From:	Jonathan Pfingsten
To:	acoll@invivomi.com
Cc:	Jan Nguyen (She/Her)
Subject:	DIAGNOSTIC LABORATORIES, LLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 632035
Date:	Friday, October 28, 2022 11:57:00 AM

Licensee: Diagnostic Laboratories, LLC
License No.: 41-31476-01
Docket No.: 030-38552
Mail Control No.: 632035

PLEASE REPLY TO THIS EMAIL TO CONFIRM RECEIPT

Dear Ms. Alex Coll:

This is in reference to your application dated July 12, 2022, requesting to renew NRC License No. 41-31476-01. 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" found at https://www.nrc.gov/docs/ML1925/ML19256C219.pdf.

1. Your letter should have been signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative (i.e., chief executive officer or delegate) as indication that management has reviewed the application and concurs in the statements and representations contained therein.

   Please submit a signed letter from a senior management representative, stating that they concur with all statements made in your application dated July 12, 2022. If you wish to be able to sign future license amendment requests, the letter from management can include a statement that you are authorized to make legal and binding commitments on behalf of Diagnostic Laboratories.

2. Item 3, Address Where Licensed Materials Will Be Used or Possessed – Your application listed specific addresses for facilities where your mobile coach operates but is not permanently stationed. Therefore, these locations will not be specifically added to your license; instead, these locations are treated as temporary jobsites. This is for awareness only; no action is required.

3. Item 3, Locations of Use – Under Item 3.c.b., you indicated that you attached preliminary radiation measurements made at the surface of the coach walls and at 1 meter from the walls with a typical PET patient load, but these were not received in your renewal application. Please submit a copy of these radiation measurements.

4. Items 5 and 6, Radioactive Material and Purposes for Which Licensed Material Will Be Used – Your application listed specific radionuclides requested for possession and utilization, as well as chemical/physical forms and the maximum amounts to be possessed. The NRC licenses any byproduct material permitted by 10 CFR 35.200 in any chemical or physical form with the listing "as needed" for the maximum amount that a licensee may possess at any one time under the license; this is how you are

currently licensed under Amendment No. 10. Additionally, your current amendment only authorizes possession and use of licensed materials under 10 CFR 35.200; however, your renewal application requests material possession and use under 10 CFR 35.100 and 35.200. The PET imaging studies being performed fall under the 10 CFR 35.200 authorization. Therefore, please confirm that you are seeking to possess and utilize materials as follows:

> "Any byproduct material permitted by 10 CFR 35.200 in any form in the maximum quantity "as needed" for the purposes of any imaging and localization study permitted by 10 CFR 35.200".
>
> And, if applicable,
>
> "Any byproduct material permitted by 10 CFR 35.100 in any form in the maximum quantity "as needed" for the purpose of any uptake, dilution, and excretion study permitted by 10 CFR 35.100."

5. Item 7, Authorized Users (AUs) – Your license currently authorizes a list of individuals as authorized users under 10 CFR 35.200 only. Your renewal request included an expanded request for materials and uses authorized under 10 CFR 35.100, as well. Your renewal request provided the same list of individuals without specifying which were to be authorized under 10 CFR 35.200 only or whose authorization was to be expanded to include 10 CFR 35.100. As such, please provide the requested authorizations for each authorized user and, if necessary, any additional information to support the expansion of their authorizations. Please note that if you are not seeking to expand your possession and use authorization to include byproduct material under 10 CFR 35.100, this item will not be applicable.

6. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Your application did not contain the requested commitment for training for individuals working in or frequenting restricted areas. Therefore, 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."

