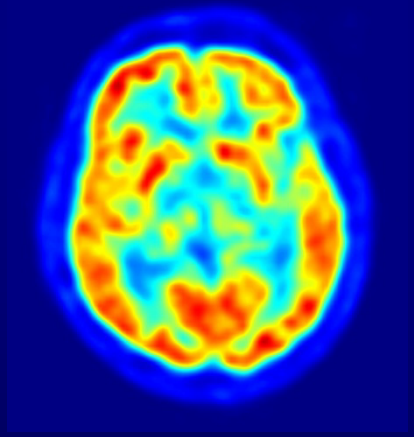
U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

HRTD
Human Resources
Training & Development

Mobile Nuclear Medicine Licensing



Radiopharmacy Licensing

Mobile Nuclear Medicine Licensing

Mobile Nuclear Medicine Licensing

- REMEMBER: This IS a medical license, but place of use is MOBILE.
- 10 CFR 35.80 - Provision for mobile medical service
- NUREG-1556, Vol. 9, Rev. 2 - Program-Specific Guidance About Medical Use Licenses

Mobile Nuclear Medicine Licensing

- **Major Focus Areas**
  - **DOT and other transportation-related issues**
    - If you license portable gauges and/or radiography, you should be familiar with these requirements; if not, get help
  - **Licensee – Host Relationship**
    - Must be well-documented and clear
    - May be multiple locations

Mobile Nuclear Medicine Licensing

- Major Focus Areas

- All areas are important to review, but other significant areas include:
  - Receipt of RAM
  - Security
  - Surveys
  - Waste storage/handling
  - Dosimetry

Radiopharmacy Licensing

Radiopharmacy Licensing

- **REMEMBER: Radiopharmacy licenses are NOT medical licenses.**
- **They are M&D (Manufacturing & Distribution) licenses; however, they are closely associated with Medical**
- **They also supply veterinarians, as well as some R&D programs**

Radiopharmacy Licensing

- **Guidance :**
  NUREG-1556, Vol. 13, Rev. 1 - Program-Specific Guidance About Commercial Radiopharmacy Licenses

- **Often this is a GREAT chance for a pre-licensing site visit to review facilities, etc.**

Radiopharmacy Licensing

- Major Focus Areas
  - Facilities & equipment
    - Review of this area is most important for this type of license
    - One of the few materials licensees that may have airborne releases close to the constraint rule – especially if they compound radioiodine

Facilities and Equipment

- Copies of their registration or license from a State Board of Pharmacy as a pharmacy, or evidence that they are operating as a nuclear pharmacy within a Federal medical institution;
  - Note: If the applicant's particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG-1556, Vol 12, for guidance on drug manufacturer requirements.

Facilities and Equipment

- Description of the facilities and equipment at each location where radioactive material will be used.
- A diagram should be submitted showing the applicant's entire facility and identifying activities conducted in all contiguous areas surrounding the facility.
- Diagrams should be drawn to a specified scale, or dimensions should be indicated. However, no blueprints since their hard to read.

Facilities and Equipment

- Descriptions of the area(s) assigned for:
  - The receipt, storage, preparation, and measurement 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;

Facilities and Equipment

- Does the diagram "flow"?
  - Is the layout logical and flow from one area to the next?
  - Are higher dose areas away from high occupancy areas and/or well-shielded?
  - Bring up issues early so licensee can adjust if possible – don't necessarily wait until pre-licensing visit to address

Facilities and Equipment

- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods.
- Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.
- Confirm that such systems will be employed for the use or storage of radioactive materials likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions;
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d);

Facilities and Equipment

- Drawings and diagrams that provide exact location of materials or depict specific locations of safety or security equipment should be marked as:

- "Security-Related Information – Withhold Under 10 CFR 2.390."

Facilities and Equipment for PET Radiopharmacies

- Copies of their registration or license as a pharmacy from a State Board of Pharmacy, or evidence that they are operating as a nuclear pharmacy within a Federal medical institution;
  - Note: If the applicant's particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG-1556, Vol 12, for guidance on drug manufacturer requirements.

Facilities and Equipment for PET Radiopharmacies

- Description of the facilities and equipment at each location where radioactive material will be used.
  - Includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) 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. Again, no blueprints!

