10/84
Radiation Specialist Date

Reviewed By: D. J. Sreniawski, Chief D J Sreniawski 12/10/84
Nuclear Materials Safety Section 2 Date

Approved By: W. L. Axelson, Chief 12/10/84
Nuclear Materials Safety and Date
Safeguards Branch

8502130311 11pp

Inspection Summary

Special Inspection on August 8 and 17 and November 19, 20, and 27, 1984 (Report No. 30-14802/84-01(DRSS))

Areas Inspected: This was a special unannounced inspection to review the facts surrounding several allegations received by the NRC in a telephone conversation with an anonymous alleger on July 24, 1984.

Results: Of the nine allegations made, three were substantiated and one is unresolved. Six items of noncompliance were identified. One item of noncompliance was not related to the allegations.

DETAILS

1. Persons Contacted

*Mike Slugaj, Technologist
**Ram Gunabalan, M.D., Radiation Safety Officer
David Slugaj, Driver
Ann Smith, Syncor Corporation
James Camburn, Michigan Department of Public Health - Division of Radiological Health
George Selan, Technologist
Carol Winter, Technologist
Cathy Panosian, Technologist
Kathy Cantlon, Technologist
Pierre Atallah, M.D., Director, Cardiac Diagnostic and Rehabilitation Center
***Jan Campbell, Consultant, Cardiac Diagnostic and Rehabilitation Center
Karen Taliercio, Technologist

*Denotes those present at the exit interview.
**Exit interview by telephone on August 8 and November 27, 1984.
***Interviewed by telephone.

2. Purpose of Inspection

On July 24, 1984, Region III received a telephone call from an anonymous individual who alleged that certain of the licensee's activities were in violation of the license.

The special inspection was in response to the following allegations:

a. Licensee personnel have been told by Dr. R. Gunabalan that they will be fired if they contact state, federal, or local officials.

b. (1) At some time after July 20, 1984, the licensee obtained a 500 millicurie generator. The generator sits behind a glass shield with no side or back shielding next to the dark room where another technician often works.

(2) The office above the generator was surveyed by State of Michigan personnel. The state personnel requested lead shielding be put around the generator or on the ceiling. The alleger claimed that the ceiling was painted with silver paint to make people think it was metal shielding.

c. Alleger stated that records are not kept and no accuracy, linearity, or geometrical variation tests have been performed on the recently installed dose calibrator.

d. The alleger stated that a patient was injected with Tc-99m on June 28, 1984, with dose #234503 that was drawn on June 25, 1984. This was done at the Dalcoma Clinic, 43555 Dalcoma, Suite 2, Mt. Clemens, Michigan. The patient was told that the injection did not work. She was reinjected with a dose that was drawn on June 28, 1984.

e. Needles and all waste are disposed in normal trash. No surveys are performed and no storage for decay.

f. The alleger stated that the driver, who transports unit doses to the licensee's facilities, is 15 or 16 years old. He has no film badge, no labels on the packages, improper containers, and no instructions in case of accidents.

g. Copies of the license, operating procedures, etc. were taken away from the other facilities they serve.

h. Old generators are stored in the hallway.

i. No molybdenum-99 breakthrough tests are performed.

3. Facilities

Authorized licensed material use locations are:

Woodward Nuclear Laboratory P.C.
3800 Woodward Avenue
Suite 1202

Farmington X-Ray
23800 Orchard Lake Road
Suite 103
Farmington Hills, Michigan

South Allen Radiology
22031 Ecorse Road
Taylor, Michigan

Medical X-Ray
31500 Schoolcraft
Livonia, Michigan

*Radiological Imaging Consultants
10151 Michigan Avenue
Dearborn, Michigan

Taylor Nuclear Medicine
23265 Eureka Road
Taylor, Michigan

Radiological Imaging Consultants
43555 Dalcoma, Suite 2

Radiological Imaging Consultants
222 East Sixth Street
Royal Oak, Michigan

Cardiac Diagnostic and
Rehabilitation Center
2370 Walton Blvd.
Rochester, Michigan

**Shores Nuclear and Ultrasound
Diagnostics
Suite 102
24025 Greater Mack Avenue
St. Clair Shores, Michigan

*Operations at this location have been suspended temporarily.
**Base station.

Authorized Users are:

Ram Gunabalan, M.D.
Michael Lala, M.D.
Subhash Khullar, M.D.