7. Item 9, Facility Diagram – The provided diagrams do not appear to explicitly show the hot lab, quiet rooms, or storage locations within the trailer, either within the hot lab or for calibration sources.
    a. Please submit a diagram of the hot lab, showing equipment and material placement, as well as location of quiet rooms/patient injection chairs. Please include dimensions and shielding, so that calculations can be independently verified. In addition, please identify the licensed material storage location within the trailer on the facility diagrams.

    b. The application discussed the use of private bathrooms at the clients' facilities but did not discuss the use of quiet rooms and/or a patient waiting area within

client facilities. Please provide the following:

i. Confirm if you plan to utilize quiet rooms at licensee facilities in addition to client provided restrooms.
ii. If you plan to utilize quiet rooms, please confirm that your client service agreement would provide for the licensee's use of the facilities at the client's site, the conduct of surveys for contamination and radiation levels in and around client quiet rooms to ensure public dose limits are not exceeded, and that these areas are left free of contamination following use.
iii. Please confirm that the bathroom will be dedicated to PET patients only.

c. It appears that you may have multiple trailers since you indicated multiple camera models. If this is the case, please supply facility diagrams for the additional trailers, indicating the installed shielding and any additional equipment. Alternatively, you may confirm that any additional trailers are identical to the one submitted, with the same dimensions, installed shielding, and specifications.

d. Please confirm if the hot lab door is lockable.

8. Item 9, Facility Diagrams – Your application included the results of the shielding calculations conducted by a consultant. Please provide the following information:
   a. The calculation assumes only one patient will be waiting in the uptake room at a time.
      i. Please confirm that this is the standard practice, by scheduling constraints or procedural restrictions, for your trailers.
      ii. If this is not standard practice, please confirm that the addition of a second patient waiting in the uptake room would not impact compliance with occupational or public dose limits.

   b. The calculation provided assumes a 12 mCi average dosage; this is a decrease from the previous assumption of 15 mCi. Please confirm the average dosage administered in your mobile trailers.

9. Item 9, Radiation Monitoring Instruments – Your application stated that you have implemented and will maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and the meet the requirements of 10 CFR 35.61.

   If you will be performing your own calibrations, please identify the source that you will use by source manufacturer and model number, nuclide, activity, and calibration accuracy. Otherwise, state that "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

10. Item 9, Other Equipment and Facilities – If your well counter is located in your hot lab, please describe additional shielding of the detector.

11. Item 10, Material Receipt and Accountability – Your application did not contain the

specific commitments contained in NUREG-1556, Volume 9, Revision 3 concerning material receipt and accountability. Therefore, please provide the following commitments:

We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded
- licensed material in storage is secured from unauthorized access or removal
- licensed material not in storage is maintained under constant surveillance and control
- records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

12. Item 10, Leak Tests – Your application did not contain the specific commitments contained in NUREG-1556, Volume 9, Revision 3 concerning leak tests. Therefore, please provide the following commitments:
    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."

13. Item 10, Safe Use of Unsealed Licensed Materials – Your application contained the following commitment:

    "We have developed and will implement and will maintain written procedures for safe use of unsealed byproduct material that meet the requirements10 CFR 20.1101 and 10 CFR **20.1301**."

    The requested commitment has been updated in NUREG-1556, Vol. 9, Rev. 3. Therefore, please confirm and update your commitment with the following statement:

    "We have developed and will implement and maintain written procedures for the safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR **20.1201**."

14. Item 10, Safe Use of Unsealed Licensed Materials –
    a. The "Emergency Procedures" section of NUREG-1556, Vol. 9, Rev. 3, Appendix V, requests licensees or applicants commit to develop, implement, **and maintain** emergency procedures in accordance with the radiation protection program required by 10 CFR 20.1101. Additionally, the section lists a number of specific topics to be addressed in your emergency response procedures. Please provide the following commitments:
        i. Provide the statement: "We will develop, implement, **and maintain written** emergency procedures in accordance with the radiation protection program required by 10 CFR 20.1101."
        ii. Confirm that your emergency procedures include the various topics addressed in the "Emergency Procedures" section of NUREG-1556, Vol. 9, Rev. 3, Appendix V.

    b. Your application contained the commitment or confirmation that you have developed, documented, and implemented procedures that "assure radioactive materials are transported in accordance with Department of Transportation regulations as outlined in 49 CFR Parts 170-189". Please confirm that your **written** procedures specifically include:
        i. use of approved packages
        ii. use of approved labeling
        iii. conduct of proper surveys
        iv. complete and accurate shipping papers
        v. bracing of packages
        vi. security provisions
        vii. written emergency instructions

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov.

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 medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as 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 Pfingsten, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I
(610) 337-5170