



Mr. Kevin Null
Materials Licensing Branch
U.S. NRC, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

September 30, 2009

Mr. Null:

Enclosed is our response to your letter dated July 30, 2009, pertaining to control number 318192—Application for a commercial radiopharmacy license and control number 318193—application for a possession license for the production of radioactive material using an accelerator.

With regards to the response for the application for the commercial radiopharmacy:

A copy of "Appendix C", as the original application's submission was intended to be, is included in this response letter.

The following items submitted are different than what was on our original application:

- Item 1. Materials and Proposed Uses
- Item 2. Individuals Responsible for Radiation Safety Program
- Item 4. Facilities and Equipment; e.
- Item 10. Dosage Measurement Systems; b.

With regards to the response for the application for a possession license for production of radioactive material using an accelerator:

The following items submitted are different than what was on our original application:

- Item 1. Radioactive Material; a.
- Item 3. Individuals Authorized to Handle Licensed Material
- Item 5. Facilities and Equipment; e., f.

I hope you find everything in order. If you have any questions, please feel free to contact me at Spectron mrc, 574-271-2800.

Sincerely,

A handwritten signature in black ink, appearing to read "KRozycki", is written over a horizontal line.

Kirk Rozycki, R.Ph.
Radiation Safety Officer

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September 30, 2009

United States
Nuclear Regulatory Commission
Region III
Mr. Kevin Null
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Pertaining to control number: 318192

RE: Application for a commercial radiopharmacy license.

Mr. Null:

The following responses pertain to your letter dated July 30, 2009.

A copy of "Appendix C," as the original application's submission was intended to be, is included in this response letter as Attachment A.

➤ See Attachment A

1. Materials to be Possessed and Proposed Uses

- a) We may distribute radiochemicals and radioactive drugs to medical use licensees, including other radiopharmacies, and to institutions engaged in medical research. Radiochemicals and radioactive drugs to be distributed may include bulk F-18 fludeoxyglucose (FDG), F-18 sodium fluoride (NaF), F-18 fluorothymidine (FLT), Ga-68 gallium macroaggregated particles/microspheres, new or used generators, including those with a positron decay scheme; and gallium-67, indium-111, and technetium-99m labeled radiopharmaceuticals.

We confirm that we will not redistribute sealed sources for calibration and medical use.

b) Sealed Sources in Inventory

| <u>Manufacturer</u> | <u>Isotope</u> | <u>Activity</u> | <u>Type</u> | <u>Model #</u> | <u>Quantity</u> |
|-----------------------|----------------|-----------------|-------------|----------------|-----------------|
| Isotope Product Labs. | Na-22 | 250 uCi | E Vial | RV-022 | 1 |
| Isotope Product Labs. | Na-22 | 0.1 uCi | Rod | GF-022 | 1 |
| RadQual | Ge-68 | 0.56 uCi | syringe | BM06068 | 1 |

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Sealed sources that may be purchased in the future:

| <u>Manufacturer</u> | <u>Isotope</u> | <u>Activity</u> | <u>Type</u> | <u>Model #</u> | <u>Quantity</u> |
|---------------------|----------------|-----------------|-------------|---------------------|-----------------|
| Eckert & Ziegler | Co-57 | 5 mCi | E Vial | RV-057-5M | 1 |
| Eckert & Ziegler | Co-57 | 0.1 uCi | Rod | GF-0012 | 1 |
| Eckert & Ziegler | Na-22 | 250 uCi | E Vial | RV-022-250U | 1 |
| Eckert & Ziegler | Na-22 | 0.1 uCi | Rod | GF-022-R3-0.1u-NIST | 1 |
| RadQual | Co-57 | 5 mCi | E Vial | BM06-57 | 1 |
| RadQual | Co-57 | 0.1 uCi | Rod | BM08-57 | 1 |
| RadQual | Na-22 | 250 uCi | E Vial | BM06-22 | 1 |
| RadQual | Na-22 | 0.1 uCi | Rod | BM08-22 | 1 |
| RadQual | Ge-68 | 0.1 uCi | Rod | BM08-68 | 1 |

Please note that Isotope Product Laboratories is now an Eckert & Ziegler Company (Eckert & Ziegler Isotope Products).

Please replace "Item No. 5 Radioactive Material" in our original application for a commercial radiopharmacy license, dated April 29, 2009, pages 17-19, with these revisions.

➤ See Attachment B

2. Individuals Responsible for Radiation Safety Program

Authorized Nuclear Pharmacists:

Cardinal Health Materials License, License No. 34-29200-01MD

- Cardinal Health Authorized Nuclear Pharmacists
 - Kirk J. Rozycki
 - Stanley Miller
 - Bettina M. Hickman
 - Todd M. Holiday
 - Mark R. Peters

➤ See Attachment C

Spectrum Pharmacy Materials License, License No. 13-26367-01MD

- Gregory S. Hiatt

➤ See Attachment D

The following individuals need to be added as Authorized Users under "Item No. 7 Individual(s) Responsible for Radiation Safety Training and Their Experience" in our original application for a commercial radiopharmacy license, dated April 29, 2009.

- Robert A. Galloway
- Mark F. Hiatt

- David P. Trump
 - Zachary N. Reichert
 - Erin M. Smeltzer
 - Robert Beeler
 - Scott Minor
- See Attachment E

3. Training Program for Individuals Working in or Frequenting Restricted Areas

We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualification of the instructors; method of training; method for assessing the success of the training; and the frequency of the training and refresher training.

4. Facilities and Equipment

- a. Effluents System Schematic
 - See Attachment F1 and F2
- b. HEPA filters are traditionally used in clean room environments or laminar flow hoods to remove particulates in the air to achieve a particular ISO class or sterile work environment.

Reasons why we do not use HEPA filters to trap particulates include:

- We do not have any processes that generate radioactive airborne particulates directly or as a byproduct. Only radioactive gases/fumes/vapors are produced as byproduct materials entering our effluent system.
- We measure with an ionization detector all air effluents leaving our facility continuously (in uCi/cc) to ensure compliance with 10 CFR 20.1101(d) and 21.1302(b).

- c. Effluent filter saturation will be determined by monitoring the release of radioactivity in uCi/cc that may be present in our air effluents before leaving the exhaust stack on the roof before general distribution. Effluent concentrations will be reviewed weekly. Weekly variations greater than normal levels expected may be indicative of filter saturation. The timing of the increase in radioactive effluent release and survey results will help to identify which process the increase is due to. The filtration system for that process will be replaced.

General radiation safety procedures to be followed:

- Filters are only to be handled wearing waterproof gloves.
- Filters are to be surveyed before replacing to verify the need to replace due to saturation.
- Filter surface survey readings greater than 50 mR/hr and effluent measurements that routinely rise above background, to near the release rate that is allowed in table 2 of appendix B to 10 CFR part 20, will be the trigger point for replacement of the filter.
- Filters are to be allowed to decay before replacing.

d. Location of APTEC-NRC ionization chamber and monitor

- See Attachment F1 and F2

It is not practical (since it is a part of our permanent ducting in our effluent system) to send the APTEC-NRC ionization detector to the manufacturer for calibration. Therefore, we have developed a calibration procedure (with guidance from the manufacturer) that we will perform in-house. The calibration procedure will be performed annually.

We will calibrate the system using a range of 10^{-8} to 10^{-5} uCi/cc. Calibration will be based on the manufacturer's recommendation and protocol. Sensitivity will be validated through dilution schemes for linearity and minimum detectability.

Alarm set points for APTEC-NRC Vent Gas Monitor

- Alert: 0.1 uCi/cc
- High Alarm: 5.0 uCi/cc

Procedures/Actions to be taken at alarm set points:

At the 0.1 uCi/cc alert:

- Reset the alert. See if the alerting condition reappears or if it was an anomaly due to a power fluctuation.
- Check to ensure blowers in effluent system are on and functioning.
- If alert continues, a minor spill may have occurred in the cyclotron room (i.e., line break or valve malfunction), in the pharmacy (i.e. physical spill), or a spill inside a mini-cell during chemical syntheses (i.e., line rupture).
- Locate the cause of the Alarm. Check remote gamma detectors located in the pharmacy and cyclotron room for signs of increased activity above normal expected levels.

Check to see what processes are occurring and see if anything is abnormal or unusual.

- Once the cause of the alert has been identified, follow radiation safety procedures for handling a minor spill, unless the cause is better defined as a major spill. Then follow the emergency procedures for that or those specific for the process in question.

At the 5.0 uCi/cc high alarm:

- A major spill or release may have occurred inside or outside a protective enclosure. Reset high alarm to see if it continues or if it was an intermittent release or if it was an anomaly related to a power outage.
- If the alarm reactivates, the pharmacy heating and cooling system should be shut down until the source of the release can be identified. If the cyclotron is running, it may need to be shut down as well, if it is identified as the cause of the release.
- Identify the source of the release. Immediately check the remote gamma detectors to identify if radiation levels are higher in the pharmacy or cyclotron. The release could be due to a malfunction or line failure with a chemical synthesis inside a mini-cell, a physical spill and release of material in the pharmacy, or from a line break or blown target window in the cyclotron.
- If the spill is not contained within the mini-cell or hot cell, follow the appropriate emergency procedures for a major spill and/or additional emergency procedures for the identified process.

The monitoring system will be utilized to ensure compliance with 10 CFR 20.1101(d) and 21.1302(b) by:

- Comparing weekly average concentration levels with regulatory limits
- We will only perform a COMPLY code evaluation if average concentrations released on an annual basis are greater than regulatory limits specified in table 2 of appendix B to 10 CFR part 20.

e. COMPLY code evaluation

- To be performed only if annual averaged released effluent concentrations exceed regulatory limits specified in table 2 of appendix B to 10 CFR part 20.

➤ See Attachment G

- f. Doses are drawn inside the hot cell using external manipulators. Attached to the hot cell is a shielded side extension. The side extension has a manually opened shielded door for access from the front, a remotely operated sliding shielded door between it and the hot cell on the inside, and a remotely operated sliding tray that moves in and out of the hot cell. Syringes and pigs are loaded manually (and removed manually) from the side extension of the hot cell. We receive no exposure from loading the doses to be drawn or from drawing the doses. We do receive exposure capping the doses (pigs) manually, placing them into the shipping containers, and preparing the doses for shipment. Also, the side extension is never opened from the front unless the inner shielded sliding door between it and the hot cell is closed. This ensures that the person placing or removing pigs from the side extension will not receive any additional exposure from the product vial in the hot cell.

