

APP C1

NAVAL RADIOACTIVE MATERIAL PERMIT

REVIEW CHECKLIST

NUCLEAR MEDICINE

COMMAND: _____

PERMIT NUMBER: _____

TYPE OF ACTION: _____

NAVY AND MARINE CORPS PUBLIC HEALTH CENTER

REVISED NOVEMBER 2007

REVIEWER/DATE: _____

SECOND REVIEW/DATE: _____

GUIDELINES FOR PREPARATION OF
NAVAL RADIOACTIVE MATERIAL PERMIT APPLICATION FOR HOSPITALS

1. The enclosed Naval Radioactive Material Permit (NRMP) Application Checklist should be completed without reference to any documentation submitted previously and should reflect current operating procedures. Retain a copy of your application package, which will become an integral part of your permit. Submit the application to Navy and Marine Corps Public Health Center (NMCPHC). The Naval Radiation Safety Committee (NRSC) will consider your application and issue your permit.

2. The extent of your radiation safety program is dependent on the "Types of Use" of radioactive material as defined in 10 CFR 35.100 through 35.600 and 35.1000. NRC NUREG-1556 Vol. 9 contains details on the program requirements and provides model radiation safety procedures. Follow the guidance in NUREG-1556 Vol. 9 in completing your application, except as modified for the following items of the application form:

Item 2 Applicant's Name and Mailing Address

Command name: _____

Address: _____

Item 3 Locations of Use

Give complete address, **including building numbers** where radioactive material is used or stored.

Item 4 Person to be contacted.

Include name and title, telephone and fax numbers, and e-mail address.

Items 5 and 6 Radioactive Material and Purpose

(a) Prepare your application in the format as described in NUREG 1556 Volume 9 pages 8-7 thru 8-9 and 8-13 thru 8-15 (Table format) for only the types of use for which you have authorized users and the necessary equipment and facilities (see Appendix C, Table C-2).

(b) If you request radioisotopes for use as stated in 10 CFR 31.11 for in vitro laboratory procedures, including carbon-14 Bactec, state whether each isotope will be used within the limits of 10 CFR 31.11. You may be authorized to use any isotope listed in 10 CFR 31.11 under the provisions of 31.11 if:

(1) Inventory limits of 31.11 are observed.

(2) In vitro isotope usage is physically and administratively separate from medical isotope use involving internal or external administration to humans or animals.

(c) If you request radioisotopes for use as stated in 10 CFR 35.200, state whether generators, gases, or aerosols will be used by your command. Additional information will be needed if aerosols are used (See [Guide for Diagnostic Nuclear Medicine](#) page 32).

(d) If you request 10 CFR 35.400 sealed sources, state the radionuclide, number, maximum activity per source, total activity possessed at any one time, model number and manufacturer.

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(e) If you request use of a Sr-90 eye applicator, submit a copy of your rules for safe handling or adopt the NRC's "Rules for Safely Handling a Strontium-90 Eye Applicator", which are provided.

(f) Provide information to identify any sources not addressed in NUREG 1556 Volume 9, including nickel-63 sources used in gas chromatographs and accelerator-produced sealed sources used for calibration (ex: cobalt-57). Please provide in table format as described in NUREG 1556 Volume 9 pages 8-7 thru 8-9 and 8-13 thru 8-15.

(g) Please Provide Sealed Source Device Registry Numbers for all sealed Sources, unless they are in exempt quantities or are included in 10 CFR 35.65.

Radioactive Material	Manufacturer/Model Number (Sealed sources only)	Chemical/Physical Form	Maximum Quantity	SSDR Number (Sealed sources only)	Purpose of Use

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RULES FOR SAFELY HANDLING A STRONTIUM-90 EYE APPLICATOR

From NRC Information Notice No. 90-58

- *1. Wear your TLD(s) whenever you handle the Sr-90 eye applicator. Finger ring dosimeters should be worn with the detector on the palm side of the hand.
2. Remove the Sr-90 eye applicator from its secured storage location just before use. Do not leave it out any longer than necessary.
3. After removing the Sr-90 eye applicator from its secured storage location:
 - a. Do not touch the treatment end of the applicator with your hands or other portion of your body,
 - b. Always hold the applicator by its handle, and
 - c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.
4. If the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge, or gauze dampened with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge, or gauze. Do not sterilize by holding the swab, or gauze in your hand.
5. During treatment, hold the patient's eyelids open with tape or other device, not with your fingers.
6. Immediately after treatment and/or resterilization, return the Sr-90 eye applicator to its storage container and to its secured location (e.g., locked cabinet).
7. Do not remove any metal or plastic inserts from the manufacturer-supplied storage container. These items are generally a part of the container's shielding. Removal of these items can lead to excessive and unnecessary radiation exposures.

