UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

April 26, 2022

Jaime Wills, Director of Operations
Delaware Imaging Network
12 Omega Drive, Building L
Newark, DE 19713

SUBJECT: DELAWARE IMAGING NETWORK, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 630251

Dear Mrs. Wills:

This is in reference to your application dated February 22, 2022, requesting to renew NRC License No. 07-16529-01. In order to continue our review, we need the following additional information. Please be aware that all "Item", "Section", and "Appendix" references below are referring to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses"

1. Item 5 and 6, Radioactive Material and Use – Please confirm the following:
    a. Please confirm that, for your requests for possession and utilization of byproduct material permitted by 10 CFR 35.100 and 35.200, you are requesting "Any" chemical and/or physical form.
    b. Please confirm that the "Purpose of Use" for the requested byproduct material permitted by 10 CFR 35.100 will be for "Any uptake, dilution, and excretion study permitted by 10 CFR 35.100".
    c. Please confirm that the "Purpose of Use" for the requested byproduct material permitted by 10 CFR 35.200 will be for "Any imaging and localization study permitted by 10 CFR 35.200".
    d. Please confirm whether you are requesting to possess any sources that do not fall under 10 CFR 35.65.

2. Items 5 and 6, Radioactive Material and Use – Please provide the following:
    a. Confirm that you will not utilize PET materials under this license. OR
    b. Confirm that you will utilize PET materials under this license and provide the following PET-related requests under Appendix C to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses":
        i. Please confirm which facility/facilities will utilize PET materials.
        ii. Please provide shielding calculations for your PET/CT facility. Please resubmit your PET/CT facility diagram, which should be drawn to scale with scale used indicated, and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The calculations should include any workload assumptions used.

iii. Please provide principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, besides, and below PET areas.
iv. For PET, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

3. Item 7, Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) – You are not required to submit the roles and responsibilities of the RSO. No response is required for this item with respect to your license renewal application. As such, the roles and responsibilities of the RSO were not reviewed with respect to your license renewal application, though this item may be reviewed in a future inspection.

4. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – You provided a commitment to implement the model training program outlined in NUREG-1556, Volume 9, Revision 3, Appendix J, "Model Training Program". While the model training program contained in Appendix J is acceptable for meeting regulatory requirements, please provide the following commitment: "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

5. Item 9, Radiation Monitoring Instruments – Your application stated that you would establish and implement the model procedures of NUREG-1556, Vol. 9, Rev. 3, Appendix K, "General Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program". A section of this appendix specifically refers to ***independently*** calibrating radiation survey instruments. Additionally, you committed to having the survey meters calibrated by either MPM Products or an equivalent service vendor, while also stating "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations". While the Agreement State license number was provided for MPM products, there was not an explicit commitment for "equivalent service vendors" being licensed by the NRC or an Agreement State to perform instrument calibrations. No additional information was required concerning the description of the instrumentation that will be used to perform required surveys.

   As such, please provide the following commitment: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

6. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application contained a description of the procedures you have developed, implemented, and maintained for calibrating dose calibrators. We do not require this procedure as part

of your application process. This information was not reviewed as part of the licensing process; however, it may be reviewed in a future inspection.

7. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application contained a description of the means for calibrating your dose calibrator. However, your application did not include the confirmation your calibrations would be performed in accordance with nationally recognized standards or the manufacturer's instructions. Therefore, please provide the following commitment: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

8. Item 10, Occupational Dose – Your application included two commitments concerning personnel monitoring/occupational dose: the first was a commitment to establish and implement the model procedures outlined in Appendix M; the second was a commitment to either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limit in 10 CFR Part 20, or to provide dosimetry that meets the requirements listed within NUREG-1556, Volume 9, **Revision 2**. Please update your commitments by providing the following:
   - A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose **in excess of the limits in 10 CFR 20.1502**."
     OR
   - A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, **Rev. 3**, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'" –
     OR
   - A description of an alternative method for demonstrating compliance with the referenced regulations

