

From: [Sara Forster](#)
To: [Western, Evan](#)
Subject: RE: Cardinal Health License Renewal including 10 CFR 35.1000 commitments, NRC Lic. No. 34-29200-01MD
Date: Tuesday, March 14, 2023 11:35:00 AM
Attachments: [image002.png](#)
[image003.png](#)

Hello, Evan:

As we discussed this morning, some clarifications regarding the approvals of authorized individuals would be helpful, in reducing the number of letters listed in the TieDown condition to your license, and in minimizing the times when the license needs to be amended, just to update certain authorized individuals or procedures. Please see below for additional information requested via the cover letter to Cardinal Health's (your) renewed license.

At this time, we are going ahead with updating the individuals authorized for 10 CFR 35.1000 NorthStar system, as requested in your December 15, 2022 letter. Note that the System Administrator Backup was not updated as part of the review. By updating the license to the current 10 CFR 35.1000 NorthStar licensing guidance commitments, the system administrator qualifications will be reviewed at inspection and there will be no need to update the license, when the individual assigned to the role changes.

Thank you,

Sara Forster

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ADDITIONAL INFORMATION REQUEST:
(from the renewal cover letter at [629623 Cover Letter for Cardinal Health-Nuclear Pharmacy Services to License No. 34-29200-01MD\(ML22181A202\)](#))

In reviewing your renewal application, we have noted some missing information needed to complete the review – absent use of prior submitted letters. We have also noted some discrepancies with information currently included on the license. **To update your license to reflect the most current information, to amend possession limits and locations of use, to remove outdated letters, and make any other needed changes, please provide the following information via signed and dated**

letter:

1. ACTINIUM-225 AUTHORIZATION (Subitem 8.K.):

In the previous amendment to the license, the possession limit was limited to a single location of use. Please indicate whether use of Actinium-225 is limited to the single Indianapolis, Indiana location use; and whether any changes to the possession limit are needed.

2. GERMANIUM-68 & GALLIUM-68 AUTHORIZATION (Subitems 6.M., 6.N., 9.M. & 9.N.):

In the application, germanium-67 & gallium-67 were listed, although those are not authorized for the described use. Please confirm that the application contained a typographic error, and that previously authorized radionuclides were correct. In addition, please note the description of the use of germanium-68/gallium-68 generators, as previously provided in letters listed in Condition Nos. 25.H. through 25.N. to the enclosed license. Please provide a current description of the use of these generators, including how they will be received, transferred between locations listed on the license, and ultimately disposed.

3. YTTRIUM-90 AUTHORIZATIONS (Subitems 8.S., 8.T., 9.S. & 9.T.):

In the previous amendment to the license, the possession limit was limited to an overall limit. In the application, the possession limit appears to be indicated as per-facility. Please indicate both the overall and per-location possession limits, to be indicated on the license. Also, processes for preparing & redistributing SIR-Spheres and TheraSphere were not included in the application. Please note the description of TheraSphere use in letters listed in Condition No. 25.U. to the enclosed license. Please provide a current description of the use of yttrium-90 microspheres.

4. CARBON-14 AUTHORIZATION (Subitems 6.V. & 9.V.):

A description of the carbon-14 capsule use was provided in letters listed in Condition No. 25.O. and 25.P. to the enclosed license. The description was omitted from the renewal application. Please provide a current description of the use of carbon-14 capsules.

5. MOLYBDENUM-99 AUTHORIZATION (Subitems 6.W. & 9.W.):

The application omitted information requested in NRC's Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.1000 guidance concerning the use of the NorthStar RadioGenix® System. Please note that this information was previously provided in letters listed in Condition Nos. 25.Q. through 25.T. to the enclosed license. Please provide a current description of the use of these generators, in accordance with the applicable guidance.

6. HONOLULU, HAWAII LOCATION OF USE (Condition No. 10.A.5):

The application omitted this location of use. Please note that this information was previously provided in letters listed in Condition Nos. 25.F. and 25.G. to the enclosed license. If the location is no longer in use, under the license, please provide final close-out surveys for the removed location. If the location was inadvertently omitted from the license, please provide a description of the facilities including a current facility diagram.

7. EAST LANSING, MICHIGAN LOCATION OF USE (Condition No. 10.A.12):

The application listed the street number as 138, but the listed street number is 846. Please either

confirm that the correct street number is 846, or provide additional information as to the change in street number. If the location has changed, and the change in street number is due to a change in location of use, please provide final close-out surveys for the removed location.

8. PRINCETON, WEST VIRGINIA LOCATION OF USE (Condition No. 10.A.20):

The application listed the street number as 34, but the listed street number is 296. Please either confirm that the correct street number is 296, or provide additional information as to the change in street number. If the location has changed, and the change in street number is due to a change in location of use, please provide final close-out surveys for the removed location.

9. REVIEW & APPROVAL OF AUTHORIZED INDIVIDUALS (Condition Nos. 12.B. & 12.C):

The application requested a continued authorization to approve authorized nuclear pharmacists (ANPs) and non-medical authorized users (non-med AUs), under the license. Please note that – in accordance with this previously approved authorization – we have removed the list of non-medical authorized users from Condition No. 13.C. as listed on Amendment No. 69 to the referenced license. In addition, we have noted that criteria for reviewing and approving authorized individuals was previously provided in letters listed in Condition Nos. 25.B. through 25.E. to the enclosed license. Please provide a current description of required training & experience for both ANPs and non-med AUs. Please include how the training will be evaluated and documented by the Radiation Safety Officer and the Radiation Safety Committee, and include a confirmation that records of reviews & approvals of designated individuals will be maintained for at least 3 years following those individuals' last use of licensed material.

10. TRAINING PROGRAM (Item 8 from NRC Form 313):

The application omitted a training program for all individuals with access to or frequenting areas where radioactive materials will be used or stored. We have noted that a training program was previously provided in the letter listed in Condition No. 25.B. to the enclosed license. Please provide a current description of the licensee's training program, including training format, instructors, topics covered, for each group of workers – including ancillary personnel such as office workers and janitorial staff, etc., as well as ANPs and non-med. AUs – allowed access to areas authorized for use or possession of licensed material.