NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Midwest Division - RMC, LLC d/b/a Research Medical Center 2316 E Meyer Blvd. Nuclear Medicine/Radiation Oncology Kansas City, MO 64132 **Report Number(s)** 2022001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-13959	24-18625-01	06/29/2022-07/27/2022

LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows.

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☑ 3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

A. 10 CFR 35.60(b) requires licensees to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(continued on next page)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE	Ashley McClellan	8/19/22
NRC INSPECTOR	Elizabeth D. Tindle-Engelmann	Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2022.08.05 08:57:10 -05'00'
BRANCH CHIEF	Michael A. Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.08.05 07:26:23 -05'00'

Add Continuation Page

Materials Inspection Report (Continued)

Contrary to the above, from July 2021 to June 30, 2022, the licensee did not calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, in July of 2021, the licensee obtained a rubidium-82 radionuclide generator which had a dynamic detector as the instrumentation required by 10 CFR 35.60(a). However, there are no nationally recognized standards or manufacturer's instructions for calibration of a dynamic detector, so the licensee was unable to calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions

The licensee cannot implement a corrective action since the rubidium-82 radionuclide generator inherently cannot comply with 10 CFR 35.60(b). However, as of June 30, 2022, the licensee met the criteria described in EGM-13-003 for use of enforcement discretion. The licensee intends to meet the criteria described in EGM-13-003 going forward to allow the NRC to use enforcement discretion in future inspections of the rubidium-82 radionuclide generator.

This is a Severity Level IV violation (Section 6.3).

B. 10 CFR 35.63(c) requires that, for other than a unit dosage, the license must determine the activity either by (1) direct measurement of radioactivity; (2) a combination of measurement of radioactivity and mathematical calculations; or (3) a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements.

Contrary to the above, from July 2021 to June 30, 2022, the licensee did not determine the activity in radiopharmaceutical dosages containing rubidium-82 before it was administered to patients for medical use. Specifically, in July of 2021, the licensee obtained a rubidium-82 radionuclide generator, which used a dynamic detector to determine the activity of the rubidium-82 radiopharmaceutical. This detector has no nationally recognized standards or manufacturer's instructions for calibration. Therefore, the dynamic detector does not meet the requirements for determination of activity in a radiopharmaceutical dosage.

The licensee cannot implement a corrective action since the rubidium-82 radionuclide generator inherently cannot comply with 10 CFR 35.60(b) and thereby cannot comply with 10 CFR 35.63(c). However, as of June 30, 2022, the licensee met the criteria described in EGM-13-003 for use of enforcement discretion. The licensee intends to meet the criteria described in EGM-13-003 going forward to allow the NRC to use enforcement discretion in future inspections of the rubidium-82 radionuclide generator.

This is a Severity Level IV violation (Section 6.3).

C. Condition 14.A. of Amendment 77 of License Number 24-18625-01 dated February 10, 2022, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 2021 (ML21231A263).

The application dated July 28, 2021, states, in part, that the licensee has developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR, Part 20, Subpart K, and 10 CFR 35.92.

The licensee's Policy IS-NM-008, "NM RADIOACTIVE WASTE DISPOSAL," (last revised in August of 2020) was developed as the licensee's written waste disposal procedures for licensed material. Section IV of the policy describes the various waste processioning procedures such as decay-in-storage and transfer of waste for burial. Section IV E states, in part, that material not suitable for decay-in-storage must be transferred to a burial site.

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Materials Inspection Report (Continued)

Contrary to the above, as of June 28, 2022, the licensee failed to develop, implement, and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also met the requirements of the applicable section of 10 CFR, Part 20, Subpart K, and 10 CFR 35.92. Specifically, the licensee failed to include in its written procedures provisions for determining whether waste was suitable for decay-in-storage and met the criteria for decay-in-storage pursuant to 10 CFR 35.92 such as ensuring the physical half-life of the byproduct material was less than or equal to 120 days; this led to the licensee storing waste with a half-life greater than 120 days for decay-in-storage. Furthermore, the licensee's procedure did not describe the types of waste that must be transferred for disposal. These two omissions led to individuals involved in the waste management program to believe that all waste generated onsite was suitable for decay-in-storage.

The licensee revised their Policy IS-NM-008, "NM RADIOACTIVE WASTE DISPOSAL" to describe each waste stream generated by the licensee. The revisions included determination of suitability for decay-in-storage, survey requirements, and recordkeeping requirements. The licensee planned to conduct training on the revised policy by August 30, 2022. Additionally, the RSO committed to supervising the initial implementation of the new policy to ensure that revisions were effective and expectations were understood.

This is a Severity Level IV violation (Section 6.3).