*It is strongly recommended that a whole-body Thermoluminescent Dosimeter (TLD) and/or finger ring TLD be worn when handling a Sr-90 eye applicator.

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This table is a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in the below table and then check the boxes indicating which documents pertaining to the RSO are being included in the permit application. An applicant may copy the checklist and include it in the permit application.

Items 7 through 12 of Naval Radioactive Materials Permit Application For Medical Department Activities

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7.1: Radiation Safety Officer Name:</p> <p><i>*For personnel who hold a board certification, a copy of the certificate shall be submitted with the permit application</i></p>	<p>1a) Previous license number (if issued by NRC) or NRMP number that authorized the uses requested and on which the individual was specifically named as the RSO.</p> <p style="text-align: center;">OR</p> <p>1b) Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities. (Submit certification certificates)</p> <p style="text-align: center;">OR</p> <p>1c) Description of the training and experience specified in 10 CFR 35.900(b).</p> <p style="text-align: center;">OR</p> <p>1d) Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.</p> <p style="text-align: center;">AND</p> <p>2) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p> <p style="text-align: center;">AND</p> <p>3) Letter from management delegating authority to RSO. (See Appendix I, NUREG 1556 Volume 9)</p>	

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Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7.2: Authorized Users Names and Requested Uses for Each Individual</p> <p>Names:</p> <p><i>*For personnel who hold a board certification, a copy of the certificate shall be submitted with the permit application.</i></p> <p><i>See attached table.</i></p>	<p>1a) Previous license number (if issued by NRC) or NRMP number on which the physician was specifically named as an AU for the uses requested.</p> <p style="text-align: center;">OR</p> <p>1b) Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H and as applicable to the use requested. (Submit certification certificates)</p> <p style="text-align: center;">OR</p> <p>1c) Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p style="text-align: center;">OR</p> <p>1d) A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>2) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	
<p>Item 7.3: Authorized Nuclear Pharmacists</p> <p>Names:</p> <p><i>*For personnel who hold a board certification, a copy of the certificate shall be submitted with the permit application.</i></p> <p><i>See attached table.</i></p>	<p>1a) Previous license number (if issued by NRC) or NRMP number on which the individual was specifically named ANP.</p> <p style="text-align: center;">OR</p> <p>1b) Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a). (Submit certification certificates)</p> <p style="text-align: center;">OR</p> <p>1c) Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or sufficient to independently operate a nuclear pharmacy (10 CFR 35.980).</p> <p style="text-align: center;">AND</p> <p>2) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	

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<p>Item 7.4: Authorized Medical Physicists</p> <p>Names:</p> <p><i>*For personnel who hold a board certification, a copy of the certificate shall be submitted with the permit application.</i></p> <p><i>See attached table.</i></p>	<p>1a) Previous license number (if issued by NRC) or NRMP number on which the individual was specifically named as an AMP for the units requested.</p> <p style="text-align: center;">OR</p> <p>1b) Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b). (Submit certification certificates)</p> <p style="text-align: center;">OR</p> <p>1c) Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested.</p> <p style="text-align: center;">OR</p> <p>1d) Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.</p> <p style="text-align: center;">AND</p> <p>2) If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	
<p>Item 8: Training for Individuals Involved in the Usage of Permitted Radioactive Material</p>	<p>1) Specify what topics will be covered and include a table that identifies the groups of workers who will receive training and the method and frequency of training. See Appendix J of NUREG Guide 1556 Volume 9 and 49 CFR 172.704 for required training topics and frequency of training.</p> <p>2) You may make the following statement that: "We will follow the model procedures in Appendix J, NUREG 1556 Volume 9." This is acceptable for topics to be covered.</p> <p style="text-align: center;">OR</p> <p>Submit alternate procedures to be reviewed for approval.</p> <p style="text-align: center;">AND</p> <p>3) A statement that: "We will maintain records of training to include date, duration, place, instructor, subjects covered and names of attendees."</p> <p style="text-align: center;">AND</p> <p>4) Certify that all hazardous materials employees have been trained and tested in accordance with 49 CFR 172.702 for transportation of radioactive materials (RAM).</p>	

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Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9.1: Facility Diagram	<p>A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:</p> <ul style="list-style-type: none"> • Drawings should be to scale, and indicate the scale used. • Indicate the direction of north. • Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored. • For types of use permitted by 10 CFR 35.100 and 35.200, applicants should provide room numbers for areas in which byproduct materials are used or prepared for use (i.e., “hot labs”). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. • For types of use permitted by 10 CFR 35.300 and 35.400, applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75. The discussion should include a description of shielding, if applicable. For types of use permitted by 10 CFR 35.500, the applicant should provide the room numbers of use. • Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and • Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.). (Evaluate this during the Command’s Inspection per Mr. Diaz.) <p>In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.</p>	

