Joe Lombardo
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

Cody Phinney, MPH
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

NOTICE OF PUBLIC HEARING

SIERRA RADIOPHARMACY, 601 MILL STREET, RENO, NV 89502, IS REQUESTING A VARIANCE, #755, FROM THE NEVADA STATE BOARD OF HEALTH REGULATIONS.

NOTICE IS HEREBY GIVEN THAT SIERRA RADIOPHARMACY, 601 MILL STREET, RENO, NV 89502, has requested a variance from Nevada Administrative Code (NAC) 459.1955 Preparation for decommissioning: Plan for financing; financial assurance; records, sections 459.1955(1) and (9).

A public hearing will be conducted on December 1, 2023, at 9:00 am by the Nevada State Board of Health to consider this request. This meeting will be held online and at physical locations, listed below.

Physical Locations:
Southern Nevada Health District (SNHD)
Red Rock Trail Rooms A and B
280 S. Decatur Boulevard; Las Vegas, Nevada 89107

Nevada Division of Public and Behavioral Health (DPBH)
Hearing Room No. 303, 3rd Floor
4150 Technology Way; Carson City, Nevada 89706

Meeting Link:
https://teams.microsoft.com/l/meetup-join/19%3ameeting_NzU5NjI4NzYtNjMwZS00ZjNmLThhZDUtZjU1MmJmZDkzNDM0%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%22faba961c-6d7e-488b-8c7c-60c19eff2cbd%22%7d

Please Note: If you experience technical difficulties connecting online, please call into the meeting to participate by phone.

Join by Phone:

1-775-321-6111
Phone Conference ID Number: 810 627 039#

SIERRA RADIOPHARMACY, 601 MILL STREET, RENO, NV 89502, is requesting a variance from NAC.459.1955(1) and (9) which states, in relevant parts:

NAC 459.1955 Preparation for decommissioning: Plan for financing; financial assurance; records.

1. A plan for financing decommissioning, as described in subsection 10, must be submitted by each applicant for a license authorizing the possession and use of:

(a) Unsealed radioactive materials with a half-life of more than 120 days in quantities that exceed 10^5 times the applicable quantities set forth in NAC 459.362; or

(b) The involvement of a combination of radionuclides when R divided by 10^5 is greater than 1.

[. . .]

9. Financial assurance for decommissioning must be provided in accordance with the following amounts:

(a) Not less than $1,125,000 is required if:

(1) The amount of radioactive material is greater than 10^4, but less than or equal to 10^5 times the applicable quantities described in NAC 459.362, in unsealed form; or

(2) R, for a combination of radionuclides, divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.

(b) Not less than $225,000 is required if:

(1) The amount of radioactive material is greater than 10^3, but less than or equal to 10^4 times the applicable quantities described in NAC 459.362, in unsealed form; or

(2) R, for a combination of radionuclides, divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.

(c) Not less than $113,000 is required if:

(1) The amount of radioactive material is greater than 1010 times the applicable quantities described in NAC 459.362, in sealed sources or plated foils; or

(2) R, for a combination of radionuclides, divided by 1010 is greater than 1.

The authority of the State Board of Health to consider and grant a variance from the requirements of a regulation is set forth at NRS 439.200 and NAC 439.200 – 439.280.

Persons wishing to comment upon the proposed variance may appear at the scheduled public hearing or may submit written testimony at least five days before the scheduled hearing to:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Anyone wishing to testify for more than five minutes on the proposed variance must petition the Board of Health at the above address. Petitions shall contain the following: 1) a concise statement of the subject(s) on which the petitioner will present testimony; 2) the estimated time for the petitioner's presentation.

This notice has also been posted at the following locations:

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH (DPBH), 4150 TECHNOLOGY WAY, CARSON CITY, NV

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH WEBSITE
http://dpbh.nv.gov/Boards/BOH/Meetings/Meetings/

NEVADA PUBLIC NOTICE WEBSITE
https://notice.nv.gov/

4150 Technology Way, Suite 300 ● Carson City, NV 89706 ● (775) 684-4200 ● Fax (775) 687-7570 ● dpbh.nv.gov

ALL IN GOOD HEALTH.

Joe Lombardo
Governor

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DEPARTMENT OF HEALTH ANDHUMAN SERVICES
NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

Cody Phinney, MPH
Administrator

Ihsan Azzam, Ph.D.,M.D.
Chief Medical Officer

MEMORANDUM

DATE: **November 13, 2023**

TO: **John Pennell, Chair**
State Board of Health

FROM: **Cody Phinney, Administrator**
Division of Public and Behavioral Health

RE: Variance Case #755 Sierra Radiopharmacy

Subject: Case #755, Sierra Radiopharmacy, variance to Nevada Administrative Code (NAC) 459.1955 Preparation for decommissioning: Plan for financing; financial assurance; records, sections 459.1955(1) and (9).

Staff **Review**

For the reasons stated below and with the conditions specified, DPBH staff recommend the State Board of Health approve Case #755, Sierra Radiopharmacy, request for a variance to NAC 459.1955(1) and (9).

NEVADA ADMINISTRATIVE CODE (NAC) 459.1955(1) and (9) state, in relevant part,

1. A plan for financing decommissioning, as described in subsection 10, must be submitted by each applicant for a license authorizing the possession and use of:

(a) Unsealed radioactive materials with a half-life of more than 120 days in quantities that exceed 10^5 times the applicable quantities set forth in NAC 459.362; or

(b) The involvement of a combination of radionuclides when R divided by 10^5 is greater than l.

(....)

9. Financial assurance for decommissioning must be provided in accordance with the following amounts:

(a) Not less than $1,125,000 is required if:

(1) The amount of radioactive material is greater than 104, but less than or equal to 10^5 times the applicable quantities described in NAC 459.362, in unsealed form; or

(2) R, for a combination of radionuclides, divided by 10^4 is greater than l but R divided by 10^5 is less than or equal to l.

(b) Not less than $225,000 is required if:

(1) The amount of radioactive material is greater than 103, but less than or equal to 10^4 times the applicable quantities described in NAC 459.362, in unsealed form; or

(2) R, for a combination of radionuclides, divided by 10^3 is greater than1 but R divided by 10^4 is less than or equal to 7.