D. 10 CFR 35.610(e) requires, in part, that a licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit, initially and at least annually.

Contrary to the above, from July 2019 through June 2022, the licensee failed to ensure that all authorized users and authorized medical physicists participated in drills of emergency procedures for the remote afterloader unit initially and at least annually. Specifically, in July of 2019, one authorized user, who was listed on the license, used the device but failed to participate in the licensee's emergency procedure drills initially. Additionally, in September of 2021, one authorized user, who was listed on the license, used the device but failed to participate in the licensee's emergency procedure drills annually. Furthermore, as of June 28, 2022, two authorized medical physicists listed on the license, who had not used the device, failed to participate in the licensee's emergency procedure drills initially and at least annually.

Upon identification of the violation, the licensee committed to training the authorized medical physicists and authorized users who had not participated in drills of emergency procedures for the remote afterloader unit within the last year, participate in drills of emergency procedures for the remote afterloader unit within 30 days. To ensure operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit initially, the licensee developed a step in the onboarding process to require the training prior to authorization to use the remote afterloader unit. To ensure operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit at least annually, the licensee added the training to their annual requirements.

This is a Severity Level IV violation (Section 6.3).

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Midwest Division - RMC, LLC	030-13959	24-18625-01

4. Report Number(s):	5. Date(s) of Inspection:
2022001	06/29/2022-07/27/2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Elizabeth D. Tindle-Engelmann	02240	2	87130, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Josh McIlvain, MS, DABR	jmcilvain@dtcinc.com	913-424-3640

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☑ Announced	☑ Main Office ☐ Field Office	06/29/2024 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection. The licensee was a medical facility located in Kansas City, Missouri, with authorization to for diagnostic and therapeutic uses of byproduct material pursuant to 10 CFR 35.100-400, a remote afterloader unit pursuant to 10 CFR 35.600, and yttrium-90 microspheres pursuant to 10 CFR 35.1000. The licensee's radiation safety officer (RSO) was a consultant that was onsite frequently and available by phone as needed. The licensee used another consultant, from the same organization that supplied the RSO, to perform program reviews and equipment calibrations. The licensee maintained a radiation safety committee that met quarterly.

The nuclear medicine department was staffed with five full-time nuclear medicine technologists and five nuclear medicine students. The licensee's nuclear medicine staff administered approximately 20 PET and SPECT doses per day, 4 doses of unsealed byproduct material requiring a written directive, and 1-4 microsphere doses per month. The department received unit doses of technetium-99m, fluorine-18, gallium-68, and copper-64 as needed from a licensed radiopharmacy; other radionuclides were used less frequently.

The radiation oncology department was staffed by two full-time authorized medical physicists that supported the high dose rate (HDR) remote afterloader program and the gamma stereotactic radiosurgery program (GSR). However, the GSR was on a separate license. The radiation oncology department delivered approximately 200 HDR fractions per year, primarily using gynecological applicators.

Observations

The inspector observed ambient radiation level surveys, dose calibrator quality control, dose preparation and administration, package receipt surveys, and rubidium-82 radionuclide generator daily checks. The licensee's staff demonstrated decay in storage procedures, package return procedures, a sealed source inventory, and a microsphere dose preparation.

Interviews with licensee personnel indicated adequate knowledge of radiation safety and security concepts and procedures. The inspector reviewed the following records: area surveys, dose calibrator calibrations, dosimetry, HDR spot checks, HDR full calibrations, package receipt, package return, program reviews, radiation safety committee meeting minutes, sealed source leak tests and inventories, select policies and procedures, spill reports, training, treatment plans, waste logs, and written directives.

Materials Inspection Record (Continued)

The inspector performed independent and confirmatory radiation measurements using a RadEye G (serial number: 30337, calibration expiration: 03/29/2023). Results were consistent with the licensee's survey records and postings.

Findings

A. 10 CFR 35.60(b) and B. 10 CFR 35.63(c)

The licensee received and commissioned a rubidium-82 radionuclide generator in July of 2021. This type of generator is unable to comply with 10 CFR 35.60(b) and 10 CFR 35.63(c) because of the dynamic detector that is used in the infusion cart for the determination of activity of each dosage.

This led to a violation of 10 CFR 35.60(b) which requires licensees to calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. In July of 2021, the licensee obtained a rubidium-82 radionuclide generator which had a dynamic detector as the instrumentation required by 10 CFR 35.60(a). However, there are no nationally recognized standards or manufacturer's instructions for calibration of a dynamic detector, so the licensee was unable to calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions.

