`NJ Department of Environmental Protection
BUREAU OF ENVIRONMENTAL RADIATION
RADIOACTIVE MATERIALS SECTION
PO BOX 415, TRENTON, NEW JERSEY 08625-0415
Radioactive Material License Application Instructions
Rev 0, August 2007

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Regulations:

Use of radioactive material in New Jersey is governed by New Jersey Administrative Code Title 7, Department of Environmental Protection, Chapter 28, Radiation Protection Programs (NJAC 7:28). Regulations for licensing of naturally occurring or accelerator produced radioactive material are in subchapter 4 (§4). Regulations for licensing of byproduct and source material are in §52-§64 inclusive. Chapter 10, Code of Federal Regulations, Part 71 (10 CFR 71), "Packaging and Transportation of Radioactive Material" are the applicable regulations in New Jersey for the packaging and transport of radioactive material.

Assistance:
Please call the Radioactive Materials Section at 609-984-5462 with any questions regarding completion of a New Jersey radioactive material license application.

Documentation:
This guidance may be used to prepare documentation regarding licensing of radioactive material use in the State of New Jersey. Documentation includes:

- License Application – use form NJRAD-313
- License Amendment – use form NJRAD-313
- License Renewal – use form NJRAD-313 or BER's license renewal certification form: NJRAD-102
- Radioactive Material License Fee Worksheet – use form NJRAD-101
- License Termination – use form NJRAD-314

NOTE: There are no provisions to apply for a NJDEP radioactive material license over the internet. Only paper applications will be accepted.

Keeping Licenses Current:

The licensee is obligated to keep the license current. If any of the information provided in the original application changes in a way that requires an amendment to the license as specified in the NUREG-1556 series, or in any way affects specific items concerning NJDEP jurisdiction, the licensee must submit an application for a license amendment to reflect the change, before the change takes place. The licensee should identify the specific changes in the amendment request and discuss the basis for the changes.

Reciprocity Application:

Refer to §4.2 for recognition of licenses from other jurisdictions. See section on reciprocity for further information.

Comment [JBC1]: What section

License Termination:
If a licensee wishes to terminate one or many NJDEP radioactive material licenses, the Administrator must sign and submit form NJRAD-314 to the Bureau of Environmental Radiation at the address above requesting the termination The Bureau may respond with a list of further documentation required to be submitted to the Bureau. License termination is only in effect after the licensee receives a letter stating such per NJDEP per §4.12(c).

Completing License Application Form NJRAD-313:

- Complete page 1 of Form NJRAD-313.
- Use page 2 of NJRAD-313 or facsimile to answer items 5 through 12 and 14, as appropriate.
- Answers to each item must be preceded with the number of the item being answered.
- Do not make reference to documents previously filled with the State or any other government agency for a new license application. For license renewal or license amendment, include as attachments all necessary support information as require by §4.6(j).
- Submit all documents, including drawings, if practicable, on 8-1/2 x 11 inch paper. If submission of larger documents is necessary, fold them to 8-1/2 x 11 inches.
- Identify each drawing with drawing number, revision number, title, date, scale, and applicant's name. Clearly indicate if drawings have been reduced or enlarged.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Do not submit personal information about employees.
- All submittals must be typewritten text on clear paper, using 12-point Times New Roman font. Avoid formatting (bold, italics) unless absolutely necessary.
- Do not submit copies of NRC or NJDEP licenses.
- Submit an original, signed application and one copy of all the attachments.
- The NJDEP suggests that the submittal be sent return receipt so that the licensee will have a record that the NJDEP has received the submittal.
- Retain one copy of the license application for your records.

Comment [JBC2]: d

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Item Number 1:
Each submittal of a new license application or renewal to an existing New Jersey radioactive material license requires the use of form NJRAD-313. It is acceptable for an amendment request to be submitted in a letter. Additional guidance may be found in section 8.1 of the particular license application guidance document referenced for your category of license as described on page 7 of this document. See NJAC 7:28-52.32 (§52.32) for byproduct material license applications; §52.37 for license renewals; and §52.38 for license amendments.

Item Number 2:
List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office Box number is an acceptable mailing address. See section 8.2 of your license category's license application guidance.