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<p>Item 9.2: Radiation Monitoring Instruments</p>	<p>If the command's radiation survey instruments are calibrated by a Navy RADIAC Calibration Facility then state on the application: "All radiation survey instruments are calibrated by (name of facility)."</p> <p style="text-align: center;">OR</p> <p>If any radiation survey instruments are not calibrated by a Navy RADIAC Calibration Facility, submit procedures used by the calibration facility which must meet the requirements of 10 CFR 20 and 10 CFR 35.61.</p> <p style="text-align: center;">AND</p> <p>A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.</p> <p style="text-align: center;">AND</p> <p>A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used." Refer to Appendix K of NUREG Guide 1556 Volume 9 for guidance.</p> <p style="text-align: center;">AND</p> <p>A statement that: "We will continue to note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the daily check source requirement" (Information Notice 2001-03 Ser OEM/12091 28 June 2001).</p>	
<p>Item 9.3: Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material</p> <p><i>Note: Submit the procedures with your permit application for review purposes only.</i></p> <p><i>Note: Procedures and results used shall be available during inspections.</i></p> <p><i>Note: The manufacturer's instructions and results shall be available for review during inspections.</i></p>	<p>A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards."</p> <p style="text-align: center;">OR</p> <p>A statement that: "Equipment used to measure dosages will be calibrated in accordance with the manufacturer's instructions."</p> <p style="text-align: center;">AND</p> <p>A statement that: "Unit doses will be measured only by direct measurement prior to medical use."</p>	
<p>Item 9.4: Sealed Sources (Brachytherapy) and Therapy Unit - Calibration and Use</p>	<p>We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.</p> <p style="text-align: center;">AND</p> <p>A statement that: "The brachytherapy source(s) are in compliance with 10 CFR 35.432." Submit your supporting documentation</p> <p style="text-align: center;">AND</p> <p>A statement that: "The calibration of strontium-90 source(s) used for the treatment of ophthalmic conditions, complies with 10 CFR 35.433." Submit your supporting documentation.</p>	

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Item 9.5: Other Equipment and Facilities	<p>Attach a description of additional facilities and equipment.</p> <p>For manual brachytherapy facilities, we are providing a description of the emergency response equipment.</p> <p>For remote afterloader facilities provide a description of the following:</p> <ul style="list-style-type: none"> • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; and • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons. • Emergency response equipment. <p>For therapy related computer systems, a statement that: The treatment planning systems have successfully completed an acceptance test and the documentation will be available for inspection.”</p>	
Item 10.1: Safety Procedures and Instructions	<p>Attached procedures required by 10 CFR 35.610</p> <p><i>(§35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma Stereotactic Radiosurgery unit)</i></p>	
Item 10.2: Occupational Dose	<p>A statement that: “We will follow the model procedures in Appendix M, NUREG 1556 Volume 9.”</p> <p style="text-align: center;">OR</p> <p>A description of an alternative method for demonstrating compliance with the referenced regulations.</p>	
<p>Item 10.3: Area Surveys</p> <p><i>Note: Submit the procedures with your permit application for review purposes only if Appendix R is not used.</i></p>	<p>A statement that: “We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.” Submit your procedures.</p> <p style="text-align: center;">OR</p> <p>A statement that: “We will follow the model procedures in Appendix R, NUREG Guide 1556 Volume 9.”</p> <p style="text-align: center;">AND</p> <p>In addition to the surveys required by Part 20, a permittee shall survey with a radiation detection instrument at the end of each day of use, all areas where unsealed byproduct material was prepared for use or administered regardless</p>	

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Item Number and Title	Suggested Response	Check box to indicate material included in application
	of whether a written directive was required or not.	
Item 10.4: Safe Use of Unsealed Licensed Material	<p>A statement that: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.” Submit your procedures.</p> <p style="text-align: center;">OR</p> <p>A statement that: “We will follow the model procedures in Appendix T, NUREG Guide 1556 Vol. 9.”</p>	
Item 10.5: Spill Procedures	<p>A statement that: “We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.” Submit your procedures.</p> <p style="text-align: center;">OR</p> <p>A statement that: “We will follow the model procedures in Appendix N, NUREG Guide 1556 Volume 9.”</p>	
Item 11: Waste Management	<p>A statement that: “We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.” Submit your procedures.</p> <p style="text-align: center;">OR</p> <p>A statement that: “We will follow the model procedures in Appendix W, NUREG Guide 1556 Volume 9.”</p> <p style="text-align: center;">AND</p> <p>A statement that: “We will dispose of all Low Level Radioactive Waste (LLRW) that is not specified as Decay in Storage through the LLRW disposal program managed by Radiological Affairs Support Office (RASO).”</p> <p style="text-align: center;">AND</p> <p>The radioactive waste items will be inventoried semi-annually against the decay in storage log-book to ensure all waste is accounted for.</p>	

