

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinal.com



CardinalHealth

August 4, 2016

Kevin Null
Radioactive Materials Licensing
U.S. NRC Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

RE: Additional Information for Amendment Request for Radioactive Material License Number 34-32840-01, Cardinal Health PET Manufacturing Services, East Lansing, MI, control number 591400.

Mr. Null:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) submits the following information as discussed in an August 3, 2016 telephone conversation between the NRC and Cardinal Health regarding the amendment request letters dated July 6, 2016 and August 1, 2016.

Cardinal Health has contracted with Ameriphysics to perform the characterization of and prepare the shipping papers for the GE PETtrace 8 cyclotron that is to be moved from the St. Louis, MO facility to the East Lansing, MI facility. Ameriphysics has prepared a description of the characterization process, which is attached to this letter. Process knowledge is used to estimate the activity of each of the various radionuclides that are expected in the cyclotron, and these estimates are included in the attachment. The estimates account for the time that the cyclotron has been out of operation, as the machine was last used on August 14, 2015. The non-destructive assay will be performed when the cyclotron is removed from its concrete vault but prior to shipment from St. Louis; this is because activated radionuclides present in the concrete would affect the assay if it were performed with the cyclotron still inside the vault.

The cyclotron's targets will also be shipped. The targets will be placed inside the cyclotron tank to take advantage of the inherent shielding of the cyclotron magnets and tank. These targets will also undergo the same characterization assay as the cyclotron. However, because target workloads can vary significantly, Cardinal Health's process knowledge is used for the initial estimate of the targets' activities. The expected radionuclides that have been previously detected in targets is listed in Attachment B, and the maximum activity estimates account for radioactive decay over the time that the cyclotron has been out of operation.

An initial examination of the activity expected to be shipped demonstrates that this activity does not exceed the maximum possession quantities on the East Lansing facility license. The

Kevin Null
NRC Region III Licensing
August 4, 2016

Page 2

characterized activity for shipment will be summed with the inventory of radioactive materials on-hand at the East Lansing facility and then compared to the possession limits of the East Lansing RAM license prior to shipping. This comparison will be documented and will be kept on file at both the St. Louis and East Lansing facilities. In the event that the results of this process indicate that any possession limits would be exceeded by transferring the cyclotron and its targets to the East Lansing facility, the cyclotron will be placed back in its original location in the vault at the St. Louis facility. Cardinal Health would then submit a request to increase the possession quantities at the East Lansing facility prior to transportation of the cyclotron.

If you have any questions regarding this request, please contact Evan Western at 614.553.4555.

Sincerely,



Glenn Sullivan
Corporate Radiation Safety Officer
Director, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Encl: Characterization Process for Cardinal Health St. Louis PETtrace 8 Cyclotron
Estimated Activities of Cyclotron Targets

cc: Jason Foster, MRSO, Loc. 5860
Rob Symons, Loc. 5860
License File 5860 (3)
Rick Hasselkus

ATTACHMENT A

**Characterization Process for Cardinal Health St. Louis PETtrace 8
Cyclotron**

Characterization Process for Cardinal Health St. Louis PETtrace 8 Cyclotron

Ameriphysics performs the characterization of cyclotron systems and components through the use of process knowledge, historical characterization of similar machines, and the use of non-destructive assay (NDA).

Process Knowledge

Process knowledge indicates that the nature of residual radioactivity in the cyclotron is activation rather than contamination. That is, the radiations detected are from decays occurring within the volumetric matrix of the material rather than at its surface in the form of fixed or removable contamination. This will be verified during the characterization of the cyclotron by performing removable contamination and dose rate surveys prior to performing gamma spectroscopy on the materials.

Ameriphysics will utilize our previous experience with the cyclotrons (including manufacturer technical specifications, previous ISOCS gamma spectroscopy, and samples) to help determine the final activity of the cyclotron and associated components. One example of this is the decision to conservatively use the gamma spectroscopy Minimum Detectable Activity (MDA) as an estimated activity of a particular radionuclide for the purposes of shipment based on the process knowledge that the radionuclide was not seen above MDA; however, known to be present at an activity below the MDA.

Based on process knowledge and historical characterization of similar machines, we know that the predominant isotopes associated with the Cardinal Health - St. Louis PETtrace 8 cyclotron consist of the isotopes identified in Table 1. In addition, based on the duration of operation, frequency of use, and time that it has been removed from service, we anticipate that the activity associated with the cyclotron will be comparable to the activities identified in Table 1.

**Table 1: Isotopic Distribution and
Estimated Activity for Cardinal Health - St. Louis PETtrace 8 Cyclotron**

Nuclide	Activity (mCi)
Na-22	<0.076
Mn-54	1.1
Co-56	<0.162
Co-57	0.599
Co-58	*<0.161
Fe-59	<0.239
Co-60	0.48
Zn-65	*0.463
Cd-109	<1

Ag-110m	<0.14
Sb-124	0.035
Cs-134	<0.14

*This radionuclide may be up to 10X higher

On-site Characterization of the Cyclotron and Associated Items

For the purposes of isotopic characterization, Ameripysics will perform gamma spectroscopy via non-destructive assay (NDA) of the cyclotron and its components using the Canberra InSpector 1000 equipped with an IPROL-1 LaBr 1.5x1.5 probe and analyzed using the Genie 2000 and ISOCS™(In-situ Object Counting System) software. ISOCS™ by Canberra is a software package and is factory developed and calibrated to the IPROL-1 LaBr gamma system. The factory calibration includes NIST traceable sources and modeling code for specified geometry sets. The geometry and parameter settings used for the ISOCS count will be noted for each component and maintained in a characterization file.

The gamma spectroscopy provides both an actual determination for the majority of objects characterized and also provides a verification that no additional radionuclides are present after identification of all gamma lines in the spectrum. The information obtained from the ISOCS characterization will be compared to the receiving facility's Radioactive Materials License to ensure compliance, and used to prepare the shipping papers for the materials.

ATTACHMENT B

Estimated Activities of Cyclotron Targets

Estimated Activities of Cyclotron Targets

Using Cardinal Health's process knowledge, including material composition and gamma spectroscopy measurements, the following activated radionuclides are expected in the niobium cyclotron targets used at Cardinal Health PET Manufacturing facilities. Based on the usage of the targets and accounting for the decay of the radionuclides since the targets have been removed from service, the expected maximum activities in the targets are listed as follows:

Nuclide	Activity (mCi)
Cr-51	ND*
Mn-54	0.18
Co-56	0.23
Co-57	0.55
Co-58	0.01
Nb-94m	0.22
Cd-109	0.66
Ta-182	0.03

ND* = 10 half-lives have passed since targets were removed from service, and no measureable activity is expected.

Tomczak, Tammy

From: Null, Kevin
Sent: Thursday, August 04, 2016 2:07 PM
To: Tomczak, Tammy; Taylor, Tiresha
Subject: attached letter needs to go into ADAMS
Attachments: 160804 Add 2nd Cyclotron Phase I deficiency response.pdf;
NRCform665GENERIC(incoming)CARDINALheatlh08042016.docx

Tiresha/Tammy,

Please enter the attached 8/4 letter into ADAMS and send me the ML number.

Also attached is a 665.

Thanks,

Kevin