In August 1984, Dr. Lala submitted an application for a new NRC license. Three of the ten Radiological Imaging consultants' authorized locations, Farmington X-Ray, South Allen Radiology, and Taylor Nuclear Medicine, were requested as places of use. Dr. Lala was granted a license on September 25, 1984.

4. Inspection Findings

a. The allegation stating Dr. Gunabalan told technologists they will be fired if they contacted regulatory officials is unresolved.

On August 8, 1984, this matter was discussed with Dr. Gunabalan. At that time he stated that two employees were about to be discharged for business reasons. A new technologist was in fact being oriented at the Shores facility on that day. Dr. Gunabalan denied ever firing any employee for contacting regulatory officials or telling employees that they would be fired upon such contact. Following the November inspection, he reiterated his denial of this allegation.

Six employees of Radiological Imaging Consultants were interviewed. All denied hearing Dr. Gunabalan make this statement; however, when asked if they knew of anyone who could have been fired for this reason, names of former employees were mentioned. During subsequent interviews with these employees, the following information was obtained:

The former employees denied they had previously been told by Dr. Gunabalan that they would be fired upon contacting regulatory agencies. However, each stated that prior to dismissal they were accused of providing sensitive information to the NRC concerning the allegations addressed in this report. Both stated they had been "laid-off" due to lack of work. Each questioned this reason for lay-off because new technologists have since been hired. In addition, one individual who was laid-off was reassigned to other facilities for the two weeks prior to dismissal.

One individual feels that discrimination as defined by 10 CFR 30.7(a) has occurred and has retained a lawyer to pursue this matter through the Michigan Civil Courts.

b. (1) The allegation concerning improper shielding of the generator was not substantiated. A Mallinckrodt Mo-99 two curie generator was shipped to the Shores Nuclear and Ultrasound Diagnostic facility on July 20, 1984. The first elution occurred on July 23, 1984. Prior to this date each facility received only unit doses from Syncor Corporation. According to the technologist, the generator was placed in the scanning room alcove in a lead shield. This alcove is the same area where unit doses were received. After three or four days the generator

was moved into a room with a larger working space. A review of invoices from Mallinckrodt indicated that a lead "Ultra Shield" had been shipped with the generator. This shield is formed to fit the contour of the generator. During the inspection, the generator was observed fully clad in the lead Mallinckrodt Ultra Shield. Radiation levels at one foot from the generator were less than 1 mR/hr which is acceptable.

No item of noncompliance was identified.

(2) The alleger stated that State health personnel surveyed the office above the generator and requested that shielding be put around the generator or on the ceiling. The alleger stated that the licensee sprayed the ceiling with silver paint to make people think they put up metal shielding.

The Radiation Safety Officer (RSO) stated that shortly after the move of Shores Nuclear and Ultrasound Diagnostics to the Greater Mack Avenue address (Shores), in late 1980 or early 1981, an individual whose office was above the licensee's facility called State health personnel. The individual was concerned that he was being exposed to radiation. Only unit doses from Syncor were being used at that time.

The Michigan Division of Radiological Health was contacted on August 17, 1984 to confirm their involvement in this matter. It was learned that in March 1981 they received a call from a tenant of the building which houses the Shores facility. The tenant was concerned about a possible radiation hazard to himself since his office was above the Shores scanning room. Michigan sent an inspector to survey the tenant's office. No radiation hazard was found. However, to further assure the tenant, the Michigan inspector recommended that Shores personnel monitor the tenant's office for a period of at least three months. Shores personnel obtained monthly film badges from Landauer services and attached them to the ceiling under the tenant. Exposure records indicate that these monthly film badges were used between April 25, 1981 and April 24, 1982. All results were minimal.

The inspector observed that approximately six ceiling tiles were painted a silver color. The technologist indicated that the tiles were painted to suggest that shielding had been provided to appease the tenant in the office above. This portion of this allegation was substantiated. The inspector surveyed the generator on August 8. At one foot all readings were less than 1 mR/hr.

No items of noncompliance were identified.

c. The alleger stated that records are not kept and that no accuracy, linearity, or geometrical variation tests had been performed on the recently installed dose calibrator. The allegation was not substantiated. During a review of dose calibrator records of the five facilities visited, it was determined that the required tests

have been performed and the results of these tests indicated that the dose calibrator was within ±5% of the limits as specified by License Condition No. 19.

As of November 20, 1984, the licensee had not installed a new dose calibrator.

