UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

July 2, 2012

NMED 110-482

The Queen's Medical Center
Attn: Ms. Darlena Chadwick,
Vice President,
of Patient Care Professional Services
1301 Punchbowl Street
Honolulu, Hawaii 96813

SUBJECT: NRC INSPECTION REPORT 030-14522/2011-001 AND NOTICE OF VIOLATION

Dear Ms. Chadwick:

This refers to the reactive inspection conducted on September 19-24, 2011, at your facility in Honolulu, Hawaii, with continued in-office review through June 13, 2012. The inspection was conducted in response to a medical event that occurred at your facility on September 13, 2011. The medical event was documented in your notification report to the NRC dated September 13, 2011. The preliminary inspection findings were discussed with you and Mr. Brian Oyadomari Radiation Safety Officer (RSO), at the conclusion of the onsite portion of the inspection. Additional information was obtained by telephone and electronic mail correspondence. In-office reviews included an evaluation of your report dated September 28, 2011 (ML11277A105), and your thirty day report dated October 21, 2011 (ML11314A212), summarizing your assessment of the medical event. A final exit briefing was conducted by telephone with Mr. Oyadomari and other members of your staff on June 13, 2012.

The inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observation of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) (Enclosure 1) because they were identified by the NRC. The circumstances surrounding them are described in detail in the inspection report (Enclosure 2). The violations involved failures to: (1) develop, maintain and implement procedures for the safe use of unsealed licensed material (2) implement the "Hot Lab Responsibilities" written procedure; and (3) implement "Rules for Safe Use of Radiopharmaceuticals" written procedure related to unsealed licensed material.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its Enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

Should you have any questions concerning this inspection or the enclosed report, please contact me at (817) 200-1130 or Rick Muñoz at (817) 200-1220.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch A

Docket No.: 030-14522
License No.: 53-16533-02

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 030-14522/11-001
3. Excerpt from NRC Information Notice 96-28

cc w/Enclosures 1 and 2:
Hawaii Radiation Control Program Director

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NOTICE OF VIOLATION

The Queen's Medical Center
Honolulu, Hawaii

Docket: 030-14522
License: 53-16533-02

During an NRC reactive inspection conducted during the period of September 19, 2011, through June 13, 2012, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. License Condition 21 of NRC Byproduct Materials License 53-16533-02, Amendment 63, requires, in part, that the licensee shall conduct its program in accordance with license application dated August 30, 2004. Item 10.3 of that license application, "Safe Use of Unsealed Licensed Material" states, in part, that the licensee has developed and will implement and maintain written procedures for safe use of unsealed licensed material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

   10 CFR 20.1101 (a) states that each licensee shall develop document and implement a radiation protection program commensurate with the scope and extent of licensed material and sufficient to ensure compliance with the provisions of this part. 10 CFR 20.1101 (b) states that the licensee shall use to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are as low as is reasonably achievable (ALARA).

   Contrary to the above, from August 30, 2004, through September 13, 2011, the licensee failed to develop, implement and maintain written procedures for the safe use of unsealed licensed material that met the requirements of 10 CFR 20.1101 and 10 CFR 20.1301. Specifically, the licensee's program failed to address the storage, segregation, or disposal of unsealed therapeutic doses to prevent inadvertent use of the radiopharmaceutical. As a result, a technologist inadvertently injected a dose with the wrong radionuclide and activity into a patient.

   This is a Severity Level IV violation (Section 6.3)

2. License Condition 21 of NRC Byproduct Materials License 53-16533-02, Amendment 63, requires, in part, that the licensee shall conduct its program in accordance with license application dated August 30, 2004. Item 10.3 of that license application, "Safe Use of Unsealed Licensed Material" states, in part, that the licensee has developed and will implement and maintain written procedures for safe use of unsealed licensed material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

   Item number 6 of the "Daily Checklist for Hot Lab Responsibilities" and item number 5 under the "Daily Checklist for On Call Technologist" procedures required the technologist to "Throw Away All Expired Doses."

