UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

January 22, 2026

Emily L. Murphy, R.Ph.
Radiation Safety Officer
CPI Pharmacy Services Holding, LLC
d/b/a Hot Shots Nuclear Medicine
3960 Patient Care Dr., Suite 105
Lansing, MI 48911

Dear Dr. Murphy:

This letter is regarding the request dated June 17, 2025, signed by Aaron Barnes, Pharm.D., Associate Corporate RSO, for the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-26597-01.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 13, Rev. 2, dated March 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." This guidance is available on the U.S. NRC website at: https://www.nrc.gov/docs/ML1907/ML19079A207.pdf

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 8.2, "Item 2: Name and Mailing Address of Applicant," of the guidance, specifies that the legal name of the applicant's corporation or other legal entity be identified in the license application.

   Item 2 of the submitted license application omitted your company's legal name.

   Currently your license identifies your company's legal name as CPI Pharmacy Services Holding, LLC, d/b/a Hot Shots Nuclear Medicine. A recent check with the Michigan Department of Licensing and Regulatory Affairs (LARA) Corporations Division revealed that CPI Pharmacy Services Holding, LLC, remains actively registered. Though, their records identify that the assumed name registration for Hot Shots Nuclear Medicine expired on December 31, 2020.

   Clarify if your company's legal name remains CPI Pharmacy Services Holding, LLC, d/b/a Hot Shots Nuclear Medicine. As applicable, include documentation demonstrating the active registration of the assumed name.

2. Section 8.5.1, "Sealed and/or Unsealed Byproduct Material," of the guidance, identifies that licenses who request a possession limit in excess of the quantities specified in Title 10 of the *Code of Federal Regulations* (10 CFR) §30.72, "Schedule C – Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," submit an emergency plan, as specified in 10 CFR §30.32(i).

   Your application did not address Emergency Planning.

   Please confirm that you will maintain licensed quantities below the quantities specified in 10 CFR §30.72 requiring consideration for emergency planning.

3. Section 8.5.1, “Sealed and/or Unsealed Byproduct Material,” of the guidance, describes that the application should identify if potentially volatile materials (e.g., iodine-123, iodine-131), will be manipulated at the commercial radiopharmacy and if so, specify where manipulation occurs (i.e., a hood or a hot cell).

   It appears that the manipulation of volatile radioactive materials is limited to the compounding of iodine-131 capsules.

   If correct, please respond confirming that the manipulation of potentially volatile radioactive materials is limited to compounding iodine-131 capsules in the room described in your application that is dedicated to storing and handling volatile materials.

4. Section 8.5.1, “Sealed and/or Unsealed Byproduct Material,” of the guidance, specifies that applicants must submit information specifying each radionuclide requested, the form, and the maximum activity to be possessed at any one time. For sealed sources, the applicant must also submit the manufacturer and model number of each requested sealed source.

   Your application does not identify the manufacturer and model number of each requested sealed source.

   Therefore, please resubmit your application providing the manufacturer and model number of each sealed source, activity per source and the maximum requested possession limit.

5. Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” of the guidance, identifies that a licensee authorized to possess licensed material in excess of the limits specified in 10 CFR §30.35, “Financial Assurance and Recordkeeping for Decommissioning,” must submit a decommissioning funding plan or provide certification of financial assurance for decommissioning.

   As specified in 10 CFR §30.35(e)(2), the decommissioning funding plan must be submitted at intervals not to exceed 3 years and at the time of license renewal, with adjustment to account for changes in costs and the extent of contamination.

   Your application did not include a decommissioning funding plan or the provision of financial assurance for decommissioning.

   If applicable, please resubmit your application providing a decommissioning funding plan, including all of the following as specified in 10 CFR §30.35(e)(1):

   - A detailed cost estimate for decommissioning, in an amount reflecting:
     - The cost of an independent contractor to perform all decommissioning activities;
     - The cost of meeting the 10 CFR §20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR §20.1403, the cost estimate may be based on meeting the 10 CFR §20.1403 criteria;

- The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
- An adequate contingency factor.

- Identification of and justification for using the key assumptions contained in the DCE;
- A description of the method of assuring funds for decommissioning from 10 CFR §30.35(f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
- A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
- A signed original of the financial instrument obtained to satisfy the requirements of 10 CFR §30.35(f) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

6. Section 8.6.1, "Distribution and Redistribution of Sealed and Unsealed Materials," of the guidance, describes that radiopharmacies that plan to transfer, distribute, or redistribute licensed material to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage should describe procedures to ensure that licensed material is securely and safely provided to the mobile medical licensee.

   Section 6.1, "Distribution and Redistribution of Sealed and Unsealed Materials," of your license application included the following statement:

   "We have also developed procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees. If they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage, then delivery will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery, *or a keyed entry is available to be used*."

   Your statement varies from the statement specified in Section 6.1 and Appendix B of the guidance in that it adds the phrase, "or a keyed entry is available to be used." Your addition introduces unnecessary ambiguity and appears to conflict with what the guidance envisions, and the regulations permit for ensuring the security of licensed radioactive materials.

