From: "Troy Curnutt" [redacted] E6
To: <jlm5@nrc.gov>
Date: 12/7/05 5:52PM
Subject: Advanced Isotopes of Idaho

Jim, sorry for the delay. I wanted to make sure I addressed all the topics in appendix C.

Please e-mail me with any questions or concerns.

Please see the attached "NRC Response Aii" PDF with associated information.

Thanks in advance,

Troy Curnutt

Advanced Isotopes of Idaho

4968 Rainbow Lane

Chubbuck Idaho 83202

[redacted] E6

Exemption b6 [redacted]

Exemption b6 [redacted] E6

B-2

470722

Appendix C: Suggested Format for Providing Information Requested in Items 5 through 11 of 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.		**See attached "Nuclides-Form-Quantity-Uses"**	[X]
	AND			
	For potentially volatile materials (e.g., iodine-131):			
	• Specify whether the material will be manipulated at the radiopharmacy		[X] **See Attached "Procedures for Handling millicurie quantities of radio-iodine"**	
	For sealed materials:			
	• Identify each radionuclide (element name and mass number) that will be used in each source;		**See Attached "Brachytherapy Seed Information"**	[X]
	• Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested;		**See Attached "Brachytherapy Seed Information"**	[X]
	• We confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State;		[X]	
	• We confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State		[X]	
	For depleted uranium, specify the total amount (in kilograms).		**999 Kg**	[X]
5	**RADIOACTIVE MATERIAL *(Cont'd)***			
	Financial Assurance and Record Keeping for Decommissioning			
	If financial assurance is required, submit documentation required by 10 CFR 30.35.		**N/A**	[ ]
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		[X]	
	• Describe all licensed material to be distributed or redistributed.		**See attached "Nuclides-Form-Quantity-Uses"**	[X]

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 [X]
- We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging. [X]

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont'd)*

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; **See Attached Policy & Procedure Manual** [X]
- We confirm that the manufacturer's packaging and labeling will not be altered; [X]
- We confirm that the generator will not be distributed beyond the expiration date shown on the generator label; [X]
- 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 [X]
- We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed. [X]

For Redistribution of Sealed Sources C 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 [X]
- 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. [X]

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont'd)*

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 [X]
- 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 [X]

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. [X]

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 [X]
- 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. [X]

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED *(Cont'd)*

For radiopharmaceutical preparation, we will perform:

- compounding of iodine-131 capsules; [X]
- radioiodination; [X]
- technetium-99m kit preparation; and [X]
- other, specify. [ ] [ ]

Supply specific information concerning the use of sealed sources for reference and calibration, and depleted uranium. **Please see original application, including policy & procedure manual.** [X]

We will provide customer the following radiation protection services involving licensed material:

- leak testing; [ ] [X]

See Attached

Policy & Procedure Manual

- instrument calibration; and [ ] [X]
- other, specify. [ ] [X]

See Attached

Policy & Procedure Manual

Page 50 (6.4)(A)(B)(C)(D)

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 the flow of authority between executive management and the RSO. **See Attached Organizational Chart** [X]

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE *(Cont'd)*

For the Radiation Safety Officer (RSO), provide:

- Name of the proposed RSO: [X]

  See Attached

  Vincent T. Curnutt

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; **See Original attached information on** [X]

  Vincent T. Curnutt

OR

- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to commercial nuclear pharmacies. **See Original attached information on** [X]

  Vincent T. Curnutt

Note: See Appendix G for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.Figures G-1 and G-2 are specific to RSO training and experience.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)

For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:

- Name of the pharmacist; **See Original attached Training and Experience and Preceptor Statement Catherine A. Heyneman** [X]

AND

- A copy of the State pharmacy licensure or registration of the pharmacist; [ ]

AND

- A copy of the license (NRC or Agreement State) on which the individual was specifically named as an ANP; [ ]

OR

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as ANP; [ ]

