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Director

**APPLICATION FOR RADIOACTIVE MATERIAL LICENSE  
HUMAN USE**

*INSTRUCTIONS: Complete Items 1-27 if this is an initial application or renewal application of a license. Read the instructions attached to this application. Use supplemental sheets where necessary. Item 28 must be completed and signed. Retain one copy of this application. Submit entire application in duplicate to the above address.*

1. This is an application for ( <i>check appropriate item</i> ) <input type="checkbox"/> New License PRC Number _____  <input type="checkbox"/> Renewal of License No. _____ Expiration Date of Current License _____	2. Facility Name, Mailing Address, and Phone Number of Applicant, including Zip Code and E-mail Address ( <i>Institution, Firm, Clinic, Physician, etc.</i> ).				
3. Address(es) and phone number where radioactive material will be used or possessed ( <i>P.O. Box numbers are not acceptable</i> ).	4. Name of person to be contacted about this application.  <div style="text-align: center;">Telephone number.</div>				
5. RADIATION SAFETY OFFICER (RSO): Name of person appointed as RSO and title. Attach: Duties and Responsibilities; Training and Experience ( <i>complete Supplement</i> ); Letter of RSO Appointment; Letter of Authority Signed by Management; Letter of Acceptance by RSO.					
6. RADIOACTIVE MATERIALS FOR MEDICAL USE					
<b>Diagnostic Radioactive Material</b>	<b>Check Desired Item</b>	<b>Maximum Possession Limit (Millicuries)</b>	<b>Therapy Radioactive Material</b>	<b>Check Desired Item</b>	<b>Maximum Possession Limit (mCi)</b>
20.3.3.305.F NMAC For In Vitro Studies	<input type="checkbox"/>		Iodine-131 for uses $\leq$ 33 mCi	<input type="checkbox"/>	
20.3.7.704 NMAC	<input type="checkbox"/>		Iodine-131 for uses $>$ 33 mCi	<input type="checkbox"/>	
20.3.7.705 NMAC	<input type="checkbox"/>		20.3.7.708 NMAC	<input type="checkbox"/>	
Mo-99/Tc-99m Generator	<input type="checkbox"/>		Manual Brachytherapy Seeds	<input type="checkbox"/>	
Sealed Sources for Diagnosis (specify) _____	<input type="checkbox"/>		Sr-90 for Ophthalmic Use	<input type="checkbox"/>	
			Others: ( <i>Fill out Item 6a</i> )		

6a. OTHERS: Radioactive Material Not Listed In Item 6, including sealed sources used for calibration and reference.			
Element and Mass Number	Chemical/Physical Form	Maximum Possession Limit Millicuries	Use of Radioactive Material

