Spectron
mrc l.l.c.

Mr. Kevin Null
Materials Licensing Branch
U.S. NRC, Regioin 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,

Kirk Rozycki, R.Ph.
Radiation Safety Officer

MEDICAL RADIOISOTOPE CENTER L.L.C.
P.E.T. Radiopharmaceuticals
17490 Dugdale Drive • South Bend, Indiana 46635-1545 • 574-271-2800

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

Manufacturer	Isotope	Activity	Type	Model #	Quantity
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

Sealed sources that may be purchased in the future:

Manufacturer	Isotope	Activity	Type	Model #	Quantity
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):	Surface	3 Feet
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 l(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 germainium-68, itself, poses minimal risk. Therefore, financial assurance and a decommissioning funding plan should not be required.

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.	**RADIOACTIVE MATERIAL**		
	Sealed And/Or Unsealed Byproduct Material		
	For unsealed materials:		
	• Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit.		☑
	AND		
	For potentially volatile materials (e.g., iodine-131):		
	• Specify whether the material will be manipulated at the radiopharmacy.	☐	N/A
	For sealed sources and discrete sources of radium-226:		
	• 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;	☑	N/A
	• 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	☑	N/A
	• If the above information cannot be provided for the discrete source of radium-226, describe the discrete source and its physical boundaries.		☐
	For depleted uranium, specify the total amount (in kilograms).		300 Kg

Attachment A

APPENDIX C

Item No.	Title and Criteria	Yes	Description Attached
5.	**RADIOACTIVE MATERIAL** *(Cont.)* **Financial Assurance and Recordkeeping for Decommissioning** If financial assurance is required, submit documentation required by 10 CFR 30.35.		☑
6.	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED** For radiopharmaceuticals: • We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72; and	☑	
	• Describe all licensed material to be distributed or redistributed.		☑
	For generators: • We confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and	☑	
	• We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.	☑	
	For redistribution of used generators: • Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport;		☑
	• We confirm that the manufacturer's packaging and labeling will not be altered;	☑	
	• We confirm that the generator will not be distributed beyond the expiration date shown on the generator label;	☑	
	• We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and	☑	
	• We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.	☑	

Item No.	Title and Criteria	Yes	Description Attached
6.	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont.)***		
	For Redistribution of Sealed Sources — for Brachytherapy or Diagnosis:		
	• 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	☐	
	• 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.	☐	
	For Redistribution of Calibration and Reference Sealed Sources:		
	• 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	☑	
	• 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.	☑	
	For Redistribution of Prepackaged Units for *In Vitro* Tests:		
	• We confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.	☐	

Item No.	Title and Criteria	Yes	Description Attached
6.	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont.)***		
	For Redistribution to General Licensees:		
	• We confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and	☐	
	• We confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.	☐	
	For Redistribution to Specific Licensees:		
	• We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and	☐	
	• We confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 10 CFR 20.1901 and 20.1904.	☐	
	For Redistribution to Discrete Sources of radium-226:		
	• We confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute them.	☐	
	• 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.	☐	
	For radiopharmaceutical preparation, we will perform:		
	• compounding of iodine-131 capsules,	☐	
	• radioiodination,	☐	
	• chemical synthesis of PET radiopharmaceuticals,	☑	
	• technetium-99m kit preparation, and	☑	
	• other, specify.	☐	☐

Item No.	Title and Criteria	Yes	Description Attached
6.	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont.)***		
	Supply specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and depleted uranium.		☑
	We will provide customers the following radiation protection services involving licensed material:		
	• leak testing,	☐	☐
	• instrument calibration, and	☐	☐
	• other, specify.	☐	☐
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**		
	For applicant's management structure, provide:		
	• An organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO.		☑
	For the Radiation Safety Officer (RSO), provide:		
	• Name of the proposed RSO;		☑
	AND		
	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;		☑
	OR		
	• Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.		☐
	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.		
	For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:		

APPENDIX C

Item No.	Title and Criteria	Yes	Description Attached
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE** ***(Cont.)***		
	• Name of the proposed ANP;		☑
	AND		
	• Pharmacist's license number and issuing entity;		☑
	AND		
	For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):		
	• Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.		☑
	OR		
	For an individual qualifying under 10 CFR 32.72(b)(4):		
	• Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material,		☐
	AND		
	• Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.		☐
	OR		

Attachment A

Item No.	Title and Criteria	Yes	Description Attached
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE** ***(Cont.)***		
	For an individual qualifying under 10 CFR 35.55(a):		
	• Copy of the certification(s) of the specialty board whose certification process has been recognized[2] under 10 CFR 35.55(a);		☐
	AND		
	• 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;		☐
	AND		
	• If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59;		☐
	OR		
	For an individual qualifying under 10 CFR 32.72(b)(2)(ii):		
	• Description of the training and experience specified in 10 CFR 35.55(b), demonstrating that the proposed ANP is qualified by training and experience;		☐
	AND		
	• 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;		☐
	AND		
	• If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.		☐

APPENDIX C

Item No.	Title and Criteria	Yes	Description Attached
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE** ***(Cont.)***		
	Notes: • 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.		
	For each proposed Authorized User (AU), provide the following: • Name of each proposed AU; **AND** • Types, quantities, and proposed uses of licensed material; **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; **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; **OR**		☐ ☐ ☐ ☐

