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

June 26, 2020

EA-20-051
EN 54057

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

SUBJECT: NRC INSPECTION REPORT 030-14522/2019-001 AND NOTICE OF VIOLATION

Dear Ms. Chadwick:

This letter and the enclosed report refer to the special inspection conducted on May 28-30, 2019, at your facility in Honolulu, Hawaii, with continued in-office review through February 19, 2020. The inspection was conducted in response to a medical event that occurred on May 8, 2019, and was reported to the U.S. Nuclear Regulatory Commission's (NRC's) Operations Center on May 9, 2019, Event Notification 54057. The medical event involved an administration of yttrium-90 (Y-90) TheraSphere glass microspheres for radioembolization of blood vessels in the liver, which resulted in the right lobe of the patient's liver receiving less than the prescribed radiation dose.

Based on the preliminary information in your report to the NRC, and information gathered in subsequent communication with the NRC, the NRC initiated a special inspection to review the circumstances surrounding the medical event. The objectives of the special inspection included, but were not limited to: (1) developing a sequence of events associated with the medical event, (2) evaluating your investigation and causal analysis, (3) reviewing previous Y-90 administrations to determine if there were prior similar occurrences, (4) reviewing your procedures for Y-90 administrations, and (5) reviewing and assessing your corrective actions regarding the medical event.

The inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the NRC rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, a review of records relevant to the medical event and previous Y-90 procedures, observation of licensed activities and facilities, and interviews with personnel.

The enclosed report presents the results of this inspection. The inspector discussed the preliminary inspection findings with you and members of your staff on May 30, 2019, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and members of your staff on June 25, 2020.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations are not related to the medical event, but rather are related to the implementation of your personnel dosimetry program. The apparent violations involve the failure to: (1) monitor individuals' exposure from licensed and unlicensed radiation sources, (2) implement certain elements of your radiation protection program, and (3) provide instruction to individuals who were likely to receive in a year an occupational dose in excess of 100 mrem.

Following the onsite inspection, you provided the NRC with an analysis of the estimated radiation doses received by nine individuals during calendar years 2011-2019 and determined that none of the individuals exceeded the NRC's regulatory limits for occupational dose during any of the years evaluated. However, because of the programmatic nature of the failures regarding the implementation of your dosimetry program and lack of adequate oversight of licensed activities, a substantial potential existed for several individuals to exceed the NRC's regulatory limits for occupational radiation dose during multiple years.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) request a predecisional enforcement conference (PEC) or (2) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a meeting Notice to announce the time and date of the conference. Please contact Ms. Patricia A. Silva, Chief, Materials Inspection Branch, at 817-200-1455 within 10 days of the date of this letter to notify the NRC of your intended response to either participate in a PEC or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC Web site at https://www.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation

gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

Additionally, based on the NRC's special inspection of the medical event, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. This violation was evaluated in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed Notice of Violation (Notice). The violation is being cited in the enclosed Notice because it was identified by the NRC during the inspection.

You are required to respond to the Notice in Enclosure 1 and should follow the instructions specified in the enclosed Notice when preparing your response. As previously discussed, the guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. Information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC's 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 "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and any responses will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Ms. Patricia A. Silva of my staff, at 817-200-1455.

Sincerely,

Mary C. Muessle

Digitally signed by Mary C. Muessle
Date: 2020.06.26 10:28:24 -05'00'

Mary Muessle, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Notice of Violation
2. NRC Inspection
   Report 030-14522/2019-001

cc w/Enclosures:
Jeffrey Eckerd, Manager
State of Hawaii Radiation Control Program

NRC INSPECTION REPORT 030-14522/2019-001 AND NOTICE OF VIOLATION DATED June 26, 2020

Distribution

RidsOeMailCenter Resource;	RidsNmssOd Resource;	RidsOgcMailCenter Resource;
RidsSecyMailCenter Resource;	RidsOcaMailCenter Resource;	RidsOigMailCenter Resource;
RidsEdoMailCenter Resource;	EDO_Managers;	RidsOcfoMailCenter Resource;
RidsOiMailCenter Resource;	RidsRgn1MailCenter Resource;	RidsRgn3MailCenter Resource;
SMorris, RA	BMaier, ORA	GWilson, OE
AVegel, DRA	MHerrera, DRMA	FPeduzzi, OE
MMuessle DNMS	JKramer, ORA	SWoods, OE
LHowell, DNMS	LSreenivas, OE	JPeralta, OE
JGroom, ORA	JWeaver, ORA	AMoreno, CA
R4DNMS_MIB	LWilkins, CA	VDricks, ORA
MBurgess, NMSS	RSun, NMSS	ARoberts, ORA

S:\DNMS\Lynn DOC\QUEENS choice letter NOV IR.docx
ADAMS ACCESSION NUMBER:
☒SUNSI Review: ADAMS: ☐ Non-Publicly Available ☒Non-Sensitive
Keyword:
By: JFK ☒ Yes ☐ No ☒ Publicly Available ☐ Sensitive

OFFICE	RIV:MIB	C:MIB	ACES:TL	RC	D:DNMS
NAME	JFKatanic	PASilva	JGroom	DCylkowski	MMuessle
SIGNATURE	*/RA/*	/RA/	/RA/	/RA/	Mary C. Muessle Digitally signed by Mary C. Muessle Date: 2020.06.26 10:29:05 -05'00'
DATE	5/29/2020	6/3/2020	6/9/2020	6/17/2020	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

The Queen's Medical Center
Honolulu, Hawaii

Docket No. 030-14522
License No. 53-16533-02
EA-20-051

During an NRC inspection conducted May 28-30, 2019, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Contrary to the above, on May 8, 2019, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedure "TheraSphere Radioembolization of Hepatic Malignancies," dated February 1, 2016, and undated TheraSphere checklist had not been revised to reflect recent changes in roles and responsibilities for TheraSphere administration, did not contain sufficient written guidance for verifying that the administration set had been properly primed, and did not contain the TheraSphere vendor's guidance regarding the troubleshooting of problems that can occur during administration set priming or TheraSphere administration, such as "difficulty priming the administration set" or "excessive fluid flow resistance is experienced during infusion."

This is a Severity Level IV violation. (NRC Enforcement Policy Section 6.3.d.1)

Pursuant to 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 identical copies mailed to Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov, within 30 days of the date of this letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-20-051" 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 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 requiring information 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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's 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.

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).

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

Dated this 26th day of June 2020

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-14522
License No.:	53-16533-02
Inspection Report No.:	030-14522/2019-001
EA No.:	EA-20-051
EN No.:	EN 54057
Licensee:	The Queen's Medical Center
Location Inspected:	1301 Punchbowl Street Honolulu, Hawaii
Inspection Dates:	Onsite May 28-30, 2019, with in-office review through February 19, 2020
Exit Meeting Date:	June 25, 2020
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved by:	Patricia A. Silva Chief, Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachments:	Summary of Licensee Radiation Dose Data Supplemental Inspection Information

EXECUTIVE SUMMARY

The Queen's Medical Center
NRC Inspection Report 030-14522/2019-001

On May 28-30, 2019, the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at the licensee's facility located in Honolulu, Hawaii. The inspection was conducted in response to a medical event that occurred on May 8, 2019, and was reported to the NRC Operations Center on May 9, 2019, Event Notification 54057. The medical event involved the administration of yttrium-90 (Y-90) TheraSphere glass microspheres for radioembolization of blood vessels in the liver.

Program Overview

The Queen's Medical Center (licensee) is authorized under NRC Materials License 53-16533-02 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35. One of the authorized licensed activities is the use of Y-90 microspheres under 10 CFR 35.1000. Licensed activities involving Y-90 microspheres are authorized to be performed at the licensee's facility located in Honolulu, Hawaii.