For items 7 through 27, check the appropriate box(es) and submit a detailed description of the requested information. Begin each item on a separate sheet. Identify the item number in the lower right corner of each page. If you indicate that an appendix to the NUREG-1556 vol.9 (or vol.13) rev.1 guide will be adopted, provide relevant facility-specific information, to complete the item.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION PROTECTION PROGRAM	16. WASTE DISPOSAL (check one)
<input type="checkbox"/> Names and Titles; and	<input type="checkbox"/> Appendix W Procedures Adopted; or
<input type="checkbox"/> Specialties and Duties.	<input type="checkbox"/> Equivalent Procedures Provided.
7a. TRAINING AND EXPERIENCE PROGRAM	17. EMERGENCY PROCEDURES (check one)
<input type="checkbox"/> Preceptor Attestation for Each Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist; and	<input type="checkbox"/> Appendix N Procedures Adopted; or
<input type="checkbox"/> Certificates and Experience Documentation; and	<input type="checkbox"/> Equivalent Procedures Provided.
<input type="checkbox"/> Training Program for Ancillary Personnel.	18. TRANSPORTATION (check all applicable)
8. FACILITY	<input type="checkbox"/> Appendix Z Procedures Adopted; or
<input type="checkbox"/> Description and Diagram.	<input type="checkbox"/> Equivalent Procedures Provided; or
8a. ALARA POLICY	<input type="checkbox"/> Mobile Medical Service Procedures.
<input type="checkbox"/> ALARA Policy Commitment.	19. THERAPEUTIC USE OF PHARMACEUTICALS (check all applicable)
9. EQUIPMENT	<input type="checkbox"/> Appendix T Procedures Adopted; or
<input type="checkbox"/> Description and Safety Operating Procedures.	<input type="checkbox"/> Equivalent Procedures Provided; or
9a. DOSE CALIBRATOR	<input type="checkbox"/> Written Directive Procedures Provided (Appendix S).
<input type="checkbox"/> Description and Operating Procedures.	20. THERAPEUTIC USE OF SEALED SOURCES
10. RADIATION MONITORING INSTRUMENTATION	<input type="checkbox"/> Equipment-Specific Procedures Provided.
<input type="checkbox"/> Description and Specifications	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES AND AEROSOLS (e.g., Xenon-133)
11. CALIBRATION OF INSTRUMENTS (check one)	<input type="checkbox"/> Specific Procedures Provided.
<input type="checkbox"/> Appendix K Procedures Adopted for Items 9 and 10; or	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIALS IN ANIMALS
<input type="checkbox"/> Equivalent Procedures Provided.	<input type="checkbox"/> Specific Procedures Provided.
12. PERSONNEL DOSIMETRY PROGRAM (check one)	23. GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIALS
<input type="checkbox"/> Completed Table on page 3; or	<input type="checkbox"/> Specific Procedures Provided.
<input type="checkbox"/> Documentation demonstrating appropriate doses.	24. RECORDS, REPORTS, AND NOTIFICATIONS (check one)
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS (check one)	<input type="checkbox"/> Appendix X and Y Procedures Adopted; or
<input type="checkbox"/> Appendix O Procedures Adopted; or	<input type="checkbox"/> Equivalent Procedures Provided.
<input type="checkbox"/> Equivalent Procedures Provided.	25. DECOMMISSIONING AND SURETY PLAN (check one)
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (check one)	<input type="checkbox"/> Facility-specific Procedures Provided; or
<input type="checkbox"/> Appendix P Procedures Adopted; or	<input type="checkbox"/> Commitment to 20.3.3.311 NMAC.
<input type="checkbox"/> Equivalent Procedures Provided.	26. LICENSE FEES (see 20.3.16 NMAC)
15. AREA SURVEYS (check one)	<input type="checkbox"/> License Applicant: I understand that annual licensure fees will apply based on type of license requested.
<input type="checkbox"/> Appendix R Procedures Adopted; or	<input type="checkbox"/> Holder of License: I have paid in full all annual fees.
<input type="checkbox"/> Equivalent Procedures Provided.	

ITEM 12 - PERSONNEL DOSIMETRY PROGRAM: TABLE			
12a. PERSONNEL DOSIMETRY <i>(check appropriate box)</i>		12b. STATE AND NVLAP APPROVED SUPPLIER	12c. EXCHANGE FREQUENCY
WHOLE BODY	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER ( <i>Specify</i> )	
FINGER	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER ( <i>Specify</i> )	
WRIST	<input type="checkbox"/>	FILM	
	<input type="checkbox"/>	TLD	
	<input type="checkbox"/>	OTHER ( <i>Specify</i> )	
12d. BIOASSAY (Describe conditions requiring bioassay, frequency, action levels, regulatory guide adopted, etc.):			
27. The applicant has reviewed Table 1 of the Instructions and certifies that is <input type="checkbox"/> Not subject to Increased Controls requirements based on the quantities of radioactive materials requested; or <input type="checkbox"/> Subject to Increased Controls requirements based on the co-location and quantities of radioactive materials requested and the requirements of the U.S. NRC Order, EA-05-090, will be implemented as described in this application ( <i>Attach a description of how the requirements will be met</i> ).			
28. CERTIFICATE <i>(This item must be completed by the applicant)</i>			
28a. The undersigned 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 the New Mexico Radiation Protection Regulations (20.3.3 NMAC), and that all information contained herein, including any supplements attached hereto, is true and correct to the best of their knowledge and belief.			
28b. APPLICANT ( <i>Signature</i> );		OR/AND	CERTIFYING AGENT ( <i>Signature</i> )
APPLICANT NAME ( <i>Type or Print</i> );		OR/AND	CERTIFYING AGENT NAME ( <i>Type or Print</i> )
TITLE			
DATE			

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE HUMAN USE

**SUPPLEMENT**

**Preceptor Attestations:** All preceptor attestation forms could be found on the Bureau's web site:

<http://www.nmenv.state.nm.us/nmrcb/ram.html>

## RADIOACTIVE MATERIAL LICENSE

### INSTRUCTIONS FOR COMPLETING FORM RPS-16-HU HUMAN USE

An applicant for a radioactive material license should complete form RPS-16-HU in detail. The applicant should endeavor to cover the entire radioisotope program with one application, if possible. However, separate applications should be submitted for Medical Teletherapy and Gamma Irradiators. Additional sheets with clear reference to the application item should be appended, when necessary, to provide complete information. All additional sheets that are submitted with the application must be numerated, dated, and cross-referenced to the item in the application or topic to which it refers.