Attachment A

Item No.	Title and Criteria	Yes	Description Attached
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE *(Cont.)***		
	• Description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials. The applicant may find it convenient to describe this training and experience using a format similar to Tables G-1 and G-2 in Appendix G.		☐
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL)**		
	Occupationally Exposed Workers and Ancillary Personnel		
	We have developed and will implement and maintain written procedures for a training program for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training.	☑	
	Personnel Involved in Hazardous Materials Package Preparation and Transport		
	We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable.	☑	
	Instruction for Supervised Individuals Preparing Radiopharmaceuticals	**Need Not Be Submitted with Application**	
9.	**FACILITIES AND EQUIPMENT**		
	Provide a copy of the registration or license from a State Board of Pharmacy as a pharmacy, or provide evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution;	☑	☑
	AND		

Attachment A

Item No.	Title and Criteria	Yes	Description Attached
9.	**FACILITIES AND EQUIPMENT *(Cont.)***		
	Describe the facilities and equipment to be made available at each location where radioactive material will be used. For PET radiopharmacies, the description should include the method used to physically transfer licensed material to the different processes (e.g., chemical synthesis, dispensing). A diagram should be submitted that shows the applicant's entire facility and identifies activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.		☑
	Include the following information:		
	• Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage;		☑
	• Sufficient detail in the diagram to indicate locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;		☑
	• Descriptions of the ventilation systems, including gloveboxes or fume hoods, with pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of radioactive materials likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and,		☑
	• Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within constraints for air emissions established under 10 CFR 20.1101(d)		☑
10.	**RADIATION SAFETY PROGRAM**		
	Audit Program	**Need Not be Submitted with Application**	
	The applicant's program for reviewing the content and implementation of its Radiation Protection Program will be examined during inspections, but it should not be submitted in the license application.		

Item No.	Title and Criteria	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM** *(Cont.)*		
	Instruments		
	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";	☐	
	OR		
	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;	☑	
	OR		
	A description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment.		☐
	Material Receipt and Accountability		
	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,		

APPENDIX C

Item No.	Title and Criteria	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont.)***		
	• 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.		
	Occupational Dosimetry		
	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, and 10 CFR 20.2106, as applicable.	☑	
	Public Dose	**Need Not Be Submitted with Application**	
	The applicant's program to control doses received by individual members of the public will be examined during inspection, but it should not be submitted in a license application.		
	Safe Use of Radionuclides and Emergency Procedures		
	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 19.11(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;		

Item No.	Title and Criteria	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM** *(Cont.)* • 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 that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50 and other requirements, as applicable.		
	Surveys 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.	☑	
	Dosage Measurement Systems 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;		☑
	AND		
	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©";	☑	

Attachment A

APPENDIX C

Item No.	Title and Criteria	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont.)***		
	AND		
	If applicable, include a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers;		☑
	OR		
	If applicable, include a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer or other entity.		☐
	Transportation	**Need Not Be Submitted with Application**	
	The applicant's program for transportation will be examined during inspection but should not be submitted in a license application.		
	Minimization of Contamination		
	The applicant does not need to provide a response to this item under the following condition: NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections of NUREG-1556, Vol. 13, Rev. 1: Section 8.9, "Item 9: Facilities and Equipment"; Section 8.10.6, "Safe Use of Radionuclides and Emergency Procedures"; Section 8.10.7, "Surveys"; Section 8.10.13, "Leak Tests"; and Section 8.11, "Item 11: Waste Management."		
	Radioactive Drug Labeling for Distribution		
	Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the "transport radiation shield" or on the container used to hold the radioactive drug); and agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs.		☑
	Radioactive Drug Shielding for Distribution		
	For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide:		☑
	• The radionuclide and the maximum activity for each type of container (e.g., vial, syringe),		

Attachment A

Item No.	Title and Criteria	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM** *(Cont.)* • 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. **Leak Tests** 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.	☑	
11.	**WASTE MANAGEMENT** **Pharmacy-generated Radioactive Wastes** 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. **Returned Wastes from Customers** 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: • 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 that meet the requirements in 10 CFR 20.2001(a), 10 CFR 30.33, and 10 CFR 71.5, as applicable.	☑ ☑	

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

Manufacturer	Isotope	Activity	Type	Model #	Quantity
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

Confidential - Internal Use Only

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

Abab, Hamid 04/06
Abdallah, Al-Hasan 11/03
Admasu, Samuel M.
Aeschliman, Daryl 09/06
Afari-Tawiah, George 09/06
Alberto, Alan
Albrecht, Jeffrey 06/03
Alfrey, Byron A.
Allmer, Michael P. 02/03
Alsbrook, Nicholas 06/07
Altaye, Dawit
Amin, Kamal C.
Ancona, Peter L.
Anderson, Weston 12/04
Andrews, David S.
Angel, Marilyn 06/05
Antoon, Debra Ann C. 06/03
Arnold, Aaron D. 06/03
Arnold, David 06/04
Atwood, Amy 10/06
Augustine, Luke
Ault, Daniel 10/04
Avantes, Roxana
Awadallah, Robert

