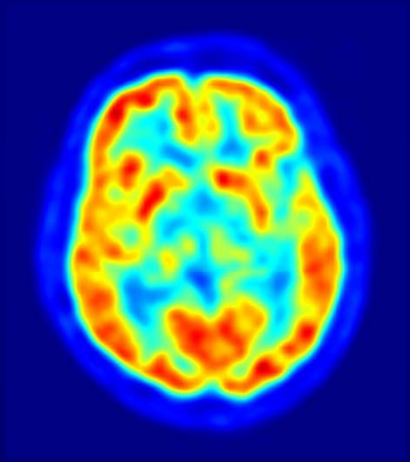
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

HRTD
Human Resources
Training & Development



Radiopharmacy Licensing

Laws and Regulations

Laws and Regulations

Atomic Energy Act of 1954, as amended (Public Law 83-703)

- **Retained Atomic Energy Commission (AEC) established by Atomic Energy Act (AEA) of 1946**
- **Mission: "...to encourage widespread participation in the development and utilization of atomic energy for peaceful purposes..." and "...to prepare regulations that would protect public health and safety from radiation hazards...:**
- **Section 274b establishes State Agreements program**

Laws and Regulations

Energy Reorganization Act of 1974, as amended (Public Law 93-438)

- **Abolished AEC, established NRC to focus on regulation of nuclear power and nuclear materials and Department of Energy to promote nuclear power and nuclear materials**

- **Scope of NRC responsibility: commercial nuclear power reactors, non-power research, test, and training reactors; fuel cycle facilities; uses of byproduct materials, source material, and special nuclear material.**

Laws and Regulations

10 CFR Part 30: "Rules of general applicability to domestic licensing of byproduct material"

- **30.4 "Byproduct material means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process or utilizing special nuclear material" (i.e., made radioactive by a nuclear reactor)**
- **defines types of licenses**
- **specifies materials exempt from licensing**

Laws and Regulations

10 CFR Part 30 Regulations

- Rules of general applicability to domestic licensing of byproduct material“
- NOTE: Part 40 definitions for licensing of source material also use the term "byproduct material" to mean the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. Only Part 30 byproduct materials licensing is addressed in this course.

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- Expands the definition of byproduct material to include any discrete source of radium-226, any material made radioactive by the use of a particle accelerator, and certain other discrete sources of naturally occurring radioactive material.

- Commission made only one major change - the definition of “discrete source”

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- ***Discrete Source*** **is now defined as "a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities."**

- **Removed portion of definition that said it was a radionuclide "distinct from the sources of radiation present in nature."**

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- Draft proposed rule was published in Federal Register on 7/28/06;
- Public comment period ended 9/11/06;
- Draft FRN with Final rule sent to States for comment in March 2007.
- Commission voted on it and SRM was issued in May 2007;
- The FRN was revised to incorporate the revised definition of discrete source, editorial changes suggested in the SRM, and discussion of NARM materials used for military operations.

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- Final rule noticed in the Federal Register (72 FR 55864) on October 1, 2007.
- Final regulations effective on November 30, 2007.
- The final transition plan to facilitate an orderly transition of regulatory authority with respect to the byproduct material defined in paragraphs (3) and (4) of section 11e. of the Atomic Energy Act of 1954, as amended, was noticed in the Federal Register (72 FR 59157) on October 19, 2007.

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- States and territories' waivers terminated in 3 Phases
- On November 30, 2007, the Commission terminated the waivers of the Phase 1 States.
- Phase 1 States retained regulatory authority over NARM as of the November 30 effective date.

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- The Phase 1 States included the 34 current Agreement States and the non-Agreement States of: Delaware; Indiana; Montana; and Wyoming.
- Phase 1 also included District of Columbia; Puerto Rico; U.S. Virgin Islands; Federal Government Agencies; and Federally Recognized Indian Tribes

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- The Phase 2 States included Guam, Idaho, Missouri, South Dakota, Vermont, West Virginia, and all other U.S. territories and possessions not in Phase 1
- Phase 2 was effective September 30, 2008

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- **The Phase 3 States included Alaska, Connecticut, Hawaii, Michigan, New Jersey, Virginia, and any Canadian licensees**
- **Phase 3 was effective August 7, 2009**

Laws and Regulations

Energy Policy Act of 2005 (Public Law 109-58)

- The NARM users in non-Agreement States (and other areas) have, from their respective effective date, 6 months to submit an amendment request, or 12 months to submit a new license application for NARM.