(c) Not less than $113,000 is required if:

(1) The amount of radioactive material is greater than 10^{10} times the applicable quantities described in NAC 459.362, in sealed sources or plated foils; or

(2) R, for a combination of radionuclides, divided by 10^{10} is greater than 7.

Summary of Variance Request:

Variance applicant Sierra Radiopharmacy ("Applicant") submitted a request for variance from the requirements of NAC 459.1955(1) and (9) on October 11, 2023. The Applicant is requesting relief from the financial assurance requirements for the possession and use of two Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators to manufacturing radiopharmaceuticals for nuclear medicine studies.

Intent of Regulation:

The intent of NAC 459.1955 is to ensure funds are available to decommission and decontaminate a facility containing radioactive material should a licensee abandon the facility, go bankrupt, or for any other reason fail to decommission or decontaminate a facility.

Degree of risk to public health or safety:

The adverse risk would be the financial cost to ship Ge-68/Ga-68 generators back to the manufacturer for disposal. However, the use of radiopharmaceuticals from Ge-68/Ga-68 generators will improve public health and safety. Ga-68 radiopharmaceuticals developed from these generators have proven superior to the current Indium-III (In-111) radiopharmaceutical for the early diagnosis of neuroendocrine tumors NETs, which include cancers of the liver and pancreas. In addition to their enhanced diagnostic capabilities Ga-68-labelled radiopharmaceuticals also reduce radiation exposure to NET patients by a factor of 5 as compared to In-III labelled radiopharmaceuticals.

Background Information:

Ge-68/Ga-68 generators are closed systems consisting of a column containing a resin on which Ge-68 is fixed by adsorption. The Ge-68 undergoes radioactive decay to produce Ga-68. The Ga-68 is removed from the generators by eluting it from the column with asterile acid solution. The Ga-68 is soluble in the acid solution and readily elutes *off* the resin column. While the Ge-68, which is insoluble, remains fixed on the column, and continues to decay to provide additional Ga-68 for future elutions.
Although Ge-68/Ga-68 generators are new, they operate in a manner similar to the well known and widely used Molybdenum-99/rechnetium-99m (Mo-99/rc-99m) generators. NAC 459.1955 applies to radioactive material with a half-life greater than 120 days. A half-life is the amount of time it takes for one half of the atoms in a radioactive substance to decay. Because Ge-68 has a half-life of271 days, it requires financial assurance whereas the Mo-99/rc-99 generators with half-lives less than 120 days do not require financial assurance. Since the Mo-99/rc-99 generators have been used safely and successfully for several decades, we expect the Ge-68/Ga-68 to be just as safe.

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The U.S. Nuclear Regulatory Commission (NRC) has evaluated the financial assurance requirements for the GE-68/Ga-68 generators and has delegated to their regional offices authority to grant exemptions from the Decommissioning Funding Plan (DFP) requirements, when certain conditions are met. This delegation was issued in two Memorandums available at the following links {See Attachment A): https://www.nrc.gov/docs/ML1707/ML17075A487.pdf and

https://www.nrc.gov/docs/ML1608/ML16082A4l5.pdf

Even though the NRC provides relief from their DFP requirements, which correspond to NAC 459.1955(1), they still require their licensees to provide financial assurance in the amounts of $225,000.00 for two Ge-68/Ga-68 generators and $1,125,000.00 for more than two but less than 20 generators.

The Applicant is also requesting a variance from the financial assurance amounts required by NAC 459.1955(9). The NRC memorandum dated July 13, 2017, states the need for decontamination due to spills or leakage from these generators would be minimal. Based upon this evaluation, the expected cost to dispose of the generators would be the cost associated with shipping the generators back to the manufacturer. This cost is comparable to the cost associated with Mo-99/rc-99 generators that do not require financial assurance. Since the Applicant also owns the building where the generators will be stored and used, risk associated with this variance would not affect other persons such as a landlord or property management company.

The Applicant will comply with all the same conditions required by NRC for licensees who apply for a variance from their DFP requirements. Specifically, the Applicant has agreed to ensure a legally binding agreement is in place to return the generators to the manufacturer or distributor when the generators are no longer used. The legally binding agreement for the return of the generator(s) will include:

{I) a commitment that the generator recipient shall return the generator to the manufacturer or distributor;

(2) a commitment that the generator manufacturer or distributor shall accept receipt of the returned generator;

(3) that conditions for the manufacturer or distributor's receipt of the generator are reasonable and facilitate the return of the generator;

(4) that the manufacturer or distributor is authorized to possess the radioactive material;

(5) that the parties to the agreement are the recipient(s) of the generators and the manufacturer or distributor(s) of the generators;

(6) that the agreement is signed by persons authorized to enter into legally binding agreements on behalf of the recipient(s) and manufacturer or distributor(s); and

(7) that the agreement is dated.

The Applicant has committed to complying with the above conditions (see Attachment B).

The Applicant's radioactive materials license will have the following license condition:

"Notwithstanding the requirements of {NAC) 459.1955(1) and (9), the licensee is exempt from the requirement to have a decommissioning funding plan and financial assurance needed for the possession and use of one or two Ge-68/Ga-68 medical use generators (make/model# of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated ___ ,"

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Approval of the variance with the above conditions will minimize the risk to public health and safety to the extent practical.

Exceptional and undue hardship:

Strict application of 459.1955(1) and (9) would require the Applicant to submit and fund a DFP. The requirements for a DFP can be costly because it must contain a detailed decommissioning cost estimate and funding assurance. The generators expire after one year and will be returned to the manufacturer for final disposal. This is the same disposal method used for similar generators (Mo-99/Tc-99), which do not require a DFP or financial assurance. Compliance with the regulation in this case is unduly burdensome given a DFP and financial assurance is not necessary provided the applicant has a legally binding agreement in place to return the generators to the manufacturer or distributor.