Notify NJDEP of changes in mailing address; these changes do not require a fee. See Category N in this document for bankruptcy and change of control.

Item Number 3:
Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used or stored (e.g., include locations for field studies or other off-site locations; list activities to be conducted at each location). A Post Office Box address is not acceptable. See section 8.3 of your license category's license application guidance.

Item Number 4:
Identify the individual(s) who can answer questions about the application and include telephone number(s) and email address(es). This is typically the proposed RSO, unless the applicant has named a different person. The NJDEP will contact this individual if there are questions about the application. See section 8.4 of your license category's license application guidance.

Notify the NJDEP if the contact person or his or her telephone number changes so that NJDEP can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

Item Number 5:
List the radioactive materials that will be used under this license. Include:

- For unsealed materials:
  - Element and mass number;
  - Chemical and/or physical form;
  - Maximum amount in millicuries which will be possessed at any one time;
  - Users of this material (see item 7);
  - Purpose for which the radioactive material will be used. Use categories in §4.7(b) and or 10 CFR 30.

Comment [JBC3]: what part 0 categories?

- For potentially volatile materials (e.g., I-123, I-125, I-131, H-3, Kr-85, Xe-133):
  - Element and mass number;
  - Chemical and/or physical form; specify whether the material will be free (volatile) or bound (non-volatile);
  - Maximum amount which will be possessed at any one time for each form;
  - Users of this material (see item 7);

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- Purpose for which the radioactive material will be used.
- For sealed materials:
  - Identify each radionuclide (element name and mass number) that will be used and specify the maximum activity per source in millicuries. Also, specify the maximum number of sources or total activity for each radionuclide;
  - Provide the manufacturer's (distributor's) name, model number, and serial number for each sealed source and device requested;
  - Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by the NRC;
  - 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 the NJDEP.

Comment [JBC4]: Beyond what nrc expects

Comment [JBC5]: Or an AS (how should they confirm?)

Comment [JBC6]: What?

- Provide an Emergency Plan (if required per 10 CFR 30.72 Schedule C. Guidance is provided in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," dated January 1992, and Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses." NUREG 1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," dated January 1988, also contains valuable information.
- Provide a decommissioning funding plan (if required per 10 CFR 30.35 and 10CFR 30 Appendix C). A licensee authorized to possess licensed material in excess of the limits specified in §52.35 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning
- For a broad scope license, see section J under "Categories".
- See section 8.5 of your license category's license application guidance for further details and information on emergency plans, decommissioning funding plans, and record keeping.
- All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use.

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Item Number 6:
Check all categories of radioactive material use that apply. The applicant should describe in general terms the purposes for which the licensed material will be used. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for exposure of workers and members of the public to radiation and radioactive materials. Additional descriptions and required information are on the following pages of this guidance.

Item Number 7:
List the name, title, training and experience of the person designated as Radiation Safety Officer. See section 8.7 of your license category's license application guidance. If this facility has a Radiation Safety Committee or Isotope Committee, describe the committee's responsibilities, duties, titles of the membership, and meeting frequency.

List the name(s), title, training and experience of individual(s) who will use, directly supervise or approve the use of radioactive materials as described in §4.7 and 10 CFR 30. This is unnecessary for a broad scope license.

Item Number 8:

Describe the training program for each group of workers who require personal monitoring equipment as per §7.4. Submit a description of the radiation safety training program developed 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; or identify the model training program described in the appropriate base NUREG corresponding to your particular type of licensed program and submit a statement that this training program will be implemented. See section 8.8 of your license category's license application guidance.

Comment [JBC7]: ?

Item Number 9:
Describe laboratory facilities, remote-handling equipment, storage containers, shielding, fume hoods, etc. Sample diagrams should be provided that take into consideration shielding, the proximity of radiation sources to unrestricted areas and other items related to radiation safety. When radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems including pertinent airflow rates, pressures, filtration equipment and monitoring systems. For special application facilities, such as those facilities described above, you will need to specify their locations (i.e. buildings and room numbers). See section 8.9 of your license category's license application guidance.

Item Number 10:
Describe the radiation protection program at the facility as required in §6. See section 8.10 of your license category's license application guidance. Include copies of all documents relating to radiation protection procedures and control measures (e.g. emergency procedures, spill control, surveys performed and their frequency, etc.). Include:

Comment [JBC8]: ?