- NARM toolbox:

  http://nrc-stp.ornl.gov/narmtoolbox.html

Licensing Concepts

Licensing Concepts

- Although we try to be consistent, there are both NRC Regional differences and NRC/Agreement State differences in doing licensing (IMPEP reviews will look for internal consistency within an NRC Region or Agreement State).
- Licensing is best learned by “DOING”; reviewing amendments is a great way to learn licensing.
- Inspecting improves performance of license reviewers; reviewing licenses improves performance of inspectors.

Licensing Concepts

Basic Rules for License Reviewers

- **License Reviewers Must THINK!**
- **No two applications are the same (even if the text is the same, the context is unique)**
  - **What is appropriate for one facility may not be appropriate for another**
  - **Review applications in light of inspection history and current policy**

Licensing Concepts

Basic Rules for License Reviewers

- License Reviewers Must Be Knowledgeable
  - Know health physics to make safety judgments
  - Know regulations and policies to ensure licensee will be in compliance
  - Keep current with technology changes to understand licensee programs
  - MENTORS - Communicate with other reviewers/inspectors to stay current and have a consistent approach

Licensing Concepts

Basic Rules for License Reviewers

- License Reviewers Make Important Decisions
  - Lack of adequate commitments can result in unsafe conditions
  - Approving submissions that are contrary to the regulations can result in noncompliance
  - Excessive procedures may cost licensee money with little effect on safety
  - What is appropriate for one facility may not be appropriate for another
  - Approving a poor licensing package can make an inspector's job much more difficult

Licensing Concepts

NRC Assumptions:

- **Consistently following requirements leads to safety**
- **The way to ensure consistent compliance with requirements, and therefore safety, is through comprehensive management controls**
- **Licensees are motivated to be safe and compliant**

Licensing Concepts

The NRC (and States) ensure the safe and secure use of radioactive materials through:

- **Regulations**
- **Standards and guidance**
- **Licensing**
- **Inspection**

Types of Licenses

- 30.4 “License, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in this Part and Parts 31 through 36 and 39 of this chapter.”

- Licenses
  - Specific license of limited scope
  - Specific license of broad scope
  - General license
  - Material exempt from licensing

The Application

The Application

The license application and other supporting documents will contain:

- **Commitments: statements of current and/or future actions or conditions, which can be enforced**
- **Supporting information: descriptive information necessary to show that contract is likely to be fulfilled.**
- **Miscellaneous statements: which could fall into commitments, supporting information, or neither.**

The Application

Commitment

1. Only non-volatile forms of iodine will be used.

2. Surveys will be performed at least weekly in areas where licensed materials are used.

Supporting Information

1. In-vitro studies will be performed using commercially available kits.

2. Radiation Safety staff includes 2 full-time HP techs who perform surveys.

The Application

How to review (and re-review) the application

- Read entire application
- Review inspection history and docket file for issues
- Use the appropriate checklist (Appendix in Final NUREG-1556 volume for this type of license)
- Compare submittal to all applicable regulations, regulatory guides, and policy to make sure nothing was missed