Approval of this variance is not expected to affect other persons subject to the regulations. There are three other radiopharmacies in Nevada. None have applied for a variance to use these generators but, if they did DPBH would support their variance for a DFP and if they also owned their own property, DPBH would support their variance from financial assurance requirements under the same conditions.

Staff Recommendation

DPBH staff recommend the State Board of Health approve Case #755, Sierra Radiopharmacy, a request for variance to NAC 459.1955(1) and (9), with the condition that the Applicant will implement the commitments in attachment A and limit their possession to no more than two Ge-68/Ga-68 generators (100 millicuries (mCi) of material).

Impairment to the purpose of the regulation:

Approval of this variance will not impair the purpose of the regulation because the legal agreement between the Applicant and the manufacture or distributor provides a very simple method for disposing of expired generators. The generators expire after one year and will be returned to the manufacturer for final disposal. This disposal method should be adequate to ensure the licensee will not have any Ge-68/Ga-68 generators remaining at its site if the licensee decides to terminate the license. This is the same disposal method used for similar generators such as Mo-99/Tc-99 generators, which do not require a DFP or financial assurance.

Public Comments:

Notice of the hearing is scheduled to be posted on the Division of Public & Behavioral Health website at http://dpbh.nv.gov/Boards/BOH/Meetings/Meetings/ and at the 4150 Technology Way Office in Carson City, NV 89706 by November 16, 2023 by 9:00 am. The Division of Public & Behavioral Health is not aware of any objections to this variance by any local authorities, and no public comments have been received to date.

Presenter:

John Follette, Manager Radiation Control Program
Division of Public and Behavioral Health
Bureau Health Protection and Preparedness

Attachments:

A. NRC Memorandums
B. Applicants Commitments

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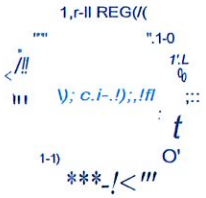

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 29, 2016

MEMORANDUM TO: Daniel H. Dorman, Regional Administrator
Region I

Cynthia D. Pederson, Regional Administrator
Region III

Kriss Kennedy, Regional Administrator
Region IV

FROM: Marc Dapas, Director *IRA/*
Office of Nuclear Material Safety
and Safeguards

SUBJECT: AUTHORIZATION FOR GRANTING SPECIFIC EXEMPTION FROM DECOMMISSIONING FUNDING PLAN REQUIREMENT FOR GERMANIUM-68/GALLIUM-68 GENERATORS

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 35.19 and Management Directive 9.26, "Organization and Functions, Office of Nuclear Material Safety and Safeguards," this memorandum is being issued to delegate to the regions the authority to grant an exemption from the decommissioning funding plan (DFP) requirements in 10 CFR 30.35(a)(1) for the possession and use of Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators, when certain conditions are met.

This memorandum authorizes the regions to issue an exemption, when requested, only as such for Ge-68/Ga-68 generators, and only if a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals. The legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back. The regions should consult with regional counsel or the Office of General Counsel (OGG) to confirm that a legal binding agreement is in place prior to issuing the exemption.

CONTACT: Said Daibes, NMSS/MSTR
(301) 415-6863

The NRC has developed the technical basis for this exemption and the conditions under which it may be authorized. The basis and the limiting conditions are enclosed.

Concerns have been raised with respect to the resources needed to develop and maintain a DFP for Ge-68/Ga-68 generators. After careful analysis, staff agrees this DFP requirement could be an impediment and may limit patient access to the radiopharmaceuticals developed from these generators.

The Advisory Committee on the Medical Uses of Isotopes evaluated the restrictive aspects of the DFP requirement for Ge-68 that arise from 10 CFR Part 30 regulations and concluded that the subject requirement is preventing or deterring the use of promising Ga-68 diagnostic imaging agents for patients (Agencywide Documents Access and Management System Accession No. ML15231A047).

Licensing staff may issue exemptions from the 10 CFR 30.35 DFP requirements to a licensee or applicant under Part 35.200 (medical facility) or 10 CFR Part 32.72 (nuclear pharmacy) who applies for possession of Ge-68/Ga-68 medical use generators, if the licensee submits and maintains for U.S. Nuclear Regulatory Commission inspection, a legally binding agreement that ensures the device will be returned to the manufacturer or distributor at the end of use. The licensing staff shall add the following condition to the license:

> "Notwithstanding the requirements of 10 CFR 30.35 (a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (make/model# of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated _____"

The NRC has concluded that the planned action will be sufficient to ensure public health and safety, while at the same time allowing access to the radiopharmaceuticals developed from these generators until a permanent regulatory solution is reached through rulemaking. A direct final rule process has been initiated.

Enclosure:
Technical Basis for Germanium-68
Gallium-68 Generator Decommissioning
Funding Plan Exemption and Licensing
Guidance

The NRG has developed the technical basis for this exemption and the conditions under which it may be authorized. The basis and the limiting conditions are enclosed.

Concerns have been raised with respect to the resources needed to develop and maintain a DFP for Ge-68/Ga-68 generators. After careful analysis, staff agrees this DFP requirement could be an impediment and may limit patient access to the radiopharmaceuticals developed from these generators.

The Advisory Committee on the Medical Uses of Isotopes evaluated the restrictive aspects of the DFP requirement for Ge-68 that arise from 10 CFR Part 30 regulations and concluded that the subject requirement is preventing or deterring the use of promising Ga-68 diagnostic imaging agents for patients (Agencywide Documents Access and Management System Accession No. ML15231A047).

Licensing staff may issue exemptions from the 10 CFR 30.35 DFP requirements to a licensee or applicant under Part 35.200 (medical facility) or 10 CFR Part 32.72 (nuclear pharmacy) who applies for possession of Ge-68/Ga-68 medical use generators, if the licensee submits and maintains for U.S. Nuclear Regulatory Commission inspection, a legally binding agreement that ensures the device will be returned to the manufacturer or distributor at the end of use. The licensing staff shall add the following condition to the license:

> "Notwithstanding the requirements of 10 CFR 30.35 (a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (make/model# of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated _____"

The NRG has concluded that the planned action will be sufficient to ensure public health and safety, while at the same time allowing access to the radiopharmaceuticals developed from these generators until a permanent regulatory solution is reached through rulemaking. A direct final rule process has been initiated.