OR

- A copy of previous NRC license issued to a commercial radiopharmacy prior to December 2, 1994, on which the pharmacist was specifically named as an authorized user; [ ]

OR

- A copy of the pharmacist's certification(s) from the radiopharmacy board(s) approved by NRC; [ ]

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE *(Cont'd)*

OR

• Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience, and written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy;	**See Attached Training and Experience and Preceptor Statement** **Catherine A. Heyneman**	[X]
AND		
• Description of the recentness of training, if necessary.		[ ]

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE *(Cont'd)*

For each proposed Authorized User (AU), provide the following:

• Name of each proposed AU;	N/A	[ ]
AND		
• Identify types, quantities, and proposed uses of licensed material;		[ ]
AND		
• A copy of 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		
• 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 Figures 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.	[X]

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.	[X]
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;	[X] **Idaho will not issue a Pharmacy License until the NRC issues a RAM License**	[ ]
AND		
Describe the facilities and equipment to be made available at each location where radioactive material will be used. A diagram should be submitted showing the applicant's entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.	**See Original attached information Description of facility, with photos**	[X]
Include the following information:		
• Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage;	**Please see new attached map.**	[X]
• 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;	**Please see new attached map.**	[X]
• 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 with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and	**Please see attached Procedures for Handling millicuries quantity of Radioiodine**	[X]
• Verification that ventilation systems ensure that effluents are within 10 CFR 20.1301 and are ALARA constraints for air emissions established under 10 CFR 20.1101(d)	**Please see attached Procedures for Handling millicuries quantity of Radioiodine**	[ ]
10. RADIATION SAFETY PROGRAM	**Need Not be Submitted with Application**	
Audit Program		
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.	**See attached Policy and Procedure manual Page 33**	
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, "Program-Specific Guidance About Radiopharmacy Licenses," dated September 1999;		[ ]
OR		
We will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG-1556, Vol. 13, "Program-Specific Guidance About Radiopharmacy Licenses," dated September 1999, and instruments will be calibrated by other persons authorized		[X]

by the 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. [ ]

10. RADIATION SAFETY PROGRAM *(Cont'd)*

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; [X]

AND

We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months; [X]

AND

We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that: [X]

- 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, 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. [X]

10. RADIATION SAFETY PROGRAM *(Cont'd)* **Need Not Be Submitted with Application**

Public Dose

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: [X]

- facility and personnel radioactive contamination minimization, detection, and control; **See attached Policy and Procedure manual**
- performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use; and **See attached Policy and Procedure manual**
- use of protective clothing and equipment by personnel **See attached Policy and Procedure manual**

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;

10. RADIATION SAFETY PROGRAM *(Cont'd)*

AND

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

- 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

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50, 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. [X]

10. RADIATION SAFETY PROGRAM *(Cont'd)*

Dosage Measurement Systems

Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, and photon-emitting radioactive drugs; **See attached description of "Capintec CRC-15E" Dose Calibrator** [X]

AND

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, 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 requirements in 10 CFR 32.72(c)". [X] **See Original attached Policy and Procedure manual**

AND

If applicable, include a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers; **Dose calibrator does not require correction factors to accurately read Beta emitters** [ ]

OR

If applicable, include a means for ensuring the accuracy of beta-correction factors supplied by the instrument manufacturer or other entity. **Dose calibrator does not require correction factors to accurately** [ ]

read Beta emitters

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.

10. RADIATION SAFETY PROGRAM *(Cont'd)* — **Need Not Be Submitted with 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: "Facilities and Equipment; Radiation Safety Program - Safe Use of Radionuclides and Emergency Procedures; Radiation Safety Program - Surveys; Radiation Safety Program - Leak Testing; and Waste Management" of NUREG - 1556, Vol. 13, dated September 1999.