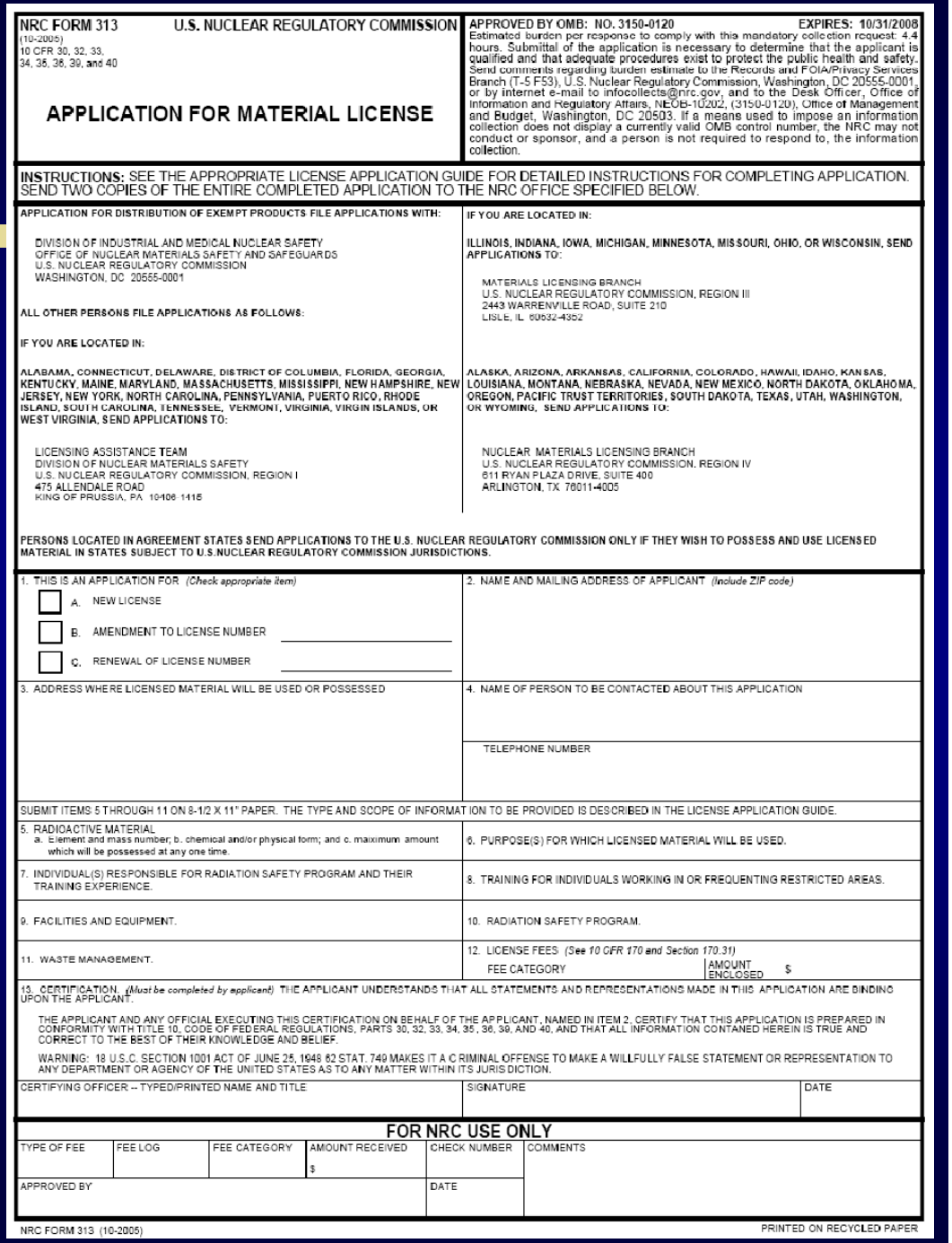
The Application

How to review (and re-review) the application

- Review current license tie-down commitments
- Use common sense
- Identify deficiencies; use temporary markers (General rule: don't make permanent markings on any official copy that you handle.)
- Re-review everything at least once

NRC Form 313 Application for Material License

(see end of presentation For full page version)



NRC FORM 313 (10-2005)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS

APPROVED BY	DATE

NRC FORM 313 (10-2005) PRINTED ON RECYCLED PAPER

NRC Form 313
Application for Material License

Section 1 - Type of Application

- New license
- Amendment to existing license
- Renewal of existing license

NRC Form 313
Application for Material License

Section 2 - Name and mailing address of applicant

- **Should be a corporation or other institutional entity...infrequently a private individual.**

- **Note: The State in which mailing address is located is used to determine the license number for NRC Part 30 licenses.**

NRC Form 313
Application for Material License

Section 3 - Address(es) where licensed material will be used or possessed.