Enclosure:
Technical Basis for Germanium-68
Gallium-68 Generator Decommissioning
Funding Plan Exemption and Licensing
Guidance

ML16082A415

OFC	MSTR	MSTR	MSTR	OGG	MSTR	Tech Ed	NMSS
NAME	SDaibes	MFuller	DBollock	**Via e-mail** CEnoland	PHenderson for DCollins	**WMoore**	MDapas
DATE	3/22/16	4/12/16	5/23 /16	6/14 /16	7/20/16	7/25/16	7/29/16

OFFICIAL RECORD COPY

Technical Basis for Germanium-GB Gallium-68 Generator Decommissioning Funding Plan Exemption and Licensing Guidance

Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators are widely used in Europe but are only now emerging from limited clinical trials in the U.S. They provide access to Ga-68 labelled radiopharmaceuticals that have proven to be effective for significantly earlier diagnosis and management of neuroendocrine tumors (NET}. In addition to their enhanced diagnostic capabilities and specificity, Ga-68-labelled radiopharmaceuticals also permit a reduction in effective dose compared to the currently used clinical radiopharmaceutical standard.

Because Ga-68 decays by positron emission, it is used for positron emission tomography (PET) diagnostic medical imaging procedures. Most radionuclides for PET imaging require a large and expensive particle accelerator such as a cyclotron. Compared to an accelerator, the Ge-68/Ga-68 generators have an advantage of lower cost, which permits wider availability. Having more generators available in more locations across the country is a significant advantage, because being close to patients is a necessity with Ga-68's 68-minute half-life.

Ga-68 radiopharmaceuticals developed from these generators have proven superior to the current Indium-111 (In-111) radiopharmaceutical for the early diagnosis of NETs, which include cancers of the liver and pancreas. Highly metastatic cancers in their final phases, such as NETs are difficult to diagnose, with an average of 7 years from symptom onset to confirmed diagnosis among U.S. patients. The number and variety of available treatments, including surgery and peptide receptor radionuclide therapy, make **it** critical to determine the extent of the disease early and accurately for proper management.

In addition to their increase in diagnostic speed and accuracy, Ga-68 labelled radiopharmaceuticals also permit reduced patient doses. The U.S. Nuclear Regulatory Commission's (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) found that with Ga-68 radiopharmaceuticals, NET patients would receive nearly a five-fold reduction in effective dose compared to **In-111** labelled radiopharmaceuticals. ACMUI also found that physicians will gain superior diagnostic accuracy, resulting in quicker diagnoses, earlier initiation of proper therapy, and improved patient outcomes.

Ge-68/Ga-68 generators operate in a manner similar to Molybdenum-99/Technetium-99m generators. They are closed systems consisting of a column containing a resin on which the parent radionuclide is fixed by adsorption. For Ge-68/Ga-68 generators, the parent radionuclide is Ge-68 and decays by electron capture to continuously produce the Ga-68 daughter product. The Ga-68 is removed from the generators by eluting it from the column with a sterile hydrochloric acid solution. The Ga-68 is soluble in the acid solution and readily elutes off the resin column.

In contrast, the parent radionuclide Ge-68 is insoluble, remains fixed on the column, and continues to decay to provide additional Ga-68 for future elutions. Some small amount of Ge-68 is present in each eluate, but as noted in the ACMUI report on Ge-68/Ga-68 generators (Agencywide Documents Access and Management System [ADAMS] Accession No. ML15231A047) and peer review references, this amount is so small it cannot be measured with a standard dose calibrator.

Enclosure

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 30.35, "Financial Assurance and Recordkeeping for Decommissioning," applicants must have a Decommissioning Funding Plan (DFP) to obtain a license to possess Ge-68/Ga-68 generators. Several prospective licensees have raised concerns about the resources needed to develop a DFP for these generators. After analyzing the available literature and preparing a comprehensive report on this issue, the ACMUI concluded that a DFP is not necessary to protect workers or the public from the insignificant radiological risks associated with the use of these generators as long as the generators are returned to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 for patients or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals. The NRC staff independently verified ACMUI's safety basis and assumptions and agrees with the recommendations in the report.

10 CFR 30.35 requires that:

> (a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section....

Ifan applicant is seeking a license to possess quantities of unsealed byproduct material less than 10^5 times the quantities set forth in 10 CFR Appendix B to Part 30 but greater than 10^3 times those quantities, then the applicant has the option of either submitting a decommissioning funding plan as described in paragraph 30.35(e) or a certification of financial assurance in the amount described in paragraph 30.35(d).

The amount of financial assurance required at paragraph 30.35(d) is $1.125 million for quantities greater than 10^4 but less than or equal to 10^5 times the quantities in Appendix B to Part 30, and $225 thousand for quantities greater than 10^3 but less than or equal to 10^4 times the quantities in Appendix B.

Ge-68 Possession Limit (millicurie fmCi11[1]	**Financial Assurance required (§ 30.35)**
Less than or equal to 0.1	none
Greater than 0.1 to 1	$225,000
Greate r than 1 to 1O	$1,125,000
Greater than 10	Decommissioning Funding Plan is required to determine the amount of financial assurance required

[1] Note that these values are in mCi, (e.g. 0.1 microcurie [µCi] times 10^5 equals 10 mCi)

A typical new Ge-68/Ga-68 generator contains 50 mCi at its calibration date; under the NRC regulations, its possession triggers the need for a DFP. However, even with this proposed exemption, licensees must continue to provide **financial assurance** in amounts described above if they possess other radionuclides in quantities requiring a DFP. The amount would be based on their license to possess other (i.e., non Ge-68) unsealed byproduct material as described in 10 CFR 30.35(a)(1). Licensees possessing more than 2 and up to 20 Ge-68 generators (>100 to 1000 mCi) would then be subject to the requirement in§ 30.35(d) for a minimum $1,125,000 in financial assurance for the decommissioning of sites with byproduct materials in quantities with comparable risk. Licensees possessing one or two Ge-68 generators (50 to 100 mCi) would be subject to a $225,000 minimum. The NRC staff agrees with ACMUI that these amounts are more than adequate to cover the principal action for the complete decommissioning of sites with Ge-68/Ga-68 generators, which would be accomplished by the return of the generators to a manufacturer or distributor at the end of use. One reason for the decision to provide for exemption request and approval is that the need for decontamination due to spills or leakage from these generators would be minimal. These are the same financial assurance decommissioning funding requirements as those for possessors of other non-alpha-emitting byproduct radionuclides of comparable activity based on Appendix B to Part 30.

