



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 14, 2017

Brian K. Hardesty, R.Ph.
Vice President and Radiation Safety Officer
Guardian Pharmacy of Indianapolis Nuclear L.L.C.
d/b/a Radiopharmacy of Indianapolis
6538 Corporate Dr.
Indianapolis, IN 46278

Dear Mr. Hardesty:

In the letter dated June 29, 2017, you requested to add an authorization for the possession and use of germanium-68/gallium-68 (Ge-68/Ga-68) generators to your NRC License No. 13-32637-01MD. In that letter, you provided supporting documentation including commitments and a generic "Return Agreement for GalliaPharm™ ⁶⁸Ge/⁶⁸Ga Generators," signed by you and Alica Hue, Sales & Customer Support for Eckert & Ziegler RadioPharma GmbH (E&Z). We have reviewed submitted information, including the absence of a surety trust agreement and certification required for the possession of the types and quantities of material requested. Please note that we cannot add an authorization for possession and use of germanium-68, absent additional information, including required financial assurance and a legally binding agreement for the return and acceptance of returned generators between Guardian Pharmacy of Indianapolis, L.L.C. d/b/a Radiopharmacy of Indianapolis, NRC License No. 13-32637-01MD and the generator manufacturer, E&Z.

Concerning the request to add the referenced authorization, additional information is needed to complete our review as follows:

1. The above-referenced letter requested an authorized use that omitted explicit reference to the Eckert and Ziegler GalliaPharm™ germanium-68/gallium-68 generator. Please note that the U.S. Nuclear Regulatory Commission (NRC) licensing guidance document, "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator," dated October 17, 2016 (ML16287A403), outlines expectations for materials and use authorizations, limited to use of the Eckert and Ziegler GalliaPharm™ germanium-68/Gallium-68 generator.

Accordingly, please confirm that the requested use authorization is specific to the E&Z GalliaPharm™ generator.

2. The above-referenced letter indicated that the Radiation Safety Officer (RSO) and Authorized Nuclear Pharmacists (ANPs) would be trained in the safe use, regulatory requirements, and hazards with use of germanium-68 and gallium-68. However, the application was unclear as to which ANPs would be authorized for germanium-68/gallium-68 generator use, and that such training would be received prior to receiving a gallium-68/germanium-68 generator at your facility. Finally, the letter was unclear as to whether the RSO or other individual ANPs listed on your license have already received training.

Accordingly, please confirm that all ANPs and the RSO currently listed on the license should be authorized for use of the germanium-68/gallium-68 generators and will receive training prior to use. In addition, please provide documentation of training the RSO or other ANPs have already received in use of the germanium-68/gallium-68 generators to be authorized on the license.

3. The licensing guidance document referenced above outlines explicit licensee commitments that the NRC may accept in approving the licensee for germanium-68/gallium-68 generator use. Such commitments were excluded from the request.

Please provide commitments in accordance with pages 5-7 of the guidance document. For your convenience, copies of these pages are attached to this message. In the alternative, for each omitted or revised commitment, please explain why the guidance document was not used and justify any alternative response.

4. The licensing guidance document for Ge-68/Ga-68 generators includes an option for licensees and applicant the authority to update Radiation Protection Programs – without a license amendment – provided that such authority is requested and a confirmation that certain conditions will be met is included with the request. We have noted that the above-referenced letter was silent as to intentions to make changes to the Radiation Protection Program.

Accordingly, please confirm that no such authorization is requested. In the alternative, please refer to the guidance document, pages 7-8, and include a request for flexibility to update the program with your response. A confirmation that conditions will be met as specified in the guidance should also be included with any such request.

5. Via memo dated July 29, 2016 (ML16082A415), NRC's Office of Nuclear Material Safety and Safeguards (NMSS) authorized the NRC Region III Office to grant specific exemptions from the 10 CFR 30.35(a)(1) DFP requirement noted above. As noted in the memo, our office may grant such an exemption provided that the application provides documentation, including Financial Assurance (FA) certification based on possession limit. Note that, for up to two generators and up to 100 millicuries total, FA amount is \$225,000. To date, although a surety bond has been required, no standby trust agreement nor certification have been submitted on behalf of Guardian, on behalf of the licensee's request to receive, use, and possess Ge-68/Ga-68 generators. The NRC Region III office cannot issue a Ge-68/Ga-68 generators authorization prior to receipt and review of FA documents, as required by 10 CFR 30.35.

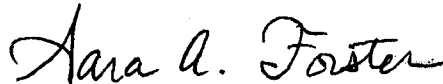
Accordingly, please submit additional FA documents (Standby Trust Agreement (STA) and Certification) in the amount of \$225,000 (for a PL of up to two generators and 100 millicuries total, as indicated in the initial application), as required by 10 CFR 30.35. For additional guidance, please refer to Appendix A, "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning" of NUREG-1757, Volume 3, revision 1, "Financial Assurance, Recordkeeping, and Timeliness." For your convenience, key relevant checklists and guidance are attached to this letter. FA must be in place and review complete prior to amending the NRC license for possession of this material.

B. Hardesty

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Please provide a written response to this letter by September 28, 2017. Your response should be dated and signed by authorized personnel. You may submit your response via facsimile to my attention at (630) 515-1078. Include the reference control number 600076 with your response. We will resume our review once we receive your response. If you have any questions, or if you need additional time to submit requested information, please do not hesitate to contact me at 630-829-9892 or sara.forster@nrc.gov.

Sincerely,



Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 13-32637-01MD
Docket No. 030-37428

Enclosures: 1. Eckert & Ziegler germanium-68/gallium-68 licensing guidance (excerpt)
2. NUREG 1757 surety bond licensing guidance (excerpt)

4.2 Radionuclides, Form, Possession Limits, and Purpose of Use

The applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. The NRC Form 313 must be used to submit this information. For example, the following provides the format for an acceptable request:

For commercial nuclear pharmacy licensees:

| | |
|--------------------------------------|--|
| Radionuclides | Ge-68 Ga-68 |
| Chemical/Physical Form (Item 5) | Any |
| Maximum Possession Limit (Item 5) | 100 mCi of Ge-68 100 mCi of Ga-68 |
| Authorized Use (Form 313 Item 6) | For use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies. For preparation and distribution of radioactive drugs in accordance with 10 CFR 32.72 and radiochemicals for non-medical use to authorized recipients. |

Note Ga-68 eluent is not a radioactive drug until it has been prepared in accordance with an FDA accepted IND application or an FDA approved New Drug application (NDA). Prior to preparation, the Ga-68 eluent is considered a radiochemical.

4.4 Authorized Individuals [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(1)]:

The NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized to use the Eckert and Ziegler GalliaPharm™ generator to develop/create Ga-68. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by the NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that an individual is qualified to be an AU or ANP.

Identify each AU or ANP and provide documentation of his/her training and experience in the use of the Eckert and Ziegler GalliaPharm™ generator. NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation for uses defined under 10 CFR 35.200 and 35.300," and NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" or other formats may be used to document this training and experience. The individual will be considered qualified for use of the Eckert and Ziegler GalliaPharm™ generator if the licensee demonstrates that the individual meets the following:

- 1) Is currently listed on a license or permit (NRC, Agreement State, or Broad Scope License, or a permit issued by a NRC Master Materials Licensee) as an ANP under 10 CFR 35.55, "Training for an authorized nuclear pharmacist;"

Physicians or nuclear pharmacists, working under supervision of an AU or ANP described above, are authorized to elute the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies in accordance with 10 CFR 35.27.