Medical Event

On May 8, 2019, a medical event occurred that met the criteria in 10 CFR 35.3045(a)(1)(i). The licensee determined that the right lobe of the patient's liver received approximately 46.4 Gy (4,640 rad) instead of the prescribed dose of 120 Gy (12,000 rad), a difference of greater than 0.5 Sv (50 rem) to an organ, and that differed from the prescribed dose by approximately 61.3 percent.

The medical event occurred as the result of the administration of an activity of Y-90 TheraSphere microspheres to the liver that was less than the activity necessary to deliver the prescribed radiation dose to the liver. The direct cause of the medical event appears to be an unknown obstruction in the microcatheter that prevented the flow of TheraSphere microspheres from reaching the target. The NRC identified that the contributing causes were related to the licensee's failure to maintain its Y-90 TheraSphere administration procedure and checklist. The NRC determined that the root cause of the medical event can be attributed to the failure on the part of The Queen's Medical Center's management, the Radiation Safety Officer, and the Radiation Safety Committee to evaluate and manage the risks associated with Y-90 TheraSphere administrations.

One Severity Level IV violation was identified regarding the licensee's failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee implemented several corrective actions following the occurrence of the medical event, including providing additional training to individuals involved with these procedures, and revising its Y-90 TheraSphere administration checklist.

Dosimetry Program

During the NRC's review of the May 8, 2019, medical event and related records, the inspector identified that several Interventional Radiology physicians involved with Y-90 administrations had not routinely worn their assigned personnel dosimeters, which are intended to be used to monitor radiation dose to the individuals. Although the licensee was aware since at least 2016 that several Interventional Radiology physicians had inconsistently worn or had not worn their assigned personnel dosimeters for multiple years, the licensee did not propose, plan, or implement corrective actions to address the identified deficiencies.

At the NRC's request, the licensee performed a retrospective evaluation of the radiation dose received by the Interventional Radiology physicians. The licensee's evaluation addressed the radiation dose received by nine Interventional Radiology physicians during calendar years 2011 to 2019. The licensee's evaluation concluded that there were no exposures in excess of NRC's regulatory limit for any Interventional Radiology physician for any year evaluated.

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material, (2) implement a radiation protection program commensurate with the scope and extent of licensed activities, and (3) provide instruction to occupationally exposed individuals.

The root cause of the failures associated with the licensee's dosimetry program can be attributed to the failure on the part of the licensee management, the Radiation Safety Officer, and the Radiation Safety Committee to provide adequate oversight of the licensee's Radiation Safety Plan and to take corrective actions to address identified deficiencies in the personnel dosimetry program.

Following the onsite inspection, the licensee implemented several corrective actions to address the personnel dosimetry issue, which included revising relevant associated licensee policies and providing individuals with instruction regarding the licensee's policies regarding personnel dosimeters.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87103, 87132)

1.1 Program Scope

The Queen's Medical Center (QMC or licensee) is authorized under NRC Materials License 53-16533-02, to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35. One of the authorized licensed activities is the use of yttrium-90 (Y-90) microspheres under 10 CFR 35.1000. Licensed activities involving Y-90 microspheres are authorized to be performed at the licensee's facility located in Honolulu, Hawaii.

1.2 Observations and Findings

This inspection report is limited to observations and findings related to the licensee's use of Y-90 TheraSphere glass microspheres under 10 CFR 35.1000 and the licensee's personnel dosimetry program. The inspector observed licensed activities at the licensee's facilities, reviewed records, procedures, and documents maintained by the licensee, and interviewed licensee personnel. The inspector also obtained and reviewed additional documents provided by the licensee following the onsite inspection.

2 Medical Event (IP 87103, 87132)

2.1 Inspection Scope

On May 21, 2019, the NRC chartered a special inspection in response to a medical event that occurred at QMC. The objectives of the special inspection included, but were not limited to: (1) developing a sequence of events associated with the medical event, (2) evaluating the licensee's investigation and causal analysis, (3) reviewing previous QMC Y-90 administrations to determine if there were prior similar occurrences, (4) reviewing the licensee's procedures for Y-90 administrations, and (5) assessing the licensee's corrective actions regarding the medical event.

The inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities and facilities, and interviewed licensee personnel. Following the onsite inspection, the inspector reviewed additional records that that were provided by QMC.

2.2 Observations and Findings

2.2.1 Background

The Y-90 administration program has existed at QMC since 2011. On August 3, 2011, NRC License 53-16533-02, Amendment No. 63, was issued to QMC, authorizing the use of Y-90 SIR-Spheres microspheres under 10 CFR 35.1000. On April 8, 2015, NRC License 53-16533-02, Amendment No. 71, was issued to QMC, authorizing the use of Y-90 TheraSphere glass microspheres under the provisions of 10 CFR 35.1000.

10 CFR 35.40(a) requires that a written directive be properly prepared, dated, and signed by an Authorized User (AU) prior to an administration of TheraSphere

microspheres. The information on the written directive enables the licensee to properly order the correct Y-90 TheraSphere vial activity needed to deliver the prescribed activity or radiation dose to the patient. TheraSphere microspheres are supplied by the vendor in standard activity vials or are available as a custom activity vial. The vial is ordered so that it will be the appropriate activity at the planned date and time of the patient administration. TheraSphere microspheres are supplied in a 1.0 milliliter V-bottom vial that is measured by the licensee in a dose calibrator to verify the activity prior to administration.

TheraSphere microspheres are delivered to the patient via an infusion through microcatheterization of an artery that leads to the tumor site. The procedure is performed in an Interventional Radiology (IR) suite. After the patient has been catheterized and is ready for the administration, the vial of Y-90 is placed into an acrylic box that has been equipped with a single-use administration set. The administration set consists of a series of one-way valves, tubing, and an injector assembly that is deployed to administer or infuse the Y-90 to the patient through the microcatheter to the targeted site. At the completion of the administration, the microcatheter is withdrawn from the patient, the administration set is disassembled, radiation surveys are performed, and any waste is collected for final measurement and disposal.

2.2.2 Event Chronology

The following is a sequence of events regarding the medical event referenced in this report. Where times are available, they are approximate and given are in Hawaii Standard Time:

2015-2016

- The patient receives Y-90 SIR-Spheres radioembolization in August 2015, and Y-90 TheraSphere radioembolization in March and September 2016.

May 2, 2019

- The Radiation Safety Officer (RSO) reviewed the TheraSphere Dosimetry Calculation form for the patient's fourth Y-90 radioembolization procedure. The calculation included the treatment volume calculated by an IR physician and lung shunt calculation made by an AU. The scheduled treatment date and time were indicated on the form, as well as the Y-90 vial activity size selected and vial calibration date and time. The form was forwarded to the QMC Nuclear Medicine Department.
    - The radiation dose to be delivered to the target volume in the right lobe of the patient's liver was 120 Gy. In order to deliver the desired radiation dose at the scheduled date and time of the procedure, a Y-90 TheraSphere activity of 1.3 GBq (34.4 mCi) would need to be administered.
- The Dosimetry Calculation form was used by a QMC Nuclear Medicine Technologist to order the Y-90 vial from the TheraSphere vendor.
    - The scheduled treatment date and time was noted as: May 8, 2019, at 1230.

- The Y-90 TheraSphere activity ordered was: 3.0 GBq vial (81.1 mCi); calibrated for May 5, 2019.