Backus, James E.
Bains, Deepak 07/06
Badrian, Michael
Baker, William J.
Ballinger, Susan J.
Balogh, William M.
Bare, Aaron 12/05
Barkentin, Scott 12/05
Barlow, Craig C. 06/04
Barnett, Seth 07/06
Barrett, Thomas
Bartkowiak, William 06/03
Bartucca, Anthony 12/03
Baugh, Mark 12/04
Baugher, Rebecca 04/05
Baylin, Lysa
Beach, Michele 06/07
Beaven, Walter
Becker, Lora 10/04
Becker, Sarah 06/06
Begian, Laura 04/07
Beightol, Robert 11/05
Bell, Eric 06/06
Bellingan, John
Bellizzi, Robert
Ben, Sunday Ahmed
Bennett, Jeffrey A.
Benson, Katherine A.
Biber, Marshall
Bilhorn, Tracey
Billig, Rebekah 10/06
Binion-Richards, Kim 10/04
Bjorklund, Stanley 06/03
Blair Sallie M.
Blevins, Michael 03/06
Blizinski, Mark 10/04
Block, Peter A. 04/05
Bodine, Leah 09/07
Bohmer, Daniel 12/06
Bolek, Melissa
Bolinger, Kathryn A.
Boncross, Peter 07/04
Bonomo, Ryan C. 06/03
Bowman, Arthur A.
Bowman, Jason L. 06/03
Bowman, Paul D.
Brady, Thomas 06/04
Brewer, Keith 01/09
Briggs, John J. 03/04
Bright James M.
Bright, Bruce C.
Bright, Lonzo
Broderick, Patrick
Bronnenberg, Tracey
Brown, Cathy 10/04
Brown, Jerrod 03/06
Brown, Nadja 03/06
Brown, Tim 02/04
Brown, Robert 10/06
Bryant, April R.
Bryant, Charles W.
Burgin, Matthew W. 09/03
Burns, William 06/06
Burriss, Timothy A.
Burton, Daniel 06/06
Bussey, Ronald 08/04

Callicott, C. Bevin
Calloway, Steve P.
Calonico, Victor
Cameron, Jay. P. 02/03
Caristo, Anthony 10/04
Carlo, John Alan
Carnes, Paul
Carp, Elizabeth 06/04
Carpenter, Daniel E.
Carringan, Alison 06/03
Carter, Diedre 02/06
Carter, Thomas 12/06
Carter, Todd W.
CdeBaca, John
Chamberlian, Chris
Champ, Matt
Chan, Ardan
Chandler, Gary
Chang, Danny
Chang, Joe 11/05
Chee, Michael W.
Childs, Jim 07/07
Choi, Kevin C.
Choi, Sung 09/06
Christopher, Melissa 06/03
Chukwu, Celista 11/06
Chun, Byung Sam
Claunch, Scott
Clemens Jr. Martin D. 06/03
Clough, Keith
Coker, Jimmy R. 06/03
Colangelo, Anthony
Colberg, Marco 11/04
Coley, David 03/07
Collazo, Jesus
Condella, Maria 03/04
Connahan, Carrie 02/03

Attachment C

CARDINAL HEALTH

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Revision: 249 6/12/2009

Conrad, Casey 05/09
Cornette, George
Costanzo, Jerry L.
Council, Robert C. 03/03
Coupal John J. 05/03
Cowin, Susan 06/04
Craig, James D. 01/04
Craig, Scott 12/06
Crew, Clayton
Cross, Bradley L.
Crowe, Rocke
Cruz, Jose 1/08
Csernyik, Leslie A.
Cullather, Mary Ruth
Curet, Stephen B. 05/03
Czapczynski, Joseph
Czarnecki, Carl 04/06
Czarnomski, John E.

D'Amico, Steven A.
D'Orazio, August 05/04
Dadey, Christin I.
Dagit, Angela 03/07
Daidone, Connie 09/05
Davidson, James 10/04
Davis, Christine 07/08
Davis, Douglas M.
Dawson, James 03/06
Dawson, Margaret 03/07
Dawson, Mont
De Leeuw, Elizabeth 05/03
Dean, Aubrey 10/04
Defenbaugh, Dennis H. 06/03
Degan, Suzanne 04/04
deHoll, Christopher John 07/03
Deines, Darlene 10/06
Delaney, Jonathan 10/07
Della, Anthony
Dewbre, Kimberly
DiBenedetto, Leana 03/11
Dickerson, Joseph 01/04
Dietrich, Jeffrey A.
Dillon, Jeffrey D. 05/03

Dimenna, Michael 10/04
Dines, Brett
Dingman, Victoria 04/06
Dinh, Anthony 07/06
Dirksen, J. William
Dolfi, Angela C.
Dosch, Adam 08/06
Douglass, Phillip A.
Drapkin, Edward C.
Draves, Kelly, 02/03
Driskell, Phillip D.
Du, Xuan Thanh 05/08
Dubuc, Amanda 09/05
Duford, Kimberly 08/04
Duncan, Yvette
Dunphy, Kurt F.
Duong, Nhan
DuPriest, William D.
Duren, Kimberly 09/04
Dyer, Jay

Eames, JoAnna S. 05/03
Eaton, Stephanie Dawn 04/05
Eddington, David
Edwards, Cowan C.
Eier, Susan Renee 07/07
Elkins, Angela C.
Ellert, Benjamin Ray 05/08
Emberger, Oliver 05/03
Engstrom, David
Estrada, Adrian
Estrada, Lisa A.
Evans, Sydney B.
Even, Gregory A.
Everette, Rhonda 07/07
Ezekiel, John 05/05

Fagbemi, Olubukoa 03/04
Fang, Chung
Farmer, William, 03/05
Fedeles, Ron
Feininger, Loralee 01/03