5. License Commitments

An applicant requesting authorization for the Eckert and Ziegler GalliaPharm™ generator shall commit to the following:

- Providing instructions and/or training on the manufacturer's procedures to all individuals involved in Ge-68/Ga-68 generator use, commensurate with the individual's duties to be performed;
- Not to opening, breaching, or physically modifying the Eckert and Ziegler GalliaPharm™ generator in any way;
- Following the manufacturer's procedures, including: generator set-up; generator elution; drug preparation; Ge-68 breakthrough testing; and final disposition;
- To eluting the generator in accordance with the manufacturer's stated frequency and procedures to minimize the concentration of Ge-68 in the eluate;
- Not using an expired generator for preparation of materials that will be administered to patients or human research subjects;
- Only using a generator that has a clearly marked expiration date;
- After installation, eluting the generator and properly disposing of the eluate prior to the first use of eluate for testing or human use;
- Developing and implementing written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's 0.001 percent breakthrough limit, i.e., the presence of Ge-68 in excess of a ratio of 0.01 µCi Ge-68 per 1 mCi Ga-68;
- Not knowingly administer to a patient or human research subject any material containing Ga-68 which is determined to exceed the manufacturer's 0.001 percent breakthrough limit;
- If the generator has not been eluted within 48 hours, then discarding the first eluate prior to use (e.g., if the generator is used Friday and the next elution is not until Monday morning then the first eluate shall be discarded);
- Measuring the breakthrough of the generator at least once every 7 calendar days when in use;
- Removing a generator from use if the measured Ge-68 breakthrough exceeds the manufacturer's stated breakthrough limit;
- Not returning a generator to service until the breakthrough has been measured again in a new elution and determined to be below the manufacturer's stated breakthrough limit.

- Maintaining a record of the breakthrough tests for at least 3 years. These tests should include the ratio of the measured activity of Ge-68 per Ga-68 corrected for the time of elution, time and date of the elution, time and date of the measurement, and the name of the individual who made the measurement;
- Developing and implementing written emergency procedures for leaking or damaged generators;
- Notifying by telephone the NRC Operations Center (301-816-5100) and the manufacturer/distributor of the generator within 7 calendar days after discovery of an eluate (excluding eluates from flushing the generator in accordance with manufacturer procedures) that exceeded the manufacturer's stated breakthrough limits of Ge-68;
- Include in the report to the NRC Operations center the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the manufacturer/distributor was notified; and the action taken;
- Reporting, in writing, within 30 days of a failed breakthrough calculation in accordance with the rules for medical events, and reportable events as applicable;
- Sending a written report to the appropriate NRC Regional Office within 30 days after discovery of an eluate (excluding eluates from flushing the generator in accordance with manufacturer procedures) that exceeded the manufacturer's stated breakthrough limits of Ge-68. Include in the written report the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report made as described above;
- Wipe testing all areas of licensed material use, including the generator storage and kit preparation areas, for contamination each day of use; and
- Wipe testing the generator casing quarterly for expired or unused generators in storage for more than 3 months.

6. Radiation Protection Program Changes [10 CFR 35.26]

An applicant initially applying for authorization for use of the Eckert and Ziegler GalliaPharm™ generator for preparation of Ga-68 radiopharmaceuticals for imaging and localization studies may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation protection program:

1. The revision does not require a license amendment under 10 CFR 35.13;
2. The revision is based upon NRC's current guidance for use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;

3. The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;
4. The affected individuals are instructed on the revised program before the change is implemented;
5. The licensee shall retain a record of each change for 5 years; and
6. The record will include a copy of the current guidance for use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management representative who reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

7. Notes to Licensees

7.1 Labeling

Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 for medical licenses and 10 CFR 32.72(a)(4) for commercial nuclear pharmacy licenses.

7.2 Survey of Dosages

Assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63). Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ± 20 percent from the prescribed dosage, except as approved by an AU.

7.3 Waste Disposal

7.3.1 Eluate Disposal

Due to breakthrough, the eluate may contain small amount of Ge-68 activity, which has a half-life of greater than 120 days (the half-life of Ge-68 is 270.8 days). Depending on the activity of Ge-68, composition of the waste, and state, local, and federal regulations, the licensee may need to:

- Dispose the waste in accordance with 10 CFR 20.2003. Please note that the waste generated during elution and dose preparation is acidic. For final disposal, the acidic solution may need to be placed into a chemical waste container; or
- Transfer the waste to an authorized recipient.

Additional information can also be found in reference IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 28, 1994.

4.2 PRESCRIBED AMOUNT

This section applies only to reviews of submissions that demonstrate financial assurance using one or more of the three prescribed amounts established in 10 CFR Parts 30, 40, and 70.

When a licensee proposes to use a prescribed amount of financial assurance, the purpose of the review of the certification of financial assurance is to ensure that, based on the licensed possession limits and the applicable quantities specified in 10 CFR 30.35(d), 40.36(b), or 70.25(d), the licensee is eligible to use a prescribed amount and, if eligible, that the prescribed amount is appropriate.

INFORMATION TO BE SUBMITTED

The information supplied by the licensee or responsible party should be sufficient to allow the NRC staff to determine if the certification of financial assurance was developed in accordance with NRC regulations and guidance. The NRC staff's review should verify that the certification of financial assurance satisfies all of the information summarized under "Evaluation Criteria," below.

In determining whether use of a prescribed amount is allowable and whether the prescribed amount is appropriate, the NRC staff will use the method outlined in 10 CFR 30.35, 40.36, and 70.25. Additional guidance on this method is contained in Appendix A to this volume. Appendix A also contains a table showing (for each isotope with a half-life greater than 120 days) the activity levels for which prescribed amounts of financial assurance are allowed under NRC regulations. The table also shows the prescribed amounts that are applicable to specific activity levels for each isotope.

Note that the prescribed amounts of financial assurance listed are current at the time of publication. Check the applicable parts of 10 CFR Parts 30, 40, and 70 for the most recent prescribed amounts.

The worksheet below can be used to help determine the total prescribed amount required for one or more licenses. In completing the worksheet, the preparer should enter the required prescribed amounts under all applicable parts of 10 CFR (i.e., Parts 30, 40, and 70) on the appropriate lines and add them to yield the total required prescribed amount.

Appendix A to this volume contains guidance—including recommended wording and checklists—to assist licensees in preparing certifications of financial assurance that will be acceptable to the NRC. The NRC staff should use this guidance to the extent necessary in reviewing certifications of financial assurance submitted by licensees.

EVALUATION CRITERIA

The information supplied by the licensee should be sufficient to allow the NRC staff to determine if the licensee's certification of financial assurance is adequate by comparing it with applicable NRC regulations and guidance. A certification of financial assurance is acceptable if it meets all four of the following conditions:

- (1) Use of a prescribed amount of financial assurance is allowed, based on the licensed possession limits and the applicable quantities specified in 10 CFR 30.35(d), 40.36(b), or 70.25(d), and on the absence of subsurface contamination, as specified in 10 CFR 30.35(b), 40.36(b), or 70.25(b).
- (2) Where the licensee is authorized to possess more than one radionuclide, the unity rule (as defined in Appendix B to Part 30) is applied to all radionuclides with half-life greater than 120 days.
- (3) The prescribed amount is correct, based on the licensed possession limits and the applicable quantities specified in 10 CFR 30.35(d), 40.36(b), or 70.25(d). Figure 4.1 provides a worksheet for determining the required prescribed amount.
- (4) The certification of financial assurance includes all necessary information, including the name of the licensee, the locations of the facilities for which financial assurance is provided, the amount and types of materials authorized for possession under the license, and the prescribed amount(s).

| WORKSHEET FOR DETERMINING THE REQUIRED PRESCRIBED AMOUNT | | |
|---|--|----------------------------------|
| Applicable Part of 10 CFR (Check all that apply): | <input type="checkbox"/> Part 30 <input type="checkbox"/> Part 70 | <input type="checkbox"/> Part 40 |
| | | Required Prescribed Amount (\$) |
| Part 30 (Sealed Sources): | | _____ |
| Part 40: | | _____ |
| Part 70: | | _____ |
| Total of all prescribed amounts for all licenses: | | _____ |

Figure 4.1 Worksheet for Determining the Required Prescribed Amount

EVALUATION CRITERIA

The NRC staff will verify that the financial assurance mechanism supplied by the licensee or responsible party meets the general requirements for all financial assurance mechanisms listed below *and* the applicable specific requirements listed in the following sections.