All items in the application should be completed. If the applicant adopts some of the model procedures listed in the corresponding NUREG-1556 vol. 9 (or vol.13) rev.1 guidance, then the applicant must provide some facility-specific information on a separate sheet to the application. Submission of an incomplete and unsigned application will not be processed and will be returned to the applicant. A full set of the New Mexico Radiation Protection Regulation may be downloaded from the web site: [http://www.nmcp.state.nm.us/nmac/\\_title20/T20C003.htm](http://www.nmcp.state.nm.us/nmac/_title20/T20C003.htm)

If you are renewing an existing New Mexico license, fill-out Items 1-9, and 26 through 28 of the application form and provide an updated Radiation Protection Program. You must fill-out and provide documentation on other items from the application if significant changes to those items (procedures) have occurred during the last 5 years of operation under the license.

The applicant should retain a copy of the completed application. **Submit two copies of completed application form and all supporting documentation to the New Mexico Environment Department, Radiation Control Bureau, PO Box 26110, 1190 Saint Francis Drive, Suite S2100, Santa Fe, New Mexico, 87502-6110.**

**Item 1. Type of License:** The applicant must check the type of license requested. For new license application the applicant shall submit their registration number issued by the Public Regulation Commission (PRC Number) or specify whether their business is registered with the New Mexico Taxation and Revenue Department to do business in New Mexico.

**Item 2. Facility Name, Mailing Address, and Phone Number:** The "applicant" is the organization or person legally responsible for possession and use of the radioactive materials specified in the application. Address should indicate mailing address, zip code, telephone number, fax number, and e-mail address of the applicant. For additional information refer to Section 8.2<sup>1</sup>.

**Item 3. Address where radioactive materials will be possessed:** Indicate address at which radioactive material will be possessed and used, if different from that listed in Item 2, and indicate if radioactive material will be used at temporary job sites throughout New Mexico not under exclusive federal jurisdiction. A post office box number is not acceptable for actual location of use or possession of radioactive material. For additional information refer to Section 8.3<sup>1</sup>.

**Item 4. Name and phone of contact person:** Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed Radiation Safety Officer (RSO), unless the applicant has named a different person as the contact. For additional information refer to Section 8.4<sup>1</sup>.

**Item 5. Radiation Safety Officer:** Attach documentation demonstrating the training and experience for the appointed RSO, fill out the Supplement, and identify the duties and responsibilities as authorized by the applicant and accepted, in accordance with signed letter of authorization for the RSO by the certifying agent, and a letter of acceptance signed by the appointed RSO. For additional information refer to Section 8.10<sup>1</sup>.

**Item 6. Radioactive materials for medical use:** Place a check mark next to the name of each isotope that will be in possession of the applicant. For radioactive materials not listed in the table, please describe them in Item 6a.

**Item 6a. Other radioactive materials for medical use:** Fill out this item if the desired isotopes are not listed in Item 6. For each radioisotope:

- List the name of each radioisotope and its mass number;  
Example: "carbon-14", "cobalt-60", etc;
- List the chemical and/or physical form for each radioisotope as it is going to be used by the applicant; and
- List the maximum activity and quantity to be possessed at any one time, including material held for storage, or as waste. If more than one chemical or physical form of a particular radioisotope is desired, a separate possession limit should be stated for each form.

Example: An applicant desiring to use two chemical forms of iodine-131 must specify both the form and possession limit for each form:

Iodine-131	Iodide	10 millicuries.
Iodine-131	Iodinated Human Serum Albumin	5 millicuries.

<sup>1</sup> <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf>

If the radioactive material is contained in sealed sources, then the applicant must specify the manufacturer, model number, quantity and activity of each sealed source and provide a Sealed Source and Device Registry (SSDR) sheet or SSDR number.

Example: Cobalt-60 Iso Corp. Model Z-54 3 sealed sources not to exceed 100 millicuries each.