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 the container used to hold the radioactive drug); and agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs

Radioactive Drug Shielding for Distribution — [X]

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); — **Please see originally attached Policy & Procedure Manual**
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and — **Please see Attached Unit Dose Syringe Pigs**
- Indicate 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. — **Please see originally attached Policy & Procedure Manual**

10. RADIATION SAFETY PROGRAM *(Cont'd)*

Leak Tests — [X]

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

NUCLIDES-FORM-QUANTITY-USES

Radioactive Material	Chemical and/or physical form	Maximum Quantity	Authorized Uses
A. Molybdenum-99	Any molybdenum-99 technetium-99m generator manufactured, labeled, packaged, and distributed in accordance with specific license issued pursuant to 32.22 of 10 CFR Part 32 or a specific license issued to a manufacturer by the NRC pursuant to equivalent regulations.	30 Curies	Production of technetium-99m pertechnetate. Redistribution to authorized recipients
B. Xenon-133	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 the FDA.	2 Curies	Distribution to authorized recipients
C. Iodine-131	Any form listed in 10 CFR 35.300	500 mCi	Dispensed and/or distributed prepared radiopharmaceuticals to authorized recipients. Iodine-131 as iodine listed in 10 CFR 35.300 for compounding and dispensing as iodine-131 capsules and distributed to authorized recipients.
D. Technetium-99m	Any form listed in 10 CFR 35.200	30 Curies	Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparation of radiopharmaceuticals.
E. Any radioactive material except Iodine-131 and Technetium-99m, listed in 10 CFR 35.100	Any form listed in 10 CFR 35.100	As Needed	Dispensing and/or distributing prepared radiopharmaceuticals to authorized recipients.
F. Any radioactive material, except Iodine-131 and Technetium-99m, listed in 10 CFR 35.200	Any form listed in 10 CFR 35.200	As Needed	Dispensing and/or distributing prepared radiopharmaceuticals to authorized recipients.
G. Uranium (depleted in the isotope Uranium-235)	Plated or encapsulated metal	500 Kilograms	As shielding material in generators