May 7, 2019

1045 The ordered Y-90 dose was received from the TheraSphere vendor. A QMC Nuclear Medicine Technologist measured and verified the Y-90 TheraSphere vial in a dose calibrator. A QMC radiation physics technician provided a second verification of the dose calibrator activity measurement. The dose was measured to be 1.633 GBq (44.1 mCi). Allowing for decay it would be approximately 1.3 GBq (34.4 mCi) at the scheduled date and time of the Y-90 administration.

May 8, 2019

1113 The patient arrived for the procedure. In the console area of the IR suite, an IR technologist prepared the TheraSphere administration set while the radiation physics technician observed the preparation. As the TheraSphere administration set was prepared, the radiation physics technician observed the preparation and read and checked off steps for "Administration Set Priming" from the QMC TheraSphere checklist. Priming of the administration set was performed with normal saline and was continued until no bubbles were observed in the administration set and saline flowed freely out of both needle holes of the needle injector assembly.

1125 A pre-sedation evaluation and physical examination was performed on the patient, a medical history was taken, and consent for the procedure was obtained.

1149 A pre-administration time out was performed to verify patient identification, known allergies, and to verify the procedure to be performed and equipment needed.

1152 The IR physician began the process to catheterize the patient and insert the microcatheter into the right hepatic artery.

1200 IR staff called Nuclear Medicine and informed them they were ready for the patient Y-90 dose to be brought down. The patient dose was brought to the IR suite.

1230 The AU, who was present in console area of the IR suite, reviewed, signed, and dated the properly prepared written directive.

1240-1254

- The primed and prepared administration set and Y-90 TheraSphere dose were brought into the IR procedure room.

- The radiation physics technician read and checked off steps for "Dose Vial Preparation" from the QMC TheraSphere checklist. The IR physician checked the administration set for proper set up and connections, verified that the administration set was properly primed without any visible air

bubbles, verified the microcatheter position in the patient, and verified that saline could be easily introduced into the microcatheter with no unusual pressure, resistance, or blockage.

- The radiation physics technician read and checked off steps for "Dose Delivery and Time Out" from the QMC TheraSphere checklist. A time out was performed to verify the details of the written directive, including the Y-90 activity and patient identification.

- The radiation physics technician read and checked off steps for "Final Assembly" from the QMC TheraSphere checklist. The IR physician pushed the needle injector assembly tabs down onto the TheraSphere dose vial until a firm click was felt and heard. The IR physician performed a wet connect of the microcatheter to the administration set.

- The IR physician opened the pinch clamp and began to flush the Y-90 TheraSphere microspheres into the patient. As the IR physician commenced the administration of the Y-90, they immediately observed several small fast-moving bubbles in the outlet tubing, followed by what they believed to be TheraSphere microspheres settling in the outlet tubing. As the IR physician attempted to further administer the dose by continuing to flush with saline, they felt resistance and pressure. As the pressure increased, excess saline was automatically vented through the administration set pressure relief valve into the pressure relief vial.

1301 The radiation physics technician called the assistant RSO on their cell phone. The assistant RSO, who was in the quarterly QMC Radiation Safety Committee (RSC) meeting, left the meeting and went to the IR suite.

1305-1315

- The AU, IR physician, assistant RSO, and other staff present assessed the situation, confirmed that the administration set was properly set up, discussed options for proceeding with the administration, and ultimately decided to cease the administration in the interest of patient safety and radiation safety.

- The radiation physics technician read and checked off steps for "Disassembly" from the QMC TheraSphere checklist. The microcatheter was withdrawn from the patient. The microcatheter, attached tubing, dose vial, and needle injector assembly were placed into the waste jar for analysis. Radiation surveys of the work area and personnel did not reveal any radioactive contamination.

1327 The waste jar was measured by the assistant RSO and radiation physics technician to evaluate the residual radioactive material in order to help determine the radiation dose delivered to the patient.

1334 The procedure was documented by the licensee as being over.

1600

- The RSO and assistant RSO performed positron emission tomography (PET) imaging of the waste jar contents and the patient in order to help determine the radiation dose delivered to the patient.

- Based on the collective information gathered, the RSO and assistant RSO calculated the Y-90 activity delivered to the patient and resultant radiation dose to the target (liver). They determined that a reportable medical event occurred.

May 9, 2019

1130 The patient's representative was notified of the medical event and the outcome of the procedure.

1308 The RSO reported the medical event to the NRC in accordance with 10 CFR 35.3045(a)(1)(i). The ordering physician and oncologist were notified of the medical event.

2.2.3 Dose Determination and Notifications/Reports to the NRC

10 CFR 35.3045(a)(1)(i) requires, in part, that a licensee report any event in which the administration of byproduct material results in a dose that differs from the prescribed dose by more than 0.5 Sv (50 rem) to an organ or tissue, and the total dose delivered differs from the prescribed dosage by 20 percent or more. For the purposes of this report, 1 rem = 1 rad.

In order to determine the radiation dose delivered to the target (liver), the licensee first determined the residual radioactive material that remained in the administration set and microcatheter and subtracted that value from the initial measured amount of radioactive material in the Y-90 vial. To accomplish this, consistent with the TheraSphere vendor's guidance, the licensee performed radiation surveys of the waste jar from the procedure and determined the residual radioactive material that remained in the administration set and microcatheter. Based on this evaluation, it was determined that the target (liver) received approximately 38.7 percent of the prescribed dose.

The licensee also removed the waste container contents and performed PET imaging of the administration set and microcatheter in an effort to validate or further refine the radiation dose data. The PET imaging analysis determined that the target (liver) received approximately 40 percent of the prescribed dose.

Therefore, the two assessment methods, radiation surveys of the waste jar and PET imaging analysis of the contents of the waste jar, were in strong agreement and could be used as an accurate determination of the radiation dose delivered to the target (liver).

Based on the licensee's analysis, they determined that the right lobe of the patient's liver received approximately 46.4 Gy (4,640 rad) instead of the AU's prescribed dose of 120 Gy (12,000 rad), a difference of greater than 0.5 Sv (50 rem) to an organ, and that differed from the prescribed dosage by approximately 61.3 percent. This, therefore, met the criteria for reporting of medical events in 10 CFR 35.3045(a)(1)(i).

10 CFR 35.3045(c) requires that the licensee notify the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee discovered the medical event on May 8, 2019, and reported it to the NRC Operations Center on May 9, 2019, no later than the next calendar day after discovery. (Event Notification 54057)

The inspector determined that the medical event did not meet the NRC's criterion to be considered an Abnormal Occurrence.

10 CFR 35.3045(d) requires, in part, that the licensee submit a written report to the appropriate regional office within 15 days of the discovery of the medical event. The licensee provided its initial written report to the NRC Region IV Office on May 21, 2019, within 15 days of the discovery of the medical event (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML19144A138). Based on the information discussed during the inspection, the licensee provided a revised written report with additional clarifying information on May 30, 2019 (ADAMS Accession No. ML20115E246).

The licensee did not anticipate any adverse effects to the patient as s a result of the medical event.

2.2.4 Causal Analysis

The Queen's Medical Center Causal Analysis

In its May 21, 2019, written report to the NRC for the medical event, QMC noted that there was high resistance to flow during the administration and that the cause of the obstruction was under investigation.

The licensee sent the microcatheter and associated components of the administration set to the TheraSphere vendor for analysis. The vendor's analysis included visual inspection, radioactive measurement, digital microscope examination, and pressure/flow tests of the returned components. The licensee provided the results of the vendor's analysis to the NRC (ADAMS Accession No. ML20115E246). The vendor's radiation measurement and microscopy indicated that the majority of the residual microspheres were within the outlet tubing and the outlet tubing/microcatheter connection.