4.3.1 GENERAL CRITERIA APPLICABLE TO ALL FINANCIAL ASSURANCE MECHANISMS

- The financial assurance mechanism is an originally signed duplicate; and

FINANCIAL ASSURANCE OVERVIEW

- The wording of the financial assurance mechanism and supporting documents conforms to the model documents provided in Appendix A of this volume (e.g., for a trust fund, refer to the section on trust funds).
- If the wording and supporting documents do not conform exactly to the model documents in Appendix A, the NRC staff will follow the procedures outlined in Section 4.3.3.

4.3.2 SPECIFIC CRITERIA FOR FINANCIAL ASSURANCE MECHANISMS

4.3.2.2 SURETY BONDS

In addition to the general criteria outlined in Section 4.3.1, a surety bond submission that meets the following *additional* criteria will be acceptable to the NRC:

- The following items have been included in the submission:
 - surety bond;
 - standby trust agreement and all supporting documentation (see Section 4.3.2.10); and
 - copy of broker/agent's power of attorney authorizing the broker/agent to issue bonds.
- The company issuing the surety bond is listed in the most recent edition of the U.S. Department of the Treasury's Circular 570, "Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies," for the State where the surety bond was signed and has an underwriting limitation greater than or equal to the level of coverage specified in the bond. If evidence of the issuing company's qualifications is not provided in the submission, the reviewer will consult the most recent edition of Circular 570, which is published annually on approximately July 1 and is updated periodically in the *Federal Register*. (Circular 570 can also be found on the World Wide Web at <<http://www.fms.treas.gov/c570/index.html>>.)
- The surety bond is payable to a standby trust fund that meets all applicable NRC requirements, as discussed in the section on standby trust funds (Section 4.3.2.10).
- The broker/agent's power of attorney authorizes the broker or agent to issue bonds on behalf of the issuing company.
- The surety bond is in an amount that is at least as great as the licensee's cost estimate or prescribed amount—unless the surety bond is being used in combination with another financial assurance mechanism(s), in which case the amount of the surety bond must at least equal the difference between the cost estimate or prescribed amount and the sum of the coverages being provided by the other mechanism(s).
- No credit is taken for earnings on any financial assurance mechanism (e.g., a surety bond) that does not set aside actual funds as prepayment for site control and maintenance activities.

4.3.2.10 STANDBY TRUST FUNDS

In addition to the general criteria outlined in Section 4.3.1, a standby trust fund submission that meets the following *additional* criteria will be acceptable to the NRC:

- The following items have been included in the submission:
 - standby trust agreement;
 - Schedule A;
 - Schedule B;
 - Schedule C;
 - specimen certificate of events;
 - specimen certificate of resolution; and
 - letter of acknowledgment.
- The trustee is an appropriate Federal or State government agency or a financial institution that has the authority to act as trustee and whose trust operations are regulated and examined by a Federal or State agency. If evidence of the trustee's qualifications is not provided in the submission, the reviewer will evaluate the trustee's qualifications as follows:
 - The word "National" in the title of a financial institution signals that the institution is *Federally regulated*, as do the words "National Association" or the initials "N.A." following its title. To determine whether such a financial institution qualifies as an acceptable trustee, the reviewer will access the Federal Financial Institutions Examination Council's (FFIEC) Trusts Institutions Search database on the World Wide Web at <<http://www.fdic.gov/bank/individual/trust/>>, and look to see that the bank branch has full trust powers.

Alternatively, the reviewer may contact the appropriate district office of the Office of the Comptroller of the Currency (OCC) and confirm that the institution (1) is Federally regulated *and* (2) has Federally regulated trust operations. The OCC's home page on the World Wide Web is located at <<http://www.occ.treas.gov>>. As of the date of this revision, the four district offices of the OCC, along with the States and territories under their jurisdiction, are as follows:

- Northeastern District Office (Telephone: (212) 790-4055)—CT, DE, northeast KY, ME, MD, MA, NH, NJ, NY, NC, PA, RI, SC, VT, VA, WV, District of Columbia, Puerto Rico, and Virgin Islands.
- Southern District Office (Telephone: (214) 720-7052)—AL, AR, FL, GA, southern KY, LA, MS, southeast MO, OK, TN, and TX.
- Central District Office (Telephone: (312) 360-8881)—IL, IN, northeast and southeast IA, central KY, MI, MN, eastern MO, ND, OH, and WI.
- Western District Office (Telephone: (720) 475-7650)—AK, AZ, CA, CO, HI, ID, central and western IA, KS, western MO, MT, NE, NM, NV, OR, SD, UT, WA, WY, and Guam.

- The word "State" in the title of a financial institution signals that the institution is State regulated. U.S. branches of foreign banks are usually regulated by the State in which they are located. To determine whether a State-regulated financial institution qualifies as an acceptable trustee, the reviewer will access the FFIEC's Trusts Institutions Search database on the World Wide Web at <<http://www.fdic.gov/bank/individual/trust/>>, and look to see that the bank branch has full trust powers.

Alternatively, the reviewer may contact the applicable State banking authority and confirm that the institution (1) is State regulated, *and* (2) has State-regulated trust operations.

- The titles of some financial institutions do not suggest that they are either Federally regulated or State regulated. In many such cases (but not all), these institutions are State regulated. This is also often true in the case of domestic branches of foreign banks.
- The licensee has not assumed any real rate of return on funds in the standby trust that apply to decommissioning.
- The licensee has not assumed a real (i.e., inflation adjusted), after-tax rate of return greater than one percent per year on funds in the standby trust that apply to site control and maintenance.
- In the event that funds from the licensee's primary financial assurance mechanism(s) have been deposited into the standby trust fund, and under the appropriate assumptions regarding earnings on the trust, the current market value of the standby trust is sufficient to pay for all required activities.
- The maximum withdrawal of funds at one time for a particular activity (i.e., decommissioning or site control/maintenance) is limited to 10 percent of the remaining funds available for that activity unless approval from the appropriate party (i.e., the NRC or the party responsible for site control and maintenance) is attached.
- Schedule A to the standby trust agreement allows the trustee to access the full amount of coverage (using multiple withdrawals as necessary) to conduct all decommissioning and/or site control and maintenance activities. The amount shown in Schedule A must be at least as great as the licensee's cost estimate or prescribed amount.

Checklist 1 Master Checklist for Decommissioning Financial Assurance

Name of Licensee/Applicant _____

Mailing Address _____

Facility Address _____

License Number(s) _____

Date of Submission _____

Applicable Parts of 10 CFR (check all that apply):

| | |
|----------------------------------|----------------------------------|
| <input type="checkbox"/> Part 30 | <input type="checkbox"/> Part 40 |
| <input type="checkbox"/> Part 70 | <input type="checkbox"/> Part 72 |

Type of Submission:

- Certification of Financial Assurance → attach Checklist 2
- Decommissioning Funding Plan → attach Checklist 3
- Decommissioning Plan → attach Checklist 13-A

Type of Mechanism:

- Surety, Insurance, or Other Guarantee Method
 - Surety Bond → attach Checklist 5-A
 - Letter of Credit → attach Checklist 6-A
 - Insurance → attach Checklist 7-A
 - Parent Company Guarantee → attach Checklist 8-A
 - Self-Guarantee → attach Checklist 9-A

To help licensees and applicants make the initial decisions called for in Checklist 1, this section discusses each of the three major decision points:

- Confirmation that financial assurance is required (see Section A.1.2)
- Use of a Certification of Financial Assurance or a Decommissioning Funding Plan (see Section A.1.3)

A.1.4.2 Method 2: Surety, Insurance, or Guarantee

Under the surety, insurance, or guarantee method, an entity with adequate financial strength (e.g., bank, insurer, or other financial institution) guarantees that the required amount of funds will be available whenever needed. Unlike prepayment, this method does *not* require the full amount of decommissioning funds to be set aside by the licensee in advance. Instead, the licensee typically pays an annual fee to the provider of the surety, insurance, or guarantee. Specific surety, insurance, or guarantee instruments include the following:

SURETY BOND

A surety bond is a guarantee by a company that it will fund decommissioning if the licensee fails to do so. Licensees must pay an annual fee to the issuing company to provide the bond and may have to provide substantial collateral, depending on the licensee's financial condition. Surety bonds must be accompanied by a standby trust.