1. Audits of the program
2. Dosimetry:
    a. Describe the methods used for personnel dosimetry, including type of dosimeter, frequency of changing, methods for calibration and processing or the name of the supplier.
    b. Include any proposed bioassay program.
3. Radiation Detection
    a. List the radiation detection instrumentation to be used under this license. This list should include:
        i. Make and model of the instrument (and probe if appropriate)
        ii. Number of these units.
        iii. Type of radiation detected.
        iv. Instrument sensitivity (range in mr/hr, cpm, etc.)

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b. Describe the method and frequency of calibration of each instrument listed above. If a consultant is employed to perform this service, specify the company's name and address;

4. Material receipt and accountability
5. Occupational dose projections and control mechanisms
6. Public dose projections and control mechanisms
7. Safe use of radionuclides and emergency procedures. Include the ALARA program and all applicable procedures.
8. Surveys and their frequency
9. Transportation. Include procedures and regulations to follow for any transport of radioactive materials from or between any of the licensee sites listed above.

Comment [JBC9]: Beyond nrc?

Comment [JBC10]: Beyond nrc -

Comment [JBC11]: Vague – not clear what's expected. See 1556 vol 2, 8.10.9.6 and 1556 vol 1

Item Number 11:
Describe the methods that will be used for disposing of radioactive waste and estimate the type and amount of activity involved for each method. If a commercial waste disposal service is employed, give the company's name and address. See section 8.11 of your license category's license application guidance.

Comment [JBC12]: Beyond nrc

Item Number 12:
Use the accompanying form BER-101 to calculate the fees required for this application.

Item Number 13:
If you answered "yes" to this question, provide details of each denial.

Item Number 14:

Form NJRAD-313 must be signed and license fee check (payable to "Treasurer, State of New Jersey") must be enclosed. To ensure adequate management involvement, **a management representative must sign the submitted application acknowledging management's commitments and responsibility** for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations
- Completeness and accuracy of the radiation safety records and all information provided to NJDEP (§52.9)
- Knowledge about the contents of the license and application
- Compliance with current NJDEP and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program.
- Prohibition against discrimination of employees engaged in protected activities (§52.7)

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- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in §52.7and §52.10, respectively.
- Obtaining NJDEP's prior written consent before transferring control of the license.
- Notifying NJDEP, Bureau of Environmental Radiation in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

Categories of Licensees

This section will describe the different categories of licensees from NJRAD-313, item 6, and will itemize additional submittal requirements.

A. Portable Gauge:

Certain portable gauges may be exempt from NJDEP licensing requirements. **10CFR31** provides a listing of exempt devices.

Comment [JBC13]: what

The requirements for a non-exempt portable gauge license may be found at §52.1 or 10 CFR 31.32. Portable gauges are of many different designs based, in part, on their intended use (e.g., to measure moisture, density, thickness of asphalt, liquid level). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety concerns. Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v1/r1/. This NUREG provides guidance to an applicant in preparing a portable gauge license application. It is not intended to address the research and development of gauging devices or the commercial aspects of manufacturing, distribution, and service of such devices. Within this document, the phrases "portable gauge" or "gauging devices," and the term "gauge" may be used interchangeably.

Comment [JBC14]: what

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B. Industrial Radiography

Industrial radiography is defined in §17.2 and 63.1 as the examination of the macroscopic structure of materials by non-destructive methods using sources of radiation. Guidance for this license application may be found in §17 and in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v2/ . Also see: http://www.nj.gov/dep/rpp/xrm/index.htm.

Comment [JBC15]: ?

C. Sealed Source

A sealed source, as defined in §52.1 or 10CFR31.4 means any byproduct material or NARM encased in a capsule designed to prevent leakage or escape of the byproduct or NARM material. License requirements for this material may be found in §52.1. Radiation safety programs for the use of byproduct material or NARM as a sealed source

Comment [JBC16]: ?

Comment [JBC17]: ?

or device are structured on the presumption that the byproduct material or NARM will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used. NRC maintains the National Sealed Source and Device Registry (NSSDR) of radiation safety information on sealed sources and devices containing byproduct material. Agreement States also provide information on their radiation safety evaluations to NRC for the registry. Both NRC and the Agreement States use the information in the registry. Thus a vendor needs to provide detailed information about its sealed source or device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the United States.