The vendor observed nine kinks in the microcatheter, but it could not be confirmed whether any of these kinks were present prior to or during the patient treatment, or if the kinks occurred during post-procedure handling of the microcatheter. Pressure/flow tests performed by the vendor indicated that the administration set without the microcatheter was functioning as expected. Although a septum fragment from the vial was observed in the returned TheraSphere vial, it did not block the flow path to the administration set. Pressure/flow tests confirmed that there was resistance of flow through the microcatheter. Additionally, a leak was observed near one of the kink locations on the microcatheter. Based on the analysis, the vendor concluded that "with the available information, the most likely direct cause of this event is significant obstruction in the microcatheter causing hindered flow rate."

After the licensee personnel reviewed the vendor's analysis, they asked the vendor to perform additional analysis of the microcatheter. The vendor flushed the microcatheter

and pushed a metal string through the microcatheter. No resistance was felt as the metal string was pushed through the microcatheter. A filter paper was used to collect any particles that were flushed or pushed out of the microcatheter. Nothing was collected on the filter paper and no septum fragment or blood clots were found and, thus, were ruled out by the vendor as a possible cause of the hindered administration.

The vendor's analysis concluded that based on the available information, the most likely direct cause of this event was significant obstruction in the microcatheter causing hindered flow rate. However, the vendor concluded that it could not be confirmed the root cause of the obstruction in the microcatheter in this event, such as kinks or catheter defect.

NRC Causal Analysis

The NRC reviewed the circumstances of the medical event and the licensee's and TheraSphere vendor's analysis of the causal factors. The medical event occurred as the result of the administration of an activity of Y-90 TheraSphere microspheres to the right lobe of the patient's liver that was less than the activity necessary to deliver the prescribed radiation dose to the liver. The direct cause of the medical event appears to be an unknown obstruction in the microcatheter that prevented the flow of TheraSphere microspheres from reaching the target.

Although the TheraSphere vendor's analysis concluded that there were kinks in the microcatheter, and a leak near one of the kink locations, the kinks and small tear leading to a leak could have been caused during post-administration handling. During post-administration handling, the microcatheter was removed from the patient, placed into the waste jar, later removed from the waste jar for PET imaging, positioned for PET imaging, put back into the waste jar, and then later packaged to be sent to the TheraSphere vendor for analysis, resulting in considerable handling.

All persons involved in the Y-90 administration who were interviewed by the inspector, including the IR physician, confirmed that the microcatheter was easily flushed prior to attaching it to the administration set, and that there was no pressure observed during the flushing. Meaning, there was no indication prior to the TheraSphere administration that there was an obstruction or any kinks or tears in the microcatheter that would hinder flow or cause resistance during the TheraSphere administration.

Although the TheraSphere vendor's analysis did not identify any physical obstruction in the catheter, it is unclear whether the bubbles observed by the IR physician at the onset of the TheraSphere administration played any role in the obstruction or resistance to flow. The inspector performed additional review of the conditions that could have led to bubbles, which are: (1) if the pinch clamp is not closed when the needle injector assembly is pushed into the TheraSphere vial; (2) if the needle injector assembly is not fully immersed into the TheraSphere vial; or (3) if there is insufficient or over-vigorous priming of the administration set.

Based on multiple interviews with individuals involved with the medical event, the licensee's procedure "TheraSphere Radioembolization of Hepatic Malignancies," dated February 1, 2016, and undated TheraSphere checklist were closely followed for setting up the administration set. Based on interviews performed by the inspector, the pinch

clamp was closed when the needle injector assembly was pushed into the TheraSphere vial and therefore was not the source of the observed bubbles.

Additionally, based on interviews performed by the inspector, it was established that the IR physician pushed the needle injector assembly tabs down onto the TheraSphere dose vial until a firm click was felt and heard. Multiple individuals recalled hearing the affirmative click, indicating that the needle injector assembly was fully immersed into the TheraSphere vial and therefore was not the source of the observed bubbles.

That leaves insufficient or over-vigorous priming of the administration set as a potential cause of the bubbles. The administration set assembly and priming was performed by an IR technologist, with a radiation physics technician reading the QMC Y-90 TheraSphere administration checklist. The inspector determined that this was a change from previous QMC TheraSphere administrations.

For previous administrations, the RSO or assistant RSO would go through the checklist and assemble the administration set, prime it, and then wait in the IR suite for the IR physician to prepare the patient for the administration. The RSO and/or assistant RSO waited in the IR suite as a patient care consideration because they did not want the procedure to be delayed if they left and had to be summoned back. As microcatheter insertion can be a complex procedure, it often required a fair amount of time and routinely took the RSO and assistant RSO away from other radiation safety and administrative duties while they were waiting for the patient to be prepared for the procedure. As a result, several months prior to May 8, 2019, the licensee decided to transition the administration set assembly and priming and Y-90 TheraSphere checklist reading from the RSO/assistant RSO to other QMC staff.

The RSO and assistant RSO identified the IR technologist with the most familiarity with Y-90 microsphere administrations as the ideal candidate to transition the administration set assembly and priming duties. This individual had previously been trained on the licensee's procedure and checklist for Y-90 administrations and attended TheraSphere vendor-led training presentations. Before the administration set assembly and priming duties were transferred from the RSO/assistant RSO to the IR technologist, additional classroom and on-the-job training was performed specifically regarding TheraSphere administrations.

The RSO and assistant RSO observed the IR technologist perform the administration set assembly and priming activities for several TheraSphere administrations and documented this additional on-the-job training. After full competency was established, the administration set assembly and priming duties were transferred from the RSO/assistant RSO to the IR staff.

Under the new roles and responsibilities, the IR technologist would be supported by a radiation physics technician. The radiation physics technician was responsible for reading off the QMC Y-90 TheraSphere checklist at the various steps, including: gathering of materials and supplies required for TheraSphere administration; administration set priming; Y-90 TheraSphere dose vial preparation; final assembly; administration; disassembly; and cleanup.

The Y-90 TheraSphere administration on May 8, 2019, when the medical event occurred, was the first Y-90 administration where neither the RSO nor assistant RSO

were present during administration set assembly, priming, or at the onset of the administration. It was the first occasion where the IR technologist performed the administration set assembly priming without the direct observation of the RSO or assistant RSO. It was also the first time that the radiation physics technician performed the act of reading and checking off the Y-90 administration checklist during an actual Y-90 administration without the direct observation of the RSO or assistant RSO.

The licensee's procedure and checklist for Y-90 TheraSphere administration had not been revised to address these changes to roles and responsibilities, or the transition of these duties from the RSO and/or assistant RSO to the IR technologist and radiation physics technician.

Furthermore, the licensee's procedure and checklist for Y-90 TheraSphere administration did not contain sufficient written guidance for verifying that the administration set had been properly primed. It also did not contain the TheraSphere vendor's guidance regarding actions to be taken when difficulty is encountered during priming of the administration set. For the administration on May 8, 2019, all the individuals involved in the procedure who were interviewed by the inspector stated that it is relatively easy to prepare the administration set but that it is challenging to prime the administration set. Challenges included the introduction of bubbles into the system by the action of withdrawing saline into the syringe, as well as the difficulty observing bubbles at or within connection points in the administration set.

When the IR encountered resistance to flow during the Y-90 TheraSphere administration, the staff who were present posed several different ideas as to how to resolve the issue. The radiation physics technician telephonically summoned the assistant RSO for support. The assistant RSO arrived and assessed the situation. It was determined that some of the suggested approaches to resolve the situation could potentially result in radiation safety concerns or a radiological contamination incident. Therefore, the collective decision was made to cease the Y-90 TheraSphere administration.