In the event the external manipulators were to break and the doses had to be drawn by hand, the following items are available for remote handling as a back-up system:

- Lead shield or tungsten cannonball to hold the product vial
 - Syringe shield, lead or tungsten, which may interlock with the vial shield
 - Tongs or equivalent devices to pull, assay, and transfer the dose
 - Needle recapping device (nerd, tongs, or equivalent)
 - PET L-block shield
- g. We currently use the following chemical synthesis units: GE Tracerlab MX FDG, Bioscan FDG-Plus FDG Production System, and Bioscan Reform-Plus Reformulation System. All materials necessary for the synthesis of FDG come prepackaged as a gamma irradiated one-time-use hardware kit and a separate reagent kit. The hardware kit is made up of manifolds that contain the valves, tubing, and reaction vial; ports for syringes, reagents, and filters; and connections for receipt and delivery of radioactive material and for collection of radioactive waste from the synthesis process. After synthesis is complete, the remaining reagents and water flush and rinse any remaining activity in the hardware kit and its tubing into a separate waste collection vial that sits shielded next to the synthesis box inside of the mini-cell. Typically, just prior to the next day's

production run, the hardware kit, its tubing, and attached reagents are removed and discarded into a shielded waste barrel. Also, it should be noted that all air effluents are captured into a gas bag during this synthesis procedure.

Our planned maintenance (PM) program for the chemical synthesis units includes weekly and monthly maintenance and a yearly PM. Maintaining a regular PM schedule eliminates the need for physically inspecting parts that may become worn or brittle from repeated radiation exposure. Our maintenance and PM program ensures that all necessary tubing or parts are replaced before they are adversely affected by radiation. PM is typically performed 24 hours after last use, allowing the units to be at or near background radiation levels.

Personnel trained or possessing the skills and experience to perform planned maintenance on the chemical synthesis units include Robert Galloway, Mark Hiatt, and David Trump. Personnel yet to be trained include Kirk Rozycki, Zachary Reichart, and Gregory Hiatt. In-house initial training for planned maintenance of all the chemical synthesis units was provided to Robert Galloway by Bioscan. Training received or yet to be received has been or will be performed in-house by Robert Galloway and Mark Hiatt through on-the-job training.

Personnel trained in the daily set-up of the chemical synthesis units for radioactive drug production include Robert Galloway, Mark Hiatt, David Trump, Gregory Hiatt, Kirk Rozycki, and Zachary Reichart. In-house initial training for set-up and operation of all the chemical synthesis units was provided to Robert Galloway by Bioscan. Training received or yet to be received has been or will be performed in-house by Robert Galloway through on-the-job training.

General radiation safety procedures for the chemical synthesis units inside the mini-cells for radioactive drug production include:

- The mini-cell should never be opened during a chemical synthesis procedure once the heating process has begun.
- After a completed chemical synthesis, the mini-cell should not be opened until necessary, to allow for maximum decay time—typically greater than 12 hours or approximately 6 half lives.

- Immediately after opening a mini-cell, a survey should be performed with a hand held GM meter. The radiation field should be within reasonable levels before proceeding.
- All manipulations performed inside the mini-cell on the chemical synthesis unit require the wearing of waterproof gloves.
- All planned maintenance should be performed when the chemical synthesis unit is at or near background radiation levels.

In the event the chemical synthesis unit is to be used again in the same day, these additional radiation safety procedures are to be followed:

- A self-reading or alarm-rate dosimeter should be worn.
- The maximum amount of time possible will be allowed (for maximum decay) from the end of the previous chemical synthesis to the time to begin preparation for the next.
- All non-required personnel must leave the restricted area during the disposal of the hardware manifold, tubing, and reagent kits.
- The hardware kit, tubing, and reagent kits are to be removed as quickly as possible using remote handling tools, if feasible, and placed into the appropriate shielding.
- A survey of the mini-cell should be performed with a hand held GM meter. The radiation field should be within reasonable levels before proceeding with the preparation for the next synthesis.

In the event of a failure during the chemical synthesis process, the following radiation safety procedures must be followed:

- The mini-cell cannot be opened unless authorized by the RSO or an authorized user that is on site at the time.
- Identification of a line failure will quarantine the mini-cell until the following day and that production run will be lost.
- Any other malfunction, other than a line failure, will be analyzed on a case by case basis, to determine if manual intervention can be performed quickly and safely and must be overseen by the RSO or an authorized user that is on site at the time.

Dosimetry to be worn:

- Whole body and extremity at all times

- Self-reading or alarming-rate dosimeters when chemical synthesis units are to be cleaned out and re-used more than once in the same day.
- h. The shielding material for our primary unit dose pigs is lead (Biodex PET Unit Dose Pig). The shielding material for our one or two dose primary shipping containers is also comprised of lead (Biodex PET Shipping Container). (Please refer to Attachment F1, F2, F3, and F4 in our application for a commercial radiopharmacy license, dated April 29, 2009, for additional information.)

We also use Cardinal Health's tungsten shields for unit doses that we ship in ammo cans. The ammo cans have no shielding except for the addition of a tungsten sleeve that the unit dose slides into. (Please refer to Attachment G1 and G2 of our radiopharmacy application, dated April 29, 2009, for additional information.)

Our last type of unit dose shielding we have available for use is A-TECH's tungsten pet pig. (Please refer to Attachment H1 and H2 of our radiopharmacy application, dated April 29, 2009, for additional information.)

- i. Our chemical synthesis units are all kept inside mini-cells. The mini-cells are comprised of 75 mm lead shielding.
- See Attachment H

The average radiation levels of the two mini-cells used for daily production of F-18 FDG at the surface and at 3 feet are the following and are dependent on the amount of F-18 transferred from the cyclotron:

| Average Radiation Levels (mR/hr): | <u>Surface</u> | <u>3 Feet</u> |
|-----------------------------------|----------------|---------------|
| Top mini cell | 1.5 mR/hr | 0.15 mR/hr |
| Bottom mini cell | 2 mR/hr | 0.15 mR/hr |

5. Occupational Exposure

- a. We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106, as applicable.

- b. Dosimetry provided to carriers who deliver radioactive material products to Spectron's customers include:
 - Whole Body
 - Left and Right Extremity

- c. An accidental airborne release may be detected by the following:
 - Alert or alarm for the air effluent system or an increase over normal background levels
 - Unexplained increase over typical background activity from:
 - Room area monitors
 - Remote gamma probes in ceilings of the radiopharmacy and cyclotron
 - Survey meters
 - Multi or single channel analyzers

In any circumstance in which manual intervention may cause the potential release of airborne contamination:

- Emergency procedures for the task at hand are to be followed under the supervision of the RSO or an authorized user.
- All unnecessary personnel are to be evacuated from the area and the area restricted to entry.
- All involved personnel are to wear face masks to minimize any possible intake of radioactivity.

Because the half life of the radionuclide that will be used 90+ percent of the time is less than two hours, the guidelines are such that the exposure is treated as external only. Any possible airborne contamination with personnel will require whole body surveys with a survey meter and wipe tests for surface contamination. All measurements will be collected and calculations will be made using the appropriate accepted guidelines.

- 6. We will use equipment that meets the general radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 13, Rev. 1, 'Program-Specific Guidance About Commercial Radiopharmacy Licenses,' and instruments will be calibrated by other persons authorized by NRC, an Agreement State, or a licensing State to perform that service.

- 7. We have developed, and will implement and maintain, written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906; and

We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months; and
We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded,
- licensed material in storage is secured from unauthorized access or removal,
- licensed material not in storage is maintained under constant surveillance and control, and records of receipt, either from the licensee's own production operations or from another licensee transfer, and disposal of licensed material, are maintained.

8. We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:

- Facility and personnel radioactive contamination minimization, detection, and control;
- Performing molybdenum-99 breakthrough measurements on the first eluate after receipt of the molybdenum-99/technetium-99m generator; and
- Use of protective clothing and equipment by personnel that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.1 I(a)(3), as applicable; and

We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:

- Lost, stolen, or missing licensed material;
- Exposures to personnel and the public in excess of NRC regulatory limits;
- Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits;
- Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;
- Radioactive spills and contamination;
- Fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and
- Routine contacts with local fire departments and local law enforcement agencies (LLEA), that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50, and other requirements, as applicable.

9. We have developed and will implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103, as applicable.

10. Dosage Measurement Systems

a. We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meet the requirements in 10 CFR 32.72(c).

b. We do not intend to initially distribute beta-emitting radionuclides.

11. We did not mean to imply that Cardinal Health's tungsten pigs are used exclusively for shipping PET unit doses. The primary shielding used for PET unit doses for Specton's customers is the Biodex PET lead pigs and lead shipping containers. We do use the Cardinal Health tungsten PET pigs and shipping containers (ammo cans) on a limited basis for specific customers. We also have A-TEC's tungsten PET pigs available for use.

12. We have developed and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103.

13. We have developed and will implement and maintain written procedures for waste management that meet the requirements in 10 CFR 20.1904(b), 10 CFR 20.2001(a), 10 CFR 20.2003, 10 CFR 20.2006, 10 CFR 20.2108, 10 CFR 30.51, as applicable.

14. Financial Assurance should not required for the radiopharmacy based upon the following information:

- The half life of copper-64 is 12.8 hours.
- The half life of dysprosium-166 is 3.4 days.

Even though we have a requested possession limit of 1 Ci of Ge-68 Germanium (sealed in a Ge-68/Ga-68 generator system), the germanium decays by electron capture to gallium-68, which has a half-life of 68 minutes (<120 days). The electron capture decay scheme of germanium-68, itself, poses minimal risk. Therefore, financial assurance and a decommissioning funding plan should not be required.