The following NUREG provides assistance to applicants on submitting requests to NJDEP to possess sealed sources and devices containing byproduct material: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1/

Comment [JBC18]: What – nj is not asking to do ssd's?

D. Fixed gauge

The requirements for a fixed gauge license may be found at §52 or 10CFR31. Typically gauges are used for process control (e.g., to measure the thickness of paper, the density of coal, the level of material in vessels and tanks, and volumetric flow rate). Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v4/ . These fixed gauges containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these licensees indicates that radiation exposures to workers are generally low, if workers follow basic safety procedures, and the gauges operate as designed.

Comment [JBC19]: This reg is applicable to general licensees not specifically licensed devices as in the NUREG

E. Self-shielded irradiator

The requirements for licensing a self-shielded irradiator may be found at 10CFR36. NJDEP uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration." These self-shielded irradiators containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these licensees indicates that radiation exposures to workers are generally low, if the irradiators operate as designed and workers follow basic safety procedures. Irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

Comment [JBC20]: Part 36 is not applicable to self-shielded irrad. See 36.1

- Irradiating blood or blood products;
- Sterilizing or reducing microbes in medical and pharmaceutical supplies;
- Preserving foodstuffs;
- Studying radiation effects;

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- Synthesizing and modifying chemicals and polymers;
- Eradicating insects through sterile male release programs; and
- Calibrating thermoluminescent dosimeters (TLDs).

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v5/

F. 10CFR36 irradiator

The definition of and requirements for an irradiator license may be found at §56 or 10 CFR 36. Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v6/ . This report addresses the variety of radiation safety issues associated with irradiators, of various designs, whose dose rates exceed 5 Gray (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable to the irradiator's design. Table 1.1 describes the characteristics of commonly authorized irradiators:

Comment [JBC21]: ?

- Sources stored in pool and removed to irradiate package/product;
- Sources stored in pool and package/product lowered into pool to be irradiated;
- Dry source storage and in-air irradiation of package/product; and
- Teletherapy unit converted to non-human use.

G. Academic, research and development and other programs of limited scope including gas chromatographs and X-ray fluorescence analyzers

The definitions and requirements for an academic, research and development, and other limited scope licenses may be found at §52 or 10CFR30. Byproduct material, as defined in at §52.1 or 10CFR30.4, is used for a variety of purposes in academia, research, industry, and other fields. The following are typical uses:

Comment [JBC22]: ?

- *In vivo* studies (labeling cells, studies involving animals, excluding humans);
- *In vitro* studies;
- Analytical work/studies, including use of GCs and XRFs;
- Veterinary medicine;
- Calibration of applicant's instruments; and
- Field studies.

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/. This report provides guidance to an applicant in preparing an Academic, Research and Development and Other Licenses of Limited Scope (ARDL) application including gas chromatography devices (GC) and X-RAY fluorescence analyzers (XRF). It is not intended to address licenses of broad scope, licenses for manufacturing and distribution of byproduct material, or licenses for the use of source, or special nuclear material. Within this document, the phrases or terms, "byproduct material," "licensed material" or "radioactive material," are used interchangeably.

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H. Exempt distribution

Exemptions from the requirements for an NJDEP license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt distribution products, are provided in §52.1, "General Domestic Licensing of Byproduct Material." Exempt distribution products include silicon chips, electron tubes, resins, check sources, carbon-14 urea capsules, gunsights, and smoke detectors.

Exempt products are distributed by persons who have a specific license from the NJDEP authorizing such distribution to persons exempt from the requirements for an NRC license. The following NUREG provides assistance in preparing license applications for distribution of exempt products:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/

Comment [JBC23]: What – only nrc after 11/30

I. Medical use

Regulations for the medical use of byproduct material are found in §55 or 10CFR35.
The following NUREG provides assistance in preparing license applications for medical use of radioactive materials:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/

Comment [JBC24]: ?

