UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

February 11, 2013

Docket No. 03033207 License No. 52-25255-01

Rafael Alvarado, MHSA
Administrator
Metro Ponce, Inc.
d.b.a. Hospital Metropolitano Dr. Pila
Avenida Las Americas
Ponce, PR 00733-1910

SUBJECT: NRC INSPECTION REPORT NO. 03033207/2011001, METRO PONCE, INC., D/B/A HOSPITAL METROPOLITANO DR. PILA, PONCE, PUERTO RICO

Dear Mr. Alvarado:

On December 13, 2011, Lester Tripp of this office conducted a special safety inspection at the above address of activities authorized by your NRC license. The inspection was limited to a review of the circumstances associated with an event you reported to the NRC that was initiated on August 17, 2011, at Hospital Metropolitano Dr. Pila in Ponce, Puerto Rico. Additional information, provided in your correspondence dated October 31, 2011, was also examined as part of the inspection. The findings of the inspection were discussed with you and Dr. Adrián Álvarez of your organization at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Within the scope of this inspection, no violations were identified.

No reply to this letter is required. Please contact Lester Tripp at (610) 337-5358 if you have any questions regarding this matter.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation. We apologize for the delay in concluding this inspection.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03033207/2011001

cc:
Adrián Álvarez de la Campa, M.D., Radiation Safety Officer
Commonwealth of Puerto Rico

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Sincerely,

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James P. Dwyer, Chief
Medical Branch
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Enclosure:
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cc:
Adrián Álvarez de la Campa, M.D., Radiation Safety Officer
Commonwealth of Puerto Rico

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REGION I

INSPECTION REPORT

Inspection No.	03033207/2011001
NMED No.	110572
Docket No.	03033207
License No.	52-25255-01
Licensee:	Metro Ponce, Incorporated d.b.a. Hospital Metropolitano Dr. Pila
Address:	Avenida Las Americas Ponce, Puerto Rico 00733-1910
Locations Inspected:	Avenida Las Americas Ponce, Puerto Rico 00733-1910
Inspection Dates:	December 13, 2011, with in-office review thru January 11, 2013
Exit Meeting:	January 11, 2013

Inspector: ***/RA/*** _____ ***2/11/13*** _____
Lester Tripp — date
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/*** _____ ***2/11/13*** _____
James P. Dwyer, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Metro Ponce, Inc., d.b.a. Hospital Metropolitano Dr. Pila
NRC Inspection Report No. 03033207/2011001

An announced, special inspection was conducted to review the circumstances associated with an event initiated on August 17, 2011, at Hospital Metropolitano Dr. Pila in Ponce Puerto Rico. The event was reported to NRC on October 31, 2011, and involved the possible exposure of a patient's embryo/fetus in excess of 5.0 rem (50 milliSievert) (mSv) from a 102.2 millicurie (3.78 gigaBecquerel) (GBq) iodine-131 (I-131) therapy dosage administered to the patient. While the patient was instructed not to become pregnant for one year, the licensee estimates the patient became pregnant six days after administration of the I-131 dosage and residual I-131 in her system likely provided some exposure of the embryo/fetus. The licensee estimates the embryo-fetus received between 3.0 rem (30 mSv) and 10.2 rem (102 mSv). NRC engaged the services of a medical consultant. The medical consultant concluded there was tremendous uncertainty as to when the patient became pregnant. The medical consultant concluded that, without knowing the date pregnancy began, the committed dose to the embryo/fetus is impossible to calculate. The medical consultant did not disagree with the range of exposures calculated by the licensee. The medical consultant doubted the embryo/fetus would suffer any detrimental effects

The NRC reviewed the circumstances surrounding the unintentional dose to the embryo/fetus and determined that, although the dose occurred, it was not reportable in accordance with the provisions of 10 CFR 35.3047. 10 CFR 35.3047(a) provides that a licensee report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user. 10 CFR 35.3047(b) requires reporting of a dose to a nursing child. 10 CFR 35.3047(c) provides that the licensee notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of a dose to an embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section. The regulation clearly provides a threshold of 5 rem (50 mSv) or more before a report is required. Since it cannot be determined that the dose met that threshold, but could have fallen within a range that was less than 5 rem (50 mSv), the licensee will not be cited for not reporting the incident pursuant to 10 CFR 35.3047. A 15-day report was also not required.