Ferraro, Gaetano (Guy) 05/06
Fery, Joseph A.
Fetko, Mark
Fetty, David 07/06
Fiely, Scott A. 05/03
Figueroa, Noel 02/05
Fincannon, Tammi 10/07
Fink, John E. 03/03
Fire, Rebecca 05/06
Fisher, Christopher W.
Fisher, Kenneth
Fitch JoAnn
Flack, John A.
Foldenauer, Ian 05/05
Foo, Joseph A.
Foran, Kristina 07/04
Ford, James 10/07
Forrester, Jr. M.T.
Freund, Joseph
Friee, James A.
Frigo, Janet Borgmeyer-Fry, William 10/05
Fulbright, Mark
Furutani, Reid 09/04

Garcia, Charles
Garcia, Luis 05/06
Gardner, Marni
Gardner, Michael P.
Gedamu, Salamawitt 11/04
George, Melissa 12/04
Georgion, Carrie 05/06
Ghoreishi, Anushe
Gilbert, Weaver 12/04
Gillespie, John 05/06
Glenn, Stephanie 12/04
Glennon, Margaret
Goertz, Wayne 10/04
Gonzales, Ronald
Goodhart, Melissa 07/05
Goodwin, Alan 10/04
Goosen, Linda 05/05
Gordon, Steven 07/07
Goss, David

Attachment C

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AUTHORIZED NUCLEAR PHARMACISTS
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34-29200-01MD
(Old # 04-26507-01MD)
Revision: 249 6/12/2009

Gostanian, Armen
Gotti, Paul 05/05
Gould, Elio A.
Gren, Julie 08/03
Grant, Amy 07/06
Grasch, David A. 03/06
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 03/06
Guy, Jason P. 08/03

Hall, David Douglas 10/03
Hall, Giovanni
Hall, Holly 08/06
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 12/06
Hardee, James 12/05
Hardesty, Shawn 10/04
Harris, Kenneth 10/04
Harrison, Edward
Hart, Randy 11/00
Haslam, William 07/06
Hatcliff, Andrew 10/07
Hayes, Kelly
Hayes, Zeta Lyn
Hearn, Susan
Heath, Sidney S.
Helmich, Kelli 08/04
Henderson, Lee 03/06
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 05/03
Hoffman, Kristin M.
Hoffman, Stephanie 08/06
Hoffner, Michael 10/06
Hogan, Jeff
Holak, Betsy
Holland, Ray 03/04
Holliday, Todd 01/05
Holshouser, William
Hoogland, Gary D.
Horner, James G.
Horvath, Steve A.
Houle, Ronald
Hua, Rebecca
Hubbard, Erin
Hudek, Scott 02/03
Hudgins, Kenneth E.
Hueter, David 05/04
Hughes, Kevin 01/04
Hughes, Susan M. 05/03
Hunkapiller, Rhonda 08/06
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 08/06
Jagodzinski, David 10/04
Jandora, Thomas
Jeffers, C. Denise 02/05
Jehl, Amanda 01/06
Jeppesen, Sean
Jimerson, Jason 02/03
Jiminez, 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 02/06
Kiewel, Lori Jo
Kim, Alan
Kim, Frank 02/03
Kim, Joseph
Kimball, Kelly
Kinard, Suzanne
King, Charles E.
King, Terry 10/05
Kiar, Terence 08/03
Klisowski, Yin-Hing "Eileen"
Kloetzli, Liesel A. 04/09
Kloos, Brian
Knapp, Paul
Knishka, Scott P.
Koblenski, Dennis
Kochenash, Stephen
Kochert, Eugene L.

Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

Confidential - Internal Use Only

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

Koehler, Heather 02/03
Kohs, Gordon
Kong, Chi 02/06
Koontz, Keith
Korb, James W.
Korczynski, James 04/06
Korherr, Christopher
Kostouros, Nektarios 12/06
Krafels, Jennifer 12/06
Kroll, Michelle 04/05
Koshy, Anita James
Kraher, Kathryn
Kreienbrink, Clint P.
Kristie, Michael
Krummick, Cindy C.
Ku, Betty 04/03
Kumar, Sunita 05/06
Kusiowski, Kim
Kwan, Robert 02/06

L'Heureux, Tiffany 05/04
Lachowicz, Blaise 06/04
Lackey, Karen 07/05
Laird, Amy Michelle 06/03
Laird, Colin
Lambeth, Rhonda 12/05
Lamont, David
Lancaster, Derrick 11/05
Lane, Melinda 06/03
Lardner, Susan 11/04
Larkin, Debra 09/06
LaVallo, Pasquale A.
LeBlanc, Katheryn 07/05
Le, Peter Diep 12/06
Le, Richard
Le, Tuan L.
Lee, Arthur 05/06
Leiker, Merle
Leslie, Elizabeth 05/07
Leveritt, Samuel
Levy, Michael 06/06
Lewandowski, Bruce 06/04
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 06/03
Lowry, John James
Luisi, Nicholas
Lukacs, Joseph E.
Lunsford, Debra
Luper, Jason 06/07