- Licensees who elect to use a surety bond should refer to Section A.5 for applicable guidance.
- Licensees who use a surety bond should complete Checklist 5-A (in Section A.5).

A.1.4.5 Standby Trust Funds

As noted earlier, funds drawn from a surety bond, letter of credit, parent company guarantee, self-guarantee, or insurance policy must be placed directly into a standby trust fund if the licensee fails to conduct decommissioning as required. A standby trust fund is simply a trust fund that is not yet funded but is otherwise ready to accept monies in the event they are received from a particular source. Funds in the standby trust would then be available to pay the costs of decommissioning, just as they would with an ordinary trust fund. Standby trusts are necessary because, if the funds from surety or insurance mechanisms were paid directly to the NRC rather than to a standby trust fund, the NRC would be required to deposit the funds in the U.S. Treasury as general revenue. Consequently, the funds would not be available to pay for decommissioning costs.

- Licensees who elect to use a standby trust fund should refer to Section A.12 for applicable guidance.
- Licensees who use a standby trust fund should complete Checklist 12-A (in Section A.12).

A.2 Certification of Financial Assurance

All licensees required to provide financial assurance under 10 CFR Part 30, 10 CFR Part 40, 10 CFR Part 70, and 10 CFR Part 72 must submit a Certification of Financial Assurance. The following sections describe the use of the Certification of Financial Assurance when using a prescribed amount of financial assurance or when using a DFP. Section A.2.4 provides a Model Certification of Financial Assurance to illustrate a format acceptable to the NRC.

A.2.1 Certification of Financial Assurance Using a Prescribed Amount

For licensees that are not required to submit a DFP, the regulations prescribe three levels of financial assurance—\$113,000, \$225,000, and \$1,125,000. However, the amounts may be revised from time to time, and the regulations must be consulted to determine the currently applicable prescribed amounts when the licensee's financial assurance is reviewed. The dollar amounts shown in this guidance document are for illustrative purposes and must be revised as necessary to meet regulatory requirements. A combination of these amounts is required for licensees authorized to possess more than one type of radioactive material. For example, a licensee authorized to possess sealed sources containing byproduct material (\$113,000) and 20 mCi of source material in readily dispersible form (\$225,000) would be required to submit financial assurance for the sum of the prescribed amounts, or \$338,000. The prescribed amount specified in the regulations becomes the required level of financial assurance coverage. Licensees who use a prescribed amount must undertake the following actions, as summarized in Checklist 2:

- Determine the appropriate prescribed amount (see Section A.2.1).
- Prepare a certification of financial assurance (see Section A.2.2).
- Submit the required documentation (see Section A.2.3).

Licensees using prescribed amounts eventually may have to adjust their financial assurance coverage levels (and update their financial instruments) for one of three reasons:

- The NRC adjusts the prescribed amount specified in the regulations.
- The licensee submits a DFP containing a site-specific cost estimate instead of using a prescribed amount.
- The licensee prepares a DP with a site-specific cost estimate. Certain licensees who notify the NRC that they will terminate activities under their licenses and decommission their facilities must submit DPs (not the same as DFPs). The DP must contain "an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning," as required in 10 CFR 30.36(g)(4)(v), 10 CFR 40.42(g)(4)(v), 10 CFR 70.38(g)(4)(v), and 10 CFR 72.54(g)(5).

Checklist 2 Certifications of Financial Assurance Using a Prescribed Amount

License Number(s): _____

Applicable Parts of 10 CFR (check all that apply):

- Part 30 Part 40
 Part 70

- Determine the appropriate prescribed amount(s) (see Section A.2.1)
- Amount required under Part 30 for sealed sources: _____
 - Amount required under Part 30 for unsealed sources: _____
 - Amount required under Part 40: _____
 - Amount required under Part 70: _____
 - *Total of all prescribed amounts for all licenses:* _____
- Prepare certification statement (see Section A.2.2)
- Include the necessary documentation (see Section A.2.3):
- Certification statement (see Section A.2.4)
 - Financial instrument and supporting documentation

In addition, regardless of a particular licensee's eligibility to use a prescribed amount, any licensee may elect instead to use a DFP based on a site-specific cost estimate to determine the required level of financial assurance coverage. Licensees may wish to use a DFP if, for example, they wish to obtain the optimal amount of financial assurance, or because use of prescribed amounts may overstate a facility's decommissioning costs. In addition, a materials licensee may not base its financial assurance for decommissioning on a certification amount when the licensee's site surveys indicate the presence of residual radioactivity in amounts that would prevent the site from meeting the unrestricted use criteria in 10 CFR 20.1402. Guidance on preparing DFPs is presented in Section A.3 of this appendix.

Licensees may be eligible to use a particular prescribed amount depending on the type of license and the types and quantities of materials authorized under the particular license, as summarized below. Licensees authorized to possess only a single isotope may use the table in Attachment 1 to this appendix to determine the appropriate certification amount for a given activity level. Note that the relevant quantities and types of materials are those *authorized* under a particular license, even if a licensee does not currently or usually possess or use these same quantities and types of materials. The following discussion of applicable prescribed amounts is organized into three parts corresponding to the three general license types:

- 10 CFR Part 30—Byproduct Material
- 10 CFR Part 40—Source Material
- 10 CFR Part 70—Special Nuclear Material

Only radionuclides with a half-life of greater than 120 days are included in the determination of financial assurance requirements.

A.2.1.1 10 CFR Part 30 Prescribed Amounts

Title 10 of the *Code of Federal Regulations* Part 30 prescribes three levels of financial assurance. Check 10 CFR 30.35(d) to determine current specifications for prescribed amount. The following apply to the use of prescribed amounts by 10 CFR Part 30 licensees.

- **The middle level prescribed amount of \$225,000 applies** to 10 CFR Part 30 licensees who are authorized to possess or use unsealed byproduct material with a half-life greater than 120 days:
 - in amounts greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix B to 10 CFR Part 30; or
 - for a *combination* of isotopes, if R divided by 10^3 is greater than 1 but if R divided by 10^4 is less than or equal to 1 (when R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to 10 CFR Part 30).

A.2.2 Preparing the Certification of Financial Assurance

All licensees who are required to provide financial assurance must prepare a certification of financial assurance. In the certification of financial assurance, the licensee certifies that it has obtained financial assurance in the appropriate amount and provides the details needed to verify that the amount is accurate under NRC regulations. As discussed above, these details include the license type and the types and amounts of materials authorized by the license.

The NRC staff considers the model wording for certifications of financial assurance presented in Section A.2.4 to be acceptable. Although other wording may also be satisfactory, all certifications of financial assurance should clearly identify the licensee, the license number, the type of license (e.g., 10 CFR Part 30), the types and amounts of materials authorized by the license (including specific isotopes where applicable), the appropriate amount of financial assurance, and a certification that the information presented in the statement is accurate.

A.2.3 Submitting the Required Documentation

Under NRC's financial assurance regulations 10 CFR 30.35(b)(2), 10 CFR 40.36(b)(2), and 10 CFR 70.25(b)(2), licensees who use prescribed amounts of financial assurance must submit the following to the NRC:

- The certification of financial assurance (regulatory guidance is provided in Section A.2.2); and

- An *originally signed duplicate* of the financial instruments obtained to provide financial assurance for decommissioning. This appendix describes the allowable financial instruments first in general terms, in Section A.1, and then in detail beginning in Section A.4. Licensees should refer to these other sections to ensure that their financial assurance instruments and supporting documentation will be acceptable to the NRC. Licensees under 10 CFR Part 72 are not required to submit originals of the financial assurance documents. If certain information in the financial instrument (licensee's name, license number, and docket number and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee) changes, the licensee must, within 30 days, submit financial instruments reflecting such changes.