No items of noncompliance were identified.

d. The allegation concerning the injection of a patient with a three day old technetium-99m dose and the subsequent reinjection with the proper dose could not be substantiated. The patient in question (patient A) was scheduled for a bone scan on June 28, 1984. Patient A's chart contained the physician's diagnosis, the scan films, and a Syncor dose slip dated June 28, 1984. The Syncor dose slip (Rx 235810) was not filled in with patient A's name (see Attachment A). A search of licensee records revealed a dose slip dated June 25, 1984, with an Rx number of 234503. This dose slip was filled in with patient A's name. The technologist who performed patient A's bone scan admitted that the handwriting was his. He denied injecting patient A twice. Through a review of the schedule log and further conversation with the technologist involved, it was learned that another patient (patient B) had been scheduled for a bone scan three days before on June 25th. Patient B cancelled the appointment, thereby leaving the June 25, 1984, dose unused. Unused doses were routinely returned for credit. Syncor was contacted on August 17, 1984, and it was learned that the June 25, 1984 Rx 234503 bone scan dose had not been returned for credit.

Assuming that Patient A was injected twice, the amount of technetium-99 in the June 25 dose would have decayed to a calculated activity of approximately 4 nanocuries on June 28, 1984. The injection of this very small amount of activity would not be of any radiological significance. While injecting a patient with a three day old dose is not standard practice, it would not constitute a misadministration according to 10 CFR 35.41 definitions.

No items of noncompliance were identified.

e. The alleger stated that needles and all waste are disposed in normal trash. No surveys were performed and there is no storage for decay. This allegation was unsubstantiated.

Prior to July 23, 1984, each facility received unit doses from Syncor. During this time radioactive waste was returned to Syncor for disposal. As of July 23, 1984, the Shores facility began eluting a generator. Unit doses are now prepared at the Shores facility and transported to other facilities. Radioactive waste from the generator is held for decay in a large lead-lined container. The syringes, needles, and unused doses are returned from the other facilities to the Shores facility for decay. Other potential radioactive waste, such as counter covers, gloves, and exchange needles are held for decay at the various facilities. Each facility has adequate storage.

Four of the five facilities visited survey waste prior to disposal in normal trash and maintain records of the surveys. There were no records of such surveys at Woodward Nuclear Laboratory. Woodward personnel stated that all waste is returned to the Shores facility from that facility. A survey was performed at each facility visited and all results were within acceptable limits.

No items of noncompliance were identified.

f. The alleger stated the driver who transports unit doses is a minor and that he has no film badge, the packages were not labeled, and he has no instructions in case of an accident. In addition, it was stated that the packages are improper containers. This allegation was substantiated.

The individual who transports unit doses to three of the licensee's facilities is under 18 years of age. He had not been assigned a film badge nor had an evaluation been performed to assure that the minor has not received a dose in excess of the limits specified in 10 CFR 20.104, which states no licensee shall possess, use, or transfer licensed material in such a manner as to cause any individual within a restricted area who is under 18 years of age to receive in any period of one calendar quarter, from radioactive material in the licensee's possession, a dose in excess of 10 percent of 1.25 rems whole body and 18.75 rems extremities. The licensee is in violation of 10 CFR 20.201(b) to show compliance with 10 CFR 20.104. These regulations require an evaluation be made to assure that minor worker's dose does not exceed the specified limits.

The licensee representative stated that the current driver is temporary and that the licensee was actively seeking a new driver.

While the inspector was onsite, a package was returned. It was noted that only one White I label was affixed to the package. This labeling was in noncompliance with License Condition 19. License Condition 19 references a letter dated June 17, 1983. Item 3 of that letter states the exterior of the package will be marked "USA DOT 7A TYPE 1" as required by 49 CFR 173.350-3, and packages containing liquids will also bear the label "THIS END UP."

During an interview with the driver, it was learned that he had not been instructed as required by the aforementioned letter dated June 17, 1983. The licensee is in noncompliance of Item 4 of that letter which states: "Drivers will be trained in all items specified in 10 CFR 19.12 and will be instructed in the handling of radioactive spills and other potential emergencies. Instruction will be at hire and annually thereafter."

With regard to improper packages (container), the licensee has purchased several Samsonite attaches to be used to transport unit doses. These attaches are outfitted with foam inserts and cradles to prohibit shifting of the lead syringe holders. The licensee failed

to evaluate these packages as required by 49 CFR 173.412, which specifies design requirements for Type A packages. In addition, the licensee is in noncompliance with referenced letter dated June 17, 1983. Item 3 of that letter states that the package will conform with 49 CFR Type A design requirements.