Facilities and Equipment for PET Radiopharmacies

- 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 and/or shielding equipment (e.g., hot cells for positron-emitting radionuclides), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety, such as remote handling equipment and area monitors;

Facilities and Equipment for PET Radiopharmacies

- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods.
- Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.
- Confirm that such systems will be employed for the production, use, or storage of radioactive materials; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

Radiopharmacy Licensing

- Major Focus Areas
  - All areas are important to review, but other significant areas include:
    - Authorized user qualifications
    - Dosimetry
    - Effluent monitoring
    - Waste handling
    - Driver training

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

- The RSO, Authorized Users (AUs), and Authorized Nuclear Pharmacists (ANPs) must have adequate training and experience.
- Specific criteria are given in 10 CFR 35.55(b) and 10 CFR 32.72(b) for acceptable training and experience for ANPs.
- The minimum training and experience criteria for RSOs and AUs, although not specifically described in NRC's regulations for radiopharmacy licensees, should include:
  - a Bachelor's degree in a physical science, or
  - equivalent, and previous experience handling and supervising similar activities.
- Applicants should note that a resumé or a curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

RSO Qualifications

- 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, ANP, or AU; OR
- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.

Authorized User Qualifications

(Functions other than preparation and distribution of radioactive drugs)

- 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
- 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 of NUREG-1556, Vol. 13.

Authorized Nuclear Pharmacist (ANP) Qualifications

- ANP is defined in 10 CFR 35.2.
- An ANP must be a State-licensed or State-registered pharmacist with adequate training and experience.
- There are multiple pathways to get there, and
- It can be one of the most confusing parts of the reviewing process.
- ANP qualifications are spread between Parts 32 and 35.
- Section 8.7.2 of NUREG-1556, Vol. 13 pulls them all together.
- Use NRC Form 313 (ANP)

ANP Qualifications

Of course, first you need:

Name of the proposed ANP,

AND

Pharmacist's license number and issuing entity.

ANP Qualifications

Then:

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 Material 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

ANP Qualifications

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

ANP Qualifications

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 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.

OR

ANP Qualifications

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.