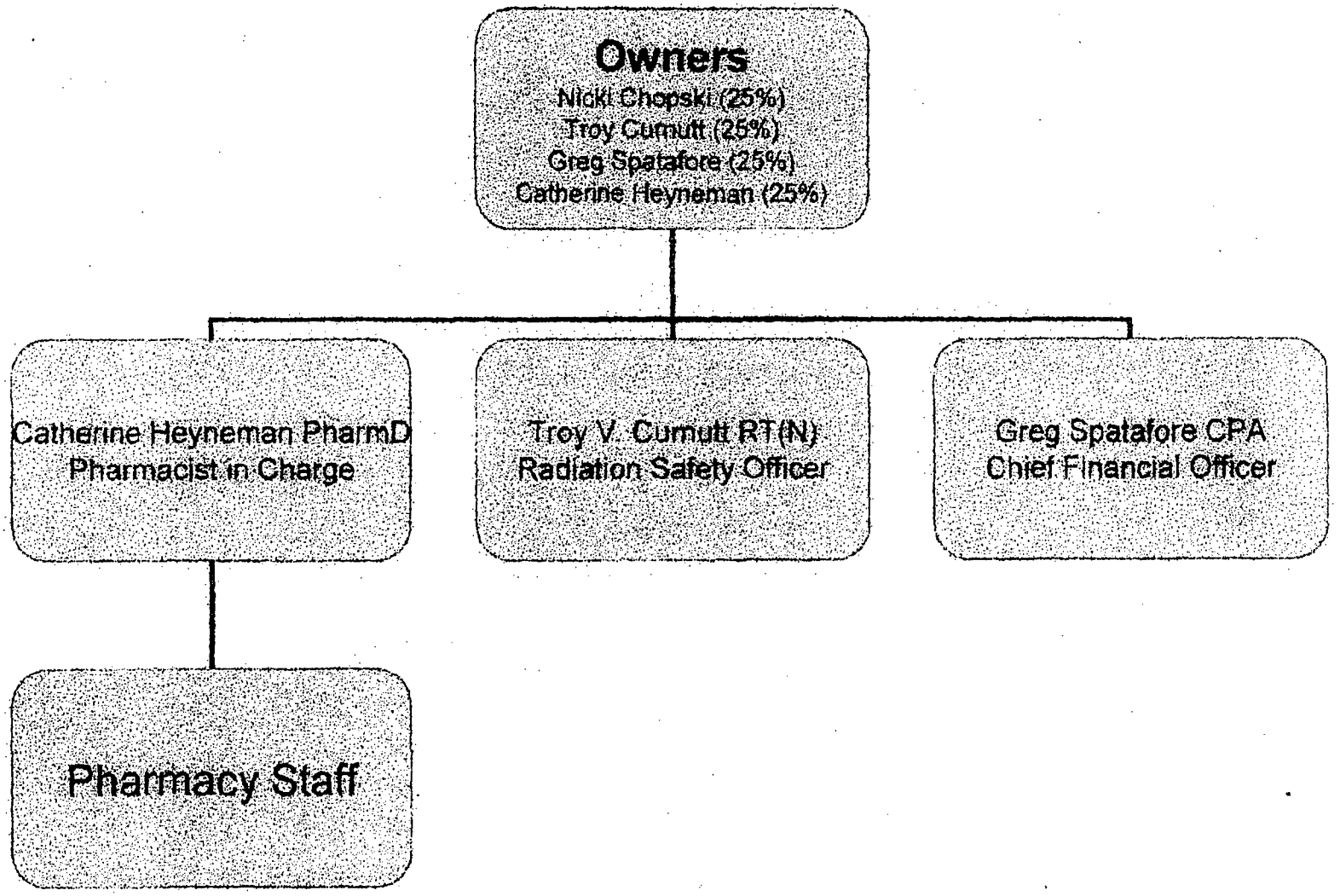
Radioactive Material	Chemical and/or physical form	Maximum Quantity	Authorized Uses
H. Any radionuclide with atomic numbers 3-83, inclusive	Sealed source. Any sealed source listed in 10 CFR 35.65 that has been manufactured, labeled, packaged, and distributed in accordance with specific license issued pursuant to 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by the NRC pursuant to equivalent regulations	250 millicuries; no single source to exceed 30 millicuries	Instrument calibration. Redistribution of sealed sources to specifically authorized recipients. Pursuant to 10 CFR 35.65(b), the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 32.11, or other persons specifically licensed to receive such source.
I. Any radioactive material	Analytical Samples	As Needed	For possession incident to the performance of wipe tests of sealed sources for the licensee and as a customer service
J. Iodine-125	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
K. Gold-198	Sealed source	500 Millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
L. Iridium-192	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
M. Cesium-137	Sealed source	500 millicuries	Receipt, storage and distribution upon prescription to authorized recipients.
N. Palladium-103	Sealed source	2 Curies	Receipt, storage and distribution upon prescription to authorized recipients.
O. Fluorine-18	Any	As Needed	Receipt, storage and distribution upon prescription to authorized recipients.
P. Yttrium-90	Liquid	As Needed	Receipt, storage and distribution upon prescription to authorized recipients.

Pursuant to 10 CFR 32.72, we request authorization to distribute the radioactive material described in Table C.2 of this application to persons licensed pursuant to 10 CFR 32.11, or under equivalent licenses of Agreement States, for the Groups indicated below:

C. Through P. (Above)	Any form listed 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 and 10 CFR 35.400 may be distributed to persons licensed pursuant to those sections.