   Contrary to the above, from August 3, through September 12, 2011, the licensee failed to throw away all expired doses. Specifically, a therapeutic dose of 3.99 mCi of

strontium-89, assayed on July 6, 2011, expired on August 2, 2011, and it remained in the hot lab area 41 days beyond its expiration date, rather than being thrown away as required.

This is a Severity Level IV violation (Section 6.3)

3. License Condition 21 of NRC Byproduct Materials License 53-16533-02, Amendment 63, requires, in part, that the licensee shall conduct its program in accordance with license application dated August 30, 2004. Item 10.3 of that license application, "Safe Use of Unsealed Licensed Material" states, in part, that the licensee has developed and will implement and maintain written procedures for safe use of unsealed licensed material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

   Item number 15 of the "Rules for Safe Use of Radiopharmaceuticals" procedure, states in part, check the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administering.

   Contrary to the above, on September 13, 2011, the licensee administered a dose and failed to check the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administering. Specifically, the licensee administered a 1.47 mCi dose of strontium-89 when the prescribed dose was for 6.0 mCi of indium-111, and did not check the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administering the dose.

   This is a Severity Level IV violation (Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, The Queen's Medical Center, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission , ATTN: Document Control Desk, Washington DC 20555-0001, with a copy to the Regional Administrator Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance was, or will be, achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is

necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 2nd day of July 2012

U.S. Nuclear Regulatory Commission
Region IV

Docket No.:	030-14522
License No.:	53-16533-02
Report No.:	030-14522/2011-001
Licensee:	The Queen's Medical Center
Location:	Honolulu, Hawaii
Dates:	September 19, 2011 through June 13, 2012
Inspector:	Rick Muñoz, Health Physicist Nuclear Materials Safety Branch A
Approved By:	G. Michael Vasquez, Chief Nuclear Materials Safety Branch A
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

The Queen's Medical Center
NRC Inspection Report 030-14522/2011-001

This was a reactive, announced inspection following the licensee's telephonic notification to the NRC Headquarters Operations Office of a medical event that occurred on September 13, 2011. The inspector reviewed licensee records, evaluation reports, and the medical consultant's report, as well as conducted interviews with licensee personnel at the licensee's facility. This report describes the findings of the inspection.

Summary of Event

The medical event involved the erroneous injection of a strontium-89 (Sr-89) unsealed therapeutic dose instead of the intended imaging dose of indium-111. Sr-89 is a bone seeker, so the patient received an unintended dose to the bone. The Sr-89 single unit dose had been in the hot lab from July 6, 2011, until September 13, 2011, after a patient did not show up for a scheduled procedure. The licensee's staff did not remove the Sr-89 dose from the hot lab drawing area and store it or dispose of it. A Certified Nuclear Medicine technologist (CNMT) accidently used the Sr-89 dose to inject a patient. (Section 2)

Causes

The licensee's assessment of the direct cause of the medical event was human error. A CNMT thought the dose was indium-111, but realized post injection that it was the expired Sr-89 dose. The CNMT administered the wrong dose following a breakdown in a number of procedural protocols. (Section 3)

Inspection Findings

The NRC identified three violations involving the failure to (1) develop, implement and maintain written procedures for the safe handling and disposal of unused therapeutic doses, (2) dispose all expired doses, and (3) verify the patient's name and identification number and the prescribed radionuclide, chemical form and dosage before administration. (Section 4)