The TheraSphere vendor's "Package Insert" provides troubleshooting guidance, including guidance for actions that can be taken if excessive fluid flow resistance is experienced during administration. These and other troubleshooting techniques were not included as part of QMC's Y-90 TheraSphere procedure or checklist.

Contributing causes are those that did not lead to the incident but made the medical event more probable. The inspector identified that the contributing causes were that the licensee's Y-90 TheraSphere administration procedure and checklist: (1) had not been revised to reflect changes in roles and responsibilities, and (2) did not include adequate troubleshooting guidance for conditions that could occur during an administration. Although a medical event occurred, QMC's failure to maintain the procedure and checklist was not the direct cause of the medical event and the medical event itself had no known consequences.

The root cause is that which establishes the conditions that allow for the contributing causes to develop, which in turn, increases the probability of the occurrence of an incident. The inspector determined that the root cause of the medical event can be attributed to the failure on the part of QMC management, the RSO, and the RSC to evaluate and manage the risks associated with Y-90 TheraSphere administrations. The

licensee did not take steps to assure that the procedure and checklist for Y-90 TheraSphere administrations were maintained and revised to address changes in the program and that adequate guidance was provided in those documents to safely and effectively implement the QMC Y-90 TheraSphere program.

2.3 Inspection Findings

At the time of the special inspection, the QMC's NRC license authorized three AUs for the medical use of Y-90 TheraSphere glass microspheres. At QMC, for Y-90 administrations, AUs that are authorized on the NRC license sign and date written directives. However, when the Y-90 administrations are performed, the Y-90 is administered by IR physicians, who are not listed on the QMC's NRC license. The Y-90 administration occurs in the IR suite by the IR physician under the supervision of an AU. This is a QMC practice that has been in place since the inception of the QMC Y-90 microspheres program. The AUs are QMC employees whereas the IR physicians are contract employees from Radiology Associates, Inc.

The NRC's review of the May 8, 2019, medical event determined that: there was a properly prepared, signed, and dated written directive for the administration; the correct activity of Y-90 TheraSphere microspheres was ordered and prepared for administration to the patient; personnel involved with the administration, including the AU, IR physician, and other staff had appropriate training commensurate with the individual's duties to be performed; the licensee had a procedure and a checklist for performing Y-90 TheraSphere administrations, although it was not maintained; the TheraSphere administration set was properly set up and used; the microcatheter size used (inside diameter) was appropriate for the Y-90 TheraSphere administration; the manufacturer and model of microcatheter was previously used at QMC for other Y-90 TheraSphere administrations with no issue; and saline was used to prime the administration set as specified in the TheraSphere vendor instructions.

The inspector performed a review of a selected sample of over 20 other Y-90 microsphere administrations performed by the licensee. The selected sample included cases for both TheraSphere and SIR-Spheres microsphere administrations that were performed at QMC in 2018 and 2019. The selection included administrations with written directives signed by all three QMC AUs and for administrations performed by several different IR physicians.

The review included all Y-90 administrations performed after the May 8, 2019, medical event up to the start date of the special inspection. For each Y-90 administration, the inspector's review included, but was not limited to: the licensee's dosimetry calculation; treatment planning; Y-90 vial activity ordered; Y90 vial activity received from the vendor; completed written directive; Y-90 vial calibration data sheet; Y-90 vial activity dose calibrator measurement; microcatheter manufacturer and model used; completed checklists, and post-administration radiation dose determinations. The review did not reveal any similar occurrence of resistance to flow during the administration and did not identify any additional medical events.

During the special inspection, on May 29, 2019, the inspector observed an actual Y-90 TheraSphere administration. Prior to the administration, the inspector reviewed: the licensee's dosimetry calculation and treatment planning for the administration; the order placed with the vendor for the Y-90 TheraSphere vial; the completed written directive;

and the Y-90 vial calibration data sheet. The inspector directly observed: reading and checking off of the Y-90 checklist; measurement of the Y-90 vial in the dose calibrator; microcatheter manufacturer and model; administration set assembly and priming; administration/infusion of Y-90 TheraSphere microspheres; removal of the microcatheter from the patient; collection of materials into the waste jar; radiation surveys of the IR suite, personnel, and waste jar; and post-administration radiation dose determinations. Licensee personnel observed and interviewed by the inspector were competent and knowledgeable of their assigned duties, no difficulties were encountered during administration set priming or during the actual administration, and the administration occurred without incident.

Violation of 10 CFR 35.41(a)(2)

Licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The inspector found that the licensee had developed procedures for Y-90 TheraSphere administrations and implemented those procedures for Y-90 administrations. However, the licensee did not maintain those procedures.

As described in Section 2.2.4, the May 8, 2019, medical event was the first Y-90 TheraSphere administration where personnel roles and responsibilities had changed regarding administration set priming and checklist reading and completion. However, prior to implementing the change, QMC failed to update its Y-90 TheraSphere procedure and checklist to reflect these changes in roles and responsibilities.

Additionally, QMC's procedure and checklist for Y-90 TheraSphere administrations did not contain sufficient written guidance for verifying that the administration set had been properly primed and did not contain the vendor's guidance regarding such topics as when difficulty is encountered during priming of the administration set. The QMC's procedure and checklist for Y-90 TheraSphere administration also did not contain information or vendor guidance to troubleshoot problems that can occur during the administration, such as the fluid flow resistance that was experienced during the May 8, 2019, medical event.

10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, on May 8, 2019, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedure "TheraSphere Radioembolization of Hepatic Malignancies," dated February 1, 2016, and undated TheraSphere checklist had not been revised to reflect recent changes in roles and responsibilities for TheraSphere administration, did not contain sufficient written guidance for verifying that the administration set had been properly primed, and did not contain the TheraSphere vendor's guidance regarding troubleshooting problems that can occur during administration set priming or administration of TheraSpheres, such as "difficulty priming the administration set" or "excessive fluid flow resistance is experienced during infusion."

The licensee's failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive was identified as a Severity Level IV violation of 10 CFR 35.41(a). (030-14522/2019-001-01)

2.4 Corrective Actions

Following the occurrence of the medical event, the licensee temporarily ceased the new practice of having the IR technologist assemble and prime the administration set and having the radiation physics technician read the Y-90 checklist. The licensee reverted to the original practice of having the RSO or assistant RSO perform these activities until the cause of the medical event could be determined.

On May 15, 2019, the TheraSphere vendor provided onsite training to the IRs, AUs, IR technologists, RSO, assistant RSO, and radiation physics technicians. The training topics included: proper administration set assembly; radiation safety; operation of the TheraSphere delivery system; safety procedures; and hands-on practice in preparing the administration set and delivery system.

Following the inspection, the licensee documented its corrective actions in a letter revised on May 30, 2019 (ADAMS Accession ML20115E246). The revised QMC Y-90 TheraSphere administration checklist was provided. Enhancements were made to indicate which person or group is responsible for the subsections of the checklist. For example, "Administration Set Priming" can be performed by the IR technologist, IR physician, or physics staff; "Final Assembly" is to be performed by the IR physician; and "Surveys" are to be performed by physics staff. Physics staff include the RSO, assistant RSO, or the radiation physics technicians.

Additionally, the QMC Y-90 TheraSphere administration checklist section "TheraSphere Administration (by IR physician)" was revised to include an information box titled "Troubleshooting to correct high resistance during infusion." The information box included several suggestions, such as verifying that the white pinch clamp is open, verifying that the tubing between the Y-90 dose vial and catheter are not pinched or kinked, applying and releasing pressure on the saline syringe several times rapidly, and tapping the infusion tubing with a hemostat or other device while applying pressure on the saline syringe.