ANP Qualifications

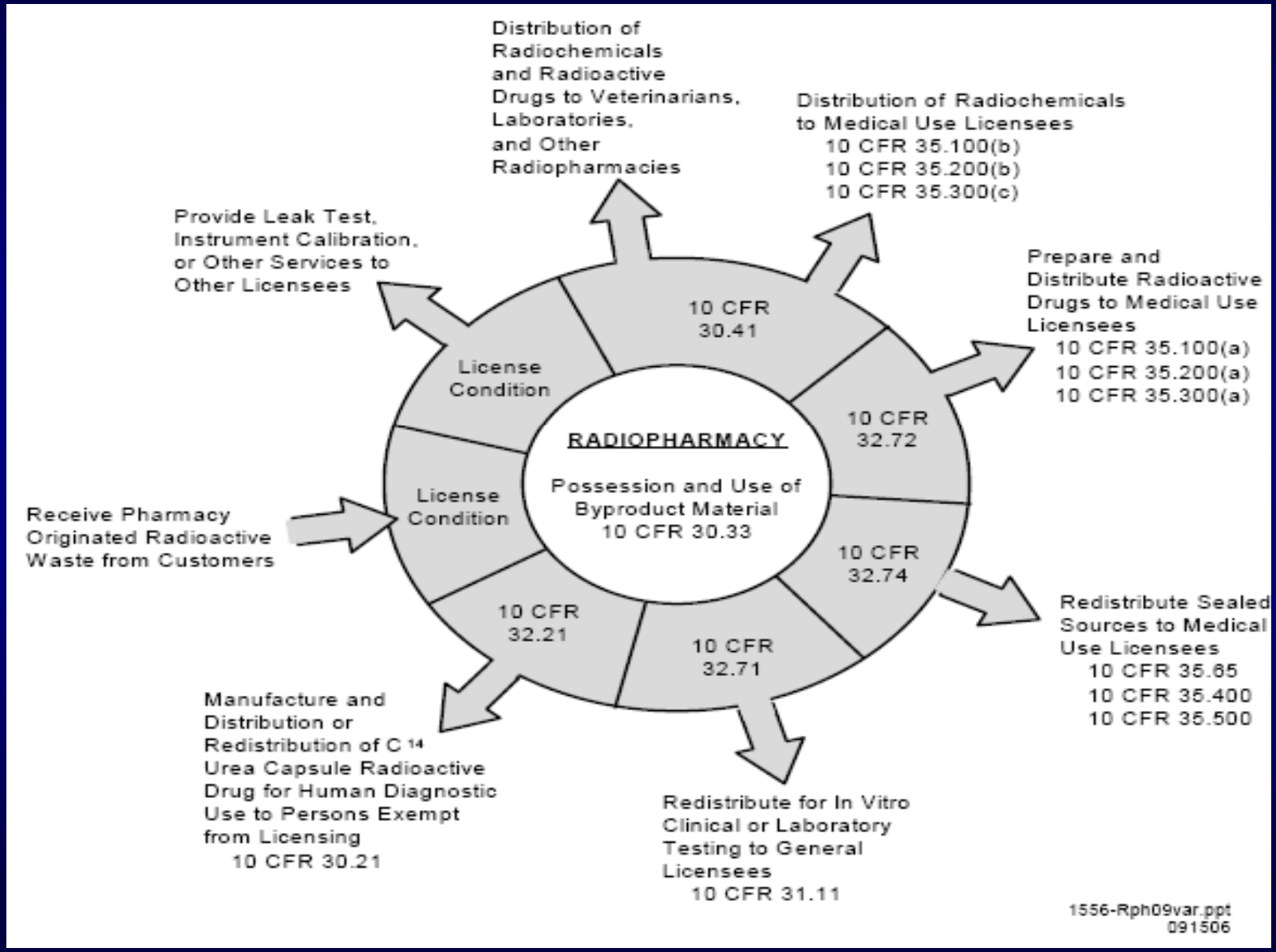
Recentness of Training

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

Section 8.6: Purpose for Which Licensed Material Will Be Used

PREPARATION OF RADIOPHARMACEUTICALS	**The applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform (e.g., compounding of iodine-131 capsules, radio-iodination, chemical synthesis of PET radiopharmaceuticals, and technetium-99m kit preparation).**
SEALED SOURCES FOR CALIBRATION AND CHECKS AND POSSESSION OF DISCRETE SOURCES OF RADIUM-226 AND DEPLETED URANIUM	Supply specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and depleted uranium for shielding.
SERVICE ACTIVITIES	Specify the customer radiation protection services involving licensed material that will be provided. The applicant should submit specific procedures for all service activities that it intends to provide.

Purpose Wheel in NUREG-1556



Description Activities Authorized By

Provide Leak Test, Instrument Calibration, or Other Services to Other Licensees	License Condition
Distribution of Radiochemicals and Radioactive Drugs to Veterinarians, Laboratories, and Other Radiopharmacies Distribution of Radiochemicals to Medical Use Licensees: 10 CFR 35.100(b), 10 CFR 35.200(b), 10 CFR 35.300(c)	10 CFR 30.41
Prepare and Distribute Radioactive Drugs to Medical Use Licensees: 10 CFR 35.100(a), 10 CFR 35.200(a), 10 CFR 35.300(a)	10 CFR 32.72
Redistribute Sealed Sources to Medical Use Licensees: 10 CFR 35.65, 10 CFR 35.400, 10 CFR 35.500	10 CFR 32.74
Redistribute for In Vitro Clinical or Laboratory Testing to General Licensees: 10 CFR 31.11	10 CFR 32.71
Manufacture and Distribution or Redistribution of C14 Urea Capsule Radioactive Drug for Human Diagnostic Use to Persons Exempt from Licensing: 10 CFR 30.21	10 CFR 32.21
Receive Pharmacy-Originated Radioactive Waste from Customers	License Condition

Commitments From the Licensee

- DISTRIBUTION AND REDISTRIBUTION OF SEALED AND UNSEALED MATERIALS
- OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL
- PERSONNEL INVOLVED IN HAZARDOUS MATERIALS PACKAGE PREPARATION AND TRANSPORT
- RADIATION MONITORING INSTRUMENTS
- MATERIAL RECEIPT AND ACCOUNTABILITY
- OCCUPATIONAL DOSE
- SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES
- SURVEYS
- DOSAGE MEASUREMENT SYSTEMS (additional information needed)
- LEAK TESTS
- WASTE MANAGEMENT
- RETURNED WASTES FROM CUSTOMERS

- These areas are verified during inspection.
- From a licensing viewpoint we accept the commitment and the licensee is bound by the commitments in the last license condition – the Tie down condition.
- The licensee is suppose to have all procedures and commitments in place by the time they receive the license.

Information Provided for Technical Review

Section 8.5 Item 5 Radioactive material - UNSEALED AND/OR SEALED 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-123, iodine-131), specify whether open containers of the materials will be manipulated at the radiopharmacy.