Brachytherapy Seed Information
^{125}Iodine & ^{103}Palladium

^{125}Iodine		^{103}Palladium	
Manufacturer	**Model**	**Manufacturer**	**Model**
Amersham	OncoSeed, Model 6711 and EchoSeed, Model 6733	Best Medical International Inc.	Best Palladium-103, Model 2335
BEBIG GmbH	IsoSeed® I-125	North American Scientific	Prospera Pd-103, Model Med 3633
Best Industries	Best® I-125 Source, Model 2301	Theragenics Corporation®	TheraSeed®, Model 200
Draximage Inc	BrachySeed™ Model LS-1		
Implant Sciences Corp	I-Plant, Model 3500		
IBt	Intersource^{125}, Model 12511		
IsoAid, LLC	Advantage I-125, Model IAI-125A		
Mills Biopharmaceuticals, Inc. (subsidiary of Mentor Corp.)	ProstaSeed®, Models 125SL and 125SH		
North American Scientific	Prospera I-125, Model Med 3631-A/M		
SourceTech Medical	Implant Seeds, Model STM1251		
Theragenics Corporation®	I-Seed I-125		


Owners
Nicki Chopski (25%)
Troy Cumutt (25%)
Greg Spatafore (25%)
Catherine Heyneman (25%)
Catherine Heyneman PharmD
Pharmacist in Charge
Troy V. Cumutt RT(N)
Radiation Safety Officer
Greg Spatafore CPA
Chief Financial Officer
Pharmacy Staff

Advanced Imaging Center of Idaho

Procedures for handling millicuries quantities of radio-iodine

1. Manipulation of radio-iodine (e.g., handling or compounding capsules, performing radioiodination, dispensing from bulk solution) will be conducted in an isolated area within the restricted area of the pharmacy. This will aid in maintaining exposure ALARA and provide a means to isolate the area in the event of a spill.

2. Radio-iodine handling will be performed in a fume hood. The ventilation for the fume hood shall be checked semi-annually to ensure adequate airflow and confirm negative pressure with respect to the area around the fume hood. Exhaust stacks for the fume hood shall be located as far as possible from the air intake points.

3. The fume hood will include the appropriate filters (activated charcoal) to minimize effluent releases.

4. Filters shall be installed and used in accordance with manufacturer's specifications (e.g., adequate airflow to ensure adequate residence time).

5. Filters shall be checked at installation and periodically, based on use, but not less than once per calendar quarter, to ensure continued efficiency.

6. The airflow through the fume hood shall be confirmed before each use.

7. Absorbent materials and dry chemical buffers, for use in the event of a spill, shall be located near the area where millicurie quantities of radio-iodine are handled.

8. Additional protective clothing shall be used when handling millicurie quantities of radio-iodine. Personnel shall use double gloves and change the outer pair frequently.

9. All personnel handling greater than 500 mCi's of ^{131}Iodine in a year shall have a bioassay performed. This is the threshold below which intakes over 1% of the annual limit on intake (ALI) are not likely, and assumes no containment. When used in a properly operating fume hood, the threshold for consideration of the need for bioassay rises to 5 curies of ^{131}Iodine.

Thyroid Bioassay

Purpose: To monitor the thyroid burden of workers exposed to more than 10 mCi of un-contained ^{131}Iodine (in non-vented conditions) or more than 50 mCi's of ^{131}Iodine.

Frequency:

1. Pharmacists, technicians, interns, RSO – weekly (Wednesday) or before Wednesday if you will not be present on Bioassay day.
2. All staff – Monthly (first Wednesday of the month).
3. Emergency – within 6 to 12 hours of a suspected ingestion or major spill.

Equipment Requirements:

1. Ludlum 2200 Thyroid Uptake System
2. Detector – Ludlum Low Energy NaI(Tl)
3. ^{133}Barium Reference Rod Source
4. Block Phantom

Set-up of Ludlum 2200 Thyroid Uptake System

1. Refer to quarterly efficiency report for current settings.

Procedure.

