UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

July 6, 2022

Evan T. Western, CHP, Manager, Health
Physics
Manufacturing Radiation Safety Officer
Cardinal Health 414, LLC
7000 Cardinal Pl.
Dublin, OH 43017

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING NEW RESEARCH AND DEVELOPMENT MATERIALS USE APPLICATION FOR CARDINAL HEALTH 414, LLC, NRC MAIL CONTROL NO. 629302

Dear Mr. Western:

Our office has reviewed Cardinal Health 414, LLC's (your) November 18, 2021 letter, including application for a new U.S. Nuclear Regulatory Commission (NRC) Materials License for research and development use of radioactive materials. Upon review, our office has determined that additional information is needed to issue a new license, regarding the materials to be authorized, the purpose of use to be authorized, the proposed Radiation Safety Officer's and Authorized User's qualifications, your training program, your facilities & equipment, your radiation safety program, and your waste management program.

Your new license application is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML21323A093. The NRC's ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

As discussed during our May 26, 2022, conversation, for additional guidance, please refer to NUREG 1556 Volumes 7, revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers," and 12, rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution."

Because the immediate request is for research & development use, it is acceptable to use the referenced volume 7 in preparing your responses. However, because the long-term objective is for the license to include manufacturing and distribution authorizations, and the standard license term is for 15 years, it may be more efficient for you to use volume 12 in preparing your response. Although each volume has its own set of procedures in its appendices, many procedures are substantively identical between volumes. Where requested information is very similar, between the two volumes, please provide information in accordance with either the immediate or long-term licensing needs.

In preparing your responses according to volumes 7, rev. 1, & 12, rev. 1, respectively, please refer to the following sections: 8.5, "Radioactive Material," pp. 8-4 to 8-12 & 8-4 to 8-12; 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-12 to 8-13 & 8-12 to 8-16; 8.7, "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience," pp. 8-13 to 8-18 & 8-17 to 8-23; 8.8, "Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)," pp. 8-18 to 8-19 & 8-23 to 8-24; 8.9, "Facilities and Equipment," pp. 8-19 to 8-21 & 8-24 to 8-27; 8.10, "Radiation Safety Program," pp. 8-21 to 8-48 & 8-28 to 8-53; and 8.11, "Radiation Safety Program," pp. 8-48 to 8-53 & 8-57 to 8-63. The NUREG 1556, Volumes 7, revision 1, and 12, revision 1, are available electronically at the NRC's ADAMS accession numbers ML18065A006 and ML18136A704. Accordingly, the volumes may be found, respectively, at the NRC websites: https://www.nrc.gov/docs/ML1806/ML18065A006.pdf and https://www.nrc.gov/docs/ML1813/ML18136A704.pdf.

RADIOACTIVE MATERIAL TO BE AUTHORIZED ON THE LICENSE (p. 5-1 of the request):

1. The request included overall possession limits for materials with atomic numbers 1 through 83, but omitted per-radionuclide and per-source possession limits for any-form and sealed-source line items, respectively.
   For the request for an authorization for any form of byproduct material with atomic numbers 1 through 83, please include a maximum possession limit per radionuclide. For the request for an authorization for sealed sources, as permitted under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.65, please provide a per-source possession limit.

2. The request included any form materials with atomic numbers 1 through 83, radium-223, and actinium-225, but was unclear as to whether materials would be volatile or non-volatile, or whether any special handling, ventilation, air monitoring and containment, accordingly, would be needed.
   For the request for any form authorizations, please clarify whether material will be volatile (unbound form) or non-volatile. If volatile, please also include a description of any specialized equipment, handling, air monitoring, and containment, etc.

3. The request included overall possession limits of 5 & 40 curies for thorium-229 & thorium-228, respectively, for possession and storage only. The application omitted a possession limit per-drum, or how material will be received at the facility. The application also was unclear as to why material needed to be received – for storage only – for an extended period of time.
   For the thorium radionuclides to be authorized for possession only, please indicate a per-drum possession limit and provide additional details as to how these will be received, packaged, contained, monitored, and stored. Please provide a narrative description of where the thorium radionuclides are received from, the form (powder, colloid, solution, chemical formula(s), etc.), and where the radionuclides will ultimately be disposed. Please also indicate why this material is needed at this time.

4. The request listed alpha-emitter possession limits that exceeded the 2 curie default values that trigger the 10 CFR 30.32(i) requirement for either an emergency plan or an evaluation showing that the maximum off-site dose caused by a release would not exceed 1 rem. No emergency plan nor evaluation was included in the request.
   As discussed, if not already submitted, please provide the evaluation as described in 10 CFR 30.32(i).

5. The request omitted a statement regarding the retention and management of records needed for decommissioning, as described in the guidance.
Regarding records to be retained for decommissioning, please confirm the statement, *"Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), as appropriate, we will maintain records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC regional office."*

6. The request indicated that no decommissioning funding plan was submitted due to sealed drums being considered by the applicant to be sealed sources. Per 10 CFR 30.4, a sealed drum does not meet the criteria necessary to be defined as a sealed source.
Accordingly, as discussed, if not already submitted, please submit a decommissioning funding plan and cost estimate for the proposed license. Upon review and approval, a financial instrument covering the amount in the cost estimate will also need to be submitted to the NRC.