In addition to submitting these materials, licensees must maintain records of the amount of financial assurance certified for decommissioning and the funding methods used for assuring funds (e.g., a copy of the financial instruments and all supporting documentation).

A.2.4 Model Certification of Financial Assurance

CERTIFICATION OF FINANCIAL ASSURANCE

Principal: [*Legal names and business address of licensee*]
NRC license number, name, and address of the facility

Issued to: U.S. Nuclear Regulatory Commission

I certify that [*insert name of licensee*] is licensed to possess the following types of [*insert all that apply: "sealed sources or plated foils with a half-life greater than 120 days licensed under 10 CFR Part 30," "unsealed byproduct material with a half-life greater than 120 days licensed under 10 CFR Part 30," "source material in a readily dispersible form licensed under 10 CFR Part 40," "unsealed special nuclear material licensed under 10 CFR Part 70" and "spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste licensed under 10 CFR Part 72"*] in the following amounts:

| <u>Type of Material</u> | <u>Amount of Material</u> |
|--|---------------------------|
| <i>[List materials and quantities of materials noted above. For byproduct materials and special nuclear materials, list separately the type and amount of each isotope authorized by the license.]</i> | |

I also certify that financial assurance in the amount of [*insert the total of all prescribed amounts calculated from Checklist 2 or the amount of the site-specific cost estimate, in U.S. dollars*] has been obtained for the purpose of decommissioning as prescribed by 10 CFR Part [*insert 30, 40, 70, or 72*].

[*Signatures and titles of officials of institution*]
[*Corporate seal*]
[*Date*]

A.5 Surety Bonds

A *payment surety bond* (or *surety bond*) is a guarantee by a surety company (or surety) that it will fund decommissioning activities if the principal (i.e., the licensee) fails to do so. In issuing a surety bond, the surety company becomes "jointly and severally" liable for the guaranteed payment, meaning that the surety assumes the licensee's obligation to fund decommissioning as its own and can be sued jointly with the licensee for the obligation. Consequently, most surety bonds include an indemnification provision that requires the principal to reimburse the surety for costs incurred in satisfaction of the principal's obligations.

A surety bond used for decommissioning financial assurance must be open ended or, if written for a specified term (such as 5 years), must be renewed automatically unless, 90 days or more prior to the renewal date, the surety notifies both the NRC and the licensee of its intention not to renew. A surety bond must also provide that the full face amount of the bond be paid to the beneficiary automatically prior to expiration, without proof of forfeiture, if the licensee fails to provide a replacement mechanism acceptable to the NRC within 30 days after receipt of notification of cancellation.

Funds drawn from a surety bond must be placed directly into a "standby trust fund" if the licensee fails to conduct decommissioning as required. A standby trust fund is simply a trust fund that is not yet funded but is otherwise ready to accept monies in the event they are received from a particular source (such as a surety bond). Funds in the standby trust would then be available to pay the costs of decommissioning, just as they would with an ordinary trust fund. (See Section A.12 for more information on standby trust funds.)

The remainder of this section discusses the primary criteria that determine whether the NRC will find particular surety bond submissions acceptable.

- Section A.5.1 describes qualifications required of the issuer (the surety company).
- Section A.5.2 addresses the adequacy of coverage.
- Section A.5.3 discusses the documentation that supports a surety bond.
- Section A.5.4 presents a model surety bond that the NRC has found to be acceptable.

This section also contains two checklists that are designed to assist licensees who wish to use surety bonds. Checklist 5-A summarizes the primary criteria used by the NRC to evaluate surety bonds. Checklist 5-B (which should be used only by licensees who revise or do not use the model wording for surety bonds) presents terms and conditions that are recommended for surety bonds.

Checklist 5-A Surety Bonds

- Documentation is complete when the following are included:
 - 1. surety bond (originally signed duplicate);
 - 2. standby trust agreement and all supporting documentation (see Section A.12 and attach Checklist 12-A);
 - 3. copy of broker/agent's power of attorney authorizing the broker/agent to issue bonds; and
 - 4. Checklist 5-B (if model surety bond wording is modified or not used).
- The company issuing the surety bond is listed in the most recent edition of Circular 570 for the State in which the bond was signed and has an underwriting limitation greater than or equal to the amount of the bond being used for decommissioning.
- The amount of the surety bond equals or exceeds the required coverage level.

A.5.1 Qualifications of the Issuer

To determine whether a company issuing the surety bond is qualified, licensees should consult the most recent edition of the U.S. Department of the Treasury's Circular 570, which is published annually on approximately July 1 and is updated periodically in the *Federal Register*. (Circular 570 can also be found on the World Wide Web at <http://www.fms.treas.gov/index.html>.) The company issuing the surety bond must be listed in *Circular 570* as qualified in the State where the surety bond was signed, and the company's underwriting limitation (also specified in Circular 570) must be at least as great as the level of coverage required for the license. A company issuing a surety can only exceed its underwriting limitation if it brings another qualified company into the agreement to share the risk. When acting together, none of the companies may exceed its individual underwriting limitation.

Also, as noted above, a surety bond must be payable to a standby trust fund. Section A.12 provides information on the qualifications of trustees of standby trusts.

A.5.2 Level of Coverage

A surety bond must be in an amount that is at least equal to the licensee's prescribed amount or estimated cost of decommissioning. The exception to this rule is a surety bond that is being combined with another financial mechanism. For a combination of mechanisms, the *sum* of the coverage provided by the mechanisms must be at least equal to the required coverage level. If the licensee's prescribed amount or estimated decommissioning cost increases to a level above the amount assured by the surety bond, the licensee must either (1) revise the surety bond to assure the higher amount or (2) obtain another financial assurance mechanism to make up the difference between the new coverage level and the amount of the surety bond.

A.5.3 Recommended Documentation

As summarized in Checklist 5-A, licensees who wish to use surety bonds to provide financial assurance for decommissioning must submit a copy of the surety bond and other documentation as discussed below. Supporting documentation may differ for licensees who submit surety bonds that differ from the recommended model.

The *surety bond* (along with any riders or amendments) signed by an authorized representative from the issuing company. The wording of a surety bond may vary, but Section A.5.4 of this appendix is a model surety bond that is acceptable to and recommended by the NRC. Licensees who wish to use other wording should refer to Checklist 5-B to be sure that the alternative wording contains all of the necessary terms and conditions.

A copy of the broker/agent's power of attorney authorizing the broker/agent to issue bonds on behalf of the issuing company. The power of attorney ensures that the surety bond is enforceable.

A *standby trust fund* must be established to receive funds from the surety bond. The standby trust fund should satisfy the criteria described in Section A.12 and in Checklist 12-A of this appendix.

A.5.4 Model Surety Bond

PAYMENT SURETY BOND

Date bond executed: _____

Effective date: _____

Principal: [*Insert legal name and business address of licensee*]

Type of organization: [*Insert "proprietorship," "partnership," "corporation," or "LLC"*]

State of incorporation: _____ (if applicable)

NRC license number, docket number, name and address of facility, and amount for decommissioning activities guaranteed by this bond: _____

Surety: [*Insert name and business address*]

Type of organization: [*Insert "proprietorship," "partnership," or "corporation"*]

State of incorporation: _____ (if applicable)

Surety's qualification in jurisdiction where licensed facility is located.

Surety's bond number: _____

Total penal sum of bond: \$ _____

Know all persons by these presents, that we, the Principal and Surety hereto, are firmly bound to the U.S. Nuclear Regulatory Commission (hereinafter called NRC) in the above penal sum for the payment of which we bind ourselves, our heirs, executors, administrators, successors, and assigns jointly and severally; provided that, where the Sureties are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum "jointly and severally" only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself, jointly and severally with the Principal, for the payment of such sum only as is set forth opposite the name of such Surety; but if no limit of liability is indicated, the limit of liability shall be the full amount of the penal sum.