1. Remove red cap from the front face of the detector for all measurements.
2. Measure the reference source by inserting the radioactive end of the ^{133}Barium rod fully into the block phantom, then place the front face of the detector on the circle and count for 2 minutes. (Compare to the source constancy range)
3. Measure the background by placing the front face of the detector in the circle on the block phantom and count for 2 minutes.
4. Measure thyroid uptake by placing the detector against the neck, below the Adam's Apple and count for 2 minutes.
5. Record the data on the record sheet.
6. Notify the RSO or pharmacist if the count is greater than 100 counts above background count.
7. Record all data into the BioRx Bioassay Program.
8. Calculate thyroid activity using the following formula:

$$\frac{(\text{neck CPM} - \text{BKG CPM})(\text{uci of Standard})}{\text{Standard CPM} - \text{BKG CPM thyroid}}$$

**** Action limit is 0.04 uCi per NRC Regulation Guide 8.20**

**** We reserve to right to contract this service with a local imaging company. A report will be generated by the imaging company and saved at Advanced Isotopes of Idaho.**

Minimum Detectable Activity (MDA)

It will be necessary to determine the sensitivity of the equipment to demonstrate that the equipment to demonstrate that the equipment used is capable of detecting action limit (0.04 uCi). The following formula will be used.

$$MDA = (3 + 3.29\,((bc/bct)(sct)(1 + sct/bct))^{1/2}) / \text{Counting efficiency}$$

bc = background counts
bct = background count time
sct = sample count time
Counting efficiency = CPM of standard source / activity of standard source

Only equipment with MDA of less then 0.04 uCi will be used to perform bioassays.

^{131}Iodine Air Monitoring

The handling of volatile Radio-iodine requires that air sampling be performed to document that the DAC is not exceeded in the restricted or unrestricted areas.

Three in-line air samplers will be used. One for the sampling of air in the restricted area (breathing zone), one for the sampling effluent air in the unrestricted area (air being vented to the environment) and the other to check the saturation status of the charcoal filters.

Frequency:

Carbon cartridges will be exchanged every 7 days and counted after cartridge exchange. In the event of a spill, the cartridge will be counted immediately.

Equipment Requirements:

1. Ludlum Model 2200 Sampling System
2. Detector – Ludlum low energy NaI(Tl)
3. Reference source 133Ba rod source
4. Carbon cartridge phantom (Background)
5. ENV & BZA carbon cartridge
6. Vacuum pump and air flow gauge

Set-up of Ludlum 2200 sampling system

1. Refer to quaterly efficiency report for current settings

Procedure:

1. Sampling system set-up – background measurement
2. place detector on the background carbon cartridge and count for 3 minutes
3. Insert the reference source 133Ba rod into the carbon cartridge phantom and count for 1 minute (Compare to the source constancy range)
4. Efficiency performed quarterly

Sampling system set-up carbon cartridge measurement

1. Obtain environmental (ENV) and breathing zone area (BZA) carbon cartridge along with flow rate (should be at least 65 on air flow gauge
2. place cartridge with flow arrow pointing down on the table top and place the detector on top of the cartridge. Count for 3 minutes.
3. Record all data into the BioRx air monitor program.

Determine uCi of radio-iodine present on filter by using the following formula:

^{131}Iodine uCi = (net CPM filter) / [(2.2 x 10^6 dpm / uCi (EF)]

EF = Efficiency Factor of well counter

Calculate uCi / ml of ^{131}Iodine concentration by using the following formula:

^{131}Iodine uCi / ml = (^{131}Iodine uCi) / (air flow through pump ml)

Maximum Derived Air Concentration (DACs) are:

1. **Restricted Area = 2×10^{-8} uCi / ml**
2. **Unrestricted Area = 4×10^{-11} uCi / ml**

SHOULD AIR MONITORING EXCEED DAC
PLEASE NOTIFY THE RSO IMMEDIATELY

Procedure for Survey and Change of the Charcoal Filters

Purpose:
To monitor the amount of 131Iodine saturation of the charcoal filters in the fume hood stack.