Attachment A

APPENDIX C

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313 for a Possession License

Attachment A

APPENDIX C

Suggested Format for Providing Information Requested in Items 5 through 11 on NRC Form 313

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|--|---|
| 5. | <p>RADIOACTIVE MATERIAL</p> <p>Sealed And/Or Unsealed Byproduct Material</p> <p>For unsealed materials:</p> <ul style="list-style-type: none"> • Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit. <p style="text-align: center;">AND</p> <p>For potentially volatile materials (e.g., iodine-131):</p> <ul style="list-style-type: none"> • Specify whether the material will be manipulated at the radiopharmacy. <p>For sealed sources and discrete sources of radium-226:</p> <ul style="list-style-type: none"> • Identify each radionuclide (element name and mass number) that will be used in each source; • Provide the manufacturer's (distributor's) name and model number for each sealed source and device and discrete source of radium-226 requested; • We confirm that each sealed source, device, source/device combination, and discrete source of radium-226 is registered as an approved sealed source, device or discrete source by NRC or by an Agreement State; • We confirm that the activity per source and/or device and its maximum activity will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State; and • If the above information cannot be provided for the discrete source of radium-226, describe the discrete source and its physical boundaries. <p>For depleted uranium, specify the total amount (in kilograms).</p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> | <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">300 Kg</p> |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|-----|----------------------|
| 6. | <p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont.)</p> <p>For Redistribution of Sealed Sources — for Brachytherapy or Diagnosis:</p> <ul style="list-style-type: none"> • We 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 <input type="checkbox"/> • We 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. <input type="checkbox"/> <p>For Redistribution of Calibration and Reference Sealed Sources:</p> <ul style="list-style-type: none"> • We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 to initially distribute such sources; and <input checked="" type="checkbox"/> • We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources. <input checked="" type="checkbox"/> <p>For Redistribution of Prepackaged Units for <i>In Vitro</i> Tests:</p> <ul style="list-style-type: none"> • We confirm that the prepackaged units for <i>in vitro</i> tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for <i>in vitro</i> tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State. <input type="checkbox"/> | | |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|---|-----|--------------------------|
| 6. | <p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont.)</p> <p>For Redistribution to General Licensees:</p> <ul style="list-style-type: none"> • We confirm that the manufacturer's packaging and labeling of the prepackaged units for <i>in vitro</i> tests will not be altered in any way; and <input type="checkbox"/> • We confirm that each redistributed prepackaged unit for <i>in vitro</i> tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees. <input type="checkbox"/> <p>For Redistribution to Specific Licensees:</p> <ul style="list-style-type: none"> • We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for <i>in vitro</i> tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and <input type="checkbox"/> • We confirm that the labeling on redistributed prepackaged units for <i>in vitro</i> tests will conform to the requirements of 10 CFR 20.1901 and 20.1904. <input type="checkbox"/> <p>For Redistribution to Discrete Sources of radium-226:</p> <ul style="list-style-type: none"> • We confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute them. <input type="checkbox"/> • We confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacture-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing sources. <input type="checkbox"/> <p>For radiopharmaceutical preparation, we will perform:</p> <ul style="list-style-type: none"> • compounding of iodine-131 capsules, <input type="checkbox"/> • radioiodination, <input type="checkbox"/> • chemical synthesis of PET radiopharmaceuticals, <input checked="" type="checkbox"/> • technetium-99m kit preparation, and <input checked="" type="checkbox"/> • other, specify. <input type="checkbox"/> | | <input type="checkbox"/> |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|---|--|--|
| 6. | <p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont.)</p> <p>Supply specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and depleted uranium.</p> <p>We will provide customers the following radiation protection services involving licensed material:</p> <ul style="list-style-type: none"> • leak testing, • instrument calibration, and • other, specify. | <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> | <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> |
| 7. | <p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>For applicant's management structure, provide:</p> <ul style="list-style-type: none"> • An organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO. <p>For the Radiation Safety Officer (RSO), provide:</p> <ul style="list-style-type: none"> • Name of the proposed RSO; <p style="text-align: center;">AND</p> <p>A copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an ANP, or an AU;</p> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies. <p><i>Note: See Appendix G for convenient formats to use for documenting hours of training in basic radionuclide handling techniques and hours of experience using radionuclides.</i></p> <p>For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:</p> | <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> | <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|---|---|---|
| 7. | <p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont.)</p> <p><i>For an individual qualifying under 10 CFR 35.55(a):</i></p> <ul style="list-style-type: none"> • Copy of the certification(s) of the specialty board whose certification process has been recognized² under 10 CFR 35.55(a); <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved; <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59; <p style="text-align: center;">OR</p> <p><i>For an individual qualifying under 10 CFR 32.72(b)(2)(ii):</i></p> <ul style="list-style-type: none"> • Description of the training and experience specified in 10 CFR 35.55(b), demonstrating that the proposed ANP is qualified by training and experience; <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved; <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59. | <p><input type="checkbox"/></p> | <p><input type="checkbox"/></p> |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|-----|----------------------|
| 7. | <p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont.)</p> <p><i>Notes:</i></p> <ul style="list-style-type: none"> • NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b). • Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2), are met. If the training and experience do not appear to meet the criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience. <p>For each proposed Authorized User (AU), provide the following:</p> <ul style="list-style-type: none"> • Name of each proposed AU; <input type="checkbox"/> <li style="text-align: center;">AND • Types, quantities, and proposed uses of licensed material; <input type="checkbox"/> <li style="text-align: center;">AND • A copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials; <input type="checkbox"/> <li style="text-align: center;">OR • A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials; <input type="checkbox"/> <li style="text-align: center;">OR | | |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|---|---------------------------------|
| 10. | <p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Instruments</p> <p>We will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J to NUREG-1556, Vol. 13, Rev. 1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses";</p> <p style="text-align: center;">OR</p> <p>We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 13, Rev. 1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses," and instruments will be calibrated by other persons authorized by NRC, an Agreement State, or a licensing State to perform that service;</p> <p style="text-align: center;">OR</p> <p>A description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment.</p> <p>Material Receipt and Accountability</p> <p>We have developed and will implement and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906,</p> <p style="text-align: center;">AND</p> <p>We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months,</p> <p style="text-align: center;">AND</p> <p>We have developed and will implement and maintain written procedures for licensed material accountability and control to ensure that:</p> <ul style="list-style-type: none"> • license possession limits are not exceeded, • licensed material in storage is secured from unauthorized access or removal, | <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> | <p><input type="checkbox"/></p> |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|---|----------------------|
| 10. | <p>RADIATION SAFETY PROGRAM (Cont.)</p> <ul style="list-style-type: none"> • exposures to personnel and the public in excess of NRC regulatory limits; • releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits; • excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas; • radioactive spills and contamination; • fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and • routine contacts with local fire departments and local law enforcement agencies <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50 and other requirements, as applicable.</p> <p>Surveys</p> <p>We have developed and will implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103, as applicable.</p> <p>Dosage Measurement Systems</p> <p>Describe 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;</p> <p style="text-align: center;">AND</p> <p>For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, or photon-emitting radioactive drugs, state: "We have developed and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meets the requirement in 10 CFR 32.72©";</p> | <div style="margin-top: 450px;"><input checked="" type="checkbox"/></div> <div style="margin-top: 150px;"><input checked="" type="checkbox"/></div> <div style="margin-top: 100px;"><input checked="" type="checkbox"/></div> | |

Attachment A

APPENDIX C

| Item No. | Title and Criteria | Yes | Description Attached |
|----------|--|--|----------------------|
| 10. | <p>RADIATION SAFETY PROGRAM (Cont.)</p> <ul style="list-style-type: none"> • A description of the type and thickness of the "transport radiation shield" provided for each type of container, and • The maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity. <p>Leak Tests</p> <p>We have developed and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, and 10 CFR 20.2103.</p> | <input checked="" type="checkbox"/> | |
| 11. | <p>WASTE MANAGEMENT</p> <p>Pharmacy-generated Radioactive Wastes</p> <p>We have developed and will implement and maintain written procedures for waste management that meet the requirements in 10 CFR 20.2001(a), 10 CFR 20.2003, 10 CFR 20.2006, 10 CFR 20.2108, and 10 CFR 30.51, as applicable.</p> <p>Returned Wastes from Customers</p> <p>We have developed and will implement and maintain written procedures for customer return of pharmacy-supplied syringes and vials and their contents, to specify that:</p> <ul style="list-style-type: none"> • only pharmacy-supplied syringes and vials and their contents may be returned to the pharmacy; • instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy; and • instructions will be provided to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste <p>that meet the requirements in 10 CFR 20.2001(a), 10 CFR 30.33, and 10 CFR 71.5, as applicable.</p> | <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> | |

Attachment B

ITEM NO. 5 RADIOACTIVE MATERIAL

Sealed/Unsealed Byproduct Material

| Byproduct, source, and/or special nuclear material | Chemical and/or physical form | Maximum possession Amount |
|--|-------------------------------|---|
| A. Any Byproduct Material with Atomic Numbers 1 through 83 | Any | 200 millicuries per radionuclide and 2 curies total, except as noted: |
| B. Carbon-11 | Any | 20 curie |
| C. Copper-62 | Any | 1 curie |
| D. Flourine-18 | Any | 20 curies |
| E. Gallium-67 | Any | 1 curie |
| F. Gallium-68 | Any | 1 curie |
| G. Germanium-68 | Any | 1 curie |
| H. Indium-111 | Any | 1 curie |
| I. Indium-113m | Any | 1 curie |
| J. Molybdenum-99 | Any | 20 curies |
| K. Nitrogen-13 | Any | 10 curies |
| L. Oxygen-15 | Any | 10 curies |
| M. Rhenium-188 | Any | 1 curie |
| N. Rubidium-82 | Any | 1 curie |
| O. Strontium-82 | Any | 1 curie |
| P. Tantalum-178 | Any | 1 curie |
| Q. Technetium-94m | Any | 1 curie |
| R. Technetium-99m | Any | 20 curies |
| S. Tin-113 | Any | 1 curie |
| T. Thallium-201 | Any | 1 curie |
| U. Tungsten-178 | Any | 1 curie |
| V. Tungsten-188 | Any | 1 curie |
| W. Zinc-62 | Any | 1 curie |
| X. Depleted Uranium | Metal | 300 kilograms |
| Y. Any Byproduct Material Authorized Under 10 CFR 35.65 | Sealed Sources | 50 millicuries |

Attachment B

ITEM NO. 5 RADIOACTIVE MATERIAL

Sealed Sources

| <u>Manufacturer</u> | <u>Isotope</u> | <u>Activity</u> | <u>Type</u> | <u>Model #</u> | <u>Quantity</u> |
|-----------------------|----------------|-----------------|-------------|----------------|-----------------|
| Isotope Product Labs. | Na-22 | 250 uCi | E Vial | RV-022 | 1 |
| Isotope Product Labs. | Na-22 | 0.1 uCi | Rod | GF-022 | 1 |
| RadQual | Ge-68 | 0.56 uCi | syringe | BM06068 | 1 |

Financial Assurance and Recordkeeping for Decommissioning

The radiopharmacy is not required to have a DFP or FA based upon 10 CFR 30.35. We will, though, maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use.