NRC Medical Consultant Report

The NRC's medical consultant reviewed the case and determined that multiple errors had occurred within the nuclear medicine department. The consultant concluded that the bone marrow dose of 650 mSv (65 rem) agreed with the licensees calculation based on the packet insert. The patient exhibited transient symptoms in eight (8) weeks with a decreased count in platelets and neutrophils showing recovery at twelve (12) weeks. Based on the National Academy of Sciences, Biologic Effects of Ionizing Radiation (BEIR) Report -VII, *Health Risks for Exposure to Low Levels of Ionizing Radiation* projections for the risk of carcinogenesis (aka cancer), the dose received in this incident, represents a stochastic effect. According to BEIR-VII, without any radiation exposure, for every 100 people there will be an average of 42 incidents of cancer. A stochastic effect represents an increase in the incident of cancer by 1, for this same population of 100 people for every 100 mSv of radiation exposure those 100 people receive. This risk is commonly expressed as 1/100/100 mSv. The patient appeared to have a

mildly increased risk for uncommon marrow cancers. The consultant agreed that the licensee's proposed corrective actions were reasonable and appropriate to preclude recurrence. (Section 5)

Licensee Corrective Actions

The licensee instituted corrective actions following its discovery of the medical event that included:

- segregation of the storage areas for therapeutic radiopharmaceuticals, long-lived diagnostic radiopharmaceuticals, and technetium-99^{m} radiopharmaceuticals with distinct container labeling,

- a double-validation entry into the electronic record system for nuclear medicine procedures that requires a second technologist to validate the correct dose has been prepared for the specified examination prior to administration, and

- development of a procedure for unused doses which are kept in the hot lab for future use until their expiration date.

The licensee's response and corrective actions were sufficient to address the causes of the incident. (Section 6)

Report Details

1 Program Overview (87103, 87131)

1.1 Inspection Scope

The inspector reviewed The Queen's Medical Center's (Queen's) NRC byproduct materials license 53-16533-02. The inspector reviewed the license docket file, written procedures, and other records maintained by the licensee. Collectively, these documents described the licensee's radiation safety program. The inspector interviewed licensee personnel to characterize the therapeutic and diagnostic imaging use of unsealed licensed material.

1.2 Observations and Findings

Queen's was authorized under NRC License 53-16533-02 to use byproduct material for diagnostic and therapeutic procedures as defined in 10 CFR 35.100-1000 under broad scope authority including a high dose rate (HDR) remote afterloader and blood irradiation program. Queen's had a byproduct material program for medical imaging and therapy, including the use of unsealed indium-111 (In-111) for diagnostic imaging and strontium-89 (Sr-89) for therapeutic applications. The nuclear medicine department employed 10 nuclear medicine technologists using six imaging cameras. Approximately 20-25 studies were performed daily using technetium-99^{m}. Radionuclides used in large quantities are ordered in bulk and delivered by the vendor radiopharmacy to the hospital radiopharmacy, where they are subdivided by the hospital radiopharmacist before delivery to the nuclear medicine hot lab, other nuclides used in small quantities are ordered in single unit doses from a vendor radiopharmacy and delivered directly to the nuclear medicine hot lab. All therapy and diagnostic imaging procedures were performed under the direction and supervision of authorized user physicians as defined in 10 CFR 35.2.

1.3 Conclusions

The radioactive materials used by the licensee were consistent with the approved usages authorized under the license.

2 Background (87131, 87103)

On July 6, 2011, a 4.0 mCi single unit dose of Sr-89 (Metastron) was delivered by the vendor radiopharmacy to the Queen's nuclear medicine department and checked into the hot lab. The patient did not arrive; therefore, the procedure was canceled. The unused single unit dose of Sr-89 remained in the lead container in the drawing area of the Queen's hot lab. It was not placed in a different storage location for disposal.

On September 13, 2011, a patient was scheduled for an In-111 (Octreotide) bone imaging scan. At 9:30 am, the patient arrived for a scheduled scan at 10:00 am. At about the same time, the 6 mCi single unit dose of In-111 was delivered to the hot lab by the vendor radiopharmacy and the package was checked-in. At approximately 10:05 am, the certified nuclear medicine technologist (CNMT) entered the hot lab drawing area, opened a sealed lead container, assayed the dose, proceeded to the injection

room, observed the patient's name, date of birth, and injected the dose. However, the technologist did not confirm that the name of the patient was the same as on the label of the dose.