- Describe the proposed use of each radioisotope in the chemical form specified in the previous item. If sealed sources are used, indicate the compatible devices or uses as per Sealed Source and Device Registry.

For experimental programs, or new and unusual uses, the maximum single dose of radioactive material to be administered should be included and the approximate number and frequency of such doses. The intended use should be outlined in detail, demonstrating radiological health safety.

**Item 7. Individuals responsible for Radiation Protection Program:** The “individuals responsible for Radiation Protection Program” are all users of radioactive materials in the applicant’s facility (RSO, Authorized User (AU), Authorized Medical Physicist (AMP), and Authorized Nuclear Pharmacist (ANP)), and all members of the Radiation Safety Committee (RSC), if applicable. The applicant must provide name, title, duties of each individual, and all isotopes listed in Items 6 and 6a, which these individuals are qualified to use. For additional information, refer to Sections 8.9, 8.11, 8.12, and 8.13<sup>2</sup>.

**Item 7a. Training and experience program:** 20.3.7 NMAC requires that the AU (AMP, or ANP) must have training and substantial experience in the proposed use, handling, and administration of radioisotopes, and, where applicable, the clinical management of radioactive patients. The applicant (or physician) should fill out the Supplement (Preceptor Attestation) to the application form and provide supporting documentation, indicating the training and experience of each individual in Item 7 that the applicant is requesting to be an AU (AMP, or ANP) for the use of isotopes listed in Items 6 and 6a.

Where a Radiation Safety Committee (RSC) is required by regulation, in addition to the information to be furnished as explained earlier, the applicant must list the names, titles, and duties of each RSC member. The applicant must submit a copy of radiological protection rules and procedures made available to individuals using radioisotopes at the institution, approved by the RSC.

Items 9 and 10 of the Supplement must be completed by the applicant’s supervisor/preceptor. The supervisor/preceptor must be an AU (AMP, ANP, etc.) in a medical institution, and experienced in the clinical use of the same radioisotopes for which the applicant is requesting authorization. Individuals working with licensed material under the supervision of an AU must receive instruction on the applicant’s written radiation protection procedures, written directive procedures (if applicable), 20.3 NMAC, and license conditions with respect to the use of radioactive material. For model training of personnel refer to Section 8.31 and Appendix J<sup>2</sup>.

The Training Program for Ancillary Personnel must include procedures for ancillary personnel working in the facility where the materials are used. The applicant must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy. These safety instructions should be commensurate with the duties of the personnel and include safe handling of patients, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU if the patient has a medical emergency or dies.

The information provided by the applicant in Items 8 through 24 constitutes the content of the applicant’s Radiation Protection Program. These items should be completed on supplemental sheets in accordance with appropriate guidance (NUREG-1556, Volumes 9 and 13 are available on the web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>), and the supporting documentation must be provided with the application. All supplemental sheets that are submitted with the application must be numerated, dated, and cross-referenced to the item in the application or the topic to which it refers.

**Item 8. Facility:** Describe the facility, shielding (permanent and portable), and provide a facility diagram where radioactive materials will be used, handled, and stored. The “facility” is the building, remote handling equipment (e.g. vehicles, mobile coaches, HDR, etc.), storage containers and areas, shielding, fume hoods, cold traps, etc. The construction and location of the facility and equipment must be adequate to secure radioactive materials, protect public health, and minimize danger to life and property. For additional information, refer to Section 8.15<sup>2</sup>.

**Item 8a. ALARA policy:** State, explicitly, commitment to the “ALARA” (as low as is reasonably achievable) levels in every aspect of the applicant’s Radiation Protection Program. For additional information on ALARA, refer to Section 1.3.1<sup>2</sup>.

**Item 9. Equipment :** Describe the radioactive-related equipment (gamma camera, HDR, well counter, thyroid uptake probe, markers, etc.) that will be used in the facility. For additional information on specific equipment requirements refer to Section 8.17 through 8.19<sup>2</sup>.

**Item 9a. Dose calibrator:** Describe the procedures for possession, use, calibration, and check of dose calibrators used to measure patient dosages. For additional information refer to Section 8.17<sup>2</sup>.

**Item 10. Radiation monitoring instrumentation :** Describe the radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments needed to monitor the adequacy of radioactive materials containment and contamination control. For additional information refer to Section 8.16 and Appendix K<sup>2</sup>.