Furthermore, this led to a violation 10 CFR 35.63(c) which requires that, for other than a unit dosage, the license must determine the activity either by (1) direct measurement of radioactivity; (2) a combination of measurement of radioactivity and mathematical calculations; or (3) a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements. In July of 2021, the licensee obtained a rubidium-82 radionuclide generator which used a dynamic detector to determine the activity of the rubidium-82 radiopharmaceutical. This radionuclide generator has no nationally recognized standards or manufacturer's instructions for calibration. Therefore, the dynamic detector does not meet the requirements for determination of activity in a radiopharmaceutical dosage.

The licensee cannot implement corrective actions for the violation of 10 CFR 35.60(b) or 10 CFR 35.63(c) since the rubidium-82 radionuclide generator inherently cannot comply with the requirements. However, the NRC issued EGM-13-003 to allow the NRC to use enforcement discretions for the violations associated with these generators when certain criteria are met. The licensee reviewed EGM-13-003 when they first began using the generator. However, at the time of the inspection the inspector determined that the licensee had not met the criteria listed in EGM-13-003 to allow for the use of enforcement discretion. Specifically, the licensee had not trained the authorized user who was using rubidium-82 chloride for medical use under 10 CFR 35.200. Because of this, the NRC was unable to use enforcement discretion for the violations associated with 10 CFR 35.60(b) and 10 CFR 35.63(c). However, as of June 20, 2022, the licensee met the criteria described in EGM-13-003 for use of enforcement discretion. The licensee intends to meet the criteria described in EGM-13-003 going forward to allow the NRC to use enforcement discretion in future inspections of the rubidium-82 radionuclide generator.

C. Written Waste Disposal Procedures

With regard to waste logs, all waste was held for decay-in-storage. However, the inspector observed that the licensee had multiple waste streams that did not meet the criteria for decay-in-storage pursuant to 10 CFR 35.92, such as lutetium-177 waste with a contaminant with a half-life greater than 120 days. Condition 14.A. of Amendment 77 of License Number 24-18625-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 2021 (ML21231A263). The application dated July 28, 2021, states, in part, that the licensee has developed and will implement and maintain

Materials Inspection Record (Continued)

written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR, Part 20, Subpart K, and 10 CFR 35.92.

The licensee's Policy IS-NM-008, "NM RADIOACTIVE WASTE DISPOSAL," (last revised in August of 2020) was developed as the licensee's written waste disposal procedures for licensed material. Section IV of the policy describes the various waste processioning procedures such as decay-in-storage and transfer of waste for burial. Section IV E states, in part, that material not suitable for decay-in-storage must be transferred to a burial site. The inspector determined that, as of June 28, 2022, the licensee failed to include in its written procedures provisions for determining whether waste was suitable for decay-in-storage and met the criteria for decay-in-storage pursuant to 10 CFR 35.92. Specifically, the licensee did not provide criteria for ensuring the physical half-life of the byproduct material was less than or equal to 120 days; this led to the licensee storing waste with a half-life greater than 120 days for decay-in-storage. Furthermore, the licensee's procedure did not describe the types of waste that must be transferred for disposal. These two omissions led to individuals involved in the waste management program to believe that all waste generated onsite was suitable for decay-in-storage.

The licensee revised their Policy IS-NM-008, "NM RADIOACTIVE WASTE DISPOSAL," to describe each waste stream generated by the licensee. The revisions included determination of suitability for decay-in-storage, survey requirements, and recordkeeping requirements. The licensee planned to conduct training on the revised policy by August 30, 2022. Additionally, the RSO committed to supervising the initial implementation of the new policy to ensure that revisions were effective and expectations were understood.

D. 10 CFR 35.610(e)

With regard to training, the inspector reviewed records of drills of emergency procedures for the remote afterloader unit. 10 CFR 35.610(e) requires, in part, that a licensee ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit, initially and at least annually. In July of 2019, one authorized user, who was listed on the license, used the device but failed to participate in the licensee's emergency procedure drills initially. Additionally, in September of 2021, one authorized user, who was listed on the license, used the device but failed to participate in the licensee's emergency procedure drills annually. Finally, as of June 28, 2022, two authorized medical physicists listed on the license, who had not used the device, failed to participate in the licensee's emergency procedure drills initially and at least annually. Upon identification of the violation, the licensee committed to training the authorized medical physicists and authorized users who had not participated in drills of emergency procedures for the remote afterloader unit within the last year, participate in drills of emergency procedures for the remote afterloader unit within 30 days. To ensure operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit initially, the licensee developed a step in the onboarding process to require the training prior to authorization to use the remote afterloader unit. To ensure operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit at least annually, the licensee added the training to their annual requirements.

Four severity level IV violations were identified as a result of this inspection (10 CFR 35.60(b), 10 CFR 35.63(c), development/implementation/maintenance of written waste disposal procedures for licensed material, and 10 CFR 35.610(e).