Frequency:
Charcoal filters will be checked every 7 days. In the event of a spill the charcoal filters will be monitored immediately.

Equipment Requirements:
See enclosed diagram on page 5

Calculation

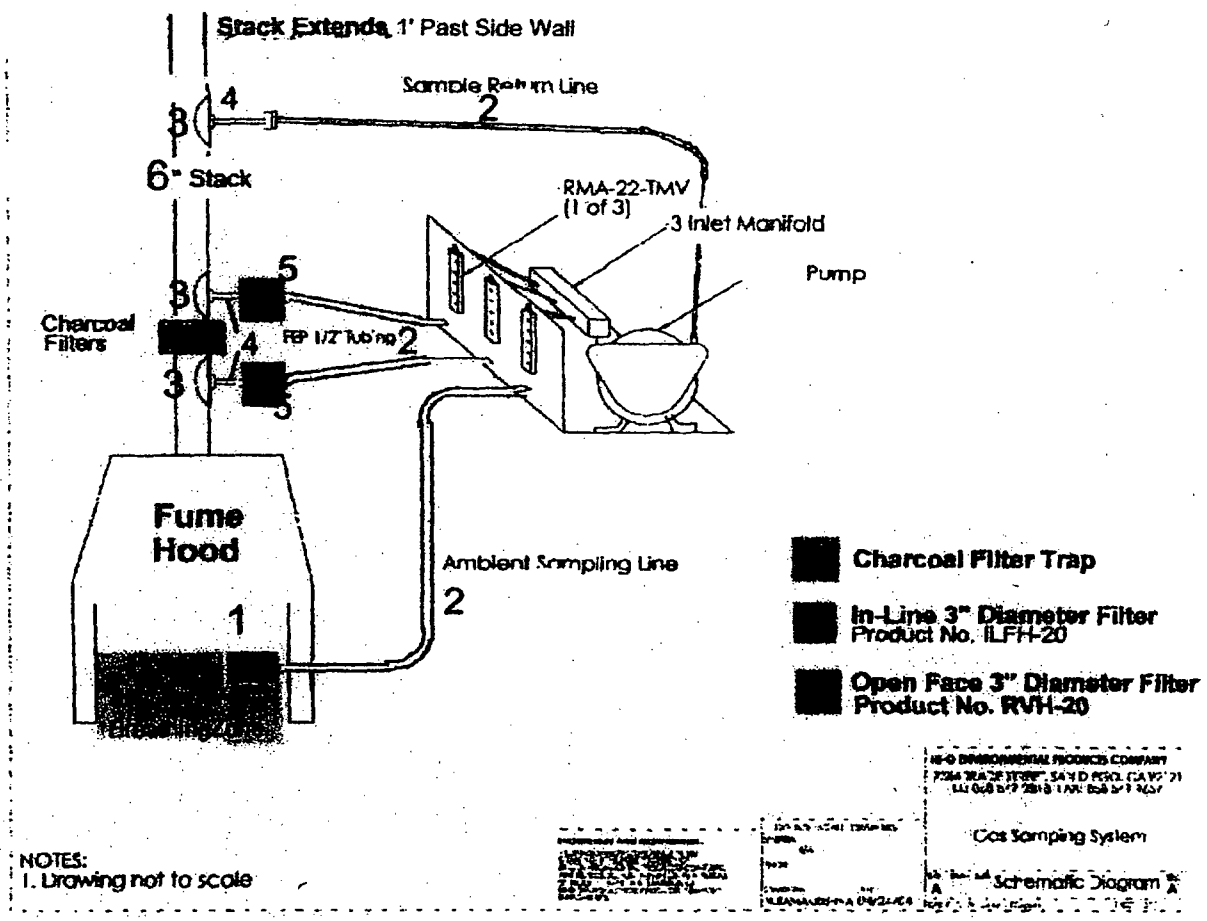
A1 = Air Sample above charcoal filters
A2 = Air Sample below charcoal filters

A1 / A2 = % Efficiency

Replace the charcoal filters when Efficiency is less then 90%.