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<sup>2</sup> <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf>

**Item 11. Calibration of instruments:** Provide procedures for calibration of the equipment (Item 9), if applicable, and the monitoring instruments (Item 10). A person is qualified to perform calibration activities only when registered and certified by New Mexico Environment Department. If the applicant is requesting to be authorized to do calibrations through their license application, then the applicant must provide calibration procedures, description of the equipment calibrations will be performed with, description of the standard sources to be used, and the names and training of the individuals conducting the calibrations. The applicant may choose to use the calibration services of registered vendors in the state. For additional information refer to Section 8.16 and Appendix K<sup>3</sup>.

**Item 12. Personnel dosimetry program:** Describe the personnel dosimetry program, which must contain provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored. When personnel monitoring is provided, the monitoring badges must be supplied by a service provider holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) and certified by the State of New Mexico. If the applicant does not have a personnel dosimetry program, then the applicant must demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 500 mrem. For additional information, refer to Section 8.22 and Appendix M<sup>3</sup>.

**Item 13. Procedures for ordering and receiving radioactive materials:** Provide procedures for ordering materials, which will ensure that the type and quantity of licensed material possessed is in accordance with the license. Provide receiving procedures to ensure that packages are secured and radiation exposure from packages is minimized. For additional information refer to Section 8.40 and Appendix O<sup>3</sup>.

**Item 14. Procedures for safely opening packages containing radioactive materials:** Describe the written procedures for safely opening packages to ensure that the monitoring of packages containing radioisotopes is conducted, and that radiation exposure to personnel coming near or in contact with the packages is minimal. For additional information refer to Section 8.33 and Appendix P<sup>3</sup>.

**Item 15. Area surveys:** Provide procedures for conducting survey evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. For additional information refer to Section 8.23 and Appendix R<sup>3</sup>.

The applicant must plan to conduct leak tests for sealed sources, and have appropriate procedures to do so. If the applicant is requesting to be authorized to do analyses of leak test samples through their license application, then the applicant must provide leak test analyses procedures, description of the equipment analyses will be performed with, description of the standard sources to be used, and the names and training of the individuals conducting the analyses. For model procedures on leak tests analyses, refer to Section 8.45 and Appendix Q<sup>3</sup>. The applicant may choose to use the services of registered vendors in the state for conducting the analyses of the leak test samples.

**Item 16. Waste disposal:** Provide provisions for waste disposal of licensed material, for example, decay-in-storage of contaminated materials and generators, or licensed material returns. Procedures for radioactive material/waste returns must ensure that the material/waste is sent to an authorized recipient. For additional information refer to Section 8.28 and Appendix W<sup>3</sup>.

**Item 17. Emergency procedures:** Develop emergency response plan for facility-specific and procedure-specific situations. The applicant must describe the procedures in response to an abnormal situation such as equipment malfunction or failure, involving the equipment described in Item 9 (refer to Section 8.21). The applicant must develop procedures in response to spills of licensed materials (refer to Section 8.25), or other relevant emergencies that may occur at the facility, such as leaking or damaged material, loss and theft of material (Refer to Section 8.38 and Appendix N<sup>3</sup>), or procedures for patients who may become sick or die.

**Item 18. Transportation:** Maintain program for the transport of radioactive material to ensure compliance with the 20.3 NMAC and DOT regulations when preparing materials for shipment or transportation, including radioactive waste. Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421 and are therefore exempt from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv per hour (0.5 mrem per hour)). For additional information refer to Section 8.47 and Appendix Z<sup>3</sup>.

Special requirements apply to mobile medical service applicants. For more information on mobile medical applicants refer to Section 8.36 and Appendix V<sup>3</sup>.

**Item 19. Therapeutic use of pharmaceuticals:** Implement and maintain procedures for safe use of unsealed licensed materials, including storage, handling, protective measures, etc. For additional information refer to Section 8.24 and Appendix T<sup>3</sup>. The applicant must describe the procedures for administering of materials when written directive (WD) is required, which will provide high confidence that licensed material is administered as directed by the AU or RSC. For additional information refer to Section 8.34 and Appendix S<sup>3</sup>.

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<sup>3</sup> <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf>

**Item 20. Therapeutic use of sealed sources:** Describe procedures for the maintenance and repair including installation, replacement, and relocation or removal of therapy unit that contains a sealed source(s). 20.3 NMAC requires that maintenance and repair (as defined above) be performed by persons specifically licensed by the State of New Mexico to perform such services. For additional information refer to Section 8.26<sup>3</sup>.