PURPOSE OF USE TO BE AUTHORIZED ON THE LICENSE:

7. The application indicated that any-form radium-223, actinium-225, and atomic number 1 through 83 would be used for research and development (R&D) as described in 10 CFR 30.4, but lacked a description of what that use would entail.
Please provide a narrative description of the R&D use of any-form materials to be conducted under the license. Please indicate the typical radionuclides, types of material, and quantities to be used at any given time, under the license.

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR T&E:

8. The request designated several non-medical authorized individuals formerly authorized for non-medical use, under the license, but was unclear whether former use was commensurate with uses for which the individuals would be authorized, under the requested new license.
To add the requested former non-medical authorized users (AU), similar non-medical AUs on the requested new license, please confirm that all formerly authorized non-medical AUs, to be similarly authorized under this license, have used material commensurate with the materials to be handled under this license.

9. The request designated Benjamin Ellert, R.Ph., as a non-medical authorized user, for research & development use, under the license. Although Mr. Ellert has previously been listed as an authorized nuclear pharmacist (ANP), the request lacked documentation that Mr. Ellert has had hands-on training using radioactive materials using materials of the types and in the quantities that are expected to be used, under the requested license.
As discussed previously, please provide documentation of Mr. Ellert's hands on experience as a non-medical AU, sufficient to add him as a non-medical AU on this license.

TRAINING PROGRAM:

10. The guidance requests a description of the radiation safety training program including "topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training." No such description was included in the request for the new license.
As discussed, please confirm that radiation safety training will be provided not only to listed authorized individuals, such as ancillary staff (housekeeping, office workers, etc.), prior to the receipt of radioactive materials at the facility, and on at least an annual basis thereafter. Please provide a list of topics to be included in the training. Please also describe the instructor qualifications, how training will be assessed, and the methods of training to be assessed.

FACILITIES AND EQUIPMENT:

11. The application included facility information sufficient to describe research & development activities to be conducted under the license.
Please note that – upon expansion of the program to include manufacturing and distribution and the opening of the drums to contain the thorium radionuclides, additional facility information will be needed as described in the referenced guidance volumes. No additional information is needed, at this time. However, if a timeline as to when the revisions to the license authorizing manufacturing & development use, etc., under the license, will be needed, it is helpful for NRC's planning for future pre-application meetings regarding the planned future license.

12. Although the application included facility information sufficient to authorized use activities, the description of the area to be used for storage of radioactive waste – including storage of the drums of thorium radionuclides – was unclear.
Please provide a description of the waste area – including where the drums of thorium radionuclides to be authorized under the license will be stored. Please indicate any specialized equipment, security, or monitoring for the area, in your response.

RADIATION SAFETY PROGRAM:

13. The application contained references to multiple NRC guidance volumes, including NUREG 1556, Vol. 12 for manufacturing & development and NUREG 1556, Vol. 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses." In addition, references to specific volumes were unclear, with respect to the applicable revisions indicated by the references to the volumes.
I**n preparing responses describing the radiation safety program, as much as possible, for clarity, please select one of NUREG 1556, volumes 7, 12, and 13. Please verify that any referenced appendix letters in your response are consistent with the referenced versions to the applicable guidance volumes. Please confirm that descriptions of & criteria for radiation monitoring instruments; instrument calibration; material receipt & accountability; occupational dose; safe use of radionuclides & emergencies; and surveys & leak tests are consistent with and meet the criteria from the guidance volume you have chosen to use in providing your response.**

WASTE MANAGEMENT:

14. The application was unclear as to exactly what waste management activities would be conducted, under the license.
    Please provide a narrative description of how waste is collected in the areas of use, how it is transferred to the waste storage areas, how it is monitored, and how it is ultimately disposed. As for the radiation safety program, please confirm that descriptions of and criteria for waste management are consistent with and meet the criteria from the guidance volume you have chosen to use in providing your response.

Please provide a response via a signed and dated letter within 21 days (on or prior to July 27, 2022). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.07.06 16:45:08 -05'00'

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Control No.: 629302

From:	Sara Forster
To:	Sandy Pavon; Martha Pavon
Cc:	Tammy Tomczak
Subject:	FW: Additional Information Request regarding New License Application for Cardinal Health, CN629302
Date:	Tuesday, September 20, 2022 12:34:14 PM
Attachments:	CN629302.Lic34-32780-05 RFAI letter public signed.pdf

Good afternoon, Sandy & Martha:

Could you please add the attached document to ADAMS? It is a Request for Information regarding the referenced Licensee Name and Mail Control Number.

Thank you!

Sara

From: Forster, Sara
Sent: Wednesday, July 06, 2022 4:53 PM
To: Western, Evan <evan.western@cardinalhealth.com>
Subject: Additional Information Request regarding New License Application for Cardinal Health, CN629302

Good afternoon, Evan:
Please see attached for the referenced Request for Additional Information, regarding your November 18, 2021 new license request. All of the NUREG 1556 guidance volumes may be found via https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html. Please let me know if you have any questions.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
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Protecting People and the Environment