Mabis, Thomas J. 06/03
Macaluso, Anthony
Mack, Nancy
MacPherson, Thomas
Madden, Allen 06/04
Mai, Thao
Makhani, Aziz A.
Mallett, Weston Beau 07/06
Mallidi, Srinivas 06/07
Malmkar, Erin 06/04
Malmquist, Kris 05/03
Mangold, Jess 06/05
Manoni, Cleto
Manrique, Ana
Mantz, Gary W.
Mar, Dwayne 06/03
Marascalso, Salvatore
Marcure, George John
Marion, S. Brent 06/04
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 06/07
McDowall, Giselle 10/04
McElfresh, John Robert
McGahee, Melissa 12/05
McIsaac, Daniel 03/09
McKelvey, Matthew 10/06
McManamy, Elizabeth 07/05
Medeiros, Douglas 01/09
Medley, Kenneth 06/03
Mehta, Shubangi 06/07
Mendoza, Cynthia
Menta, Mario J.
Mercer, Nicola 09/06
Merchant, Michael
Merket, Sherri 09/07
Messer, Elizabeth
Mettetal, Mike
Metz, Michael A. 06/03
Miano, John
Mikles, James 01/04
Miller, Eric 05/06
Miller, John A.
Miller, John B.
Miller, John S.
Miller, Meghan 10/06
Miller, Michael
Miller, Michael W.
Miller, Rick
Miller, Sherry L.
Miller, Stanley 01/05
Miller, Steven 06/03
Miller, Walter B.
Mingus, Anjuni 07/06
Minton, Terry 06/03
Mitchell, Jeff 09/06
Mitchell, Robert C.
Mitchell, Stephanie
Mizanin, Jennifer
Mohip, Rajeesh 03/06
Monk, Daniel 06/06
Moore, Jack A.
Moore, Maura

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

Revision: 249 6/12/2009

Moran, Colin 12/06
Morman, Scott 01/06
Morrill, Richard
Moster, Julie A.
Moy, Raymond 03/07
Mullins, Jonathan 10/05
Moyers, Andrew 06/03
Mumau, Timothy
Mungai, John 04/06
Murphy, Daniel F.
Musemeche, Carl 05/03
Muth, Timothy
Myers, Andrew 6/06
Myers, Christopher W. 06/03

Nacchio, Joseph
Nagem, Jonathan 06/03
Nakashima, Ken
Napier, Paul 05/03
Nash, Frank N. 06/03
Naundorf, Donna
Ndumele, Mary
Nelson, Brigett 06/03
Ngo, Linette 11/04
Nguyen, Hoa Thai
Nguyen, Hoang T.
Nguyen, Khan 07/05
Nickel, Heath 09/06
Nickman Gene G.
Niehaus, Karl E.
Norton, Stephen W. 06/03
Norton, Sharon 07/05
Nyquest, Steve

Ogden, C. Craig
Okray, Michael
Okunewitch, Thomas
Olds, Christopher S. 06/03
Oliveira, Steven R. 04/03
Oliver, Benjamin A. 09/03
Olson, Shanna L.
Olson, Tom 10/07
Osterberg, Brian 09/05
Osterberg, David M.
Owens, Andy 09/06
Owens, James C.
Owers, Randy 02/06

Paletta, John
Palmquist, Dan C.
Papineau George 06/05
Pappas, Pamela E.
Park, Brian 07/04
Park, Joo Yeon 04/09
Parker, Bryan 03/03
Pardun, Robyn 07/06
Parrish, Jeff
Patel, Chirag
Patel, Imtiyaz A.
Patel, Ketankumar Arvindbhai 07/06
Patel, Sanjaykumar 12/06
Patti, Russell A. 06/03
Paulson, Matthew 12/04
Peck, John 11/07
Pecoraro, Anthony J.
Perry, Derek 09/06
Perryman, Doug 03/06
Peters, Mark 01/05
Peters, Michael T. 06/03
Petot, Stacey L.
Petrucci, Joseph E.
Peyrovan, Peyman 11/04
Pfeiffer, Jay J.
Pflum, Nicole
Phady, Aminh T. 04/09
Phaneuf, Phillip 09/04
Pharr, Jonathan 07/06
Phelps, Kristen 10/04
Pichon, Rachi 02/03
Pinpin, Jeruel 02/06
Pittman, Eric L.
Poleon, Gregory P. 02/03
Porter, Phillip S.
Potter, Stephen
Pratschler, Shannon
Prenosil, Sandra 06/06
Presley, James
Pribyl, Daren L.
Price, Courtney 10/06
Priddle, Gaia
Proctor, Dana 05/04
Puyear, Andrea 09/04

Quesada, Stephen

Radwanski, Kimberly
Rafferty, Thomas J.
Rahman, Adam
Rahman, Zubaida
Rasmussen, Sachiko 12/05
Rath, Christie Hawkins-
Rathod, Mahipal 04/06
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. 06/03
Rickelman, Jesse 10/06
Rimar, Thomas
Ritchie, Mathew 10/04
Rivera, Frollan (Roi) 12/05
Roady, Kevin T. 11/05
Roberson, Ronald Darryl 10/02
Roberts, Russell S. 06/03
Robertson, Earl
Robertson, Steven
Robinson, C. Matthew 10/06
Robinson, Franklyn J. 11/05
Robinson, James 06/03
Robitaille, Michael
Rock, Christopher M.
Rodriguez, Noel
Roff, Bradley 05/06
Root, Dana

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Rosado, Richard 01/03
Rovnak, Christopher 06/04
Royal, James C.
Rozycki, Kirk 01/05
Ruffin, Craig 05/09
Runco, Ernest
Rush, Lawrence 03/04
Rushing, Philip 03/04
Russell, Albert E. 05/03
Ryan, Kevin M.
Rydman, Micah 10/07

Salamonski, Norbert
Samuelson, Steve 10/04
Sanchez, Eric 06/07
Sanders, April
Sanfilippo, Michael 02/03
Sartor, Jan M. 06/03
Saula, Jacqueline
Schaefer, Ashley 09/05
Schenk, John
Scherer, Jennifer
Schmidt, Michael
Schmitz, Jane E.
Schultz, Larry A.
Schultz, Robert A. 05/07
Schwartz, Rachel 08/05
Scott, Gary Zackery 07/03
Scott, Michael J. 08/08
Seale, Shannon
Seaward, Jessica 02/08
Serrin, David A. 06/03
Shambry, Matthew 09/05
Sharpe, Allison 12/06
Shayeghi, Amin Neel
Shea, Ann Marie
Sherer, Melissa 06/03
Shimley, Brian E.
Shipper, Steven A.
Shultz, Joseph E. 06/03
Simmers, Sarah 06/05
Simone, Bernard S.
Skeoch, Christine A. 06/03
Smith Laura S.