2.5 Conclusions

On May 9, 2019, the licensee notified the NRC of a medical event that met the criteria in 10 CFR 35.3045(a)(1)(i) (Event Number 54057). On May 21, 2019, in accordance with 10 CFR 35.3045(d) the licensee provided the NRC with a written report regarding the medical event. The licensee determined that the right lobe of the patient's liver received approximately 46.4 Gy (4,640 rad) instead of the prescribed dose of 120 Gy (12,000 rad), a difference of greater than 0.5 Sv (50 rem) to an organ, and that differed from the prescribed dose by approximately 61.3 percent. The licensee did not anticipate any adverse effects to the patient as a result of the medical event.

The medical event occurred as the result of the administration of an activity of Y-90 TheraSphere microspheres to the liver that was less than the activity necessary to deliver the prescribed radiation dose to the liver. The direct cause of the medical event appears to be an unknown obstruction in the microcatheter that prevented the flow of

TheraSphere microspheres from reaching the target. The NRC identified that the contributing causes were related to the licensee's failure to maintain its Y-90 TheraSphere administration procedure and checklist. The NRC determined that the root cause of the medical event can be attributed to the failure on the part of QMC management, the RSO, and the RSC to evaluate and manage the risks associated with Y-90 TheraSphere administrations.

One Severity Level IV violation was identified regarding the licensee's failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The licensee implemented several corrective actions following the occurrence of the medical event, including providing additional training to individuals involved with these procedures, and revising its Y-90 TheraSphere administration checklist.

3 Dosimetry Program (IP 87132)

3.1 Inspection Scope

On May 28-30, 2019, the NRC conducted a special inspection at QMC in response to a medical event. During the NRC's review of the medical event and related records, the inspector identified that several IR physicians involved with Y-90 administrations had not worn their assigned personnel dosimeters. To evaluate this matter, the inspector reviewed records, procedures, and documents maintained by the licensee, observed licensed activities, and interviewed personnel. Following the onsite inspection, the inspector reviewed additional information and records that were provided by QMC.

3.2 Observations and Findings

3.2.1 Background

10 CFR 20.1502 requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

The inspector identified that several IR physicians involved with Y-90 administrations at QMC had not worn their assigned individual monitoring devices, also called personnel dosimeters. Personnel dosimeters are used by the licensee to measure the radiation dose to occupationally exposed individuals. At QMC the IR physicians are contract employees from Radiology Associates, Inc.

Several of the IR physicians were involved with both NRC licensed and unlicensed activities at QMC. Licensed activities that the IR physicians participated in primarily involved the use of Y-90, as authorized in NRC Materials License 53-16533-02, under 10 CFR 35.1000. The IR physicians were also involved with unlicensed activities at QMC. These activities, which included the use of radiation-producing devices, such as

fluoroscopes and other x-ray generating devices, are called “unlicensed” or “non-licensed” because they are not licensed by the NRC.

Several IR physicians had not worn their assigned personnel dosimeter for licensed or unlicensed activities. For the purposes of Section 3 of this report, the IR physicians are referred to by number, as IR1 through IR9. In a few cases, IR physicians had not worn their assigned personnel dosimeters for months at a time, and in some cases for several years. It was determined that since the inception of the QMC Y-90 microspheres program, there were nine IR physicians who were involved with both licensed and non-licensed activities at QMC. At the time of the inspection, two of these individuals no longer worked at QMC.

The inspector’s review determined that the RSO had previously identified that personnel dosimeters were not being worn by some of the IR physicians. Specifically, the inspector reviewed the RSO’s annual radiation safety program reviews for calendar years 2016, 2017, and 2018. The 2016 annual radiation safety program review stated, “Two of the IR physicians still do not wear badges” and “Recommend that annual training be given” to IR physicians. The 2017 and 2018 annual radiation safety program reviews each stated, “Two of the IR physicians still do not wear badges.” “Badges” is jargon for personnel dosimeter.

These annual radiation safety program reviews were shared by the RSO and assistant RSO with the RSC on multiple occasions. During the May 8, 2018, RSC meeting it was discussed that most IR physicians (“4 out of 6”) were wearing their dosimeters. Implicit in that statement was that two IR physicians were not wearing their assigned dosimeters. During the November 14, 2018, RSC meeting, it was noted that IR6 and IR2 “may not be wearing their dosimeters on a regular basis.” During the February 20, 2019, RSC meeting it was noted that most IR physicians are wearing their dosimeters but that IR4 and IR2 “have readings that indicate they are not wearing their dosimeters on a regular basis.”

Although the RSO and RSC were aware of this issue, no action was taken to either enforce compliance with wearing dosimeters, to evaluate the IR physician radiation exposures for the periods when dosimeters were not worn, or to implement other appropriate corrective actions.

It was noted that IR4 became a member of the RSC starting in August 2017 and was one of the IR physicians who routinely did not wear their assigned personnel dosimeter. As an RSC member, IR4 would be responsible to oversee the use of licensed material and recommend corrective actions for identified issues related to radiation safety and compliance with the NRC regulations and the terms of the NRC license. Yet IR4 was one of the two least compliant IR physicians with respect to dosimeter use.

When the personnel dosimeter use was discussed by the inspector with the RSO and licensee senior management, there appeared to be a lack of understanding on the part of the licensee regarding the NRC regulatory requirements related to personnel monitoring. There was a misunderstanding on the part of the licensee that NRC’s only regulatory interest with respect to personnel monitoring was related to radiation dose from NRC licensed activities. It was not understood that the NRC’s personnel monitoring requirements include radiation dose from both licensed and non-licensed sources of radiation and radiation-producing devices.

Furthermore, there was a lack of awareness on the part of the RSO and licensee senior management that as an NRC licensee, the licensee is responsible for the activities of its contractors engaged with NRC licensed activities. The IR physicians work under a contract to QMC and therefore are not QMC employees. The licensee believed that simply providing personnel dosimeters to the IR physicians fulfilled QMC's regulatory obligation, regardless of whether the personnel dosimeters were ever worn by the IR physicians during licensed and non-licensed activities. There was an expressed reluctance on the part of QMC senior management and the RSO to engage with the IR physicians on the dosimetry matter because they were "not QMC employees." It was further expressed that as the licensee, they could not "make" the IR physician contractors do anything, such as wear their assigned personnel dosimeters.

3.2.2 Radiation Dose Evaluation

During the onsite inspection, the scope and extent of the IR physician personnel dosimeter issue could not be fully understood by the inspector. Historical dosimetry records and information from prior RSOs were not readily available during the inspection. At the conclusion of the onsite inspection, the NRC requested that a radiation dose evaluation be performed for all IR physicians who were engaged in licensed and non-licensed activities

On June 25, 2019, the licensee provided its "Dosimetry Audit of Interventional Radiologists During Period of RAM Use" (ADAMS Accession ML20115E239). The NRC found that the analysis was incomplete and lacking in sufficient detail to support the conclusions presented by the licensee. As a result, the licensee was requested to provide additional information.

On January 27, 2020, the licensee provided the NRC with a revised radiation dosimetry analysis (ADAMS Accession ML20115E257). In its revised analysis, the licensee made several assumptions: (1) following the NRC's onsite inspection, the IR physicians complied with wearing their assigned personnel dosimeters, and thus, there was approximately 7 months (June through December 2019) of accurate dosimetry data to determine IR physician-specific effective dose equivalent (EDE) per IR case; (2) regardless of the number of IR cases per month, if a monthly dosimeter had a recorded value, that value was used as the assigned radiation dose for the month; (3) if a monthly dosimeter had a reading of "M" and the number of IR cases that month was less than 10, the licensee assigned zero (0) mrem for that month; and (4) if a monthly dosimeter had a reading of "M" and the number of IR cases that month was greater than or equal to 10, the licensee used the IR physician-specific EDE per IR case for that month.