   Therefore, please resubmit your application with the statement provided in the guidance:

   "Describe procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach, where there is no permanent structure for byproduct material storage. For example, procedures should ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery."

If applicable, please include applicable procedures for ensuring the safety and security of sealed and unsealed materials that are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach where there is not a permanent structure for byproduct material storage.

7. Section 8.6.1, "Distribution and Redistribution of Sealed and Unsealed Materials," of the guidance, specifies that the application must include commitments related to the redistribution of sealed sources for brachytherapy or diagnosis.

   Your application did not include the applicable confirming statements specified in the guidance related to the redistribution of sealed sources for brachytherapy or diagnosis.

   Therefore, please resubmit your license application including the following confirming statements, as specified in the guidance:

   - Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements; and

   - Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

8. Section 8.6.1, "Distribution and Redistribution of Sealed and Unsealed Materials," of the guidance, identifies that the used generators may be redistributed provided that they are accompanied by the manufacturer-supplied leaflet or brochure providing radiation safety instructions for handling and using the generator.

   Section 6.1, "Distribution and Redistribution of Sealed and Unsealed Materials," of your license application included the following statement:

   "We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator, if supplied by manufacturer."

   Your statement varies from the statement specified in Section 6.1 and Appendix B of the guidance in that it adds the phrase, "if supplied by manufacturer." Your addition of this phrase appears to conflict with what the guidance envisions, and the regulations permit for ensuring the safe use of licensed radioactive materials.

   Therefore, please resubmit your license application including the following confirming statement, as specified in the guidance:

   - Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

9. Section 8.9.1, “Facilities and Equipment for Radiopharmacies,” of the guidance, identifies that applicants must provide the NRC with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

   Your application included a facility diagram and description but lacked all detail specified in the guidance.

   Therefore, please resubmit your application with a complete facility diagram and description, including:

   - A description of the facilities and equipment at each location where radioactive material will be used, including the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).

   - The diagram(s) should also include:

     (1) descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage;

     (2) sufficient detail in the diagram to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;

     (3) a general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods;

     Note that fume hoods, glove boxes and shielded hot cells should be designed, tested and maintained in accordance with applicable industry and consensus standards (e.g., Guideline for Gloveboxes, 3rd Ed., AGS-G001-2007 and ANSI/ASHRAE Standard 110-2016: Methods of Testing Performance of Laboratory Fume Hoods).

     (4) confirmation that such ventilation systems will be employed for the use or storage of radioactive materials likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and

     (5) verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR §20.1301, and are within the ALARA constraints for air emissions established under 10 CFR §20.1101(d).

     Note that pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.

10. Section 8.10.2, “Radiation Monitoring Instruments,” of the guidance, describes that the licensee must possess calibrated and operable radiation instruments to detect and measure radiation levels, radioactive contamination, and radioactivity, as applicable.

    Your application did not include a complete description of the calibrated and operable instrumentation that will be used to perform radiation monitoring.

    Therefore, please resubmit your application providing:

    - A description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors); and
    - A statement that, “We reserve the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used.”; and
    - If calibration is performed by a person or firm outside the applicant’s organization, specify that the calibration will be performed by an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees, and state the frequency of the calibrations; or
    - If the calibration is to be performed in-house, submit the instrument calibration procedure that will be used, and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.

11. Section 8.10.3, “Material Receipt and Accountability,” of the guidance, states that licensees must track licensed materials from receipt to disposal in order to ensure accountability at all times; identify when licensed materials could be lost, stolen or misplaced; and ensure that possession limits listed on the license are not exceeded.

    Your application does not include a commitment to performing physical inventories at intervals not to exceed 6 months to account for all sealed sources.

    Therefore, please resubmit your application providing the following statement:

    - “We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.”

12. Section 8.10.6, “Safe Use of Radionuclides and Emergency Procedures,” describes that licensees must make the required notifications of incidents to the U.S. NRC.

    Section 12, “Emergency Procedures,” of your license application included applicable emergency contact information for the Corporate Radiation Safety Officer, Associate Corporate Radiation Safety Officer, U.S. NRC Region III and the Local Law Enforcement Agency, but did not include all emergency contact information that may be relevant.

    I recommend that you expand the list of Emergency Contacts to also include the U.S. NRC’s 24-Hour Headquarters Operations Center, (301) 816-5100. You might also consider adding the emergency contact information for the local Radiation Safety Officer.

    As this item is only advisory in nature, no response is required unless revisions to your procedures are made to address the comment.

13. Section 8.10.8, “Dosage Measurement Systems,” of the guidance, identifies that commercial radiopharmacies must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Your application did not include a complete description of the instrumentation available for measuring the radioactivity in radioactive drugs.

Therefore, please resubmit your application providing:

- Description of the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs; and
- For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting radioactive drugs, state: “We have developed, and will implement and maintain, a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 32.72(c); and
- If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers; and
- Calculations demonstrating the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials; or
- If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity; and
- If applicable, include a description of the methodology and equipment to be used for the assay of alpha-emitting radionuclides.