Smith, Anthony
Smith, Bennett
Smith, Frank 06/04
Smith, Greg 12/08
Smith, Jeffery 03/07
Smith, Melissa A. 07/04
Smith, Michael
Snow, Stephanie 01/05
Snyder, David 02/03
Solomon, Peter
Sopp, Douglas 12/05
Sorenson, James P.
Southwick Christopher
Spillum, Tanya
Sposato, Peter J.
Springer, Isaiah 07/04
Stassen, Mark K.
Stewart, Janeen
Stoltz, Brad 03/05
Stone, James E.
Stoops, Howard 06/04
Stotler, Richard E.
Strahan, Ronald 06/03
Straly, Tad J.
Steininger, Megan 03/06
Street, Jeffrey 01/09
Strickland, Ricky 8/03
Strivens, Robyn K.
Stumler, Caryn
Suhay, Steve
Sullivan, Garry 01/06
Summers, Timothy M.
Suttle, Dana
Svec, Don E.
Svejk, Matthew J.
Swoy, Jeffrey
Syed, Shihab, 1 1/03
Szczechowicz, Frank

Tanaka, Raymond
Tarleton, Ralph Bruce
Teasdale, Amanda 10/08
Teaster, Michael 03/08
Thomas, Jamie 12/08

Thomas, Stephanie 06/08
Thomas, Trent H.
Thompson, Sheila
Thompson, Stephanie 02/03
Thompson, William
Thor, Rebecca A. 03/03
Timm, Adam 03/04
Torras, Jorge A.
Townsend, Tally 07/06
Travis, Kim L.
Tremblay, Andrea 03/07
Tribe, Teresa
Trickey, Benjamin D. 06/06
Tripode, Kevin 04/05
Trotter, James Ray 06/04
Tsang, Rene W.
Tucker, Anna 03/06
Tucker, Clyde
Tucker, Tracey
Tucker, Jennifer 07/05
Turner, Julie A.
Turney, Catherine M.

Uhm, Thomas 02/04
Unanue, Ann
Underwood, James
Unger, Howard
Usko, Sherri 12/03

Van Cott, Susan 03/07
Van Dyke, Lora 06/04
Van Heesbeke, Scott 01/05
Vargas, Mirta R.
Vebeurgt, Paul S. 06/03
Velazquez, Enrique
Vickers, Alison 07/05
Victoria, Cynthia 03/06
Vu, Nghiem 10/04
Vukovich, Jill

Wakham, Gary
Walker, Chad 06/03
Walker, Kimbly 10/03
Wallsten, Richard 12/06

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Attachment C

CARDINAL HEALTH

AUTHORIZED NUCLEAR PHARMACISTS
PROPRIETARY

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NRC Master License No.
34-29200-01MD
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Revision: 249 6/12/2009

Walter, Steve 03/06
Ward, Erin 12/06
Ward, Katie 06/07
Warnock, Jacqueline 03/06
Wasserman, William
Watts, Robert 12/06
Wear, Mark 07/05
Weatherspoon, Kyle
Webb, Jeffery Neil
Weiner, Eric
Welborn, John 01/09
Welch, Nathan 07/04
Wells, J. Michael
West, Pamela Kay
Weyandt, Theodore
Whipple, Catherine L. 08/03
White, Kirk 03/03
Whitmore, Robert 11/05
Wild, Steven 10/04
Wiley, Roxanne K.
Wilkinson, Ray
Wilson, Jeffery S. 08/03
Wilson, Marc 08/07
Wilson, Penny 08/07
Wilson, Robert E.
Winski, Thomas 07/05
Wittenberg, Donita 01/04
Wolff, Thomas B. 08/03
Wong, Carol 10/05
Wong, Dennis 08/04
Wong, Gordon 01/04
Wong, Jerome 08/03
Wong, Wayne H.W.
Wood, Steve
Wood, Tyler 07/07
Woodberry, Jerome 07/04
Worgul, Ronald L.
Wright, Carol A. 08/03
Wright, Marc 11/03
Wrzesniewski, Steven J.
Wyant, Michael B.

Yang, Benson
Yeo, Seung 08/08
Yip, Norita 08/03
Young, Carol A.
Yu, Jennifer Zhangjie
Yu, Michelle 04/09

Zawisza, Tom 05/04
Zhu, Bing Bing
Ziegler, Rachel 07/07
Zimmerman, Gary
Zipp, C. Joe
Zolnoska, Shelly 08/06
Zuehl, Joseph W. 12/05
Zylstra, Rhoda

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Attachment D

NRC FORM 374 (7-84)

NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 9 PAGES

Amendment No. 02

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Spectrum Pharmacy, Inc.	In accordance with letter received August 28, 1995 3. License Number 13-26367-01MD is amended in its entirety to read as follows:
2. 1301 Milburn Blvd. Nishawaka, IN 46544-4639	4. Expiration Date February 28, 1997
	5. Docket or Reference No. 030-32564