The NRC's "Procedures for Recognizing Certification Processes of Specialty Boards" may be found on the NRC's web page regarding the medical use of byproduct material:
http://www.nrc.gov/materials/miau/med-use-toolkit.html

Complementary guidance on inspection procedures for inspections of medical use licensees is contained in the following documents available at the NRC's web page on the Medical Use of Byproduct Material:
http://www.nrc.gov/materials/miau/med-use-toolkit.html

Inspection Procedures in the 87100 series:

- "Nuclear Medicine Programs — Written Directive Not Required,"
- "Nuclear Medicine Programs — Written Directive Required,"
- "Brachytherapy Programs,"
- "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs," and
- "Medical Broad Scope Programs."

Comment [JBC25]: Seems out of place

For human use of the radioactive material, the licensed user is an individual who will possess or use radioactive substances, prescribe dosage, administer, or arrange for the administration of said substances to human beings or irradiate, or arrange for the irradiation of human beings by said substances. For application for Human-Use licenses, physicians, in lieu of documentation of training and experience, may submit proof of certification by an appropriate board or proof of certification as fellow in an appropriate College or Faculty as per §4.7(c).

Comment [JBC26]: ?

Additionally, for Human-Use users, provide a list similar to the following:

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Users Identified in Item 5	HUMAN-USE GROUPS (check each group that applies)					
(write names)	I	II	III	IV	V	VI
maximum quantity [mCi] of the radioactive material to be licensed in each group						

J. Broad Scope

The definition of and requirements for a broad scope license for byproduct material may be found at §54 or 10CFR33. Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/ . Included in this guidance document is a new option for Type A licensees of broad scope to have increased flexibility to make changes in some program areas and revise some procedures previously approved by the NJDEP without amendment of the license.

Comment [JBC27]: ?

This NUREG is not intended to be used alone. Because broad scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution, etc.), this document frequently refers the user to other more program-specific guidance documents in the NUREG-1556 series. A single document containing all of the guidance that might be required by a broad scope licensee or an applicant for a broad scope license would be unwieldy and would quickly become obsolete as guidance in the individual program areas is revised.

Comment [JBC28]: Where does this come from?

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For question 5:

- Applicants for a Type A broad scope license typically request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.
- Licensees may request source material and special nuclear material when use of these materials is directly related to the use of byproduct material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license (e.g., sub-critical assemblies and nuclear pacemakers).
- A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained

irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.).

- Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in §54.100 or 10 CFR33.100, Schedule A. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in §54.1 or 10 CFR33.100, Schedule A, Column I.

For questions 9:

- Describe the criteria your RSC and/or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). Your description will need to include your method of classifying laboratories based on type, toxicity and quantity of byproduct material being requested.

K. Possession for manufacturing and distribution

The requirements for a possession for a specific license to possess certain items containing byproduct material to manufacture or transfer may be found at §53. Materials manufacturers are those licensees that process raw material and/or sources and distribute those processed materials or manufactured products to users as finished products. Examples are:

Comment [JBC29]: ?

- major radiopharmaceutical processor/manufacturers (not radiopharmacies);
- sealed source fabricators;
- device manufacturers; and
- other manufacturing licensees that possess and use bulk quantities of radioactive materials or sources.

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/. This report provides guidance on three types of licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials.

1. Possession for manufacturing and distribution (including distribution of products to other specific licensees authorized to receive the products);
2. Possession for distribution only (with no manufacturing); and
3. Distribution (only) for medical use (transfer of radioactive drugs, sealed sources, and devices directly to medical use licensees).

Licensing for distribution to general licensees is found in section O, and for distribution of items to persons exempt from license requirements is found in section H. Distribution-only licensees are not involved in the processing of raw materials or sources, nor in the manufacturing of devices. Distributors also include importers for purposes of distribution.

Comment [JBC30]: Not applicable to nj

L. Commercial Radiopharmacy

Commercial radiopharmacy licenses are those licenses issued by the NJDEP, pursuant to §55 or 10CFR35, for the possession and use of radioactive materials for the manufacture,

Comment [JBC31]: ?

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preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under §55 or 10CFR35.

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/. Within this NUREG, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99m MAA (macroaggregated albumin)), and from raw materials (i.e., the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in §53.1 or 10 CFR 32.11, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to §53 or 10 CFR 32. In addition, §53 or 10 CFR 32 authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to §55.1 or 10 CFR 35.74.