Attachment B

ITEM NO. 6 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Radioactive Material: A – W:

- 1) Distribution of Radiochemicals and Radioactive Drugs to Veterinarians, Laboratories, and Other Radiopharmacies.
- 2) Distribution of Radiochemicals to Medical Use Licensees.
- 3) Prepare and Distribute Radioactive Drugs to Medical Use Licensees.
- 4) Receive Pharmacy-Originated Waste from Customers.
- 5) Research and Development of Radiochemicals and Radioactive Drugs.
- 6) Redistribution of New or Used Generators: Parent/Daughter

Zinc-62/Copper 62
Germanium-68/Gallium-68
Strontium-82/Rubidium-82
Molybdenum-99/Technetium-99m
Tin-113/Indium-113m
Tungsten-178/Tantalum-178
Tungsten-188/Rhenium-188

Radioactive Material: X. Depleted Uranium:

To be used as shielding for Molybdenum-99/Technetium-99m generators.

Radioactive Material: Y. Sealed Sources:

Instrument Calibration, Check, and Reference

Radioactive Material: B., D., K., L.:

Possession and/or handling of a radiochemical for chemical synthesis of radioactive drugs and/or for transfer or distribution to authorized licensees.

Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

NRC Master License No.
34-29200-01MD
(Old # 04-26507-01MD)
Revision: 249 6/12/2008

Confidential - Internal Use Only

| | | |
|---------------------------|-------------------------|----------------------------|
| Abab, Hamid 0408 | Becker, Sarah 0808 | Burgin, Matthew W. 0903 |
| Abdallah, Al-Hasan 1103 | Begian, Laura 0407 | Burns, William 0808 |
| Admasu, Samuel M. | Beightol, Robert 1105 | Burriss, Timothy A. |
| Aeschliman, Daryl 0808 | Bell, Eric 0808 | Burton, Daniel 0808 |
| Afari-Tawiah, George 0808 | Bellingan, John | Bussey, Ronald 0804 |
| Alberto, Alan | Bellizzi, Robert | |
| Albrecht, Jeffrey 0403 | Ben, Sunday Ahmed | Callicott, C. Bevin |
| Alfrey, Byron A. | Bennett, Jeffrey A. | Calloway, Steve P. |
| Allmer, Michael P. 0203 | Benson, Katherine A. | Calonico, Victor |
| Aisbrook, Nicholas 0807 | Biber, Marshall | Cameron, Jay. P. 0203 |
| Altaye, Dawit | Bilhorn, Tracey | Caristo, Anthony 1004 |
| Amin, Kamal C. | Billig, Rebekah 1008 | Carlo, John Alan |
| Ancona, Peter L. | Binion-Richards, Kim | Carnes, Paul |
| Anderson, Weston 1204 | 1004 | Carp, Elizabeth 0604 |
| Andrews, David S. | Bjorklund, Stanley 0803 | Carpenter, Daniel E. |
| Angel, Marilyn 0808 | Blair Sallie M. | Carrigan, Alison 0803 |
| Antoon, Debra Ann C. 0803 | Blevins, Michael 0308 | Carter, Diedre 0208 |
| Arnold, Aaron D. 0803 | Blizinski, Mark 1004 | Carter, Thomas 1208 |
| Arnold, David 0804 | Block, Peter A. 0403 | Carter, Todd W. |
| Atwood, Amy 1008 | Bodine, Leah 0807 | CdeBaca, John |
| Augustine, Luke | Bohmer, Daniel 1208 | Chamberlain, Chris |
| Ault, Daniel 1004 | Bolek, Melissa | Champ, Matt |
| Avantes, Roxana | Bolinger, Kathryn A. | Chan, Ardan |
| Awadallah, Robert | Boncross, Peter 0704 | Chandler, Gary |
| | Bonomo, Ryan C. 0803 | Chang, Darry |
| Backus, James E. | Bowman, Arthur A. | Chang, Joe 1108 |
| Bains, Deepak 0708 | Bowman, Jason L. 0803 | Chee, Michael W. |
| Badran, Michael | Bowman, Paul D. | Childs, Jim 0707 |
| Baker, William J. | Brady, Thomas 0804 | Choi, Kevin C. |
| Ballinger, Susan J. | Brewer, Keith 0108 | Choi, Sung 0908 |
| Balogh, William M. | Briggs, John J. 0304 | Christopher, Melissa 0603 |
| Bare, Aaron 1205 | Bright James M. | Chukwu, Celista 1108 |
| Barkentin, Scott 1205 | Bright, Bruce C. | Chun, Byung Sam |
| Barlow, Craig C. 0804 | Bright, Lonzo | Claunch, Scott |
| Barnett, Selh 0708 | Broderick, Patrick | Clemens Jr. Martin D. 0603 |
| Barrett, Thomas | Bronnenberg, Tracey | Clough, Keith |
| Bartkowiak, William 0803 | Brown, Cathy 1004 | Coker, Jimmy R. 0803 |
| Bartucca, Anthony 1203 | Brown, Jerrod 0308 | Colangelo, Anthony |
| Baugh, Mark 1204 | Brown, Nadja 0908 | Colberg, Marco 1104 |
| Baughner, Rebecca 0405 | Brown, Tim 0304 | Coley, David 0307 |
| Baylin, Lysa | Brown, Robert 1008 | Collazo, Jesus |
| Beach, Michele 0807 | Bryant, April R. | Condella, Maria 0304 |
| Beaven, Walter | Bryant, Charles W. | Connahan, Carrie 0203 |
| Becker, Lora 1004 | | |

Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

NRC Master License No.
34-29200-01MD
(Old # 04-26507-01MD)

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Revision: 249 8/12/2009

| | | |
|--------------------------------|-----------------------------|------------------------------|
| Conrad, Casey 05/09 | Dimenna, Michael 10/04 | Ferraro, Gaetano (Guy) 05/08 |
| Comette, George | Dines, Brett | Fery, Joseph A. |
| Costanzo, Jerry L. | Dingman, Victoria 04/06 | Fetko, Mark |
| Council, Robert C. 02/03 | Dinh, Anthony 07/08 | Fetty, David 07/06 |
| Coupat John J. 05/03 | Dirksen, J. William | Fiely, Scott A. 06/03 |
| Cowin, Susan 06/04 | Doff, Angela C. | Figueroa, Noel 02/05 |
| Craig, James D. 01/04 | Dosch, Adam 08/06 | Fincannon, Tammi 10/07 |
| Craig, Scott 12/08 | Douglass, Phillip A. | Fink, John E. 03/03 |
| Crew, Clayton | Drapkin, Edward C. | Fire, Rebecca 06/06 |
| Cross, Bradley L. | Draves, Kelly, 02/03 | Fisher, Christopher W. |
| Crowe, Locke | Driskell, Phillip D. | Fisher, Kenneth |
| Cruz, Jose 1/08 | Du, Xuan Thanh 05/08 | Fitch JoAnn |
| Csemyik, Leslie A. | Dubuc, Amanda 09/05 | Flack, John A. |
| Cullather, Mary Ruth | Duford, Kimberly 08/04 | Foldenauer, Ian 08/05 |
| Curet, Stephen B. 06/03 | Duncan, Yvette | Foo, Joseph A. |
| Czapczynski, Joseph | Dunphy, Kurt F. | Foran, Kristina 07/04 |
| Czamecki, Carl 04/06 | Duong, Nhan | Ford, James 10/07 |
| Czarnomski, John E. | DuPriest, William D. | Forrester, Jr. M.T. |
| | Duren, Kimberly 08/04 | Freund, Joseph |
| D'Amico, Steven A. | Dyer, Jay | Fries, James A. |
| D'Orazio, August 05/04 | | Frijo, Janet Borgmeyer- |
| Dadey, Christin I. | Eames, JoAnna S. 06/03 | Fry, William 10/05 |
| Dagit, Angela 03/07 | Eaton, Stephanie Dawn 04/05 | Fulbright, Mark |
| Daidone, Connie 09/05 | Eddington, David | Furutani, Reid 09/04 |
| Davidson, James 10/04 | Edwards, Cowan C. | |
| Davis, Christine 07/08 | Eier, Susan Renee 07/07 | Garcia, Charles |
| Davis, Douglas M. | Elkins, Angela C. | Garcia, Luis 06/06 |
| Dawson, James 03/06 | Ellert, Benjamin Ray 05/08 | Gardner, Marni |
| Dawson, Margaret 03/07 | Emberger, Oliver 06/03 | Gardner, Michael P. |
| Dawson, Mont | Engstrom, David | Gedamu, Salamawitt 11/04 |
| De Leeuw, Elizabeth 06/03 | Estrada, Adrian | Gedamu, Melissa 12/04 |
| Dean, Aubrey 10/04 | Estrada, Lisa A. | Georgion, Carrie 05/06 |
| Defenbaugh, Dennis H. 06/03 | Evans, Sydney B. | Ghoreishi, Anushe |
| Degan, Suzanne 04/04 | Even, Gregory A. | Gilbert, Weaver 12/04 |
| deHoll, Christopher John 07/03 | Everette, Rhonda 07/07 | Gillespie, John 08/06 |
| Deines, Darlene 10/06 | Ezekiel, John 08/05 | Glenn, Stephanie 12/04 |
| Delaney, Jonathan 10/07 | | Glennon, Margaret |
| Della, Anthony | Fagbemi, Olubukola 03/04 | Goertz, Wayne 10/04 |
| Dewbre, Kimberly | Fang, Chung | Gonzales, Ronald |
| DiBenedetto, Leana 03/11 | Farmer, William, 03/05 | Goodhart, Melissa 07/05 |
| Dickerson, Joseph 01/04 | Fedeles, Ron | Goodwin, Alan 10/04 |
| Dietrich, Jeffrey A. | Feininger, Loralee 01/03 | Goosen, Linda 06/05 |
| Dillon, Jeffrey D. 06/03 | | Gordon, Steven 07/07 |
| | | Goss, David |