- **P.O. Box address is NOT acceptable here (can't use material in a P.O. Box!)**
- **Should list street address or descriptive address for <u>each</u> proposed location**
- **Only one licensee permitted per address, so may need to include suite # if multiple licensees in same building**

NRC Form 313
Application for Material License

Section 4 - Name and telephone number of person to be contacted about the application

- **May be the RSO, a consultant or a management representative**

NRC Form 313
Application for Material License

Section 5 - Radioactive Material

- Type, form, and maximum quantities of radionuclides requested
  - Maximum limit for each radionuclide where appropriate
  - Used to determine if Financial Assurance and/or a Decommissioning Funding Plan is required (30.35)
  - Used to determine if an Emergency Plan is required to be submitted (30.32(i))
  - NRC: confirm it is NRC-regulated material

NRC Form 313
Application for Material License

Section 5 - Radioactive Material continued

- Made part of the license itself in Items 6, 7, and 8
- Must be appropriate for requested use and for licensee expertise

NRC Form 313
Application for Material License

Section 6 - Purpose(s) for which licensed material will be used

- Made part of the license itself in Item 9
- Must be appropriate for licensee expertise
- Should not be "frivolous"

NRC Form 313
Application for Material License

Section 7 - Individual(s) responsible...

- Made part of license itself by explicit license condition and by "tie-down" condition
- Information re: competency and qualifications of staff and management;
- Must have an authorized user for each radionuclide and use requested

NRC Form 313
Application for Material License

Section 7 - Individual(s) responsible... continued

- Technical individuals must have appropriate training and experience; varies with the proposed materials and uses. CVs/resumes are usually not sufficient.
- Training and experience of the proposed RSO should include appropriate activities that demonstrate capability to perform RSO duties.

NRC Form 313
Application for Material License

Section 8 - Training for individuals working in or frequenting restricted areas

- Made part of license itself by "tie-down" condition
- Includes, but not restricted to, 10 CFR 19.12 "Instructions to Workers" which is required for all personnel who may exceed an occupational dose of 100 mrem per year
- Should also cover any topics needed to ensure safe use of material.

NRC Form 313
Application for Material License

Section 8 - Training for individuals working in or frequenting restricted areas, continued

- **Must have a retraining program.**
- **Must include training of ancillary personnel (for example: housekeeping, security).**

NRC Form 313
Application for Material License

Section 9 - Facilities and Equipment

- **Must address all location(s) and cannot be a P.O. Box.**
- **Other minimum facility and equipment descriptions made part of license by "tie-down" condition.**
- **Includes all "hardware" used in radiation safety; should describe special function equipment. For example: waste compactors, hot cells, etc.**

NRC Form 313
Application for Material License

Section 9 - Facilities and Equipment

- Need to be adequate to ensure that doses to radiation workers and the public will not exceed the applicable limits
- Need to be adequate to minimize “permanent” contamination

NRC Form 313
Application for Material License

Section 10 - Radiation Safety Program

- **Made part of license by explicit license condition and by "tie-down" condition.**
- **Includes all procedures used in radiation safety (standards for surveys: types, frequency, action levels; generic safe handling procedures; record keeping; use of RSC, audits, consultants; equipment maintenance programs).**

NRC Form 313
Application for Material License

Section 11 - Waste Management

- Made part of license by explicit license condition and by "tie- down" condition.
- Must meet the detailed regulations for waste in Part 20

NRC Form 313
Application for Material License

Section 12 - Licensee fees:

- **Must be submitted with the application.**

NRC Form 313
Application for Material License

Section 13 - Certification

- **Must be signed by management representative (usually not the RSO).**

- **Note: Management's role is to define radiation protection responsibilities and provide an environment in which staff can do their jobs properly.**