Comment [JBC32]: Is this correct? 32.11?

Comment [JBC33]: ?

Comment [JBC34]: ?

Applicants requesting to manufacture and initially distribute radioisotope generators, *in vitro* kits, radiochemicals and sealed sources should refer to section K of this document for specific licensing requirements.

Applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., carbon-14 tagged urea) should refer to section O of this document for specific licensing requirements..

Comment [JBC35]: Not applicable to ru

M. Well logging

Comment [JBC36]: ?

Well logging is defined in §57 or 10CFR39 as the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. §57 or 10CFR39 does not have requirements for the issuance of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells. Byproduct material, as defined in §51.1 or 10 CFR 30.4 is used for a variety of purposes to include: well logging and tracer applications involving both single or multiple well bores; conventional well logging and tracer operations; and, in some cases, research and development. Examples include the following applications:

- Sealed sources are used in cased and uncased boreholes;
- Tracer materials are used in single well applications;
- Tracer materials are used in multiple well applications (field flood study) for enhanced recovery of oil and gas wells;
- Sealed sources are used for calibration of applicant's survey instruments and well logging tools; and
- Sealed sources and tracer materials are used in the research and development of new techniques and equipment.

Comment [JBC37]: What – contradiction from previous

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Additional guidance to an applicant in preparing a well logging, tracer, and field flood study license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v14/

N. Changes of control and bankruptcy involving byproduct, source or special nuclear materials

§51.1 or 10CFR30.34(b) requires that no change of control of any NJDEP license may be transferred, assigned or in any manner disposed of unless the NJDEP give its consent in writing. §51.1 or 10CFR30.34(h) requires immediate written notification to the NJDEP following the filing of a petition for bankruptcy. Guidance for licensees and, in some cases, license applicants to use in preparing a notification to NJDEP of a change of control or bankruptcy may be found in this NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/. It also contains criteria NJDEP will use for evaluating such a notification and determining whether a new or amended license is needed.

Comment [JBC38]: ?

The regulations are clear that control of licensed activities cannot be transferred without prior written consent from NJDEP. It is not NJDEP's intent to interfere with the business decisions of licensees. However, it is necessary for licensees to notify NJDEP sufficiently before the actual change to allow time for appropriate review, whenever decisions are being considered that involve changes of control. NJDEP's focus is on the health and safety aspects, not on the financial intricacies of the proposed transaction. NJDEP will only require licensees to submit business information necessary to permit the Department to determine whether a change of control will take place. NJDEP is required by law to ensure that the public's health and safety are not compromised and therefore must be confident that when a licensee's program is undergoing a change of control, all efforts are made to ensure that the radiation safety aspects of the program are not degraded.

Although the burden of notification is on the existing licensee, it may also be necessary for the transferee or the successor to provide supporting information or to independently coordinate the change of control with the NJDEP.

In the case of bankruptcy, NJDEP regulations require that a licensee notify NJDEP in writing immediately following the filing of a voluntary or involuntary petition under the Bankruptcy Code by or against the licensee, or an entity controlling the licensee or listing the license or licensee as property of the estate, or an affiliate of the licensee. This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

No changes of control or license terminations will be authorized until all information or records concerning decommissioning of the facility, radiation doses to the public, and waste disposal (such as releases to sewers, incineration, radioactive spills, and on-site burials) have been transferred to the new licensee, if licensed activities will continue at the same location. If the license is to be terminated the owner may request the NJDEP to accept the records.

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O. Authorizing distribution to general licensees

The requirements for an NJDEP general license for persons who receive, possess, use, transfer, own, or acquire byproduct material in generally licensed products are provided in §52 or 10 CFR 31, "General Domestic Licenses for Byproduct Material." Generally licensed products include static elimination devices, gauging devices, gas chromatograph detector cells, tritium signs, *in vitro* clinical or laboratory kits, and check sources. These devices/products are distributed to general licensees by companies who have a specific license from the NJDEP authorizing such distribution.

Comment [JBC39]: ?

Comment [JBC40]: Not quite correct

The requirements to obtain an NJDEP general distribution license for persons who distribute or initially transfer byproduct material in generally licensed products are provided in §53 or 10 CFR 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

Comment [JBC41]: ?