WHEREAS, the U.S. Nuclear Regulatory Commission, an agency of the U.S. Government, pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, has promulgated regulations in Title 10, Chapter I of the *Code of Federal Regulations*,

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Part [*insert 30, 40, 70, or 72*], applicable to the Principal, which require that a license holder or an applicant for a facility license provide financial assurance that funds will be available when needed for facility decommissioning;

NOW, THEREFORE, the conditions of the obligation are such that if the Principal shall faithfully, before the beginning of decommissioning of each facility identified above, fund the standby trust fund in the amount(s) identified above for the facility;

Or, if the Principal shall fund the standby trust fund in such amount(s) after an order to begin facility decommissioning is issued by NRC or a U.S. District Court or other court of competent jurisdiction;

Or, if the Principal shall provide alternative financial assurance, and obtain NRC's written approval of such assurance, within 30 days after the date a notice of cancellation from the Surety is received by both the Principal and NRC, then this obligation shall be null and void; otherwise it is to remain in full force and effect.

The Surety shall become liable on this bond obligation only when the Principal has failed to fulfill the conditions described above. Upon notification by NRC that the Principal has failed to perform as guaranteed by this bond, the Surety shall place funds in the amount guaranteed for the facility into the standby trust fund.

The liability of the Surety shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penal sum of the bond, but in no event shall the obligation of the Surety hereunder exceed the amount of said penal sum.

The Surety may cancel the bond by sending notice of cancellation by certified mail to the Principal and to NRC provided, however, that cancellation shall not occur during the 90 days beginning on the date of receipt of the notice of cancellation by both the Principal and NRC, as evidenced by the return receipts.

The Principal may terminate this bond by sending written notice to NRC and to the Surety 90 days prior to the proposed date of termination, provided, however, that no such notice shall become effective until the Surety receives written authorization for termination of the bond from NRC.

The Principal and Surety hereby agree to adjust the penal sum of the bond yearly so that it guarantees a new amount, provided that the penal sum does not increase by more than 20 percent in any one year and no decrease in the penal sum takes place without the written permission of NRC.

If any part of this agreement is invalid, it shall not affect the remaining provisions that will remain valid and enforceable.

In Witness Whereof, the Principal and Surety have executed this financial guarantee bond and have affixed their seals on the date set forth above.

The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety.

Principal

[Signatures]
[Names]
[Titles]
[Corporate seal]

Corporate Surety

[Name and address]

State of incorporation: _____

Liability limit: \$ _____

[Signatures]
[Names and titles]
[Corporate seal]

[For every co-surety, provide signatures, names and titles, corporate seal, and other information in the same manner as for the Sureties above.]

Bond Premium: \$ _____

A.12 Standby Trust Funds

A *standby trust fund* is simply a trust fund that is not yet funded but is otherwise ready to accept monies in the event they are received from a particular source (such as a surety bond, letter of credit, or insurance). Once a standby trust is funded, the funds would then be available to pay the costs of decommissioning, just as they would with an ordinary trust fund. As in the case of an ordinary trust fund, monies in a standby trust fund are legally segregated for a specific purpose and are administered by a trustee with a fiduciary responsibility to keep or use the property in the fund for the benefit of the beneficiary.

Under the NRC's decommissioning financial assurance regulations (10 CFR 30.35(f)(2)(ii), 10 CFR 40.36(e)(2)(ii), 10 CFR 70.25(f)(2)(ii)), and 10 CFR 72.30(e)(2)(ii)), a standby trust agreement must be established to receive funds from a surety method (i.e., surety bond or letter of credit) or insurance. If the funds from these mechanisms were paid directly to the NRC rather than to a standby trust fund, the NRC would be required to deposit the funds in the U.S. Treasury as general revenue. Consequently, the funds would not be available to pay for decommissioning costs.

The remainder of this section discusses the primary criteria that determine whether the NRC will find particular standby trust fund submissions acceptable.

- Section A.12.1 describes qualifications required of the trustee.
- Section A.12.2 addresses funding and the adequacy of coverage.
- Section A.12.3 discusses the documentation that supports a standby trust fund.
- Section A.12.4 presents a model standby trust fund submission acceptable to the NRC.

This section also contains two checklists designed to assist licensees in preparing acceptable decommissioning standby trusts. Checklist 12-A summarizes the primary criteria the NRC uses to evaluate standby trust funds. Checklist 12-B (which should be used only by licensees who revise or do not use the model wording for standby trust agreements) presents terms and conditions that are recommended for standby trust agreements.

Checklist 12-A Standby Trust Funds

- Documentation is complete when the following are included:
 - 1. standby trust agreement (originally signed duplicate);
 - 2. Schedule A;
 - 3. Schedule B;
 - 4. Schedule C;
 - 5. specimen certificate of events;
 - 6. specimen certificate of resolution;
 - 7. letter of acknowledgment; and
 - 8. Checklist 12-B (if model standby trust wording is modified or not used).
- The trustee is qualified when the following conditions are true:
 - The trustee is qualified when the following conditions are true:
 - The financial institution is regulated by a Federal or State agency.
- The financial institution has authority to act as a trustee and has trust operations that are regulated and examined by a Federal or State agency.

- The *standby trust agreement* (along with any amendments) is the written document that specifies the terms and conditions of the standby trust. The wording contained in the model standby trust in Section A.12.4 is acceptable to the NRC. Licensees who use other wording should refer to Checklist 12-B to be sure that the alternative wording contains all the necessary terms and conditions.

- *Schedule A* (Section A.12.5) identifies the name and address of the licensee, the NRC license numbers covered by the standby trust, the addresses of the licensed activity, the amount of regulatory assurances demonstrated by the standby trust agreement, and the date on which these amounts were last adjusted and approved by the NRC.
- *Schedule B* (Section A.12.5) lists the property (i.e., cash, securities, or other liquid assets) initially used to establish the standby trust fund. A standby trust may be established with no property in the fund initially. In this case, Schedule B may simply state "none."
- *Schedule C* (Section A.12.5) specifies the compensation to be paid by the licensee to the trustee for its services.
- The *specimen certificate of events* (Section A.12.6) and the *specimen certificate of resolution* (Section A.12.7) provide the required format for instructing the trustee to release monies from the standby trust in order to fund decommissioning activities at the licensee's facility. When submitted as part of a financial assurance package, the specimen certificates should be unexecuted drafts. (Actual authorization to release funds from the standby trust is accomplished when completed and notarized versions of these certificates are signed by the secretary of the licensee and presented to the trustee.)
- The notarized *letter of acknowledgment* (Section A.12.8) verifies the execution of the standby trust agreement and certifies the trustee's signature and authority to enter into the agreement.
- Supporting documentation may differ for licensees who submit standby trusts that differ from the recommended model.

A.12.4 Model Standby Trust Agreement

STANDBY TRUST AGREEMENT

TRUST AGREEMENT, the Agreement entered into as of [*insert date*] by and between [*insert name of licensee*], a [*insert name of State*] [*insert "corporation," "partnership," "proprietorship," or "LLC"*], herein referred to as the "Grantor," and [*insert name and address of a trustee acceptable to NRC*], the "Trustee."

WHEREAS, the U.S. Nuclear Regulatory Commission (NRC), an agency of the U.S. Government, pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, has promulgated regulations in Title 10, Chapter I, of the *Code of Federal Regulations*, Part [*insert 30, 40, 70, or 72*]. These regulations, applicable to the Grantor, require that a holder of, or an applicant for, a materials license issued pursuant to 10 CFR Part [*insert 30, 40, 70, or 72*] provide assurance that funds will be available when needed for required decommissioning activities.

WHEREAS, the Grantor has elected to use a [*insert "letter of credit," "surety bond," "insurance policy," "parent company guarantee," or "self-guarantee"*] to provide [*insert "all" or "part"*] of such financial assurance for the facilities identified herein; and

WHEREAS, when payment is made under a [*insert "letter of credit," "surety bond," "insurance policy," "parent company guarantee," or "self-guarantee"*], this standby trust shall be used for the receipt of such payment; and

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WHEREAS, the Grantor, acting through its duly authorized officers, has selected the Trustee to be the trustee under this Agreement, and the Trustee is willing to act as trustee;

NOW, THEREFORE, the Grantor and the Trustee agree as follows:

Section 1. Definitions. As used in this Agreement:

- (a) The term "Grantor" means the NRC licensee who enters into this Agreement and any successors or assigns of the Grantor.
- (b) The term "Trustee" means the trustee who enters into this Agreement and any successor trustee.