NRC Form 313
Application for Material License

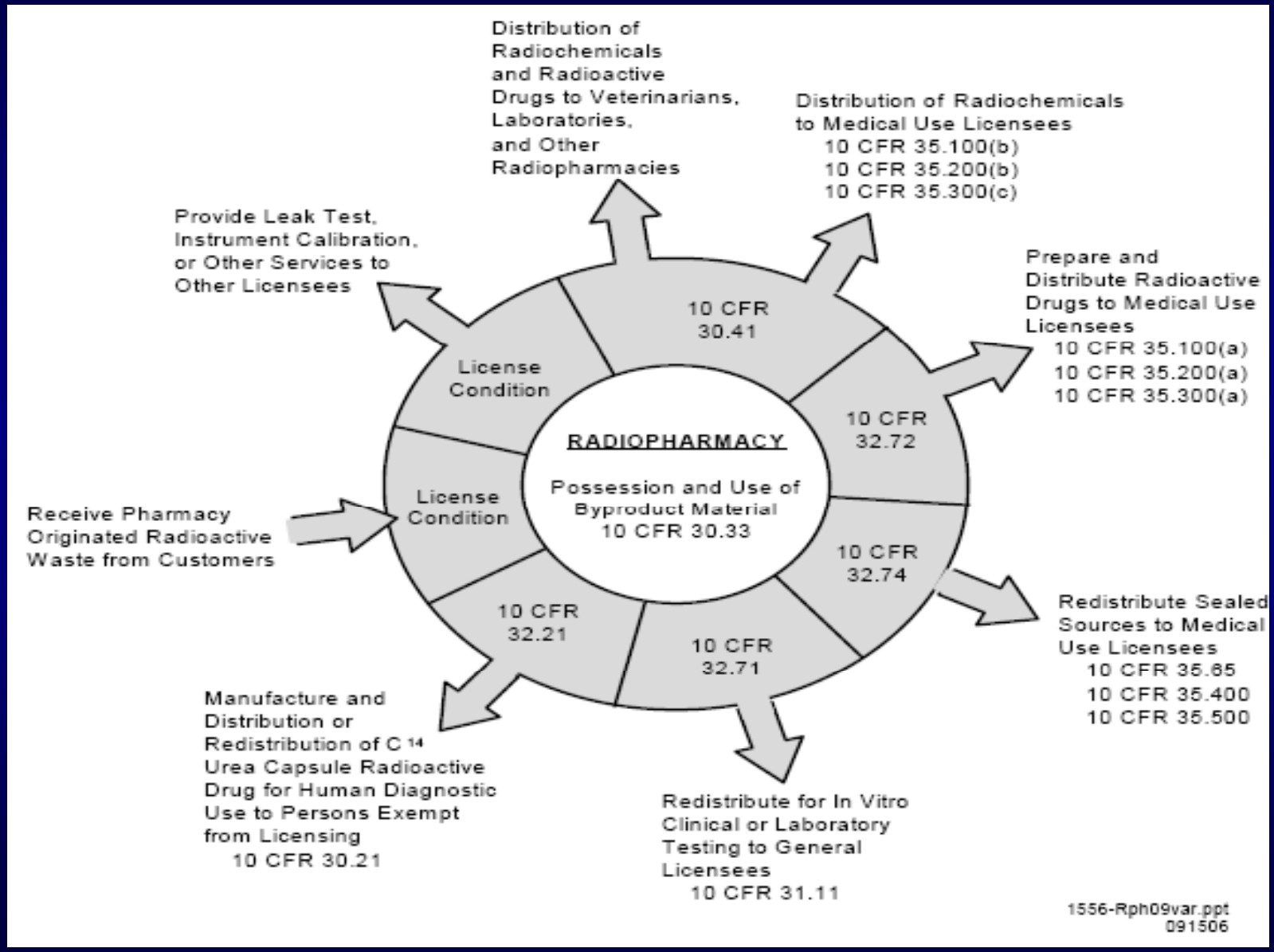
Things to remember:

- **Reviewers cannot (officially) review draft documents.**
- **Reviewers are NOT consultants; however, they ARE public servants!**
- **Everything goes to PDR (NRC Public Document Room) and ADAMS, (NRC Agency-Wide Documents Access and Management System). Certain information is withheld from public release (i.e., personal privacy and proprietary information, safeguards information, and Security-Related SUNSI-Sensitive Unclassified Non-Safeguards Information).**

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

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 résumé 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.**

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 Ra-226**
- **Confirm that each sealed source, device, source/device combination, and discrete source of Ra-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 Ra-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.

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).

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 important to decommissioning 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.

Licensing Examples and Exercises