**Item 21. Procedures and precautions for use of radioactive gases and aerosols:** Describe, at a minimum, any operations or procedures that use or generate radioactive gases or aerosols (e.g. Xe-133, Tc-99m, In-111), where and how these gases (aerosols) are handled (e. g. fume hoods, self-contained device, etc.), whether steps will be taken to trap such gases, air monitoring procedures, and whether radioactive gases are emitted to the environment. The applicant must describe the procedures and precautions taken for use of radioactive gases and aerosols, so that the exposure to personnel, the public, and the environment are minimal. For additional information refer to Section 8.22<sup>4</sup> (occupational exposure to radioactive gases), 20.3.7.703.L NMAC<sup>5</sup> (storage of gases), and 20.3.7.707 NMAC<sup>5</sup> (control of aerosol and gases).

**Item 22. Procedures and precautions for use of radioactive materials in animals:** Describe the procedures followed when radioactive materials are administered to animals for research purpose. These must include, at a minimum, isolation of the animals containing licensed materials, proper labeling and notices, proper waste disposal of materials used to clean cages of such animals, PPE, area surveys before and after experiments, and maintenance of records and survey results.

**Item 23. General rules for safe use of radioactive materials:** Describe general rules of housekeeping and best industry practices when handling and working with radioactive materials. The applicant must also provide specific handling and precaution procedures when material listed in Items 6 and 6a are used. As a part of the safe use of radioactive materials, the described procedures must emphasize on the minimizing contamination of the facility and environment to the extent practicable (refer to Section 8.27<sup>4</sup>).

**Item 24. Records, reports, and notifications:** The applicant is required to make records of each dosage and administration for medical use, including a brachytherapy dose. The applicant must describe operating procedures for collecting the appropriate records (receiving of materials, surveys, leak tests, inventory, training of personnel, emergencies, misadministration, etc.), and specify the retention time of each. For additional information refer to Section 8.42, 8.43, and Appendix X<sup>4</sup>.

The applicant must provide all past reports, required by regulations, of incidents that might compromise the health and safety of patients, health care providers, or the public. The applicant must compile procedures for reporting events as described in Section 8.44 and Appendix Y<sup>4</sup>.

**Item 25. Decommissioning and surety plan:** The applicant must determine what documentation and financial assurance must be submitted based on the type of radioactive material to be stored and handled at the facility as described in 20.3.3.311 NMAC<sup>6</sup>. Based on that determination, the applicant should submit procedures on decommissioning the facility where radioactive materials are stored and handled, or commit to follow the requirements of 20.3.3.318 NMAC when decommissioning is initiated.

**Item 26. License fees:** The applicant must understand that licensure fees will be applied pursuant to 20.3.16 NMAC, when this license application is approved by the NMED. No license fees need to be provided with the application for new license. The annual license fees are due after one year of operation under the approved NMED license. License holders must state whether they have paid in full their annual fees. License renewals will not be processed if the licensee has outstanding balances, and the corresponding license shall expire on the expiration date on the license.

**Item 27. Increased Controls requirements:** The applicant must review the quantities of concern listed below in Table 1 and determine whether or not is subject to the Increased Controls (ICs) requirements as described in the U.S. NRC Order, EA-05-090. A copy of the order may be downloaded from the links indicated on the web site: <http://www.nrc.gov/reading-rm/doc-collections/news/2005/05-164.html>

**Item 28. Certificate:** The applicant and/or the certifying agent are required to sign and date the application and certificate statement. "Certifying agent" is a representative of the individual or organization, or a legal entity, who is authorized to make binding commitments and to sign official documents on behalf of the applicant. For additional information refer to Section 8.30<sup>4</sup>.

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<sup>4</sup> <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/sr1556v9r1.pdf>

<sup>5</sup> <http://www.nmcp.state.nm.us/nmac/parts/title20/20.003.0007.htm>

<sup>6</sup> <http://www.nmcp.state.nm.us/nmac/parts/title20/20.003.0003.htm>

APPLICANTS SUBJECT TO INCREASED CONTROLS (ICs)

**TABLE 1: RADIONUCLIDES OF CONCERN**

Radionuclide	Quantity of Concern <sup>1</sup> (TBq)	Quantity of Concern <sup>2</sup> (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above <sup>3</sup>	See Footnote Below <sup>4</sup>	

<sup>1</sup> The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity exceeds the quantity of concern.