Section 2. Costs of Decommissioning. This Agreement pertains to the costs of decommissioning the materials and activities identified in License Number [*insert license number*] issued pursuant to 10 CFR Part [*insert 30, 40, 70, or 72*], as shown in Schedule A.

Section 3. Establishment of Fund. The Grantor and the Trustee hereby establish a standby trust fund (the Fund) for the benefit of NRC. The Grantor and the Trustee intend that no third party shall have access to the Fund except as provided herein.

Section 4. Payments Constituting the Fund. Payments made to the Trustee for the Fund shall consist of cash, securities, or other liquid assets acceptable to the Trustee. The Fund is established initially as consisting of the property, which is acceptable to the Trustee, described in Schedule B attached hereto. Such property and any other property subsequently transferred to the Trustee are referred to as the "Fund," together with all earnings and profits thereon, less any payments or distributions made by the Trustee pursuant to this Agreement. The Fund shall be held by the Trustee, IN TRUST, as hereinafter provided. The Trustee shall not be responsible nor shall it undertake any responsibility for the amount of, or adequacy of the Fund, nor any duty to collect from the Grantor, any payments necessary to discharge any liabilities of the Grantor established by NRC.

Section 5. Payment for Required Activities Specified in the Plan. The Trustee shall make payments from the Fund to the Grantor upon presentation to the Trustee of the following:

- (a) A certificate duly executed by the Secretary of the Grantor attesting to the occurrence of the events, and in the form set forth in the attached Certificate of Events, and
- (b) A certificate attesting to the following conditions:
 - (1) that decommissioning is proceeding pursuant to an NRC-approved plan;
 - (2) that the funds withdrawn will be expended for activities undertaken pursuant to that plan; and
 - (3) that NRC has been given 30 days prior notice of [*insert name of licensee*]'s intent to withdraw funds from the trust fund.

No withdrawal from the Fund for a particular license can exceed 10 percent of the remaining funds available for that license unless NRC written approval is attached.

In addition, the Trustee shall make payments from the Fund as NRC shall direct, in writing, to provide for the payment of the costs of required activities covered by this Agreement. The Trustee shall reimburse the Grantor or other persons as specified by NRC from the Fund for expenditures for required activities in such amounts as NRC shall direct in writing. In addition, the Trustee shall refund to the Grantor such amounts as NRC specifies in writing. Upon refund, such funds shall no longer constitute part of the Fund as defined herein.

Section 6. Trust Management. The Trustee shall invest and reinvest the principal and income of the Fund and keep the Fund invested as a single fund, without distinction between principal and income, in accordance with general investment policies and guidelines which the Grantor may communicate in writing to the Trustee from time to time, subject, however, to the provisions of this section. In investing, reinvesting, exchanging, selling, and managing the Fund, the Trustee shall discharge its duties with respect to the Fund solely in the interest of the beneficiary and with the care, skill, prudence and diligence under the circumstances then prevailing which persons of prudence, acting in a like capacity and familiar with such matters, would use in the conduct of an enterprise of a like character and with like aims, except that:

- (a) Securities or other obligations of the Grantor, or any other owner or operator of the facilities, or any of their affiliates as defined in the Investment Company Act of 1940, as amended (15 U.S.C. 80a-2(a)), shall not be acquired or held, unless they are securities or other obligations of the Federal or a State government;
- (b) The Trustee is authorized to invest the Fund in time or demand deposits of the Trustee, to the extent insured by an agency of the Federal government, and in obligations of the Federal government such as GNMA, FNMA, and FHLM bonds and certificates or State and Municipal bonds rated BBB or higher by Standard & Poor's or Baa or higher by Moody's Investment Services; and
- (c) For a reasonable time, not to exceed 60 days, the Trustee is authorized to hold uninvested cash, awaiting investment or distribution, without liability for the payment of interest thereon.

Section 7. Commingling and Investment. The Trustee is expressly authorized in its discretion:

- (a) To transfer from time to time any or all of the assets of the Fund to any common, commingled, or collective trust fund created by the Trustee in which the Fund is eligible to participate, subject to all of the provisions thereof, to be commingled with the assets of other trusts participating therein; and
- (b) To purchase shares in any investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a-1 et seq.), including one that may be created, managed, underwritten, or to which investment advice is rendered, or the shares of which are sold by the Trustee. The Trustee may vote such shares in its discretion.

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Section 8. Express Powers of Trustee. Without in any way limiting the powers and discretion conferred upon the Trustee by the other provisions of this Agreement or by law, the Trustee is expressly authorized and empowered:

- (a) To sell, exchange, convey, transfer, or otherwise dispose of any property held by it, by public or private sale, as necessary to allow duly authorized withdrawals at the joint request of the Grantor and NRC or to reinvest in securities at the direction of the Grantor;
- (b) To make, execute, acknowledge, and deliver any and all documents of transfer and conveyance and any and all other instruments that may be necessary or appropriate to carry out the powers herein granted;
- (c) To register any securities held in the Fund in its own name, or in the name of a nominee, and to hold any security in bearer form or in book entry, or to combine certificates representing such securities with certificates of the same issue held by the Trustee in other fiduciary capacities, to reinvest interest payments and funds from matured and redeemed instruments, to file proper forms concerning securities held in the Fund in a timely fashion with appropriate government agencies, or to deposit or arrange for the deposit of such securities in a qualified central depository even though, when so deposited, such securities may be merged and held in bulk in the name of the nominee or such depository with other securities deposited therein by another person, or to deposit or arrange for the deposit of any securities issued by the U.S. Government, or any agency or instrumentality thereof, with a Federal Reserve Bank, but the books and records of the Trustee shall at all times show that all such securities are part of the Fund;
- (d) To deposit any cash in the Fund in interest-bearing accounts maintained or savings certificates issued by the Trustee, in its separate corporate capacity, or in any other banking institution affiliated with the Trustee, to the extent insured by an agency of the Federal government; and
- (e) To compromise or otherwise adjust all claims in favor of or against the Fund.

Section 9. Taxes and Expenses. All taxes of any kind that may be assessed or levied against or in respect of the Fund and all brokerage commissions incurred by the Fund shall be paid from the Fund. All other expenses incurred by the Trustee in connection with the administration of this

Trust, including fees for legal services rendered to the Trustee, the compensation of the Trustee to the extent not paid directly by the Grantor, and all other proper charges and disbursements of the Trustee shall be paid from the Fund.

Section 10. Annual Valuation. After payment has been made into this standby trust fund, the Trustee shall annually, at least 30 days before the anniversary date of receipt of payment into the standby trust fund, furnish to the Grantor and to NRC a statement confirming the value of the Trust. Any securities in the Fund shall be valued at market value as of no more than 60 days before the anniversary date of the establishment of the Fund. The failure of the Grantor to object in writing to the Trustee within 90 days after the statement has been furnished to the Grantor and NRC shall constitute a conclusively binding assent by the Grantor, barring the Grantor from asserting any claim or liability against the Trustee with respect to the matters disclosed in the statement.

Section 11. Advice of Counsel. The Trustee may from time to time consult with counsel with respect to any question arising as to the construction of this Agreement or any action to be taken hereunder. The Trustee shall be fully protected, to the extent permitted by law, in acting on the advice of counsel.

Section 12. Trustee Compensation. The Trustee shall be entitled to reasonable compensation for its services as agreed upon in writing with the Grantor. (See Schedule C.)