After administering the dose, the CNMT returned to the hot lab to enter the information into Queen's Nuclear Materials Information System (NMIS), the electronic data system. It was at that point that the CNMT noticed the differences in the patient's name, radionuclide, and activity and realized s/he had injected the patient with the Sr-89 therapeutic dose rather than the prescribed In-111 imaging dose. The CNMT immediately notified the Lead Nuclear Medicine CNMT. The RSO and the authorized user, a nuclear medicine physician, were also notified at that time. The authorized user notified the patient at 11:30 am.

During the imaging procedure on September 13, 2011, the technologist did not recognize that Sr-89 was a beta emitter, did not remember that In-111 was the correct radioisotope, and failed to remember that that the minimum Octreotide dosage was 5.4 mCi. Had the technologist caught any one of these errors or noticed the incorrect patient name on the Sr-89 dose, the medical event could have been averted. In addition, Queen's assessment was that the medical event was a result of the CNMT failing to comply with 10 CFR 35.27 by not following established written radiation safety procedures.

A number of causal effects led the CNMT to administer the incorrect radionuclide. The dose administered had not been removed from the common injection area since July 6, 2011, even though it was not going to be used. Although the CNMT did observe the patient's information, the CNMT did not compare the patient's name with the name on the dose prescription label and radiopharmaceutical for the examination ordered. The CNMT did not verify the dose calibrator measurement with the specified dose on the syringe. The CNMT accepted the assay measurement of 1.5 mCi of Sr-89 instead of the prescribed dose of 5-6 mCi of In-111.

The licensee reported a medical event to the NRC in accordance with the requirements in 10 CFR 35.3045(a)(3). A preliminary notification, PNO-IV-2011-006 (ML112580187), was issued from the NRC Region IV office on September 15, 2011, NMED number 47263. The medical event involved Sr-89, a therapeutic unsealed source, being accidentally administered instead of an intended imaging dose of In-111, resulting in a radiation dose to an unintended site. Because of the use of the incorrect radionuclide (Sr-89), the licensee reported that the patient received a calculated dose of 630 mSieverts (mSv) or 63 rem, representing an unintended dose to the bone.

3 Causes of the Medical Event (87103, 87131)

3.1 Inspection Scope

Through interviews of licensee personnel and examination of and review of therapy procedures and records, the inspector evaluated the medical event to determine its direct and contributing causes.

3.2 Direct and Contributing Causes:

The NRC determined that the direct cause of the misadministration was attributed to human error involving the CNMT at Queen's failing to comply with established written radiation safety procedures.

The NRC identified a number of causal effects that led to the medical event including:

- There were no written procedures for the storage, segregation or disposal of canceled or unused therapeutic doses (before the dose expires).

- The staff failed to adhere to written procedures that required the technologist opening the hot lab for the day and the On-Call technologist to "Throw away ALL expired doses" at the beginning and end of each day. The Sr-89 dose expired on August 2, 2011, and every staff member of the nuclear medicine department had the responsibility at one time or another to dispose of the expired dose.

- The licensee had failed to individually identify or label the storage boxes located in the dose drawing and assay area under fume hood. Three boxes were in close proximity, one each for diagnostic bulk doses, quality control sources, and therapeutic doses.

- The technologist was focused on hurrying to minimize the patient's inconvenience. Imaging using In-111 cannot be performed until 24 hours post injection. The administering CNMT was more focused on the patient's comfort and convenience than ensuring procedural requirements.

- The CNMT did not follow the department's written procedures which described routine prescribed doses for each radionuclide and prohibited use of doses more than 10% different than the routine prescribed dose for that radionuclide. The routine dose for Sr-89 was 4 millicuries (mCi) and the routine dose of In-111 was 6 mCi. The dose assayed by the CNMT was 1.4 mCi of Sr-89.