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Gostanian, Armen
Gotti, Paul 05/05
Gould, Elio A.
Gran, Julie 08/03
Grant, Amy 07/08
Grasch, David A. 03/08
Grbavac, Julie Ann
Green, Richard
Green, Steven C.
Greer, Gary
Griggs, Brent
Grobinski, Robert
Groeschel, Brian 11/07
Gurgone, Mark 08/03
Guskiewicz, Melissa 08/05
Guthrie, Jeremy 03/05
Guy, Jason P. 08/03

Hall, David Douglas 10/03
Hall, Giovanni
Hali, Holly 08/08
Hamilton, Gary
Hamilton, James
Hamilton, Paul
Hamilton, W. Michael
Hang, May 12/05
Hanna, Alex, 11/03
Hannah, Charles 08/03
Hansen, Craig
Hansen, Jennifer 12/08
Hardee, James 12/05
Hardesty, Shawn 10/04
Harris, Kenneth 10/04
Harrison, Edward
Hart, Randy 11/00
Haslam, William 07/05
Hatchiff, Andrew 10/07
Hayes, Kelly
Hayes, Zeta Lyn
Hearn, Susan
Heath, Sidney S.
Helmich, Kelli 08/04
Henderson, Lee 03/08
Henn, Mark J.

Herlich, Steve
Hickman, Bettina 01/05
Hill, William 09/03
Hills, Jeremy
Hilton, James S.
Ho, Chinghan Joyce 02/04
Hoang, Karen 04/05
Hoffman, Jessica 06/03
Hoffman, Kristin M.
Hoffman, Stephanie 08/08
Hoffner, Michael 10/05
Hogan, Jeff
Holak, Betsy
Holland, Ray 08/04
Holliday, Todd 01/05
Holshouser, William
Hoogland, Gary D.
Homer, James G.
Horvath, Steve A.
Houle, Ronald
Hua, Rebecca
Hubbard, Erin
Hudek, Scott 02/03
Hudgins, Kenneth E.
Hueter, David 08/04
Hughes, Kevin 01/04
Hughes, Susan M. 06/03
Hunkapiller, Rhonda 08/08
Hunter, Bruce
Hurwitz, David A.
Hutchison, Patti 10/04
Huydic, Richard
Huynh, Quangtrinh
Hyden, Jerry
Hydro, Casey 10/04

Ingle, Gary E.
Ishee, Bradley 11/04

Jackson, Sharon
Jacobo, Sharon 11/05
Jacobs, Jessica 08/08
Jagodzinski, David 10/04
Jandora, Thomas

Jeffers, C. Denise 02/05
Jehl, Amanda 01/05
Jeppesen, Sean
Jimerson, Jason 02/03
Jimenez, Julie 05/04
Johnson, Mary E.
Johnson, Nathan 02/09
Johnson, Thomas
Johnson, Victor L. 08/04
Jones, Glenn
Jones, Jill 11/05
Jorgensen, Bruce G.
Jorgensen, Michael D.
Juergens, Karen
Julin, Charles
Just, Arthur T.

Kamara, Abdul
Kanode, Joshua 01/03
Kassel, Richard James
Kattaviravong, Phayboun 8/05
Kawamura, Russell K.
Keesee, Richard
Kegel, Cheryl 07/05
Kelly, Margaret
Khadivi, Kaveh
Khan, Saman 02/08
Kjewel, Lori Jo
Kim, Ajen
Kim, Frank 02/03
Kim, Joseph
Kimball, Kelly
Kinard, Suzanne
King, Charles E.
King, Terry 10/05
Klar, Terence 08/03
Kilsowski, Yin-Hing "Eileen"
Kloetzil, Liesel A. 04/03
Kloos, Brian
Knapp, Paul
Knishka, Scott P.
Koblenski, Dennis
Kochenash, Stephen
Kochert, Eugene L.

Attachment C

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Revision: 249 6/12/2009

Koehler, Heather 02/03
Kohs, Gordon
Kong, Chi 02/08
Koonz, Keith
Korb, James W.
Korczynski, James 04/08
Korherr, Christopher
Kostouros, Nektarios 12/08
Krafels, Jennifer 12/08
Kroll, Michelle 04/05
Koshy, Anita James
Kraher, Kathryn
Kreienbrink, Clint P.
Kristie, Michael
Krummick, Cindy C.
Ku, Betty 04/03
Kumar, Sunita 05/08
Kusiowski, Kim
Kwan, Robert 02/08

L'Heureux, Tiffany 05/04
Lachowicz, Blaise 08/04
Lackey, Karen 07/05
Laird, Amy Michelle 02/03
Laird, Colin
Lambeth, Rhonda 12/05
Lamont, David
Lancaster, Derrick 11/05
Lane, Melinda 08/03
Lardner, Susan 11/04
Larkin, Debra 09/08
LaVallo, Pasquale A.
LeBlanc, Kathryn 07/05
Le, Peter Diep 12/08
Le, Richard
Le, Tuan L.
Lee, Arthur 05/08
Leiker, Merle
Leslie, Elizabeth 05/07
Leveritt, Samuel
Levy, Michael 08/08
Lewandowski, Bruce 08/04
Lewis, Thomas 10/04
Ling, Shen-Shin

Littlefield, Daniel D.
Lomax, George
Lorentzen, Michael Scott 03/04
Love, Kelli
Loveless, Vivian S.
Lowe, Kim David
Lowery, Tammie 08/03
Lowry, John James
Luisi, Nicholas
Lukacs, Joseph E.
Lunsford, Debra
Luper, Jason 08/07

Mabis, Thomas J. 08/03
Macaluso, Anthony
Mack, Nancy
MacPherson, Thomas
Madden, Allen 08/04
Mai, Thao
Makhani, Aziz A.
Mallett, Weston Beau 07/08
Mallidi, Srinivas 08/07
Malmkar, Erin 08/04
Malmquist, Kris 05/09
Mangold, Jess 08/05
Manoni, Cleto
Manrique, Ana
Mantz, Gary W.
Mar, Dwayne 05/03
Marascalso, Salvatore
Marcure, George John
Marion, S. Brent 08/04
Marks, Ernest L.
Maronde, Ronald E. 06/03
Marshall, Joshua 10/05
Martin, Kenneth P. 12/05
Marvin, Alan J. 06/03
Masterson, Mark P.
Mathews, Ligi 10/07
Mayer, John 11/04
Mbugua, Gillian
McCarty, Mike

McClelland, Khristy 06/03
McClendon, Clifford D.
McDaniel, Cheryl 08/07
McDowall, Giselle 10/04
McElfresh, John Robert
McGahee, Melissa 12/05
McIsaac, Daniel 03/09
McKelvey, Matthew 10/08
McManamy, Elizabeth 07/08
Medeiros, Douglas 01/09
Medley, Kenneth 08/03
Mehta, Shubangi 08/07
Mendoza, Cynthia
Menta, Mario J.
Mercer, Nicola 08/08
Merchant, Michael
Merket, Sherri 08/07
Messer, Elizabeth
Mettetal, Mike
Metz, Michael A. 05/03
Miano, John
Mikles, James 01/04
Miller, Eric 05/05
Miller, John A.
Miller, John B.
Miller, John S.
Miller, Meghan 10/08
Miller, Michael
Miller, Michael W.
Miller, Rick
Miller, Sherry L.
Miller, Stanley 01/05
Miller, Steven 08/03
Miller, Walter B.
Mingus, Anjuni 07/08
Minton, Terry 08/03
Mitchell, Jeff 08/05
Mitchell, Robert C.
Mitchell, Stephanie
Mizanin, Jennifer
Mohip, Rajeesh 03/08
Monk, Daniel 08/08
Moore, Jack A.
Moore, Maura

Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

NRC Master License No.
34-29200-01MD
(Old # 04-26507-01MD)

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Revision: 249 6/12/2009

Moran, Colin 12/05
Morman, Scott 01/05
Morrill, Richard
Moster, Julie A.
Moy, Raymond 03/07
Mullins, Jonathan 10/05
Moyers, Andrew 05/03
Mumau, Timothy
Mungai, John 04/05
Murphy, Daniel F.
Musemeche, Carl 05/03
Muth, Timothy
Myers, Andrew 4/05
Myers, Christopher W. 08/03

Nacchio, Joseph
Nagem, Jonathan 05/03
Nakashima, Ken
Napier, Paul 05/03
Nash, Frank N. 05/03
Naundorf, Donna
Ndumele, Mary
Nelson, Brigett 04/03
Ngo, Linette 11/04
Nguyen, Hoa Thai
Nguyen, Hoang T.
Nguyen, Khan 07/05
Nickel, Heath 08/05
Nickman Gene G.
Niehaus, Karl E.
Norton, Stephen W. 08/03
Norton, Sharon 07/05
Nyquest, Steve

Ogden, C. Craig
Okray, Michael
Okunewitch, Thomas
Olds, Christopher S. 08/03
Oliveira, Steven R. 04/03
Oliver, Benjamin A. 05/03
Olson, Shanna L.
Olson, Tom 10/07
Osterberg, Brian 08/05