<sup>2</sup> The primary values used for compliance with implementing the Increased Controls are terabecquerels (TBq). The curie (Ci) values are rounded to one significant figure for informational purposes only.

<sup>3</sup> Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

<sup>4</sup> If several radionuclides are aggregated, the sum of the ratios of the activity of each source,  $i$  of radionuclide,  $n$ ,  $A_{(i,n)}$ , to the quantity of concern for radionuclide  $n$ ,  $Q_{(n)}$ , listed for that radionuclide exceeds one.  $[(\text{aggregated source activity for radionuclide A}) \div (\text{quantity of concern for radionuclide A})] + [(\text{aggregated source activity for radionuclide B}) \div (\text{quantity of concern for radionuclide B})] + \text{etc.} \dots \geq 1$

***Determining Which Sources Require Increased Controls***

Use the following method to determine which sources of radioactive material require increased controls (ICs):

- Include any single source larger than the quantity of concern in Table 1.
- Include multiple co-located sources of the same radionuclide when the combined quantity exceeds the quantity of concern.

- For combinations of radionuclides, include multiple co-located sources of different radionuclides when the aggregate quantities satisfy the following unity rule:  $[(\text{amount of radionuclide A}) \div (\text{quantity of concern of radionuclide A})] + [(\text{amount of radionuclide B}) \div (\text{quantity of concern of radionuclide B})] + \text{etc.} \geq 1$ .

### Guidance for Aggregation of Sources

The U.S. Nuclear Regulatory Commission (NRC) supports the use of the IAEA's source categorization methodology as defined in TECDOC-1344, "Categorization of Radioactive Sources," (July 2003) (see [http://www-pub.iaea.org/MTCD/publications/PDF/te\\_1344\\_web.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/te_1344_web.pdf)) and as endorsed by the agency's Code of Conduct for the Safety and Security of Radioactive Sources, January 2004 (see <http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004.pdf>). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (greater than 100 times the quantity of concern values listed in Table 1.) and Category 3, the smallest (equal or exceeding one-tenth the quantity of concern values listed in Table 1.). ICs apply to sources that are greater than the quantity of concern values listed in Table 1, plus aggregations of smaller sources that add up to greater than the quantities in Table 1. Aggregation only applies to sources that are co-located.

Licensees who possess sources in total quantities that exceed the Table 1 quantities are required to implement ICs. Where there are many small (less than the quantity of concern values) co-located sources whose total aggregate activity exceeds the Table 1 values, licensees are to implement ICs.

Some source handling or storage activities may cover several buildings, or several locations within specific buildings. The question then becomes: When are sources considered co-located for purposes of aggregation? For purposes of the ICs, sources are considered co-located if breaching a single security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be co-located. This logic should be continued for other barriers within or behind the inner barrier.

The following example illustrates the point. A lockable room has sources stored in it. Inside the lockable room, there are two shielded safes with additional sources in them. Inventories are as follows:

1. The room has the following sources outside the safes: Cf-252, 0.12 Tbq (0.3 Ci); Po-210, 0.36 TBq (10 Ci), and Pu-238, 0.3 Tbq (8 Ci). Application of the unity rule yields:  $(0.012 \div 0.2) + (0.36 \div 0.6) + (0.3 \div 0.6) = 0.06 + 0.6 + 0.5 = 1.2$ . Therefore, the sources would require ICs. If the sources are distributed and shipped individually, ICs would not apply because they do not exceed the quantities in Table 1.
2. Shielded safe #1 has a 1.9 Tbq (51 Ci) Cs-137 source and a 0.75 Tbq (20 Ci) Ra-226 source. The Ra-226 source (not a radionuclide listed on Table 1) is co-located with a source on Table 1 that exceeds the quantity of concern. Therefore the ICs for the Cs-137 source also cover the Ra-226 source.
3. Shielded safe #2 has two Po-210 sources, each having an activity of 0.2 Tbq (5 Ci). In this case, neither source would require ICs. (Total activity = 0.4 Tbq (10 Ci)). They do not exceed the threshold quantity 0.6 Tbq (20 Ci).

Because certain barriers may cease to exist during source handling operations (e.g., a storage location may be unlocked during periods of active source usage), licensees should, to the extent practicable, consider two modes of source usage: "operations" (active source usage) and "shutdown" (source storage mode). Whichever mode results in the greatest inventory (considering barrier status) would require ICs for each location.