In addition to maintaining the appropriate financial assurance, the licensee must submit and maintain for NRC inspection a legally binding agreement that ensures these generators will be returned to the manufacturer or distributor at the end of use. Specifically, a legally binding agreement must be in place for the licensee to return these generators to the manufacturer or distributor when each generator expires and is no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its use of Ga-68 radiopharmaceuticals. The legally binding agreement must highlight licensee commitments to return expired generators to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back. The return of expired radionuclide generators is a well-established and preferred disposal method. It is the same method currently used to dispose of nearly every expired Mo-99/Tc-99m and Strontium-82/Rubidium-82 (Sr-82/Rb-82) generator in the United States. The return of these generators is a simple method to ensure that the licensee will have no Ge-68 remaining at its site. The licensing staff shall use a license condition to require maintenance of this legally binding agreement, and the regions should consult with regional their counsel or the Office of General Counsel (OGC) to confirm that a legal binding agreement is in place prior to issuing the exemption.

The NRC staff has determined that this planned action will be sufficient to ensure public health and safety until a more permanent regulatory solution is reached through rulemaking. Concurrent with this DFP exemption authority, a direct final rule process has been initiated with the aim of amending Appendix B of 1O CFR 30.35 to include the Ge-68 limit changes from 0.1 µCi to 10 µCi. This new limit will allow a licensee to use Ge-68/Ga-68 generators and not trigger the DFP requirement.

This exemption from 1O CFR 30.35 is granted pursuant to 1O CFR 35.19 "Specific Exemptions," which states that, "The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are

authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest."

In its report (ADAMS Accession No. ML15231A047), ACMUI expressed, "For a medical licensee, the foregoing regulatory considerations creates a cascade effect leading to an extensive and expensive DFP, as a DFP must cover not only the one area where a Ge-68/Ga-68 generator is used but also all areas where radioactive materials are used under the same license." The same report concludes, "The restrictive aspects arising from the current Part 30 regulations are preventing or deterring the use of promising Ga-68 diagnostic imaging agents for patients due to the decommissioning funding plan burden for its parent Ge-68."

The NRC requirements for a DFP can be costly because each DFP will need to contain a detailed cost decommissioning estimate as required by 10 CFR 30.35(e). The Ge-68/Ga-68 generator has a 12-month expiration date, and at the end of the generator's operating life, most likely it will be returned to the manufacturer or distributor for its final disposal because return of the generator is a simple method to ensure that the licensee will have no Ge-68 remaining at its site. Accordingly, all the requirements of 10 CFR 30.35(e) for developing, funding, updating, and submitting detailed cost estimates for NRC review are unnecessary for the decommissioning of sites licensed for the use of Ge-68/Ga-68 generators.

As with any operation involving liquids, the elution of Ga-68 from Ge-68 generators is subject to the risk of spills. Because the eluate consists mostly of Ga-68 with a half-life of 68 minutes, the radiological contaminant of most concern is the parent, Ge-68. A small amount of Ge-68 is dissolved with the Ga-68 eluate in dilute hydrochloric acid in a phenomenon known as "breakthrough" that occurs with each elution. Ge-68 breakthrough is expressed as a percentage of total Ga-68 eluted from the column, corrected for decay. According to a peer-reviewed industry journal article, Ge-68 breakthrough is not more than 0.001 percent of the eluted Ga-68 activity. This concentration is low enough that, as the ACMUI report notes, less than two ounces (¼ cup) of sewerage are needed to dilute each elution to the concentration limit for disposal of Ge-68 in sanitary sewerage under 10 CFR 20.2003. It should also be noted that germanium is chemically similar to silicon and not apt to react under ambient conditions in a radiopharmacy.

The intent of this exemption is to treat all licensees equally regardless of the number of radionuclides with half-lives over 120 days on their license. For a number of licensees, Ge-68/Ga-68 generators will be the only radionuclide source with a half-life over 120 days, (Ge-68 has a half-life of 271 days). There are licensees, such as large research licensees, that already possess radionuclides with half-lives over 120 days (e.g., tritium H-3 with a half-life of 12.3 years and carbon C-14 with a half-life of 5730 years). In most instances, these licensees structure their possession limits so that by the ratio sum calculation, they stay within the two lower levels of financial assurances (i.e., $225,000 or $1,125,000). This structuring allows the licensee to avoid the level of financial assurance that requires a decommissioning funding plan. Hence, for these licensees, the exemption will remove Ge-68 from the sum of the ratios calculation performed to determine the level of financial assurance (unity rule).

Conclusion

The most efficient and effective method to provide the needed regulatory relief from the DFP requirements for licensees who desire to possess and use Ge-68/Ga-68 generators, is to provide the NRC regions with the authority to grant an exemption upon licensee request, only for Ge-68/Ga-68 generators, and only if a legally binding agreement is in place for the licensee to return these generators to the manufacturer or distributor when each generator expires and is no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its use of Ga-68 radiopharmaceuticals. The legally binding agreement must highlight licensee commitments to return expired generators to the manufacturer or distributor and also must include a manufacturer or distributor commitment to taking expired generators back. The NRC staff has determined that these conditions will be sufficient until a more permanent regulatory solution is reached through rulemaking.

Exemptions from 10 CFR 30.35 decommissioning financial assurance requirements may be issued to any person who applies for the possession and use of Ge-68/Ga-68 medical use generators, provided that the other applicable financial assurance requirements, under 10 CFR Part 30.35 are met, and the licensee submits and maintains for NRC inspection a legally binding agreement that ensures the device will be returned to the manufacturer at the end of use. The licensing staff should condition the exemption of this legally binding agreement, and the regions should consult with their regional counsel or OGC to confirm that a legal binding agreement is in place prior to issuing the exemption.