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
A. Molybdenum-99	A. Any Molybdenum-99/technetium-99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. 35 curies
B. Any byproduct material listed in paragraph 31.11(a) of 10 CFR Part 31	B. Prepackaged in vitro diagnostic test kits	B. 50 millicuries total possession limit

ATTACHMENT A

Attachment D

NRC Form 374A (9-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 2 OF 9 PAGES

License number: 13-2[illegible]67-01MD

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

Attachment D

Form 374A (3-84) U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-26../-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
E. Iodine-131	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)	E. 900 millicuries
F. Technetium-99m	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)	F. 35 curies
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)	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)	G. 50 millicuries total possession limit

ATTACHMENT A

Attachment D

NRC Form 374A — U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-20367-01MD
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

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 5 OF 9 PAGES

License number: 13-2[illegible]67-01MD
Docket or Reference number: 030-32564
Amendment No. 02

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

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 6 OF 9 PAGES

License number: 13-20367-01MD

Docket or Reference number: 030-32564

Amendment No. 02

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 Juliano
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.

ATTACHMENT A

Attachment D

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-20367-01MD

Docket or Reference number: 030-32564

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:

(i) 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

(ii) 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:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) 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

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 8 OF 9 PAGES

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.

ATTACHMENT A

Attachment D

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 9 OF 9 PAGES

License number: 13-26367-01MD

Docket or Reference number: 030-32564

Amendment No. 02

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

- 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 Specton'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:

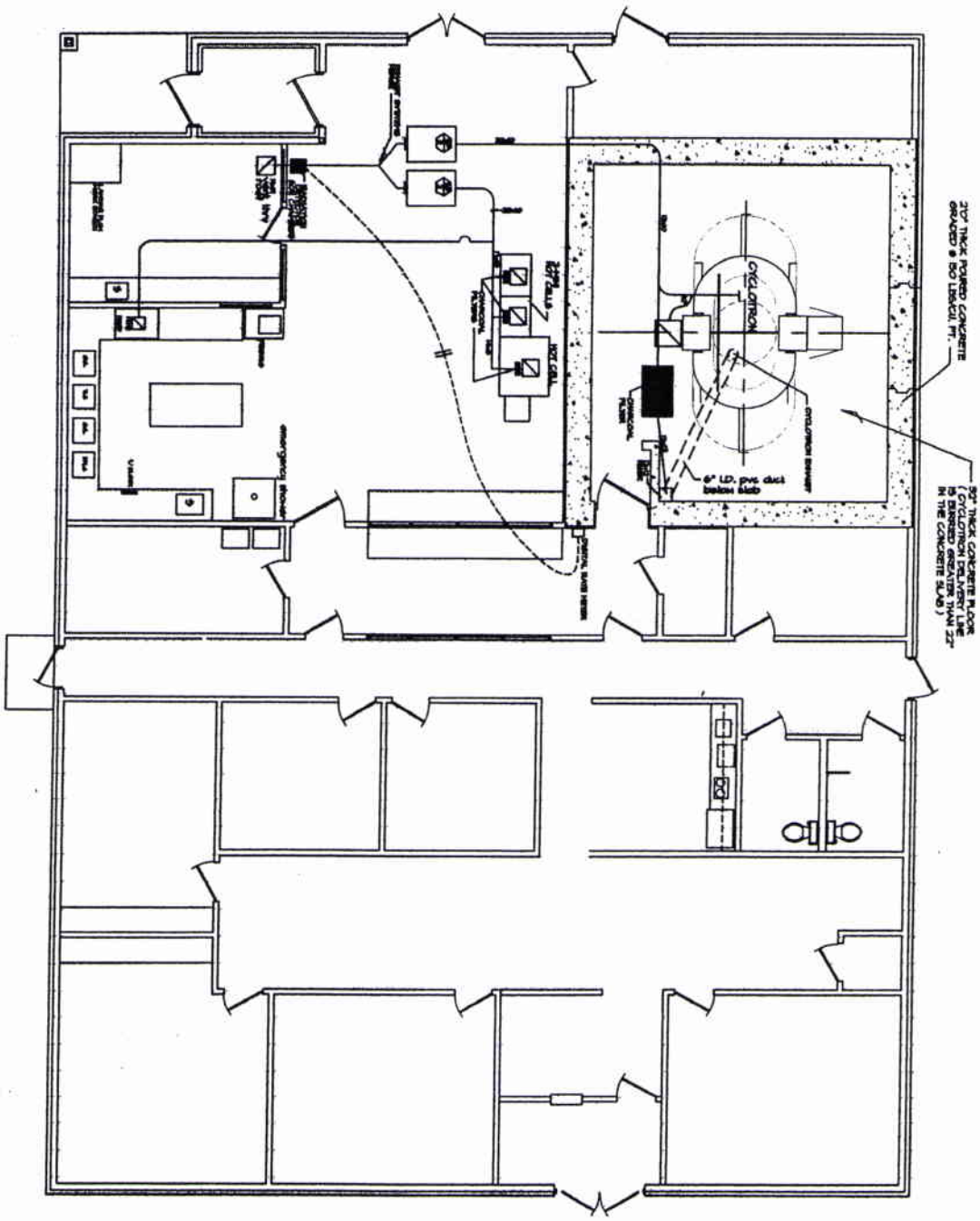
- Operation, maintenance, and repair of cyclotron
- Training and development of cyclotron engineers, technicians, and operators
- Vacation coverage for cyclotron engineers

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 F1



MECHANICAL PLAN
SCALE: 1/4" = 1'-0"