3.3 Conclusions

The licensee and the NRC concluded that human error by the CNMT contributed to the medical event. In addition, a number of causal effects contributed to the medical event. The main cause for the event was the absence of written procedures to account for storage, segregation or disposal of unused or canceled therapeutic doses and failing to follow established protocols for the safe handling of unused or expired doses.

4 Inspection Findings (87103, 87131)

4.1 Inspection Scope

The special inspection consisted of selected examination of procedures and representative records pertaining to the medical event, observations of activities, and interviews with nuclear medicine personnel. The inspector reviewed Queen's NRC byproduct material license and reviewed the licensee's established written procedures, and other records related to the use of unsealed licensed material for therapeutic and diagnostic imaging. The inspector evaluated the effectiveness of radiation safety procedures involving unsealed licensed material.

4.2 Observations and Findings

The inspector identified a total of three violations. The first violation involved the failure to develop an adequate procedure, and the remaining two violations each involved failures to follow two procedures. The violations are described below.

License Condition 21 of NRC Byproduct Materials License 53-16533-02, Amendment 63, requires, in part, that the licensee conduct its program in accordance with license application dated August 30, 2004. Item 10.3 of the license application, "Safe Use of Unsealed Licensed Material" states, in part, that the licensee has developed and will implement and maintain written procedures for safe use of unsealed licensed material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Title 10 of the Code of Federal Regulations (10 CFR) Part 20.1101(a) states that each licensee shall develop, document and implement a radiation protection program commensurate with the scope and extent of licensed material and sufficient to ensure compliance with the provisions of this part. 10 CFR 20.1101(b) states that the licensee shall use to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are as low as is reasonably achievable (ALARA).

The first violation is that Queen's had not developed and implemented procedures to address the storage, segregation or disposal of unsealed therapeutic doses in the hot lab area. The failure of the licensee to develop, implement and maintain written procedures for the safe use of unsealed licensed material that met the requirements of 10 CFR 20.1101(b) and 10 CFR 20.1301 was identified as a violation of License Condition 21. (030-14522/2011-001-01)

The licensee had developed and implemented a procedure titled "Daily Checklist for Hot Lab Responsibilities"/"Daily Checklist for On Call Technologist." Item number 6 of the "Daily Checklist for Hot Lab Responsibilities" and item number 5 under the "Daily Checklist for On Call Technologist" procedure required the technologist to "Throw Away All Expired Doses."

The second violation is that from August 3, through September 13, 2011, a therapeutic dose of Sr-89 was not thrown away after it expired on August 2, 2011. The failure to adhere to the "Daily Checklist for Hot Lab Responsibilities"/"Daily Checklist for On Call Technologist," was identified as a violation of License Condition 21. (030-14522/2011-001-02)

Item number 15 of the "Rules for Safe Use of Radiopharmaceuticals" procedure, states in part, that the licensee will check the patient's name, identification number, prescribed radionuclide, chemical form and dosage before administering the dose to the patient.

The third violation is that on September 13, 2011, the licensee administered a dose and failed to adequately check the patient's name, identification number, prescribed radionuclide, chemical form and dosage before administering the dose to the patient. Specifically, although the CNMT stated she had verified that patient's name, identification number, prescribed radionuclide, chemical form and dosage before administering the dose, the verification was not adequate to identify that none of verified parameters matched the information on the dose syringe. The CNMT verified the information on the order matched the patient rather than the information on the vial. The failure to adhere to the "Rules for Safe Use of Radiopharmaceuticals," procedure was identified as a violation of License Condition 21. (030-14522/2011-001-03)

4.3 Conclusions

The inspection identified three violations of NRC requirements involving the failure to (1) develop, implement and maintain written procedures for the safe use of unused therapeutic doses, (2) dispose of all expired doses, and (3) check the patient's name, identification number, prescribed radionuclide, chemical form and dosage before administration of the dose.

5 NRC Medical Consultant Reports (87103, 87131)

As part of the reactive inspection charter, the NRC staff contracted with a medical consultant to evaluate the medical aspects of the event and determine possible health effects associated with the radiation exposure to the patient's bone. The NRC received the consultant's report on March 16, 2012.