With Ga-68 radiopharmaceuticals, NET patients will receive lower radiation doses, and their physicians will gain superior diagnostic accuracy resulting in quicker diagnosis, earlier initiation of proper therapy, and improved patient outcomes. The NRC has determined that granting this exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.

The following licensing condition should be used to allow NRC licensing staff to issue exemptions from the 1O CFR 30.35 DFP requirements to any licensee or applicant that has shown it has met the requirements of 10 CFR Part 35.200 (medical facility) or 10 CFR Part 32.72 (nuclear pharmacy) who applies for possession of Ge-68/Ga-68 medical use generators.

> "Notwithstanding the requirements of 10 CFR 30.35 (a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (make/model # of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated ____ "

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 1, 2017

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF CLARIFICATION THAT GRANTING AN EXEMPTION FROM THE DECOMMISSIONING FUNDING PLAN REQUIREMENTS IN TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 30 DOES NOT EXEMPT LICENSEES FROM OTHER FINANCIAL ASSURANCE REQUIREMENTS, UPDATE OF LICENSING GUIDANCE, AND COMPATIBILITY DETERMINATION FOR GERMANIUM-68/GALLIUM-68 GENERATORS (STC-17-057)

Purpose: To inform Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff has updated its information concerning Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators. First, the NRC staff has revised the technical basis for granting a specific exemption from the decommissioning funding plan (DFP) requirement for Ge-68/Ga-68 generators. Specifically, the technical basis clarifies that the DFP exemption does not exempt financial assurance. The enclosed memorandum (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17075A487) provided to the NRC regions on July 13, 2017, updates a July 29, 2016, NRC memorandum (ADAMS Accession No. ML16082A415). Second, the Ge-68/Ga-68 generator licensing guidance has been revised to include the criteria needed for the DFP exemption. Last, the NRC staff has provided a compatibility determination for the DFP requirement.

Background: The Advisory Committee on the Medical Uses of Isotopes (ACMUI) evaluated the DFP requirement for Ge-68/Ga-68 generators that arise from Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 regulations and concluded that the DFP requirement was too restrictive and would prevent or deter the use of promising Ga-68 diagnostic imaging agents for patients (ADAMS Accession No. ML15231A047). The ACMUI recommended that the NRC staff exempt Ge-68/Ga-68 generator licensees from DFP requirements under certain conditions. The NRC staff analyzed the ACMUI report and agreed that the DFP requirement could impede or limit patient access to the radiopharmaceuticals developed from this generator. A typical new Ge-68/Ga-68 generator contains 50 mCi at its calibration date. Under the NRC regulations, possession of 50 mCi of Ge-68 exceeds the threshold quantity above which a DFP is required. The NRC staff determined that this exemption will ensure public health and safety and allow access to the radiopharmaceuticals developed from this generator until a permanent regulatory solution is reached through rulemaking.

Discussion: The July 29, 2016, memorandum delegated authority to the NRC regions to grant an exemption from the DFP requirement in 10 CFR Part 30 for possession and use of Ge-68/Ga-68 generators. The technical basis for the exemption relieved a licensee from the requirement for a DFP (10 CFR 30.35(a)(1)) when certain conditions were met. Specifically, the memorandum authorized the NRC regions to issue an exemption for Ge-68/Ga-68 generators when requested, only if a legally binding agreement was in place for the licensee to return the generators to the manufacturer or distributor when the generators were no longer used. The technical basis for the exemption did not remove the financial assurance requirements in 10 CFR 30.35.

The revised memorandum issued to the NRC regions on July 13, 2017, contains the technical basis for granting a specific exemption from the DFP requirement for the Ge-68/Ga-68 generators and provides (1) a clarification that granting an exemption from the DFP requirement in 10 CFR Part 30 does not exempt licensees from financial assurance requirements; (2) a list of specific elements that should be in a legally binding agreement for the return of generators to the manufacturer or distributor; and (3) a minor revision to the licensing condition that specifies that the licensee must return the Ge-68/Ga-68 generators to the manufacturer or distributor when they are no longer being used,

Lastly, the enclosed revisions to the technical basis and guidance will not impact existing granted Ge-68/Ga-68 generators DFP exemptions by NRC or the Agreement States.

The NRC has updated its licensing procedure for the use of the Ge-68/Ga-68 pharmaceutical grade generator manufactured by Eckert and Ziegler Radiopharma GmbH dated July 13, 2017, (ADAMS Accession No. ML17075A488) to include items noted above.

The Standing Committee on Compatibility (SCC) has reviewed this matter and agrees that the exemption from the DFP requirements and its conditions outlined in the technical basis for licensees who possess and use Ge-68/Ga-68 generators are a matter of compatibility. An Agreement State should adopt and implement the essential objectives of this program element With regard to meeting the financial assurance requirements in 10 CFR 30,35(b), this portion of the regulations is designated as Category Health & Safety. An Agreement State has a number of options to meet the essential objective of this requirement including:

1. Use the financial assurance monetary values from the attached technical basis document of $1,125,000 for licensees who possess more than 2 generators but less than 20 (>100 to 1000 mCi) or $225,000 in financial assurance for licensees possessing one or two Ge-68 generators (50 to 100 mCi) accompanied by a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.
2. Use the financial assurance monetary values listed in the Agreement State regulations for the quantities of Ge-68 possessed by the licensee in the generator(s) accompanied by a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.
3. Although licensees are exempt from the requirement to submit a DFP, a licensee may still choose to submit a DFP to support a different amount of financial assurance. After review and approval by the Agreement State, the licensee would provide financial assurance for the amount in the DFP.
4. Exempt their licensees from the financial assurance requirements based on a health and safety evaluation conducted and documented by the Agreement State that should include a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use.