The root cause of the event is that the patient did not comply with the licensee's instructions not to become pregnant for one year following the I-131 dose administration. On August 17, 2011, the patient signed a pre-treatment consent form that included a statement that she would not become pregnant for one year after the ablation.

Hospital Metropolitano Dr. Pila revised its patient instructions for female patients of child bearing age who receive I-131 therapy, to stress the importance of avoiding becoming pregnant just prior to, and one year after receiving therapeutic doses of licensed material. The licensee also reviewed 10 CFR Part 35 to ensure familiarity with the NRC reporting requirements.

REPORT DETAILS

I. Program Scope

Metro Ponce, Inc., d.b.a. Hospital Metropolitano Dr. Pila, is authorized by NRC License No. 52-25255-01 to use byproduct material for medical purposes, including therapeutic nuclear medicine. The licensee performs 2-4 therapy treatments monthly using iodine-131 sodium iodide (I-131). On October 31, 2011, the licensee contacted the NRC's Headquarters Operations Center to report an exposure to the embryo-fetus of an I-131 therapy patient exceeding 5.0 rem (50 milliSievert) (mSv) dose equivalent. This report was made in accordance with the requirements of 10 CFR 35.3047.

II. Sequence of Events

a. Inspection Scope

The inspector followed up on the licensee's October 31, 2011, report by: (1) performing an onsite inspection of the licensee's facilities on December 13, 2011; (2) interviewing the physician/authorized user (AU) who provided safety instructions and administered the I-131 therapy dosage to the patient; (3) reviewing the licensee's internal and external reports associated with the event; and (4) reviewing patient and hospital records associated with the event. The inspector also reviewed patient and hospital records for other therapies to confirm this was an isolated event.

b. Observations and Findings

The inspector developed the sequence of events described below.

- A twenty-six year-old female patient was diagnosed with thyroid cancer and a thyroidectomy was performed on June 30, 2011.

- The patient was referred to the licensee's AU for consultation to receive I-131 therapy to ablate any remaining thyroid tissue. During consultation with the patient on July 26, 2011, the AU reviewed written standard precautions and instructions for the I-131 therapy. The instructions included informing the patient that she could not receive I-131 therapy if she were pregnant and that a pregnancy test needed to be performed 24 to 48 hours prior to treatment. Written instructions signed by the patient stated that the patient should not become pregnant for a period of 1 year after the I-131 therapy.

- A pregnancy test was performed on July 28, 2011, and the test determined the patient was not pregnant at that time.

- The patient reported to the licensee's facility on August 17, 2011, and was administered 102.2 millicuries (3.78 gigaBecquerels) (GBq) of I-131. This administration occurred 20 days after completion of the patient's pregnancy test.

- The patient saw her obstetrician and had pregnancy tests performed on September 21 and 22, 2011, 35 and 36 days, respectively, after administration of the I-131 therapy. Both of these tests were positive. The obstetrician estimated the patient's date of conception as August 23, 2011, six days after the I-131 was administered. The patient was referred back to the licensee's AU for evaluation of the exposure received by the patient's embryo-fetus.

- On September 28, 2011, the patient returned to the licensee's facility for evaluation. The AU notified the patient of the potential harmful effects of radiation to the embryo-fetus. The AU also notified the patient's referring endocrinologist of the exposure of the embryo-fetus. The AU requested that the licensee's medical physics consultant perform an assessment of the exposure received by the embryo-fetus from the I-131 therapy.

- On October 5, 2011, the licensee's medical physics consultant estimated that the exposure to the patient's embryo-fetus from the I-131 remaining in the patient's body was between 3.0 rem (30 milliSievert) and 10.2 rem (102 milliSievert) dose equivalent. This exposure estimate was based on the obstetrician's estimated date of conception of August 23, 2011.

- On October 31, 2011, the licensee contacted the NRC's Headquarters Operations Center to report an exposure to the embryo-fetus of an I-131 therapy patient exceeding 5.0 rem dose equivalent. This report was made in accordance with the requirements of 10 CFR 35.3047(a).