Note that a dosimeter reading of "M" stands for "minimal," meaning that after the control dosimeter reading is subtracted from the personnel dosimeter reading, the resulting EDE was below the minimal reporting capabilities of the dosimeter. A summary of the licensee's radiation dose evaluation is provided in Attachment 1.

Dosimeter use by the IR physicians varied considerably per calendar year (CY). Some IR physicians had a few months each year with no apparent dosimeter use, whereas others had entire years of no dosimeter use. A simplistic indicator of no dosimeter use is an unused monthly dosimeter or a monthly dosimeter with a reading of "M" for months where the number of IR cases was greater than zero (0). Table 1 provides a summary

of the number of unused or “M” dosimeters for each IR physician. This simplification is illustrative of the scope and extent of the issue but does not take into account months where dosimeters had a reading greater than zero but that reading was inconsistent with the number of IR cases performed that month.

	2011	2012	2013	2014	2015	2016	2017	2018	2019
IR1	0	4	3	4	1	1	1	1	0
IR2	1	10	11	12	12	12	12	12	4
IR3								1	0
IR4				7	12	11	12	8	5
IR5	0	4	3	1	3	0	2	3	1
IR6	0	3	4	1	1	0	2	2	3
IR7	0	0	0	0	1	0	1	1	0
IR8								0	0
IR9	1	2							

Table 1: Number of monthly personnel dosimeters returned unused or had minimal readings “M”

The licensee’s revised analysis addressed the nine IR physicians, going back to the inception of the QMC Y-90 program in 2011. For some IR physicians for a few years, the number of Y-90 cases (NRC licensed activity) is unknown, and for other years, the specific IR physician did not participate in any Y-90 cases. The licensee’s evaluation concluded that there were no exposures in excess of NRC’s regulatory limit of 5 rem total EDE for any IR physician for any year evaluated.

The NRC evaluated the licensee’s January 27, 2020, analysis and determined that there were weaknesses and non-conservatisms in the licensee’s methodology. In particular, the licensee failed to perform quality assurance on the actual personnel dosimeter data to determine the validity of the data.

As noted above, if a monthly dosimeter had a recorded value, that value was used by the licensee as the assigned radiation dose for the month, even if it might not have been an accurate or reasonable representation of radiation dose. For example, in June 2015, IR5 performed 105 IR cases, and the personnel dosimeter reading for that month indicated a reading of 1 mrem EDE. The licensee utilized the value of 1 mrem EDE as the assigned value for that month even though there is a high likelihood that this is not an accurate or reasonable radiation dose based on 105 IR cases performed. This type of assumption could lead to the radiation dose evaluation being erroneously low.

Another inconsistency as a result of the licensee’s assumption that the dosimeter value is an accurate representation of actual personnel radiation dose can be seen in the following example. In April 2012, IR7 performed only three IR cases and had a personnel dosimeter reading of 149 mrem. Although it is possible that a few complex IR cases or poor technique could lead to this dosimeter reading, it is perhaps more likely that the dosimeter was left in the IR suite, might have been worn for more than one month (exposed to additional IR cases), or the number of IR cases for the month is not accurate.

The licensee also assumed, with no rationale provided, that for months where there were less than 10 IR cases and the personnel dosimeter reading was “M,” a radiation

dose of zero (0) would be applied rather than to apply the IR physician-specific EDE per IR case. This assumption results in a non-conservative underestimate of radiation dose. For example, in August 2014, IR5 had four IR cases and a dosimeter reading of 45 mrem EDE, so 45 mrem was applied to the dose estimate. In July 2015, IR5 had four IR cases and a dosimeter reading of "M", so zero (0) mrem was applied to the dose estimate. This approach could lead to an underestimate of radiation dose.

Based on the reasons provided above, it was concluded that several of the annual radiation dose estimates provided by the licensee are likely underestimates. The inspector attempted to ascertain the degree by which the licensee underestimated the values. For three IR physicians, IR2, IR4, and IR9, there was insufficient data for the NRC to perform an independent evaluation. Both IR2 and IR4 have many months over multiple years with insufficient dosimeter data (i.e. multiple unused dosimeters or "Ms") whereas for IR9 the number of IR cases was not provided and there was also insufficient dosimeter data. For the remaining six IR physicians, the inspector used the available dosimeter data and number of IR cases to establish a conservative value for estimated IR physician-specific EDE per IR case.

Using the NRC's conservative approach to analyzing the licensee's data, in all cases the NRC's annual radiation dose estimates were higher than the licensee's dose estimates. Even with this conservative approach, for the IR physicians with more complete dosimetry data and number of IR cases, there were no NRC calculated exposures in excess of NRC's regulatory limit for any IR physician for any year evaluated.

3.3 Inspection Findings

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material; (2) implement a radiation protection program commensurate with the scope and extent of licensed activities; and (3) provide instruction to occupationally exposed individuals.

Apparent violation of 10 CFR 20.1502

10 CFR 20.1502 requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. At a minimum, each licensee shall monitor exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, during calendar years 2011 through 2019, the licensee failed to monitor individuals' occupational exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. Specifically, during calendar years 2011 through 2019, for nine IR physicians, the licensee failed to monitor their occupational exposure to radiation from licensed and unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by the IR physicians, who were likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a), and had a substantial potential to exceed the NRC's annual limit in 10 CFR 20.1201(a).

The licensee's failure to monitor individuals' occupational exposure to radiation and radioactive material was identified as an apparent violation of 10 CFR 20.1502. (030-14522/2019-001-02)

Apparent violation of 10 CFR 20.1101(a)

10 CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

The licensee's policy RSO-14-101-B, "Radiation Safety Guidelines Regarding Personnel Monitoring," dated April 2014, states, in part, that the RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

The QMC Radiation Safety Plan, dated April 2017, provides information regarding the licensee's radiation safety program implementation. It states, in part, that the RSC shall ensure that licensed material is used in compliance with NRC regulations and establish investigational levels for occupational radiation exposures. It further provides, in part, that the RSC shall: (1) review the RSO's quarterly summary report of occupational exposure records, giving attention to excessive exposures; (2) review at least annually the RSO's summary report of the Radiation Safety Program to determine that activities are being conducted safely and in accordance with the regulations; and (3) recommend remedial action to correct any deficiencies identified in the Radiation Safety Program.

Contrary to the above, from April 2014 to May 28, 2019, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee's RSC failed to: (1) ensure that licensed material was used in compliance with the NRC regulations in 10 CFR 20.1502; (2) adequately review the RSO's quarterly summary report of occupational exposure records with regards to compliance with dosimeter usage; and (3) recommend remedial action to correct deficiencies identified in the RSO's summary report of the Radiation Safety Program with regards to compliance with dosimeter usage. Additionally, the licensee's policy "Radiation Safety Guidelines Regarding Personnel Monitoring," and its Radiation Safety Plan, failed to include provisions regarding actions to be taken when dosimeters were returned unused or had unexpectedly low exposures.

The licensee's failure to implement a radiation protection program commensurate with the scope and extent of licensed activities was identified as an apparent violation of 10 CFR 20.1101(a). (030-14522/2019-001-03)

Apparent violation of 10 CFR 19.12(a)(3)

10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, from 2011 to May 28, 2019, the licensee failed to provide instruction to individuals who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide adequate instructions regarding the proper use of dosimeters to nine IR physicians who were likely to receive in a year an occupational dose in excess of 100 mrem.