The consultant independently assessed the dose to the bone. Blood samples covering a period from before the medical event through 12-weeks post administration, were collected and analyzed. The patient exhibited transient symptoms. The blood platelet count dropped 38% in eight weeks and the white blood cell count dropped 26%, showing recovery at 12 weeks, which is consistent with exposure to Sr-89. The medical consultant calculated a bone dose of 650 mSv (65 rem), which agreed with the licensee's calculations. The medical consultant stated that the degree of bone marrow suppression (decrease in blood platelets and white blood cells) that occurred was slightly greater than expected for that calculated bone dose.

Based on the National Academy of Sciences, Biologic Effects of Ionizing Radiation (BEIR) Report -VII, *Health Risks for Exposure to Low Levels of Ionizing Radiation* projections for the risk of carcinogenesis (cancer), the dose received in this incident, represents a stochastic effect. Under the BEIR model, for each population of 100 people there will be an average of 42 incidents of cancer without any radiation exposure. A stochastic effect represents an increase in the incident of cancer by 1, for this same population of 100 people for every 100mSv of radiation exposure received by that population. This risk is commonly expressed as 1/100/100mSv. Therefore, the patient appeared to have a mildly increased risk for cancer. The consultant's assessment of the possible health effects associated with the radiation dose to unintended tissue indicated

that there was a slight risk of adverse consequences, and the patient's prognosis remained positive.

The medical consultant's report agreed with the licensee and the NRC assessments that the attributed cause for the event was simply human error. In addition, the medical consultant reviewed the case and determined that multiple errors had occurred within the nuclear medicine department.

6 Licensee Evaluation and Corrective Actions (87103, 87131)

6.1 Inspection Scope

The inspector's review of the licensee's evaluation of the medical event and corrective actions resulting from the event included interviews with licensee personnel, a review of the licensee's initial medical event report to the NRC, and a review of departmental policies and procedures.

6.2 Observations and Findings

Queen's submitted a 30 day report on September 15, 2011 (ML112580187), as required. In addition, Queen's submitted a supplemental report on October 21, 2011 (ML11314A212). Based on the licensee's interviews with nuclear medicine personnel, review of the radiopharmaceutical administration procedure, a review of the nuclear medicine information system (NMIS), and meeting with the Manager and Director of Imaging, the licensee evaluated the medical event to determine the direct and contributing causes.

Queen's initiated corrective actions in response to the medical event. Although there were standard operating procedures and departmental policies in place and experienced staff available to deter the medical event from occurring, staff failed to follow established written procedures. To reinforce the existing policies and procedures, Queen's implemented a written checklist for nuclear medicine staff to complete and initial once all tasks were completed.

6.2.1 Immediate Corrective Actions:

The nuclear medicine senior technologist took immediate corrective actions in response to the medical event which included:

- Segregated therapy radiopharmaceuticals and high-risk radioisotopes such as In-111 and Ga-67 from Tc-99^m radiopharmaceuticals.

- Contacted the local radiopharmacies requesting them to place distinctive labels at the top of all single unit dose syringe containers that identify the radioactive material contained within the lead shield.

- Segregated the storage areas for therapeutic radiopharmaceuticals, long-lived diagnostic radiopharmaceuticals, and technetium-99^m radiopharmaceuticals.

- Implemented a double-validation step into the Radiant electronic record system for all nuclear medicine procedures (except Tc-99^m, Xe-133, and blood volume

examinations). This will require a second technologist to validate the correct dose has been prepared for the specified examination prior to administration.

- Posted the document titled “Dose Range for Administration of Radiopharmaceuticals” on the hot lab wall next to the dose calibrator in order to be readily visible as a cue to the technologist during dose assays.

- Individually identified and labeled the storage boxes located in the fume hood around the dose drawing and assaying area. The diagnostic bulk dose box, the quality control source box, and the therapeutic doses boxes were distinctively identified.