14. Section 8.10.11, “Radioactive Drug Labeling for Distribution,” of the guidance, identifies that the labels affixed to radioactive drugs for distribution must have the required color, symbol and wording.

Your application did not include a commitment to affix the required labels to the transport radiation shields and syringe, vial, or other container (e.g., generator or capsule) used to hold radioactive drugs.

Therefore, please resubmit the application providing:

- Description of all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the “transport radiation shield” or on the container used to hold the radioactive drug); and
- Agree to affix the required labels to all “transport radiation shields” and to each container used to hold the radioactive drugs.

Further, I recommend that you update the numbering in Section 10.11, “Radioactive Drug Labeling for Distribution,” which appears should range from 1 through 4.

15. Section 8.10.13, “Leak Tests,” of the guidance, specifies that licensees must test sealed sources to determine whether there is any radioactive leakage.

Section 13.3, “Leak Testing,” of your license application identifies that leak test sample collection and analysis will be performed by the applicant. Further, your application describes that your will follow the model procedures in Appendix H of NUREG-1556, Volume 13, Rev. 2, “Consolidated Guidance About Materials Licenses: Program Specific Guidance About Commercial Radiopharmacy Licenses.” Though, your application further states that leak tests will be analyzed internally in accordance with PharmaLogic procedures. Your commitments are unclear and may be contradictory.

Therefore, please resubmit your application stating the following:

- “Leak test sample collection and analysis will be done by the applicant.”; and

Provide the information noted in Appendix H of NUREG-1556, Volume 13, Rev. 2, “Consolidated Guidance About Materials Licenses: Program Specific Guidance About Commercial Radiopharmacy Licenses,” or submit alternative procedures.

In accordance with 10 CFR §2.390 of the NRC’s “Rules of Practice,” a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of your request, please submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by JASON KELLY
Date: 2026.01.22 18:36:33 -06'00'
Adobe Acrobat version: 2025.001.21078

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Control No.: 647354
Docket No.: 03033629
License No.: 21-26597-01

From: Jason Kelly
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: U.S. NRC Materials License #21-26597-01MD - Request for Additional Information
Date: Thursday, January 22, 2026 6:58:11 PM
Attachments: JK25-06-647354DLT-21-26597-01 (Signed).pdf
Form 665 (RAI Letter - 1-22-2026).pdf

Martha,

Attached is a Request for Additional Information Letter dated January 22, 2026, for Materials License No. 21-26597-01MD (CPI Pharmacy Services Holding, LLC), Docket No. 030-33629, in reference to Control No. 647354. I have also completed and attached an accompanying Form 665.

Jason M. Kelly, MPH, CPH
Health Physicist
U.S. NRC Region III – DRSS MLB
Phone: (630) 829-9737
E-mail: Jason.Kelly@nrc.gov

From: Jason Kelly
Sent: Thursday, January 22, 2026 6:40 PM
To: 'emurphy@radiopharmacy.com' <emurphy@radiopharmacy.com>
Cc: abarnes@radiopharmacy.com
Subject: U.S. NRC Materials License #21-26597-01 - Request for Additional Information

Dr. Murphy:

I have reviewed the application dated June 17, 2025, requesting the renewal of your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-26597-01. Attached is a letter dated January 22, 2026, in which I am requesting additional or clarifying information. I apologize for the delay in the review. I had planned to do the review before the federal government shutdown and since been further delayed by the holidays.

With regards to the facility diagram and description, what was included with the original submission was largely satisfactory but lacks some detail that would be helpful to my understanding and review. Please identify the direction of "North," the room dimensions, and identify all adjacent areas (including suites occupied by adjacent tenets). It may also be helpful if you could include a ventilation diagram identify all air vents (including supply, returns and exhaust vents) with cubic feet per minute indicated for the purpose of confirming that negative pressure is maintained.

Further note, that several attachments following Section 10.12 were distorted with the edges or margins apparently cut off. If possible, please resubmit pages 98 – 115 of the original

submission. These pages included information relating to transport packages and containers, including references to Type A Package Testing results.

Please respond in writing within 30 calendar days, including a reference to your U.S. NRC Materials License No. 21-26597-01 and Control No. 647354 in your signed response letter. If you should need additional time to respond, please advise and I will gladly provide you with the additional time that is needed.

As a note, I have also been assigned the review of the recently submitted amendment request to add authorization for Lu-177 and to add / remove an Authorized Nuclear Pharmacist. This request has been assigned Control Number 655082. I will review that request separate from the application for license renewal, but it may be helpful that you include consideration of the request for the addition of Lu-177 in any revisions to your facility and equipment descriptions or updated procedures and commitments, as applicable.

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2056 Westings Avenue, Suite 400
Naperville, IL 60563-2657
Office: (630) 829-9737
Fax: (630) 515-1078

http://www.nrc.gov/