M1 SHEET

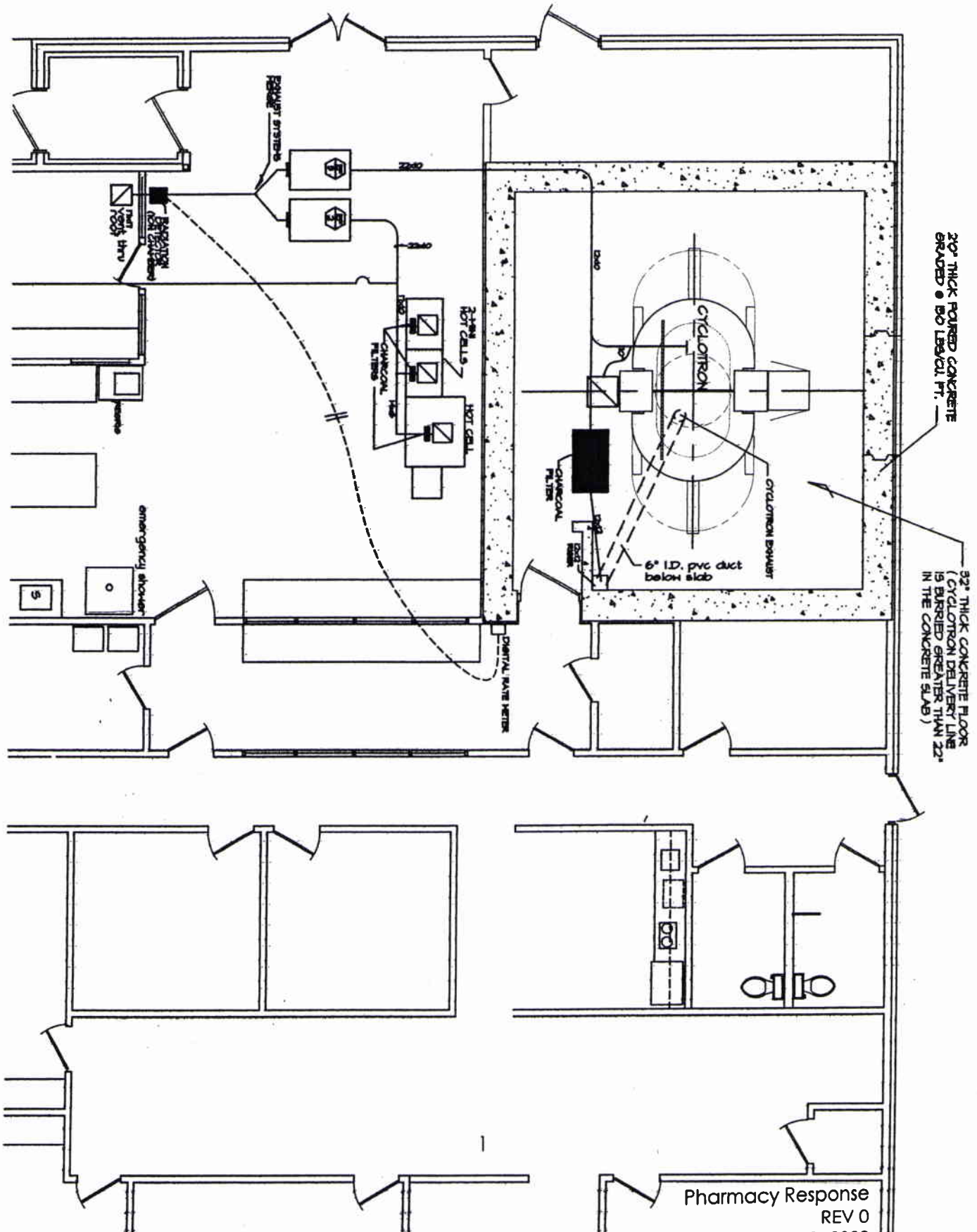
MECHANICAL PLAN

A NEW FACILITY FOR
Spectron Land, LLC
SOUTH BEND, INDIANA

DATE	ISSUE
	CONSTRUCTION
	REVISED
	REVISED

Pharmacy Response
REV 0
September 30, 2009

Attachment F2



Attachment G

COMPLY: V1.6. 9/30/2009
2:27

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. 9/30/2009
2:27

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. 9/30/2009
2:27

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.

Express

Align top of **FedEx Express Shipping Label** here.

RT 535 1 D 1512 10.01
FZ

FedEx
TRK# 0200 8689 1093 1512

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PRIORITY OVERNIGHT

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Express

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FedEx Ret...ow Copy

1 From
Date 7/30/09 Sender's FedEx Account Number 1525-8717-1
Sender's Name Kirk Rozycki Phone SM 271-2800
Company Spectron mrc
Address 17490 Dugdale DR.
City South Bend State IN ZIP 46635

2 Your Internal Billing Reference

3 To
Recipient's Name Kevin Null Phone 630 827-7854
Company U.S. Nuclear Regulatory Commission Region III
Recipient's Address Materials Licensing Branch
Address 2443 Warrenville Road Suite 210
City Lisle State IL ZIP 60532-4352

4a Express Package Service
3 FedEx 2Day
Express Freight Service
7 FedEx 1Day Freight
5 Packaging
6 FedEx Envelope*
6 Special Handling
3 SATURDAY Delivery
No 4 Yes
7 Payment
1 Sender 2 Recipient 3 Third Party 4 Credit Card 5
Total Packages
8 Residential Delivery Signature Options
No Signature Direct Signature

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