6.2.2 Long Term Corrective Actions:

- The RSO reviewed the “Rules for Safe Use of Radiopharmaceuticals” with all CNMTs as part of in-service training.

- Queen’s developed and implemented a procedure for the retention and maintenance of a record of the technologist performing the double-validation using the NMIS electronic record.

- Revised the “Radiopharmaceutical Use Authorization” written procedure to require all technologists to input all doses into the NMIS prior to radiopharmaceutical administration. This provides visual cues for the correct radiopharmaceutical for each procedure and will automatically flag doses that have not been checked in and dose assays that are not within the prescribed dose range.

- Provided the CNMT involved in the medical event with remedial training and competency validation for all high-risk radioisotopes and procedures. The lead senior technologist provided additional supervision of this technologist for specified high-risk diagnostic examinations. The CNMT eventually resigned.

- Queen’s will implement core competency validation for high-risk diagnostic examinations in the annual nuclear medicine technologist’s performance evaluation program (i.e. Performance Excellence Program).

- Implemented a Hot Lab Checklist to reinforce existing procedures. All staff were trained on the new procedure. The checklist records are be maintained and audited by the RSO or Assistant RSO.

- Implemented a Hot Lab Logbook to document tracking of high-risk doses such as I-131, Sr-89, and P-32. Technologists are required to initial the log every day even if no high-risk doses are stored. A designated technologist is required to verify completion of this tracking action the following morning.

- Developed a procedure for unused doses that are kept in the hot lab for future use until expiration.

- The RSO added the Hot Lab Checklist and Hot Lab Logbook as line item reviews in the monthly RSO audits.

6.3 Conclusions

The licensee instituted immediate and long-term corrective actions following its discovery of the medical event. Administrative and other performance improvement changes were made to the radiation protection program relative to the safe use of unsealed licensed material. The licensee's response and corrective actions were sufficient to address the causes of the event.

7 Exit Meeting Summary (87103, 87131)

A preliminary site exit briefing was conducted with the Vice President and with the RSO at the conclusion of the onsite portion of the inspection. Multiple follow-up telephone calls and electronic mail correspondence was conducted with Queen's. A final exit meeting was conducted telephonically with the Vice President and with the RSO on June 13, 2012, to review the findings as presented in this report. The licensee acknowledged the inspector's findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACT

Licensee

Brian Oyadomari, RSO
Darlena Chadwick, VP of Patient Care
Deann Ishihara-Wong, Director of Oncology Services
Ronald Digiaimo, CEO Revenue Cycle, Inc.
Jhun Fronda, Medical Physics Technician
Kathy Sugai, Nuclear Medicine Manager
Barbara Kaaiallii, CNMT
Brad Kim, CNMT
Elisa Talavera, CNMT
Mark Coel, M.D.;Authorized User
Brian Bocobo, CNMT
Gerardo Rodriquez, CNMT
Michael Quinn, CNMT
Ryan Malloy, CNMT
Roy Yonamine, CNMT
Leighton Chang, CNMT
Terry Ichinose, CNMT

INSPECTION PROCEDURES USED

87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy filing
87131	Nuclear Medicine Programs – Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-14522/2011-001-01	NOV	A violation involving the failure to develop implement and maintain procedures for the safe use of unsealed licensed material.
030-14522/2011-001-02	NOV	A violation involving the failure to follow written procedures to assure that all expired doses are thrown away.
030-14522/2011-001-03	NOV	A violation involving the failure to adhere to written procedures to assure the safe use of unsealed licensed material.

Closed

None

Discussed

None

Attachment

LIST OF ACRONYMS USED

CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
In-111	Indium-111
mCi	millicurie
mSv	millisievert
NRC	Nuclear Regulatory Commission
Queen's	The Queen's Medical Center
RSO	radiation safety officer
SOP	Standard Operating Procedures
Sr-89	Strontium-89
VIO	Violation
VP	Vice President