Osterberg, David M.
Owens, Andy 08/05
Owens, James C.
Owers, Randy 02/08

Paletta, John
Palmquist, Dan C.
Papineau George 05/05
Pappas, Pamela E.
Park, Brian 07/04
Park, Joo Yeon 04/05
Parker, Bryan 03/03
Pardun, Robyn 07/05
Parrish, Jeff
Patel, Chirag
Patel, Imtiaz A.
Patel, Kelankumar
Arvindbhai 07/05
Patel, Sanjaykumar 12/05
Patti, Russell A. 04/03
Paulson, Matthew 12/04
Peck, John 11/07
Pecoraro, Anthony J.
Perry, Derek 09/05
Perryman, Doug 03/05
Peters, Mark 01/05
Peters, Michael T. 05/03
Petot, Stacey L.
Petrucci, Joseph E.
Peyrovan, Peyman 11/04
Pfeiffer, Jay J.
Pflum, Nicole
Phady, Aminh T. 04/05
Phaneuf, Phillip 09/04
Pharr, Jonathan 07/05
Phelps, Kristen 10/04
Pichon, Rachi 02/03
Pinpin, Jeruel 02/05
Pittman, Eric L.
Poleon, Gregory P. 02/03
Porter, Phillip S.
Potter, Stephen
Pratschler, Shannon
Prenosil, Sandra 08/05

Presley, James
Pribyl, Daren L.
Price, Courtney 10/05
Priddle, Gaia
Proctor, Dana 05/04
Puyear, Andrea 08/04

Quesada, Stephen

Radwanski, Kimberly
Rafferty, Thomas J.
Rahman, Adam
Rahman, Zubaida
Rasmussen, Sachiko 12/05
Rath, Christie Hawkins-
Rathod, Mahipal 04/05
Rausch, Charity A. 07/03
Ray, Stephen 12/07
Readinger, Joel
Rech, Timothy
Redig, Brian Joseph
Rees, Trenton
Reinert, Jeff 07/05
Reinhart, Rodd 02/05
Repecki, Steven
Reyes, Robert
Rhude, Russell S. 08/03
Rickelman, Jesse 10/05
Rimar, Thomas
Ritchie, Mathew 10/04
Rivera, Froilan (Roi) 12/05
Roady, Kevin T. 11/05
Roberson, Ronald Darryl 10/02
Roberts, Russell S. 08/03
Robertson, Earl
Robertson, Steven
Robinson, C. Matthew 10/05
Robinson, Franklyn J. 11/05
Robinson, James 05/03
Robitaille, Michael
Rock, Christopher M.
Rodriguez, Noel
Roff, Bradley 05/05
Root, Dana

Attachment C

CARDINAL HEALTH

**AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY**

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NRC Master License No.
34-29200-01MD
(Old # 04-26507-01MD)
Revision: 249 6/12/2009

| | | |
|----------------------------|-------------------------|----------------------------|
| Rosado, Richard 01/02 | Smith, Anthony | Thomas, Stephanie 06/08 |
| Rovnak, Christopher 06/04 | Smith, Bennett | Thomas, Trent H. |
| Royal, James C. | Smith, Frank 06/04 | Thompson, Sheila |
| Rozycki, Kirk 01/05 | Smith, Greg 12/08 | Thompson, Stephanie 02/03 |
| Ruffin, Craig 05/09 | Smith, Jeffery 03/07 | Thompson, William |
| Runco, Ernest | Smith, Melissa A. 07/04 | Thor, Rebecca A. 03/03 |
| Rush, Lawrence 03/04 | Smith, Michael | Timm, Adam 03/04 |
| Rushing, Phillip 02/04 | Snow, Stephanie 01/05 | Tomas, Jorge A. |
| Russell, Albert E. 05/03 | Snyder, David 02/03 | Townsend, Tally 07/06 |
| Ryan, Kevin M. | Solomon, Peter | Travis, Kim L. |
| Rydman, Micah 10/07 | Sopp, Douglas 12/05 | Tremblay, Andrea 03/07 |
| | Sorenson, James P. | Tribe, Teresa |
| Salamonski, Norbert | Southwick Christopher | Trickey, Benjamin D. 06/03 |
| Samuelson, Steve 10/04 | Spillum, Tanya | Tripode, Kevin 04/05 |
| Sanchez, Eric 06/07 | Sposato, Peter J. | Trotter, James Ray 06/04 |
| Sanders, April | Springer, Isalah 07/04 | Tsang, Rene W. |
| Sanfilippo, Michael 02/03 | Stassen, Mark K. | Tucker, Anna 03/06 |
| Sartor, Jan M. 06/03 | Stewart, Janeen | Tucker, Clyde |
| Saula, Jacqueline | Stoltz, Brad 03/05 | Tucker, Tracey |
| Schaefer, Ashley 06/05 | Stone, James E. | Tucker, Jennifer 07/05 |
| Schenk, John | Stoops, Howard 06/04 | Turner, Julie A. |
| Scherer, Jennifer | Stotler, Richard E. | Turney, Catherine M. |
| Schmidt, Michael | Strahan, Ronald 06/03 | |
| Schmitz, Jane E. | Straly, Tad J. | Uhm, Thomas 02/04 |
| Schultz, Larry A. | Steininger, Megan 03/06 | Unanue, Ann |
| Schultz, Robert A. 03/07 | Street, Jeffrey 01/09 | Underwood, James |
| Schwartz, Rachel 06/05 | Strickland, Ricky 06/03 | Unger, Howard |
| Scott, Gary Zackery 07/03 | Strivens, Robyn K. | Usko, Sherri 12/03 |
| Scott, Michael J. 02/08 | Stumler, Caryn | |
| Seals, Shannon | Suhay, Steve | Van Cott, Susan 03/07 |
| Seaward, Jessica 02/08 | Sullivan, Garry 01/06 | Van Dyke, Lora 06/04 |
| Serrin, David A. 06/03 | Summers, Timothy M. | Van Heesbeke, Scott 01/05 |
| Shambry, Matthew 06/05 | Suttle, Dana | Vargas, Mirta R. |
| Sharpe, Allison 12/06 | Svec, Don E. | Vebeurt, Paul S. 06/03 |
| Shayeghi, Amin Noel | Svejk, Matthew J. | Velazquez, Enrique |
| Shea, Ann Marie | Swoy, Jeffrey | Vickers, Alison 07/05 |
| Sherer, Melissa 06/03 | Syed, Shihab, 11/03 | Victoria, Cynthia 03/06 |
| Shimley, Brian E. | Szczechowicz, Frank | Vu, Nghiem 10/04 |
| Shipper, Steven A. | | Vukovich, Jill |
| Shultz, Joseph E. 06/03 | Tanaka, Raymond | |
| Simmers, Sarah 06/05 | Tarleton, Ralph Bruce | Wakham, Gary |
| Simone, Bernard S. | Teasdale, Amanda 10/06 | Walker, Chad 06/03 |
| Skeoch, Christine A. 06/03 | Teaster, Michael 03/06 | Walker, Kimbly 10/03 |
| Smith Laura S. | Thomas, Jemie 12/08 | Wallsten, Richard 12/06 |

Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

NRC Master License No.
34-29200-01MD
(Old # 04-26507-01MD)
Revision: 249 6/12/2009

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| | |
|-----------------------------|------------------------|
| Walter, Steve 03/06 | Yip, Norita 06/03 |
| Ward, Erin 12/06 | Young, Carol A. |
| Ward, Katie 06/07 | Yu, Jennifer Zhangjie |
| Warnock, Jacqueline 03/06 | Yu, Michelle 04/08 |
| Wasserman, William | |
| Watts, Robert 12/06 | Zawisza, Tom 05/04 |
| Wear, Mark 07/06 | Zhu, Bing Bing |
| Weatherspoon, Kyle | Ziegler, Rachel 07/07 |
| Webb, Jeffery Neil | Zimmerman, Gary |
| Weiner, Eric | Zipp, C. Joe |
| Weiborn, John 01/08 | Zolnoska, Shelly 06/06 |
| Weich, Nathan 07/04 | Zuehl, Joseph W. 12/06 |
| Wells, J. Michael | Zylstra, Rhoda |
| West, Pamela Kay | |
| Weyandt, Theodore | |
| Whipple, Catherine L. 06/03 | |
| White, Kirk 02/03 | |
| Whitmore, Robert 11/05 | |
| Wild, Steven 10/04 | |
| Wiley, Roxanne K. | |
| Wilkinson, Ray | |
| Wilson, Jeffery S. 06/03 | |
| Wilson, Marc 06/07 | |
| Wilson, Penny 06/07 | |
| Wilson, Robert E. | |
| Winski, Thomas 07/06 | |
| Wittenberg, Donita 01/04 | |
| Wolff, Thomas B. 06/03 | |
| Wong, Carol 10/05 | |
| Wong, Dennis 06/04 | |
| Wong, Gordon 01/04 | |
| Wong, Jerome 06/03 | |
| Wong, Wayne H.W. | |
| Wood, Steve | |
| Wood, Tyler 07/07 | |
| Woodberry, Jerome 07/04 | |
| Worgul, Ronald L. | |
| Wright, Carol A. 06/03 | |
| Wright, Marc 11/03 | |
| Wrzesniewski, Steven J. | |
| Wyant, Michael B. | |
| Yang, Benson | |
| Yeo, Seung 06/06 | |

Attachment D

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| Form 374A U.S. NUCLEAR REGULATORY COMMISSION | | PAGE 2 OF 9 PAGES |
| MATERIALS LICENSE SUPPLEMENTARY SHEET | | License number 13-2667-01MD |
| | | Docket or Reference number 030-32564 |
| Amendment No. 02 | | |
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| C. Any byproduct material authorized under paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) | C. Any sealed source listed in paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations | C. 50 millicuries total for all sources authorized under Subitem 6.C. |
| D. Xenon-133 | D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA | D. 800 millicuries |

ATTACHMENT A

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| Form 374A (2-84) | U.S. NUCLEAR REGULATORY COMMISSION MATERIALS LICENSE SUPPLEMENTARY SHEET | PAGE 3 OF 9 PAGES | License number 13-26.../-01MD |
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| | | | Amendment No. 02 |

| | | |
|--|---|--|
| 6. Byproduct, source, and/or special nuclear material E. Iodine-131 F. Technetium-99m G. Any byproduct material, except iodine-131 and technetium-99m, listed in group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987) | 7. Chemical and/or physical form E. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200, 35.300 of 10 CFR Part 35 (effective April 1, 1987) F. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 and 35.200 of 10 CFR Part 35 (effective April 1, 1987) G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.100 of 10 CFR Part 35 (effective April 1, 1987) | 8. Maximum amount that licensee may possess at any one time under this license E. 900 millicuries F. 35 curies G. 50 millicuries total possession limit |
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ATTACHMENT A

Attachment D

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| Form 374A 7-841 | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 4 OF 9 PAGES |
| MATERIALS LICENSE SUPPLEMENTARY SHEET | | License number 13-2u567-01MD |
| | | Docket or Reference number 030-32564 |
| Amendment No. 02 | | |
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| H. Any byproduct material, except iodine-131 and technetium-99m, listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987) | H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.200 of 10 CFR Part 35 (effective April 1, 1987) | H. 400 millicuries total possession limit |
| I. Any byproduct material, except iodine-131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987) | I. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or Section 35.300 of 10 CFR Part 35 (effective April 1, 1987) | I. 500 millicuries total possession limit |
| J. Uranium (depleted in the isotope Uranium 235) | J. Metal encased in stainless steel | J. 110 kilograms |
| K. Cesium-137 | K. Sealed source (Technical operations Model 77302) | K. One source not to exceed 165 millicuries |
| 9. Authorized Use: | | |
| A. Production of technetium-99m pertechnetate. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992. | | |
| B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992. | | |
| ATTACHMENT A | | |

Attachment D

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| NRC Form 374A (5-84) | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 5 OF 9 PAGES |
| | | License number 13-20067-01MD |
| | | Docket or Reference number 030-32564 |
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

C. Instrument calibration, Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Section 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of Agreement States.