- On October 31, 2011, the licensee filed a 15-day report in accordance with the requirements of 10 CFR 35.3047(d).

c. Conclusions

The inspector concluded that the sequence of events was clear and well understood except for the uncertainty associated with the determination of the date of conception.

III. Written Safety Instructions

a. Inspection Scope

The inspector reviewed the written safety instructions provided by the licensee to therapy patients who are released from the licensee's control in accordance with 10 CFR 35.75. The inspector also interviewed the AU who provided these written safety instructions to the patient associated with the event and reviewed written records of instruction provided to the patient associated with the event.

b. Observations and Findings

10 CFR 35.75(b) requires a licensee to provide a released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 100 millirem (1 mSv). Volume 9 of NUREG-1556, "Consolidated Guidance About Materials Licenses - Program-Specific Guidance About Medical Use Licenses," contains in Appendix U, a "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials." Table U.2 uses conservative assumptions to estimate a patient administered 7 millicuries (0.24 GBq) or more of I-131 should be given instructions when authorizing the patient's release.

The inspector determined that during consultation with the patient on July 26, 2011, the AU reviewed written standard precautions and instructions for the I-131 therapy. The instructions included informing the patient that she could not receive the I-131 therapy if she were pregnant and that a pregnancy test needed to be performed 24 to 48 hours prior to treatment. The inspector noted that written instructions signed by the patient prior to the administration of her I-131 dosage on August 17, 2011, indicated that the patient should not become pregnant for a period of 1 year after the I-131 therapy. The patient received the 102.2 millicurie (3.78 GBq) I-131 therapy dose on August 17, 2011. Pregnancy tests performed on September 21 and 22, 2011, were positive. The patient's obstetrician concluded the most likely date of conception to be August 23, 2011.

c. Conclusions

The inspector concluded that, in accordance with 10 CFR 35.75(b), the licensee provided the patient with adequate instructions prior to administering her I-131 dosage and releasing her from the licensee's control. The inspector noted that it is not the licensee's responsibility to enforce patient compliance with the instructions.

IV. Exposure Assessment

a. Inspection Scope

The inspector: (1) interviewed the AU; (2) reviewed records of pregnancy test results performed on the patient; (3) reviewed the exposure assessment performed for the patient's embryo-fetus by the licensee's medical physics consultant; (4) reviewed the licensee's 15-day report dated October 31, 2011; and (5) engaged the services of a NRC Medical Consultant to perform an independent assessment of the exposure received by the patient's embryo-fetus from the I-131 therapy.

b. Observations and Findings

The AU was advised of the patient's pregnancy by the patient's obstetrician on September 28, 2011. The AU requested that the licensee's medical physics consultant perform an assessment of the exposure received by the patient's embryo-fetus from the

I-131 therapy. On October 5, 2011, the medical physics consultant used the August 23, 2011 date of conception, estimated by the patient's obstetrician, to estimate an exposure of between 3.0 rem (30 mSv) and 10.2 rem (102 mSv). The inspector noted that, using the obstetrician's estimated August 23, 2011 date of conception, the patient was not pregnant on August 17, 2011 at the time the I-131 was administered. In this case, the exposure of the embryo-fetus resulted from residual I-131 still circulating in the patient's body. The inspector noted that the uncertainty in the level of the embryo-fetus exposure reported by the licensee is due to the uncertainty in the concentration of I-131 circulating in the patient's body, not uncertainty in the date of conception.

NRC engaged the services of a medical consultant to: (1) gather medical information for the evaluation of the effects of radiation exposure on the embryo-fetus; (2) provide a professional opinion on the magnitude of the radiation dose to the embryo-fetus and probable error associated with the estimation of the dose; and (3) assess any probable deterministic effects on the embryo-fetus. In his report, received April 3, 2012, the medical consultant concluded there is tremendous uncertainty as to when the patient became pregnant. The medical consultant stated that the beta human chorionic gonadotropin (B-HCG) level from the pregnancy test performed on September 21, 2011 could be seen at 2-5 weeks gestational age, a span of 21 days. The medical consultant concluded that without knowing the date when pregnancy began, the radiation dose is impossible to calculate. The medical consultant stated that the August 23, 2011 gestational date estimated by the patient's obstetrician is an impossible assumption based on the B-HCG level. The medical consultant estimated that the embryo-fetus received between 0 rem and 10 rem (0 to 100 mSv) with a probable error of 100 percent. Further, he stated that embryonic thyroid tissue capable of concentrating I-131 is formed between 10 and 12 weeks of gestation; therefore, there would be no effects on the fetal thyroid from the I-131 administered. Finally, the medical consultant stated he doubted that there were any detrimental effects on the embryo-fetus from this event.