Consequently, the SCC also agrees that the licensing procedures for Ga-68/Ge-68 generators are an essential component of a licensing program and **it** is a matter of compatibility (see Appendix A in *Compatibility Categories and Health and Safety Identification for NRG Regulations and Other Program Elements - SA-200).* The NRC will review the NRC Regional and Agreement State radioactive materials programs' implementation through the Integrated Materials Performance Evaluation Program (IMPEP) under the performance indicator, Technical Quality of Licensing Actions. An Agreement State can demonstrate meeting this compatibility requirement by implementing written procedures for the licensing of Ge-68/Ga-68

generators that include one of the financial assurance options described above and a legally binding agreement for the return of the generator(s) to the manufacturer or distributor at the end of use if the DFP exemption is used. An example of a Ge-68/Ga-68 generator licensing guide is enclosed.

In accordance with Part VI of Management Directive 5.9 *Adequacy and Compatibility of Agreement State Programs,* an Agreement State must implement this requirement within 6 months of the date of this letter.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individuals named below:

TECHNICAL POINT OF CONTACT: Said Daibes, Ph.D.
E-MAIL: Said.Daibes@nrc.gov TELEPHONE: (301) 415-6863

COMPATIBILITY AND IMPEP POINT OF CONTACT: Duncan White
E-MAIL: duncan.white@nrc.gov TELEPHONE: (301) 415-2598

IRA Kevin Williams for/

Daniel S. Collins, Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators
2. Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance, Rev. 1 (July 13, 2017)

SUBJECT: NOTIFICATION TO CLARIFY THAT GRANTING AN EXEMPTION FROM THE DECOMMISSIONING FUNDING PLAN REQUIREMENTS IN 10 CFR PART 30 FOR GERMANIUM-68/GALLIUM-68 GENERATORS DOES NOT IMPLY THAT OTHER FINANCIAL ASSURANCE REQUIREMENTS ARE EXEMPTED (STC-17-057)

ML17075A484

OFC	MSTR	MSTR	MSTR	OGG	MSTR	MSTR
NAME	SDaibes	MFuller	DBollock	EHouseman	PMichalak	KWilliams for DCollins
DATE	3/29/17	3/29/17	4/6/17	5/15/17	7/28/17	8/1/17

OFFICIAL RECORD COPY

Sierra Radiopharmacy
601 Mill Street
Reno, Nevada 89502
775-786-9585

Licensee commitments for Ge-68/Ga-68 Generators

Please provide a signed letter with the following commitments to support your variance from NAC 459.1955(1) and (9).

Commit to obtaining and maintaining a legally binding agreement to return Germanium-68/Gallium-68 generators to the manufacturer or distributor when the generators are no longer used. The legally binding agreement for the return of the generator(s) will include:

(1) a commitment that the generator recipient shall return the generator to the manufacturer or distributor;
(2) a commitment that the generator manufacturer or distributor shall accept receipt of the returned generator;
(3) that conditions for the manufacturer or distributor's receipt of the generator are reasonable and facilitate the return of the generator;
(4) that the manufacturer or distributor is authorized to possess the radioactive material;
(5) that the parties to the agreement are the recipient(s) of the generators and the manufacturer or distributor(s) of the generators;
(6) that the agreement is signed by persons authorized to enter into legally binding agreements on behalf of the recipient(s) and manufacturer or distributor(s); and
(7) that the agreement is dated.

Commit to returning the generators within 2 months after they expire.

The above conditions are agreed upon as written:

Signed: _____ Date: _____

NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

NEVADA STATE BOARD OF HEALTH

4150 Technology Way, Suite 300 CARSON CITY, NV 89706

APPLICATION FOR VARIANCE

Please check the appropriate box that pertains to the NAC for which you are requesting a variance.

- [ ] Division Administration (NAC 439, 441A, 452, 453A, & 629)
- [X] Health Care Quality & Compliance (NAC 449, 457, 459 & 652)
- [ ] Child, Family & Community Wellness (NAC 392, 394, 432A, 439, 441A, & 442)
- [ ] Office of State Epidemiology (NAC 440,450B, 452, 453, 453A, & 695C)
- [ ] Public Health & Clinical Services (NAC 211, 444, 446, 447, 583, & 585)

Date: 10/11/2023

Name of Applicant: Sierra Radiopharmacy Phone: 775-786-9585

Mailing Address: 601 Mill Street

City: Reno State: NV Zip: 89502

We do hereby apply for a variance to chapter/section 459.1955 of the Nevada Administrative Code (NAC). (For example: NAC 449.204)

Title of section in question: Preparation for Decommissioning: Plan for Financing

Statement of existing or proposed conditions in violation of the NAC:

The existing conditions of NAC 459.1955 indicates that we would need to have a fund in the amount of $ 225,000.00 if licensing one or two Ga-68/ Ge-68 generators.

NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

NEVADA STATE BOARD OF HEALTH

4150 Technology Way, Suite 300 CARSON CITY, NV 89706

APPLICATION FOR VARIANCE

Date of initial operation (if existing): _____

ATTENTION: Please read this section closely. Your request for variance will be examined against these criteria:

Any person who, because of unique circumstances, is unduly burdened by a regulation of the State Board of Health and thereby suffers a hardship and the abridgement of a substantial property right may apply for a variance from a regulation. (NAC 439.200(1))

1. The State Board of Health will grant a variance from a regulation only if it finds from the evidence presented at the hearing that:
   - (a) There are circumstances or conditions which:
     - (1) Are unique to the applicant;
     - (2) Do not generally affect other persons subject to the regulation;
     - (3) Make compliance with the regulation unduly burdensome; and
     - (4) Cause a hardship to and abridge a substantial property right of the applicant; and
   - (b) Granting the variance:
     - (1) Is necessary to render substantial justice to the applicant and enable him to preserve and enjoy his property; and
     - (2) Will not be detrimental or pose a danger to public health and safety.

2. Whenever an applicant for a variance alleges that he/she/they suffers or will suffer economic hardship by complying with the regulation, they must submit evidence demonstrating the costs of compliance with the regulation. The Board will consider the evidence and determine whether those costs are unreasonable. (NAC 439.240)

Therefore, it is important for your variance request to be as complete as possible. It is your responsibility to attach documentation supporting your variance request.