Information Provided for Technical Review

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;**
- **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 the NRC or an Agreement State;**
- **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; and**
- **If the above information cannot be provided for the discrete source of radium-226, describe the discrete source.**

Information Provided for Technical Review

For depleted uranium, specify the total amount (in kilograms).

- **NOTE: For NRC licensees, this will add a secondary program code**

Information Provided for Technical Review

Emergency Plan

- 10 CFR 30.32(i)(1) requires an applicant for possession of radioactive materials in certain forms (unsealed, foils, plated sources, or sealed in glass), at one location, in excess of specified limits to submit:
  - An evaluation showing that release of RAM would not exceed maximum of 1 rem EDE or 5 rems to thyroid of a person offsite, or
  - An emergency plan for responding to a release of radioactive material.

- 10 CFR 30.72, Schedule C is reference for determining need for emergency plan.

Information Provided for Technical Review

Emergency Plan

- Manufacturing and distribution licensees are most likely to be affected. Iodine-125 and -131 authorizations are most likely to require an emergency plan, but be sure to evaluate all manufacturing and distribution license requests to determine if 30.32(i)(1) is applicable.

- Sample Schedule C Values:

Material	Release fraction	Quantity (Ci)
I-125	0.5	10
I-131	0.5	10

* Unity rule applies for combinations of radionuclides

Financial Assurance (FA) and Recordkeeping for Decommissioning

No response is needed from most applicants.

- **A licensee authorized to possess radioactive material in excess of the limits specified in 10 CFR 30.35 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning (See NUREG-1757, Vol. 3)**

Financial Assurance (FA) and Recordkeeping for Decommissioning

- Even if a DFP or FA is not required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where radioactive materials are used or stored and related to leaking sources. Pursuant to 10 CFR 30.35(g), licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to10 CFR 30.34(b); or

- The appropriate NRC Regional Office before the license is terminated.

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):

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe);
- Describe the type and thickness of the "transport radiation shield" provided for each type of container; and
- 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.

Note: It is not acceptable to state that the applicant will comply with DOT regulations. The dose-rate limits that DOT imposes apply to the surface of the package, not the surface of the "transport radiation shield."

Waste Management

Since radiopharmacies use mostly short-lived materials, disposal is usually done through common means:

- **Decay-in-storage (120 day half-life or less)**
- **Transfer to authorized recipient**
- **Sanitary sewer disposal per Part 20 or equivalent**

Waste Management

- Commonly, customers of radiopharmacies return waste materials (i.e., used syringes, unused doses).
- When reviewing, clarify if the licensee plans to have the customer be the shipper of returned waste or if they will take responsibility as shipper. Section 8.11.1 of Vol. 13 discusses these two methods:
  - If the customers will be the shipper, then the licensee should provide instructions for returns
  - If the pharmacy chooses to be shipper of returns, they will need to confirm that the customer follows DOT requirements for packaging and transport.

Termination of Activities

A licensee must notify NRC, in writing, within 60 days of any of the following (10 CFR 30.36):

1) the expiration of its license;
2) a decision to cease licensed activities permanently at the entire site (regardless of contamination levels);
3) a decision to cease licensed activities permanently in any separate building or outdoor area, if they contain residual radioactivity that makes them unsuitable for release according to NRC requirements;
4) no principal activities having been conducted at the entire site under the license for a period of 24 months;
5) no principal activities having been conducted for a period of 24 months in any separate building or outdoor area, if it contains residual radioactivity making it unsuitable for release according to NRC requirements.

Termination of Activities

Also related to decommissioning:

- Submit a decommissioning plan, if required by 10 CFR 30.36(g);
- Conduct decommissioning, as required by 10 CFR 30.36(h) and 10 CFR 30.36(j);
- Submit, to the appropriate NRC Regional Office, completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records to the new licensee.

Production of Radioactive Material Using an Accelerator NUREG 1556, Vol. 21

PET Licensee

A licensee who wants to produce radioactive material using an accelerator needs 2 licenses:

- One to produce the material (PET license)
- One to distribute the material (Radiopharmacy license)

We will point out the differences between the PET and Radiopharmacy license in terms of application purposes.

Differences between PET and Radiopharmacy license

- A DFP or FA is more likely to be required for a PET licensee, usually due to the activated products produced during the process.
- For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored incident to their production by an accelerator in accordance with the regulations.
- For sealed sources that are not produced, specify their proposed use (e.g., calibration of instruments).
- No ANP, only and RSO and AU's.

THE END