The licensee's failure to provide instruction to occupationally exposed individuals was identified as an apparent violation of 10 CFR 19.12(a)(3). (030-14522/2019-001-04)

3.4 Causal Evaluation

The inspector determined that there were a number of factors that contributed to the failures associated with the QMC IR physician dosimetry program. These contributing causes made it more probable that such failures would occur. The inspector identified that the contributing causes were the licensee's: (1) lack of understanding of the NRC regulatory requirements related to personnel monitoring for both licensed and unlicensed sources of radiation and radiation producing devices; (2) lack of awareness that as an NRC licensee, they are responsible for the activities of their contractors engaged with NRC licensed activities; and (3) failure to develop and implement a radiation protection program, including policies, procedures, and training programs, commensurate with the scope and extent of licensed activities.

The root cause is that which establishes the conditions that allow for the contributing causes to develop, which in turn, increases the probability of the failures to occur. The inspector determined that the root cause of the failures associated with the QMC dosimetry program can be attributed to the failure on the part of QMC management, the RSO, and the RSC to provide adequate oversight of the QMC Radiation Safety Plan and to take corrective actions to address identified deficiencies in the IR physician personnel dosimetry program.

3.5 Corrective Actions

Following the inspection, the licensee implemented several corrective actions to address the personnel dosimetry issue: (1) on July 8, 2019, the licensee sent a memo to "Radiation Film Badge Users" to note that QMC is strictly enforcing the requirement to wear a film badge (personnel dosimeter); (2) on July 15, 2019, the licensee revised its policy "Radiation Badge Monitoring Responsibility" to emphasize that dosimeters must be worn when working with or around ionizing radiation; (3) discussed the NRC requirements and licensee policy at the June 17, 2019, RSC meeting; and (4) provided an initial evaluation and revised evaluation of occupational radiation exposures of IR physicians to the NRC.

3.6 Conclusions

During the NRC's review of the May 8, 2019, medical event and related records, the inspector identified that several IR physicians involved with Y-90 administrations had not consistently worn their assigned personnel dosimeters, which are intended to be used to monitor radiation dose to the individuals. Although the licensee was aware since at least 2016 that IR physicians had not consistently worn their assigned personnel dosimeters

for multiple years, the licensee did not propose, plan, or implement corrective actions to address the identified deficiencies.

At the NRC's request, the licensee performed a retrospective evaluation of the radiation dose received by the IR physicians. The licensee's evaluation addressed the radiation dose received by nine IR physicians from 2011 to 2019. The licensee's evaluation concluded that there were no exposures in excess of NRC's regulatory limit for any IR physician for any year evaluated.

Three apparent violations were identified regarding the licensee's failure to: (1) monitor individuals' occupational exposure to radiation and radioactive material; (2) implement a radiation protection program commensurate with the scope and extent of licensed activities; and (3) provide instruction to occupationally exposed individuals.

The root cause of the failures associated with the QMC dosimetry program can be attributed to the failure on the part of QMC management, the RSO, and the RSC to provide adequate oversight of the QMC Radiation Safety Plan and to take corrective actions to address identified deficiencies in the personnel dosimetry program.

Following the onsite inspection, the licensee implemented several corrective actions to address the personnel dosimetry issue, which included revising relevant associated licensee policies and providing individuals with instruction regarding the licensee's policies regarding personnel dosimeters.

4 Exit Meeting Summary

On June 25, 2020, a final telephonic exit meeting was conducted with the Vice President of Patient Care, and other members of the QMC staff, to discuss the inspection findings. The NRC representatives described the NRC's enforcement process and the options for the licensee to request to attend a PEC or request ADR with the NRC.

Summary of IR Physician Radiation Dose Data

	2011	2012	2013	2014	2015	2016	2017	2018	2019
	IR1								
Recorded Dosimeter Dose (mrem)	539	651	651	306	362	772	896	584	234
Licensee Estimated Dose (mrem)	539	736	660	334	369	784	905	592	232
IR cases	419	373	553	333	278	557	454	416	433
Y-90 cases	U	U	5	3	0	8	5	3	4
	IR2								
Recorded Dosimeter Dose (mrem)	10	34	1	0	0	0	0	0	241
Licensee Estimated Dose (mrem)	452	395	474	605	414	384	706	440	399
IR cases	516	525	652	691	475	439	807	503	485
Y-90 cases	U	U	6	5	11	7	9	8	U
	IR3								
Recorded Dosimeter Dose (mrem)								1286	866
Licensee Estimated Dose (mrem)								1320	866
IR cases								U	886
Y-90 cases								2	59
	IR4								
Recorded Dosimeter Dose (mrem)				0	0	49	0	538	521
Licensee Estimated Dose (mrem)				774	1774	1547	1450	1539	874
IR cases				435	997	947	815	818	500
Y-90 cases				9	18	13	14	19	16
	IR5								
Recorded Dosimeter Dose (mrem)	10	378	422	596	463	599	353	353	664
Licensee Estimated Dose (mrem)	884	518	446	662	599	599	367	472	729
IR cases	678	261	200	544	519	534	556	367	498
Y-90 cases	U	U	8	5	14	9	9	17	13
	IR6								
Recorded Dosimeter Dose (mrem)	371	500	421	595	352	611	447	360	315
Licensee Estimated Dose (mrem)	371	500	476	593	502	611	579	418	352
IR cases	274	261	200	544	519	534	556	367	326
Y-90 cases	U	U	5	3	13	12	9	9	9
	IR7								
Recorded Dosimeter Dose (mrem)	1866	1621	1379	1018	1791	1693	977	1397	1352
Licensee Estimated Dose (mrem)	1866	1621	1378	1017	1955	1692	977	1496	1546
IR cases	303	228	322	391	499	526	468	451	401
Y-90 cases	U	U	5	7	9	7	9	6	8
	IR8								
Recorded Dosimeter Dose (mrem)								2526	643
Licensee Estimated Dose (mrem)								2526	643
IR cases								257	394
Y-90 cases								6	7
	IR9								
Recorded Dosimeter Dose (mrem)	151	759							
Licensee Estimated Dose (mrem)	152	758							
IR cases	U	U							
Y-90 cases	U	U							

Table note: U stands for Unknown; the data is not available

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Darlena Chadwick, RN, Vice President, Patient Care
Dale J. Shippers, RSO
Frank Goerner, PhD, Assistant RSO
Jhun Fronda, Radiation Physics Technician
Shay J. Lee, MD, Authorized User
Douglas A. Prager, MD, Authorized User
Jean Colon-Pons, MD, Interventional Radiology Physician
Anthony Herrera, MD, Interventional Radiology Physician
Darren Tasaka, RT(R), Radiologic Technologist
Roy Yonamine, Nuclear Medicine Technologist
Ryan Malloy, Nuclear Medicine Technologist
Moon Kyungki, Radiology Supplies Support

INSPECTION PROCEDURES USED

87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-14522/2019-001-01	VIO	Failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive. (10 CFR 35.41(a)(2))
030-14522/2019-001-02	AV	Failure to monitor individuals' occupational exposure to radiation and radioactive material. (10 CFR 20.1502)
030-14522/2019-001-03	AV	Failure to implement a radiation protection program commensurate with the scope and extent of licensed activities. (10 CFR 20.1101(a))
030-14522/2019-001-04	AV	Failure to provide instruction to occupationally exposed Individuals. (10 CFR 19.12(a)(3))

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violation
AU	Authorized User
CFR	*Code of Federal Regulations*
EDE	effective dose equivalent
EN	Event Notification
HST	Hawaii Standard Time
IP	Inspection Procedure
IR	Interventional Radiology
NRC	U.S. Nuclear Regulatory Commission
PET	Positron Emission Tomography
QMC	The Queen's Medical Center
PEC	Pre-decisional Enforcement Conference
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
VIO	Violation