c. Conclusions

The inspector concluded that the patient's obstetrician was best informed by the patient and available pregnancy test results and therefore best able to establish the date of conception. The licensee's estimate of the exposure to the embryo-fetus of between 3.0 rem and 10.2 rem is not significantly different from the medical consultant's estimate of between 0 rem and 10 rem.

V. Reportability

a. Inspection Scope

The inspector reviewed the licensee's actions in response to this event, and reviewed the requirements of 10 CFR 35.3047.

b. Observations and Findings

The inspector noted that while the I-131 therapy was administered to the patient on August 17, 2011, the licensee was not aware of the patient's pregnancy until September 28, 2011 and, on that date, the licensee's AU requested that the licensee's medical physics consultant perform an assessment of the exposure received by the patient's embryo-fetus. On October 5, 2011, the licensee's medical physics consultant concluded the embryo-fetus received between 3.0 rem and 10.2 rem radiation exposure. Uncertainty of the data used to make this assessment requires that an exposure range be reported.

10 CFR 35.3047(a) provides that a licensee report any dose to an embryo/fetus that is greater than 5.0 rem (50 mSv) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user. 10 CFR 35.3047(b) requires reporting of a dose to a nursing child. 10 CFR 35.3047(c) provides that the licensee notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of a dose to an embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

The regulation clearly provides a threshold of 5 rem (50 mSv) or more before a report is required. Since it cannot be determined that the exposure met that threshold, but could have fallen within a range that was less than 5 rem (50 mSv), the licensee will not be cited for not reporting the incident pursuant to 10 CFR 35.3047. In addition, a 15-day report was not required.

c. Conclusions

Because the range of estimated embryo-fetus exposures extended below the 5.0 rem reporting threshold, no 24-hour notification of the NRC Headquarters Operations Center or 15-day written report, as described in 10 CFR 35.3047, was required for this event.

VI. Corrective and Preventive Actions

a. Inspection Scope

The inspector interviewed the AU/RSO and reviewed corrective actions taken in response to this event. The corrective actions were designed to avoid radiation dose to any embryo/fetus which would be caused by administration of I-131 to a pregnant individual.

b. Observations and Findings

The inspector noted that the licensee implemented prompt and comprehensive corrective actions in response to this event. Hospital Metropolitano Dr. Pila revised its instructions for female patients of child bearing age who receive I-131 therapy to stress the importance of avoiding pregnancy just prior to, and one year after receiving therapeutic doses of licensed material. Also**, a**s a result of this event, the AU reviewed all the provisions of 10 CFR Part 35 to ensure he is familiar with all medical requirements, including NRC reporting requirements.

c. Conclusions

The inspectors determined that the licensee's corrective actions were reasonable and adequate to: (1) prevent future embryo/fetus exposures from I-131 therapies; and (2) ensure any exposures of this type are promptly reported to NRC in accordance with 10 CFR 35.3047.

VII. Exit Meeting

A preliminary exit meeting was conducted during the on-site inspection on December 13, 2011. The inspector conducted in-office reviews of records and reports and engaged the services of a NRC Medical Consultant. A final exit meeting was conducted on January 11, 2013. The inspector stated to the licensee that the NRC reviewed the circumstances surrounding the unintentional dose to the embryo/fetus and determined that, although the dose to the embryo/fetus occurred, it was not reportable in accordance of the provisions of 10 CFR 35.3047

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Rafael Alvarado, MHSA
Administrator
Hospital Metropolitano Dr. Pila

Adrián Álvarez de la Campa, M.D.
Authorized User and Radiation Safety Officer
Hospital Metropolitano Dr. Pila