D. Distribution to authorized recipients.

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Compounding of Iodine-131 capsules and distribution of these capsules to authorized recipients in accordance with statements, representations and procedures contained in application dated November 4, 1991 and letter dated January 21, 1992.

F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

J. Shielding for Mo99/Tc99m generators.

K. For use in Technical operation Model 773 calibration device for instrument calibration.

Pursuant to Sections 32.72, 32.73 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35 (effective April 1, 1987), or under equivalent licenses of Agreement States, for the Groups or Sections indicated below:

A. Unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to Group III or Section 10 CFR 35.200.

D. Gas or gas in saline may be distributed to person licensed pursuant to 10 CFR 35.200 (effective April 1, 1987).

E. through I. Any form listed in each group, Groups I, II, IV and V of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or authorized by Sections 35.100, 35.200 and 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to that Group or Section.

ATTACHMENT A

Attachment D

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| NRC Form 374A (5-84) MATERIALS LICENSE SUPPLEMENTARY SHEET | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 6 OF 9 PAGES |
| | License number 13-20367-01MD | Docket or Reference number 030-32564 |
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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1301 Milburn Boulevard, Mishawaka, Indiana.

11. A. Licensed material listed in Item 6 above, except for Subitem 6.K., shall be used by, or under the supervision of:

| | | |
|-----------------------|--------------------|------------------|
| Gary R. Klockow | Kirk Rozycki | Dawn K. Whitney |
| David S. Andrews | Quent Besing | Brian C. Blaum |
| Curtis Blaum | Scott C. Brower | Mark E. Brown |
| Dale Bultmeier | E. Dean Dome | Kurt F. Dunphy |
| Albert Easley | Gregory Edquist | Gregory Green |
| Ned Gregorio | Paul Gotti | Gregory S. Hiatt |
| Danny L. Hinel | George H. Hinkle | Louis Juliáno |
| Donald Kapolnek | Keith Koontz | James W. Korb |
| William McHugh | Stanley R. Miller | David Newbaker |
| Stephen Piepenbrink | Timothy N. Quinton | Paul D. Sale |
| John D. Scheu | Jay R. Simon | David Small |
| Cynthia Anne Smith | William Thompson | Benson Yang |
| Scott E. Van Heesbeke | Scott David Norman | |

B. Licensed material listed in Subitem 6.K. shall be used by Gregory S. Hiatt, Robert Anger, Andrea Brown or John D. Scheu.

12. At least one individual named in Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.

13. The Radiation Safety Officer for this license is Gregory S. Hiatt.

14. A. (1) The source(s) specified in Item(s) 7.C. and K. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

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| NRC Form 374A (5-84) | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 7 OF 9 PAGES |
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MATERIALS LICENSE
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Amendment No. 02

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, IL 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services:

15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

17. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

18. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

- (1) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or
- (1) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

- (1) In accordance with the directions provided by the sponsor of the IND, and
- (1) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

ATTACHMENT A

Attachment D

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| NRC Form 374A (8-88) | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 8 OF 9 PAGES |
| MATERIALS LICENSE SUPPLEMENTARY SHEET | | License number 13-26367-01MD |
| | | Docket or Reference number 030-32564 |
| | | Amendment No. 02 |

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
21. Any proposed changes in packaging, shielding or labelling shall be submitted for review to the U.S. Nuclear Regulatory Commission, Region III, Nuclear Material Licensing Section, 801 Warrenville Road, Lisle, IL 60532-4351.
22. Reagent kits may be redistributed to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of Agreement States.
23. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in application dated November 4, 1991.
24. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.
25. The licensee may use the Lineator device for doing linearity tests of its dose calibrator provided it follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.

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Attachment D

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| NRC Form 374A (5-84) | U.S. NUCLEAR REGULATORY COMMISSION | PAGE 9 OF 9 PAGES |
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| | | Amendment No. 02 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

26. The licensee shall have annual audits of their radiation safety program, performed in accordance with statements contained in application dated November 4, 1991 and letter dated January 21, 1992, and letter received August 28, 1995.

27. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in Condition 10, per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

28. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated November 4, 1991;
- B. Letters dated January 21, 1992, February 11, 1992, November 25, 1992 (excluding Items D. and F.) and December 4, 1992) and
- C. Letter received August 28, 1995 (to add a user, increase I-131 concentration of stock solution and audit modifications).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 19 1995 By Loren J. Hunter
Materials Licensing Section, Region III

ATTACHMENT A

Attachment E

Individuals Authorized to Handle Licensed Material for License for Commercial Radiopharmacy and for Possession License for an Accelerator

All individuals listed below have had numerous years experience performing the tasks and duties necessary for the operation of the PET radiopharmacy and cyclotron. All employees are cross-trained to broaden their knowledge and abilities with both the PET radiopharmacy and cyclotron. All duties and responsibilities are commensurate to each employee's training and experience.

Robert Galloway

Job Title: Executive VP/COO, Cyclotron Engineer

Duties:

- Management of the cyclotron and the facility
- Operation, maintenance, and repair of cyclotron
- Involved in the management of PET radiopharmacy's facility, equipment, and day to day operation
- All aspects and operations of the PET radiopharmacy, including chemical synthesis units, hot cells and mini-cells, and other mechanical/electrical equipment

Training and Experience:

- Formal radiation safety training by Bayer Corporation
- Introduction to RDS 111 Course by Siemens (CTI)
- Advanced RDS 111 Systems Course by Siemens (CTI)
- Spectron's in-house radiation safety training
- Spectron's In-house DOT training

Robert Galloway has a college degree in electrical engineering and is a certified mechanical engineer. He has over 25 years experience in engineering and operations of pharmaceutical manufacturing. He has over seven years experience managing and operating both a PET radiopharmacy and cyclotron. He has had extensive radiation safety training from Bayer Corporation, cyclotron on-the-job training at Siemens, and additional in-house on-the-job training provided by Robert Beeler, along with additional in-house radiation safety and DOT training provided by Gregory Hiatt.

Mark Hiatt

Job Title: Director of Technical Services, Cyclotron Engineer

Duties:

- Operation, maintenance, and repair of cyclotron.
- Management of delivery vehicles, including repair and maintenance
- All aspects and operations of PET radiopharmacy, including chemical synthesis modules, hot cells, mini-cells, and other mechanical/electrical equipment
- Repair and maintenance of back-up generator

Attachment E

Training and Experience:

- Introduction to Eclipse Systems Course by Siemens
- Advanced RDS 111 Systems Course by Robert Beeler
- Cyclotron on-the-job training by both Robert Galloway and Robert Beeler
- Spectron's in-house radiation safety training
- Spectron's in-house DOT training

Mark Hiatt has an Associates degree from Lincoln Technical Institute for mechanical, electrical, and diesel engines and systems. Mark has a master certification under A.S.E. Additionally, Mark has over five years experience working in our PET radiopharmacy and cyclotron. He has had cyclotron on-the-job training at Siemens and in-house on-the-job training provided by Robert Galloway and Robert Beeler, and radiation safety and DOT training in-house. He was hired to help Robert Galloway with the operation, maintenance, and repair of the cyclotron.

David P. Trump

Job Title: Manager of Research and New Product Development

Duties:

- Operation, maintenance, and repair of the cyclotron
- Research and development of new products
- All aspects and operations of the PET radiopharmacy

Training and Experience

- Graduate school—radiochemistry and nuclear pharmacy for 5 years
- Ph.D. Radiochemist at Mayo Clinic for 4 years
- Cyclotron training at Mayo Clinic for 4 years
- Radiation safety training by Mayo Clinic and Spectron's in-house program
- Mayo Clinic's and Spectron's in-house DOT training

David Trump has a college degree in chemistry and a Ph.D. in radiochemistry and nuclear pharmacy. He has over 13 years experience combined in PET research and cyclotron operation between Purdue University, Mayo Clinic, and his experience here at our PET radiopharmacy and cyclotron. He has had on-the-job training of cyclotron operation, maintenance, and repair while employed at Mayo Clinic, as well as on-the-job training at Spectron, provided by Robert Galloway, Mark Hiatt, and Robert Beeler. He has had radiation safety and DOT training through both Mayo Clinic's and Spectron's in-house program.

Zachary Reichert

Job Title: Research Assistant/Special Projects

Duties:

- Operation and maintenance of the cyclotron
- Research and development of new drugs
- All aspects and operations of PET radiopharmacy, including the chemical synthesis units

Attachment E

- Administrative functions for IND, NDA and general operational guidelines

Training and Experience:

- Cyclotron and radiopharmacy on-the-job training provided by Robert Galloway, Mark Hiatt, Greg Hiatt, David Trump, Kirk Rozycki, and Robert Beeler
- Spectron's in-house radiation safety training
- Spectron's in-house DOT training

Zachary Reichert has a B.S. degree in Biology from Manchester College. He has over two years experience working at our PET radiopharmacy and cyclotron. He currently is continuing training for the operation and maintenance of the cyclotron. He has had on-the-job cyclotron training provided by Robert Galloway, Mark Hiatt, and Robert Beeler, and he has had our in-house radiation safety and DOT training. He assists David Trump with development of new products and has been involved in the writing of many of Spectron's SOP's and IND's.