Four items of noncompliance were identified.

g. The allegation concerning the removal of copies of the license, operating procedures, etc., from the facilities they serve was substantiated. The inspector observed that a copy of the license, license documents, and amendments were not posted as required by 10 CFR 19.11 at the Woodward Nuclear Laboratory nor was there a notice describing where these documents could be found. Only Amendment No. 5 of the license could be found at this location. The four other facilities were posted as required.

One item of noncompliance was identified.

h. The allegation concerning old generators being stored in the hallway was not substantiated. This allegation was made one day after the first generator was put into service. A Mallinckrodt Mo-99 generator was delivered to the Shores facility on July 22, 1984.

The first elution occurred on Monday, July 23. During the inspection of this facility on August 8, three generators were observed. One was in service, the other two were packed in their original shipping containers and stored in an unused lead-lined x-ray room.

No items of noncompliance were identified.

i. The allegation concerning failure of the licensee to perform molybdenum-99 breakthrough tests was not substantiated. The inspector reviewed molybdenum-99 test records. It appeared that the tests were performed on each elution. The inspector also observed the procedure being performed. The results were within limits specified in 10 CFR 35.14(b)(4)(iii) and the methodology was adequate.

No items of noncompliance were identified.

5. Additional Findings

While gathering information concerning allegation 4.e, it was determined that the licensee is in violation of License Condition No. 19.

License Condition No. 19, which references letter dated June 17, 1983, requires that all activity be removed each day from each location and returned to the "base station." The Shores facility has been designated as the base station. Unit doses are dispensed from this facility to other places of use. Each facility visited during the August and November inspections maintained a set of calibration sources. Also, at least three facilities decay waste in storage. Unused and spent doses are held at each facility until the next doses are received, usually the following day. Failure to remove the described activity from each location daily constitutes

noncompliance with License Condition No. 19 and requires a license amendment for NRC review to determine if this practice constitutes a radiation safety problem.

One item of noncompliance was identified.

6. Exit Interview

The inspector met with those individuals indicated in Section 1 of this report at the conclusion of the initial inspection on August 8, 1984 and at the conclusion of the inspection on November 20, 1984. The discussions included a review of the allegations and the apparent items of noncompliance noted in the body of this report.

Attachment: Syncor Dose Slips

SYNCOR CORP
10646 NORTHEND AVE.

FERNDALE MI 48220
313/543-8400 Rx 01

RECORD OF RECEIPT

Hospital R. I. C. -MT. CLEMENS
Doctor GUNABALAN Date 06/25/84
Radionuclide Technetium-99m
Pharmaceutical M*D*P
Procedure Bone Imaging
Lot# TC9950-84177 Expires
Assay 18.43 mCi/Ml as of 13:00
Qty. Ordered 20.0 mCi 740.0 MBq
Dispensed mCi Dispensed By
Vol. Disp. 1.09 Milliliter Rx# 234503
Patient Name
Comment:
P.O.
EXTRA CHARGE
Use as directed by physician

SYNCOR CORP 313/543-8400
Rx 234503
Expires
Tc99m MDP

SYNCOR CORP
10646 NORTHEND AVE.

FERNDALE MI 48220
313/543-8400 Rx 01

RETURN FOR CREDIT

Hospital R. I. C. -MT. CLEMENS
Doctor GUNABALAN Date 06/28/84
Radionuclide Technetium-99m
Pharmaceutical M*D*P
Procedure Bone Imaging
Lot# TC9950-84180 Expires
Assay 18.43 mCi/Ml as of 13.00
Qty. Ordered 20.0 mCi 740.0 MBq
Dispensed mCi Dispensed By
Vol. Disp. 1.09 Milliliter Rx# 235810
Patient Name
Comment:
P.O.
EXTRA CHARGE
Use as directed by physician
00

SYNCOR CORP 313/543-8400
Rx 235810
Expires
Tc99m MDP

Found during Record Search

ATTACHMENT A

RADIOLOGICAL IMAGING CONSULTANTS
BUSINESS OFFICE: STE. 102
24025 GREATER MACK
ST. CLAIR SHORES, MI 48080
779-9700

R. GUNABALAN, M.D.

January 10, 1985

Materials Safety and Safeguards Branch
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

ATTN: Ms. Toye L. Simmons

SUBJ: Response to Notice of Violation dated Dec. 11, 1984

1. Violation: No evaluation was made to show compliance with 10 CFR 20.104, which specifies dose limits for minors.

   The minor who was employed to deliver low level radioactive packages (ie. Somsonite briefcases containing unit doses of diagnostic radiopharmaceutical doses) was not monitored for radiation exposure. He was employed for three weeks at the end of July and beginning of August, 1984 as temporary help.