Statement of degree of risk of health: The degree of risk would be very minimal with the return the Ga-68/G-68 generator back to the supplier after each use and if need be for decommisioning if required.

NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

NEVADA STATE BOARD OF HEALTH

4150 Technology Way, Suite 300 CARSON CITY, NV 89706

APPLICATION FOR VARIANCE

Please state in detail the circumstances or conditions which demonstrate that:

1. An exceptional and undue hardship results from a strict application of the Regulation:

The hardship would be the amount of money needed to be funded for the decommissioning of the generator following use of the prouduct. We could not be able to utilize this product funding $ 225,000 which we could not be able to do. We would like to see that amount taken off of this regulation for our purpose of use.

2. The variance, if granted, would not:

   A. Cause substantial detriment to the public welfare.

The variance would not cause any detriment to the public welfare. The generator would be boxed up and shipped back to the supplier in the same shipping container as was delivered to us.

   B. Impair substantially the purpose of the regulation from which the application seeks a variance.

The cost of the regulation of $ 225,000 to be able to obtain and use the Ga-68/Ge-68 generator would be detrimental to our ability to provide patients with proper diagnostic benefits.

The bureau may require the following supporting documents to be submitted with and as a part of this application:

Specific Request:

We would submit an agreement with the supplier of the generator for the purpose of returning the generator upon proper use and expiration of such.

NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

NEVADA STATE BOARD OF HEALTH

4150 Technology Way, Suite 300 CARSON CITY, NV 89706

APPLICATION FOR VARIANCE

1. Legal description of property concerned

_ 2. General area identification map

_ 3. Plot map showing locations of all pertinent items and appurtenances

_ 4. Well log (if applicable)

_ 5. Applicable lab reports

_ 6. Applicable engineering or construction/remodeling information

_ 7. Other items (see following pages)

This application must be accompanied by evidence demonstrating the costs of your compliance with regulations or specific statutory standards. Your request will be placed on the Board of Health agenda 40 days or more after receipt in this office if accompanied by the required fee (NAC 439.210). The application and supporting documentation will form the basis for the Division of Public and Behavioral Health staff report and recommendation(s) to the Board. Failure to respond to the above statements may cause the Board to deny consideration of the application at the requested Board meeting.

■ I am/we are requesting this variance request be placed on the next regularly scheduled Board of Health agenda. It is understood that I/we can attend in person at either physical location in Carson City or Las Vegas or we may attend virtual.

Signature: _____

Printed Name: DENNIS LATINO

Title: MANAGER

Date: 10/11/2023

RETURN AGREEMENT FOR IRE ELiT GALLI EO® $^{68}Ge/^{68}Ga$ GENERATORS

THIS RETURN AGREEMENT FOR IRE ELiT Galli Eo™ $^{68}Ge/^{68}Ga$ GENERATORS ("Agreement") is entered into by and between Cardinal Health 414, LLC ("Cardinal Health") and _____ ("Pharmacy") effective _____ ("Effective Date").

WHEREAS, Cardinal Health is the distributor of IRE ELiT's Galli Eo $^{68}Ge/^{68}Ga$ generator ("Galli Eo™") and Pharmacy is an end-user of the Galli Eo™; and

WHEREAS, for Galli Eo's™ distributed by Cardinal Health to Pharmacy, this Agreement documents a commitment for Pharmacy to return the Galli Eo™ to Cardinal Health and Cardinal Health to accept such returns, subject to the terms herein.

NOW, THEREFORE, in consideration of the above premises and the terms and conditions below, the parties agree as follows:

1. **Galli Eo™ Returns Terms and Conditions:**

A. For each Galli Eo™ delivered by Cardinal Health to Pharmacy, Pharmacy commits to return each such Galli Eo™ to Cardinal Health and Cardinal Health commits to accept the return of such Galli Eo™ by Pharmacy, subject to the terms and conditions of this Agreement. Note that if Cardinal Health has another licensed customer requesting the Galli Eo™ for their use, Cardinal Health may direct Pharmacy to ship the Galli Eo™ to the other licensed customer.

B. Pharmacy will contact Cardinal Health to obtain a returned materials authorization (RMA) and all Galli Eo™ returns will comply with Cardinal Health's return instructions and applicable law.

C. For each Galli Eo™ delivered by Cardinal Health to Pharmacy, Pharmacy will return such Galli Eo™ per the terms of this Agreement if Pharmacy no longer uses the Galli Eo™ to prepare ^{68}Ga radiopharmaceuticals for patients or Pharmacy ceases its preparation of ^{68}Ga radiopharmaceuticals, but in no case later than sixty (60) days after Galli Eo's™ shelf-life expiry.

D. Pharmacy will provide Cardinal Health with a copy of information on facility location(s) where Galli Eo™ will be received, used, and stored, as provided by Pharmacy to the U.S. Nuclear Regulatory Commission (NRC) or Agreement State agency, whichever applies.

E. Nothing hereunder limits any terms and conditions required by Cardinal Health for the purchase, sale and use of the Galli Eo™. Nothing hereunder requires Cardinal Health to sell or otherwise provide Galli Eo's™ to Pharmacy or any other party, unless otherwise agreed upon by Cardinal Health.

F. This Agreement may be amended or terminated by either party if the current return policies and guidelines by the NRC applicable to Galli Eo™ generators are amended, modified or explicitly codified, or if Cardinal Health no longer distributes Galli Eo™ to Pharmacy, with such termination applicable following the return of all Galli Eo's™ to Cardinal Health per the terms of this Agreement.

2 **Miscellaneous.** The terms herein represent the entire agreement between the parties regarding the subject matter herein. Notices required herein will be provided by each party to the other via overnight courier, hand delivery or certified mail/return receipt, directed to the address under the signature lines below.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties duly execute this Agreement, effective on the date first

written above.

Cardinal Health 414, LLC		**Pharmacy**	
Name	David W. Pellicciarini	**Name**	
Title	Vice President, Pharmacy Safety, Practice, and Tech. Ops.	**Title**	
Signature		**Signature**	
Address	Cardinal Health NPHS 7000 Cardinal Place Dublin, OH 43017 USA	**Address**	