Erin M. Smeltzer

Job Title: Office Manager

Duties:

- Limited operation of the cyclotron
- All aspects and operations of a PET radiopharmacy
- All administrative functions for both the PET radiopharmacy and the cyclotron

Training and Experience:

- On-the-job training provided by Gregory Hiatt and Robert Galloway
- Spectrum Pharmacy's and Spectron's in-house radiation safety training
- Spectrum Pharmacy 's and Spectron's in-house DOT training

Erin has an associate degree in business. She has over six years experience working in our PET radiopharmacy and cyclotron. She was initially trained by Spectrum Pharmacy personnel in administrative tasks, radiation safety, and DOT. All of her training since then has been on-the-job training provided by Gregory Hiatt and Robert Galloway. She is responsible for overseeing both operations during the day.

Robert Beeler

Job Title: Independent Contractor/Cyclotron Engineer

Duties:

- Operation, maintenance, and repair of cyclotron
- Training and development of cyclotron engineers, technicians, and operators
- Vacation coverage for cyclotron engineers

Training and Experience:

- Over 10+ years experience as a cyclotron engineer for Siemens (CTI)

Attachment E

Robert Beeler has over 10 years experience working for Siemens (CTI) as a cyclotron engineer and service technician. He now works as an independent contractor, providing coverage for vacations, training, and repair work for a small group of cyclotron facilities.

Scott Minor

Job Title: Independent Contractor/Cyclotron Engineer

Duties:

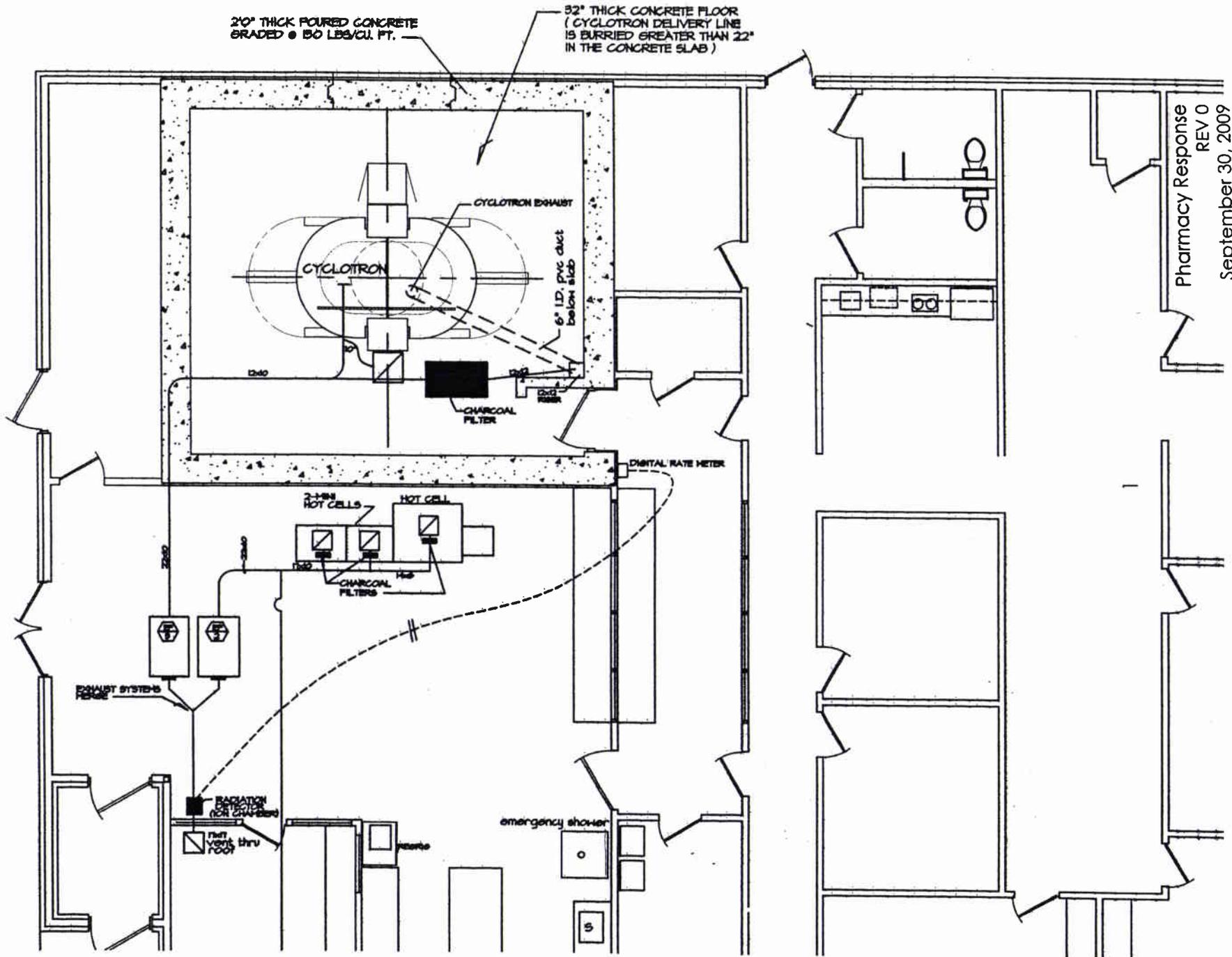
- Operation, maintenance, and repair of cyclotron
- Training and development of cyclotron engineers, technicians, and operators
- Vacation coverage for cyclotron engineers

Training and Experience:

- Several years experience as a cyclotron engineer for Siemens (CTI)
- Over seven years as an independent contractor

Scott Minor has several years experience working as a cyclotron engineer with Siemens (CTI). He now works as an independent contractor.

Attachment F2



Attachment G

COMPLY: V1.6.
2:27

9/30/2009

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH
THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS
FROM THE COMPLY CODE - V1.6.

Prepared by:

SPECTRON MRC

17490 DUGDALE DR, SOUTH BEND, IN 46635

KIRK ROZYCKI
574-271-2800

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

Attachment G

COMPLY: V1.6.

9/30/2009

2:27

SCREENING LEVEL 4

DATA ENTERED: (Based upon average release rate of 3.9796E-8
uCi/cc and an average stack flow rate of 1060
CFM)

| Nuclide | Release Rate (curies/YEAR) |
|---------|-------------------------------|
| F-18 | D 6.275E-01 |

Release height 4 meters.

Building height 9 meters.

The source and receptor are not on the same building.

Building width 28 meters.

Building length 20 meters.

STACK DISTANCES, FILE: C:\COMPLY\NEWDISTA.DAT

| DIR | Distance (meters) |
|-----|----------------------|
| N | 122.0 |
| NNE | 99.0 |
| NE | 107.0 |
| ENE | 107.0 |
| E | 122.0 |
| ESE | 107.0 |
| SE | 107.0 |
| SSE | 122.0 |
| S | 122.0 |
| SSW | 122.0 |
| SW | 122.0 |
| WSW | 122.0 |
| W | 122.0 |
| WNW | 50.0 |
| NW | 50.0 |
| NNW | 50.0 |

Attachment G

COMPLY: V1.6.
2:27

9/30/2009

WINDROSE DATA, FILE: C:\COMPLY\WR.DAT

Source of wind rose data: STAR DATA FILE: SBN0257.STR

Dates of coverage:

Wind rose location: AIRPORT

Distance to facility: 6 MILES

Percent calm: 0.00

| Wind FROM | Frequency | Speed (meters/s) |
|--------------|-----------|---------------------|
| N | 0.072 | 4.04 |
| NNE | 0.028 | 3.55 |
| NE | 0.029 | 3.77 |
| ENE | 0.033 | 3.76 |
| E | 0.060 | 4.09 |
| ESE | 0.050 | 4.34 |
| SE | 0.041 | 4.66 |
| SSE | 0.041 | 4.48 |
| S | 0.115 | 4.57 |
| SSW | 0.082 | 4.76 |
| SW | 0.110 | 4.78 |
| WSW | 0.093 | 4.92 |
| W | 0.067 | 5.38 |
| WNW | 0.069 | 5.40 |
| NW | 0.064 | 4.97 |
| NNW | 0.048 | 4.42 |

Distance from the SOURCE to the FARM producing
VEGETABLES is 122 meters.

Distance from the SOURCE to the FARM producing
MILK is 300 meters.

Distance from the SOURCE to the FARM producing
MEAT is 300 meters.

NOTES:

The receptor exposed to the highest concentration is located
50. meters from the source in the WNW sector.

He gets his VEGETABLES from a farm located
122. meters from the source in the N sector.

Attachment G

He gets his MEAT from a farm located
300. meters from the source in the N sector.

He gets his MILK from a farm located
300. meters from the source in the N sector.

Input parameters outside the "normal" range:

Attachment G

COMPLY: V1.6.
2:27

9/30/2009

None.

RESULTS:

Effective dose equivalent: 9.3E-03 mrem/yr.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

***** END OF COMPLIANCE REPORT *****

Attachment H



VON GAHLEN

SPECIFICATIONS FOR 75 MM DUAL CHEMICAL ENCLOSURE

- Modules to be installed one on top of the other.
- 75mm (3") of lead shielding in walls, roof and floor.
- Inside dimensions of each enclosure: Approximately 27" wide x 20" deep x 24" high.
- Outside dimensions of each enclosure: Approximately 39 1/4" wide x 29-3/8" deep x 29-1/2" high.
- Low profile fluorescent light fixtures.
- Switched electrical duplex outlets.
- Electrical control box mounted on the lower front side of the enclosure.
- Stainless steel liner.
- Slide out stainless steel pan approximately 25 1/2" wide x 15 1/2" deep with 1" lip to contain potential spills or leaks.
- Hinged front door with an opening approximately 27" wide x 24" high.
- 2" diameter ventilation ducts.
- Steel support stand with epoxy coating.
- Shielding for 2" conduit from the room floor to the bottom of the enclosure.
- Accessory openings with stepped lead plugs.
- Optional transfer port between hot cell and chemical modules.

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