Section 13. Successor Trustee. Upon 90 days notice to NRC and the Grantor, the Trustee may resign; upon 90 days notice to NRC and the Trustee, the Grantor may replace the Trustee, but such resignation or replacement shall not be effective until the Grantor has appointed a successor Trustee, the successor accepts the appointment, the successor is ready to assume its duties as trustee, and NRC has agreed, in writing, that the successor is an appropriate Federal or State government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The successor Trustee shall have the same powers and duties as those conferred upon the Trustee hereunder. When the resignation or replacement is effective, the Trustee shall assign, transfer, and pay over to the successor Trustee the funds and properties then constituting the Fund. If for any reason the Grantor cannot or does not act in the event of the resignation of the Trustee, the Trustee may apply to a court of competent jurisdiction for the appointment of a successor Trustee or for instructions. The successor Trustee shall specify the date on which it assumes administration of the trust, in a writing sent to the Grantor, NRC, and the present Trustee, by certified mail 10 days before such change becomes effective. Any expenses incurred by the Trustee as a result of any of the acts contemplated by this section shall be paid as provided in Section 9.

Section 14. Instructions to the Trustee. All orders, requests, and instructions by the Grantor to the Trustee shall be in writing, signed by such persons as are signatories to this Agreement or such other designees as the Grantor may designate in writing. The Trustee shall be fully protected in acting without inquiry in accordance with the Grantor's orders, requests, and instructions. If NRC issues orders, requests, or instructions to the Trustee, these shall be in writing, signed by NRC or its designees, and the Trustee shall act and shall be fully protected in acting in accordance with such orders, requests, and instructions. The Trustee shall have the right to assume, in the absence of written notice to the contrary, that no event constituting a change or a termination of the authority of any person to act on behalf of the Grantor or NRC hereunder has occurred. The Trustee shall have no duty to act in the absence of such orders, requests, and instructions from the Grantor and/or NRC, except as provided for herein.

Section 15. Amendment of Agreement. This Agreement may be amended by an instrument in writing executed by the Grantor, the Trustee, and NRC, or by the Trustee and NRC if the Grantor ceases to exist. All amendments shall meet the relevant regulatory requirements of NRC.

Section 16. Irrevocability and Termination. Subject to the right of the parties to amend this Agreement as provided in Section 15, this trust shall be irrevocable and shall continue until terminated at the written agreement of the Grantor, the Trustee, and NRC, or by the Trustee and NRC if the Grantor ceases to exist. Upon termination of the trust, all remaining trust property, less final trust administration expenses, shall be delivered to the Grantor or its successor.

APPENDIX A

Section 17. Immunity and Indemnification. The Trustee shall not incur personal liability of any nature in connection with any act or omission, made in good faith, in the administration of this trust, or in carrying out any directions by the Grantor or NRC issued in accordance with this Agreement. The Trustee shall be indemnified and saved harmless by the Grantor or from the trust fund, or both, from and against any personal liability to which the Trustee may be subjected by reason of any act or conduct in its official capacity, including all expenses reasonably incurred in its defense in the event the Grantor fails to provide such defense.

Section 18. This Agreement shall be administered, construed, and enforced according to the laws of the State of *[insert name of State]*.

Section 19. Interpretation and Severability. As used in this Agreement, words in the singular include the plural and words in the plural include the singular. The descriptive headings for each section of this Agreement shall not affect the interpretation or the legal efficacy of this Agreement. If any part of this Agreement is invalid, it shall not affect the remaining provisions which will remain valid and enforceable.

IN WITNESS WHEREOF the parties have caused this Agreement to be executed by the respective officers duly authorized and the incorporate seals to be hereunto affixed and attested as of the date first written above.

[Insert name of licensee (Grantor)]
[Signature of representative of Grantor]
[Title]

ATTEST:
[Title]
[Seal]

[Insert name and address of Trustee]
[Signature of representative of Trustee]
[Title]

ATTEST:
[Title]
[Seal]

A.12.5 Model Standby Trust Agreement Schedules

Schedule A

This Agreement demonstrates financial assurance for the following cost estimates or prescribed amounts for the following licensed activities:

| <u>U.S. NUCLEAR REGULATORY COMMISSION LICENSE NUMBER(S)</u> | <u>NAME AND ADDRESS OF LICENSEE</u> | <u>ADDRESS OF LICENSED ACTIVITY</u> | <u>COST ESTIMATES FOR REGULATORY ASSURANCES DEMONSTRATED BY THIS AGREEMENT</u> |
|---|---|---|--|
|---|---|---|--|

APPENDIX A

The cost estimates listed here were last adjusted and approved by NRC on [insert date].

Schedule B

DOLLAR AMOUNT _____

AS EVIDENCED BY _____

Schedule C

[Insert name, address, and phone number of Trustee.]

Trustee's fees shall be \$_____ per year.

A.12.6 Model Specimen Certificate of Events

[Insert name and address of trustee]

Attention: Trust Division

Gentlemen:

In accordance with the terms of the Agreement with you dated _____, I, _____, Secretary of [insert name of licensee], hereby certify that the following events have occurred:

1. [insert name of licensee] is required to commence the decommissioning of its facility located at [insert location of facility] (hereinafter called the decommissioning).
2. The plans and procedures for the commencement and conduct of the decommissioning have been approved by the United States Nuclear Regulatory Commission, or its successor, on _____ (copy of approval attached).
3. The Board of Directors of [insert name of licensee] has adopted the attached resolution authorizing the commencement of the decommissioning.

Secretary of [insert name of licensee]

Date

A.12.7 Model Specimen Certificate of Resolution

I, _____, do hereby certify that I am Secretary of [*insert name of licensee*], a [*insert State of incorporation*] corporation, and that the resolution listed below was duly adopted at a meeting of this Corporation's Board of Directors on _____, 20____.

IN WITNESS WHEREOF, I have hereunto signed my name and affixed the seal of this Corporation this ___ day of _____, 20____.

Secretary

RESOLVED, that this Board of Directors hereby authorizes the President, or such other employee of the Company as he may designate, to commence decommissioning activities at [*insert name of facility*] in accordance with the terms and conditions described to this Board of Directors at this meeting and with such other terms and conditions as the President shall approve with and upon the advice of Counsel.

A.12.8 Model Letter of Acknowledgment

STATE OF _____:

To Wit: _____:

CITY OF _____:

On this ___ day of _____, before me, a notary public in and for the city and State aforesaid, personally appeared _____, and she/he did depose and say that she/he is the [*insert title*] of _____ [*if applicable, insert "national banking association" or "State banking association"*], Trustee, which executed the above instrument; that she/he knows the seal of said association; that the seal affixed to such instrument is such corporate seal; that it was so affixed by order of the association; and that she/he signed her/his name thereto by like order.

[Signature of notary public]

My Commission Expires: _____
[Date]

Sandrik, Lauren

From: Forster, Sara
Sent: Thursday, September 14, 2017 10:08 AM
To: Song, Taehoon; Sandrik, Lauren; Pavon, Sandy
Subject: FW: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN600076
Attachments: 02500.600076.13-32637-01MD Guardian Pharmacy RFAI telecon signed.pdf

Please scan in and return to me. Thank you!

Sara x9892

From: Forster, Sara
Sent: Thursday, September 14, 2017 10:07 AM
To: 'Brian Hardesty' <bhardesty@rpofindy.com>
Subject: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN600076

Dear Mr. Hardesty:

Please see the attached file for additional information needed to complete the review of your recent amendment request for NRC Lic. No. 13-32637-01MD. Note that the attached conversation record requests additional information on or before the close of business on September 28, 2017. Additional guidance may be found in NUREG 1556, Vol. 13, rev. 1, "Program-Specific Guidance About Medical Use Licenses;" NUREG-1757, Volume 3, Revision 1, "Consolidated NMSS Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness;" Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance" (ML16287A403); and "Memo – Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators" (ML16082A415); which may, respectively, be found at:

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/>;
<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/>;
<https://www.nrc.gov/docs/ML1628/ML16287A403.pdf>; and
<https://www.nrc.gov/docs/ML1608/ML16082A415.pdf>.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have, or if additional time is needed to complete this request.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd. - Ste. 210
Lisle, IL 60532-4352
sara.forster@nrc.gov
Direct: (630) 829-9892
Facsimile: (630) 515-1078