Procedure for Charcoal Filter Removal and Replacement

1. Disconnect fume hood pump.
2. Put on disposable gloves
3. Remove filter housing unit
4. Remove top filter
5. Remove bottom filter
6. Replace with new filters
7. Replace charcoal filters in the unit
8. Reconnect fume hood pump



Supplies Description

1. Combination 2" diameter paper and TC-series cartridge holder. Open faced Filter holder with 3/8" male quick disconnect fitting.
2. Braid reinforced polyurethane vacuum sample tubing with 3/8" male & Female quick disconnects.
3. 1/2" Stainless Steel Gas Probe. Designed to extract low flow gas sample. Includes 1/2" Compression x 3/8" Male Quick Disconnect.
4. Stainless Steel Flange designed to fit 6" to 12" diameter stack & to support a single point 1/2" gas sampling probe. Includes 1/2" stainless steel bore through fitting.
5. In-Line combination 2" Diameter Filter paper & TC-series cartridge holder includes 3/8" male & female quick disconnects (out/in).
2. Braid reinforced polyurethane vacuum sample tubing with 3/8" male & female disconnects.

Ex 2

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. Advanced Imaging Center of Pocatello	3. License number 11-29215-01
2. 1151 Hospital Way, Building B Pocatello, Idaho 83201	4. Expiration date October 31, 2015
	5. Docket No. 030-37033 Reference No.

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. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed

9. Authorized use

A. Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material shall be used or stored only at the licensee's facilities located at 1151 Hospital Way, Building B, Pocatello, Idaho.

11. The Radiation Safety Officer (RSO) for this license is Vincent Troy Curnutt.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Steven T. Strickler, D.O.	35.100; 35.200

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
11-29215-01

Docket or Reference Number
030-37033

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

    A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

    D. Sealed sources need not be leak tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.

    E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

    G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
11-29215-01

Docket or Reference Number
030-37033

16. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

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

18. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 September 9, 2005
B. E-mail dated October 3, 2005

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date October 13, 2005

By Jacqueline D. Cook /RA/

Jacqueline D. Cook, Senior Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

October 13, 2005

Advanced Imaging Center of Pocatello
ATTN: Vincent Troy Curnutt, CEO
Radiation Safety Officer
1151 Hospital Way, Building B
Pocatello, Idaho 83201

SUBJECT: NEW LICENSE

Please find enclosed License No. 11-29215-01. **Please note that this license only authorizes the use of byproduct material for 35.100 and 35.200 uses. To request authorization for 35.300 use (i.e. unsealed byproduct material for therapeutic use: Sr-89, Y-90, I-131 or Sm-153) you will need to submit an amendment request proposing an authorized user who meets the requirements of 10 CFR 35.390, Training for use of unsealed byproduct material for which a written directive is required.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact me at 817-860-8189.

The NRC needs your Taxpayer Identification Number in order to make payments (refunds). Please complete and return the self-addressed, stamped NR Form 531, "Request for Taxpayer Identification Number," which is enclosed for your convenience.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC in writing of any change in mailing address.

3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area; or

   b. If you decide not to acquire or possess and use authorized material; or

c. When no principal activities under the license have been conducted for a period of 24 months.

4. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:

a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);

b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;

c. The licensee's mailing address changes;

d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or

e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.

5. Request and obtain a license amendment before you:

a. Change Radiation Safety Officers;

b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;

c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or

d. Change the name or ownership of your organization.

6. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment or renewal of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room"; choose "All Document Types" on the drop down menu; scroll down to "NUREG-Series Publications"; and select "Publications Prepared by the NRC Staff". Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-37033
License: 11-29215-01
Control: 470706

Enclosures: As stated

470722