This NUREG provides assistance to applicants in preparing license applications for a specific license to distribute generally licensed devices: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v16/ .

P. Special Nuclear Material of less than Critical Mass Quantities

Special Nuclear Material, as defined in §60.3 or 10 CFR 70.3, means plutonium (Pu), uranium (U)-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the NJDEP determines to be special nuclear material or any material artificially enriched by any of the foregoing. Typical uses include:

Comment [JBC42]: ? what 70.3 or 70.4

a) Experiments using sub-critical assemblies;
b) Foil activation experiments using Pu-238/Beryllium (Be) sources;
c) Instrument calibration;
d) Student instruction in radiation detection and measurement;
e) Nuclear pacemakers;
f) U-235 target foils experiments.

This NUREG provides assistance to applicants in preparing a license application for possession of special nuclear material of less than critical mass quantities: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v17/ This NUREG is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium, total, in the form of sealed Pu-Be neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass, as stated in §60.11. The latter quantities are considered to be up to 350 grams of contained U-235, 200 grams of U-233, 200 grams of plutonium (in any form other than Pu-Be neutron sources), or any combination of them in accordance with the following formula:

$$\frac{\text{grams U-235}}{350} + \frac{\text{grams U-233}}{200} + \frac{\text{grams Pu}}{200} < 1$$

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Q. Service Provider

Service providers provide commercial services to both specific and general licensees, and in some instances, recover both licensed and unlicensed material from the public domain. Customers who possess such radioactive material may require commercial services to manage materials at concentrations and activities they are not authorized to handle. In these unique situations, a service provider licensee is authorized to possess these radioactive materials under its license incident to performing specific services required by its customers. Optionally, licensees may elect to transfer licensed material such as radioactive waste and contaminated materials to service providers (e.g., radioactive waste brokers, decontamination and decommissioning service providers, or nuclear laundry operators).

Licensees who in the course of doing business, receive physical samples and possess equipment containing licensed materials related to the performance of service activities such as leak test and environmental sample analyses, survey instrument, and dosimetry calibration services are also included in the service provider category.

Assistance to service provider applicants in preparing a license application may be found in the following NUREG:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/. Service providers addressed in this NUREG are limited to licensed entities providing the following types of commercial services:

- Installation, relocation, removal from service, disposal, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed materials.
- Installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training or repair of Part 36 irradiators.
- Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems.
- Calibration of survey instruments and personnel dosimetry equipment.
- Leak testing of sealed sources, including analyzing the leak test kits or smears.
- Environmental sample analysis.
- Training of personnel using sealed sources.
- Calibration of medical dose calibrators.
- Nuclear laundry services.
- Waste management services including:
    - Commercial incineration
    - Compaction, Super Compaction
    - Solidification or vitrification
    - Packaging and repackaging of radioactive waste for transportation.
- Decontamination and decommissioning services.
- Site characterization services.

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R. Registration of Generally Licensed Devices Containing Greater Quantities of Certain Isotopes

Comment [JBC43]: Is this appropriate here?

The requirements for an NJDEP Registration for a Generally Licensed Device for persons who receive, possess, use, transfer, own, or acquire byproduct material in certain quantities in generally licensed products are provided in §52, "General Domestic Licenses for Byproduct Material." Generally licensed products in this category include devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)) based on the activity indicated on the label.

Comment [JBC44]: ?

These devices/products are distributed to general licensees by companies who have a specific license from the NJDEP authorizing such distribution.

Comment [JBC45]: Not quite correct

The requirements to obtain a NJDEP general distribution license for persons who distribute or initially transfer byproduct material in generally licensed products are provided in §53, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

This NUREG provides assistance to applicants in preparing license applications for a specific license to distribute generally licensed devices: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v16/

Comment [JBC46]: What does this have to do wit registration

S. License for Drinking Water Treatment Systems

Non-community non transient water treatment facilities that accumulate naturally occurring radioactive materials in their operations are required to posses a specific New Jersey radioactive material license before treatment operations commence.

Comment [JBC47]: Should they be including info about accelrators produced isotopes – vol

Comment [JBC48]: Pre-licensing visits?

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