   The policy of Radiological Imaging Consultants is that minors cannot be hired as occupational radiation workers. All occupational radiation workers are assigned film badges and instructed in their use. Drivers who transport radioactive packages are considered occupational radiation workers.

   The individuals responsible for hiring and supervising the drivers have been instructed about the terms of this policy. Two new drivers have been hired since August of 1984 and both individuals have been instructed as specified in 10 CFR 19.12, and both are monitored by film badge.

2. Violation: Contrary to DOT regulations and NRC license conditions, radioactive packages were not labeled properly.

   The radioactive packages utilized to transport unit doses of radiopharmaceuticals (ie. Samsonite briefcases) have been labeled properly with the following: (a) proper DOT labels on both sides of the briefcases (b) "USA DOT 7A TYPE A" in letters 1/2" high (c) "THIS END UP" label for liquids, since the last week of October.

   Transportation Policies and a Driver Checklist have been established. The drivers have been instructed not to transport radioactive material in packages that are not labeled properly according to NRC and DOT regulations.

3. Violation: Contrary to items specified in 10 CFR 19.12 the driver was not instructed in the handling radioactive emergencies.

The two drivers hired since October 1984 have been instructed by the consultant radiation physicist in the items specified in 10 CFR 19.12 and the handling of radioactive emergencies (part of the Transportation Policy) at the time of hiring. The individuals responsible for hiring and supervising the drivers have been instructed about this requirement and shall advise the Radiation Safety Officer or the consultant radiation physicist whenever new drivers are hired. Annually the items specified in 10 CFR 19.12 and the Transportation Policies shall be reviewed and discussed with the drivers.

4. Violation: Samsonite attache transport packages have not been certified as Type A containers.

The Samsonite attache briefcases used to transport unit doses of radiopharmaceuticals were tested as required by 49 CFR on September 20, 1984.

a. A Samsonite attache case holding the maximum of 7 syringe holders was dropped 30 feet onto concrete on September 20, 1984. The case and syringe holders withstood the impact without release of liquid inside the case from the syringes (which contained non-radioactive liquid).

b. Liquid absorption of the foam contoured interior of the attache cases was tested by pouring 20 milliliters of water into the case on September 20 ,1984. No liquid leaked outside of the case. 20 milliliters represents approximately two times the maximum volume transported.

The results of these tests are available for NRC and DOT review at 24025 Greater Mack Avenue, St. CLair Shores, MI.

5. Violation: License documents were not posted at the Woodward Nuclear Laboratory.

On November 27, 1984, the license documents were posted. The presence of the required documents was verified on December 10, 1984 during a routine inspection conducted by the consultant radiation physicist.

6. Violation: Condition No. 19 requires that all activity be removed each day from each location and returned to the "base station".

As part of an amendment request dated December 3, 1984 (Control #77482), it was requested that our license be amended to permit overnight storage of radioactive material. In a telephone conversation on December 20, 1984, Mr. McCann of NRC discussed this request with Ms. Culver, our consultant

radiation physicist, and storage of radioactive sources was to be incorporated into an amendment forthcoming from the NRC. There is adequate lead shielding (lead face shield and lead bricks) at all of the facilities currently licensed.

Sincerly,

R Gunabalan MD

Ram Gunabalan, M.D.

Weil

FEB 8 - 1985

Radiological Imaging Consultants
ATTN: Ram Gunabalan, M.D.
5339 Kellen Lane
Bloomfield Hills, MI 48913

License No. 21-20279-01

Gentlemen:

Thank you for your letter dated January 10, 1985, informing us of the steps you have taken to correct the noncompliance identified in our letter dated December 11, 1984. With respect to Item 6, while your letter states that you have filed an application for an appropriate amendment to achieve corrective action for the item of noncompliance, it should be understood that no activity is in accord with NRC regulatory requirements unless and until it is specifically authorized in an NRC license. Steps should be taken to ensure that NRC-licensed materials are hereafter possessed and used only as authorized by your license. We will examine this matter during a future inspection.

Your cooperation with us is appreciated.

Sincerely,

W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch

cc w/ltr dtd 01/10/85:
DMB/Document Control Desk (RIDS)

RIII	RIII	RIII	RIII	RIII
2/5/85 RD				
Douglas/ld	Simmons	Sremaniak	Weil	Axelson
01/28/85			2/7/85	2/7/85