9. Item 10, Material Receipt and Accountability – Your application did not contain the recommended commitments concerning material receipt and accountability. Please provide the following:
   a. A statement that: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:
      i. license possession limits are not exceeded
      ii. licensed material in storage is secured from unauthorized access or removal
      iii. licensed material not in storage is maintained under constant surveillance and control
      iv. records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

10. Item 10, Material Receipt and Accountability - Your application contained a commitment

to establish and implement the model procedures outlined in Appendix P for safely opening packages containing radioactive materials. We do not require this procedure as part of your application process. This information was not reviewed as part of the licensing process; however, it may be reviewed in a future inspection.

11. Item 10, Leak Tests – Your application contained the commitment: "We will establish and implement the model procedure outlined in Nuclear Regulatory Guide 1556, Volume #9, Revision 3, Appendix Q entitled; 'Model Leak Test Program'." Please confirm your intent to analyze your own leak test samples or update your commitment by providing the following:
    a. For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:
        i. A statement that: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67." OR

    b. For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources):
        i. A statement that: "We will conduct leak tests in-house." AND
        ii. A statement that: "The attached leak test procedures will be followed for leak tests conducted in-house." AND
        iii. Attach leak test procedures. OR
        iv. A statement that you will implement the model leak test program of the appendix of the appropriate NUREG–1556 volume for the type of use. OR
        v. If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

12. Item 10, Area Surveys – Your application contained two commitments concerning area surveys that are conflicting in tense: the first commitment was a statement that you **will establish** and implement the model procedure contained in Appendix R; the second commitment was a statement that you "**have developed** and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

    Please confirm that you **have developed** and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

13. Item 10, Safe Use of Unsealed Licensed Material – Your application included a statement that "We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301"

    Please update your commitment(s) by providing the following: "We have developed and will implement and maintain **written** procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and **10 CFR 20.1201**."

14. Item 11, Waste Management – Your application contained two commitments: the first stating that you **will establish** and implement the model procedure outlined in Appendix W; the second commitment was the explicit request detailed in the NUREG stating you **have developed** and will implement and maintain written waste disposal procedures, as required.

    Please confirm that you have 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 of 10 CFR 35.92.

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov, referencing Mail Control No. 630251.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/mat-toolkits.html. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5170 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jonathan B. Pfingsten

Digitally signed by Jonathan B. Pfingsten
Date: 2022.04.26 14:53:41 -04'00'

Jonathan Pfingsten, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-16529-01
Docket No. 030-11379
Mail Control No. 630251

cc: Garth Koniver, M.D., RSO
Michael W. Lairmore, M.S.

DELAWARE IMAGING NETWORK, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 630251 DATED APRIL 26, 2022

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DATE	4/26/22		4/26/2022					

OFFICIAL RECORD COPY

From: Pfingsten, Jonathan
To: jaime.wills@radnet.com
Cc: drmcar95@yahoo.com; wmlairmore@gmail.com; Hann, Patrick-John
Subject: NRC License Renewal - Delaware Imaging Network - Request for Additional Information
Date: Tuesday, April 26, 2022 3:05:00 PM
Attachments: L07-16529-01.630251.RAI.pdf

License No.: 07-16529-01
Docket No.: 030-11379
Mail Control No.: 630251
Licensee: Delaware Imaging Network

Good afternoon,

I have attached a request for additional information (RAI) associated with your NRC license renewal request.

Please provide a signed response to the attached RAI. NRC Region I is currently in the process of moving to a new physical location; as a result, we are requesting that the RAI response be submitted via email with a valid management signature (e.g., signing a printed copy, scanning, and emailing the document). If you have any questions, please feel free to contact me via email or at the number below.

Thank you,

Jonathan Pfingsten
Sr. Health Physicist
U.S. Nuclear Regulatory Commission
RI/DRSS/MLA
(610) 337-5170