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Item 12: Transportation	<p>List the areas of RAM transportation that apply to your command. Submit separate procedures used for each type of package shipment or receipt. For outgoing packages, include the preparation, labeling, marking and documentation of the shipment.</p> <p style="text-align: center;">AND</p> <p>State that the RSO or a qualified designee will review each transfer of RAM to ensure compliance with Department of Transportation regulations.</p>	
Item 13: Records	<p>A statement that: "Records of calibration measurements of brachytherapy sources will be retained indefinitely" (if applicable)</p> <p style="text-align: center;">AND</p> <p>A statement that: "Decay-in-storage records will be maintained indefinitely by the Radiation Safety Officer and the following items will be included in the record:</p> <ul style="list-style-type: none"> a) The date that the material was placed into storage, b) The radionuclide(s), c) Date of the disposal, d) The survey instrument used, e) The background radiation level, f) The radiation level measured at the surface of each waste container and g) The name of the individual who performed the survey" <p style="text-align: center;">AND</p> <p>A statement that: "Records of decay of strontium-90 for ophthalmic treatments will be retained indefinitely by the Radiation Safety Officer."</p>	
Item 14: Procedures for administrations when a written directive is required	<p>A statement that: "We will follow the procedures in Appendix S in NUREG 1556 Volume 9."</p> <p style="text-align: center;">OR</p> <p>Submit alternate procedures to be reviewed.</p> <p>NOTE: See NAVENVIRHLTHCEN checklist to ensure all pertinent items are meet.</p>	
Item 15: Authority and Responsibility for the Radiation Protection Program	<p>Submit your commands instruction describing the RSC's membership and responsibilities.</p>	

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The following items will be in a stand alone SOP and submitted for review:

<p><u>Standard Operating Procedures</u></p>	<p><u>Safety Instruction For Individuals Working in Or Frequenting Restricted Areas</u></p> <p>1) Individuals working with or in the vicinity of permitted material must have adequate safety instruction as required by 10 CFR Parts 19 and 35. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 100 mrem, the permittee must provide safety instructions as required by 10 CFR 19.12.</p> <p>2) Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610.</p> <p>3) 10 CFR 35.27 requires the permittees AUs and ANPs to provide safety instruction to all personnel using byproduct material under their supervision.</p> <p><u>Public Dose</u></p> <p>1) Procedures for ensuring that permitted items will be used, transported, and stored in such a way that members of the public will not receive more than 100 mrem in 1 year, and the dose in any unrestricted area will not exceed 2 mrem in any one hour from permitted operations.</p> <p>2) Ensure emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 10 mrem (TEDE) in one year.</p> <p>3) Control and maintain constant surveillance of permitted material that is not in storage and secure stored permitted material from unauthorized access, removal, or use.</p> <p><u>Opening Packages</u></p> <p>1) Establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 10 CFR 20.1906 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. Appendix P in NUREG 1556 Volume 9 contains model procedures for safely opening packages.</p> <p><u>Release of Patients or Human Research Subjects</u></p> <p>1) Guidance on the interruption or discontinuation of breast-feeding; and</p> <p>2) Information on the potential consequences of failures to follow the guidance.</p> <p>3) The permittee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material, and</p> <p>4) Instructions to the patient are required by 10 CFR 35.75(b).</p> <p>5) Appendix U in NUREG 1556 Volume 9 contains model procedures and it lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.</p> <p><u>Operating and Emergency Procedures</u></p> <p>1) Develop, implement, and maintain specific operating and emergency procedures.</p> <p style="padding-left: 20px;">a) Instructions for opening packages containing permitted material (see Section 8.33).</p> <p style="padding-left: 20px;">b) Using permitted material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Section 8.26).</p>	
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	<p>c) Instructions for conducting area radiation level and contamination surveys (see Section 8.23).</p> <p>d) Instructions for administering permitted material in accordance with the written directive (see Section 8.34).</p> <p>e) Steps to ensure that patient release is in accordance with 10 CFR 35.75 (see Section 8.35).</p> <p>(f) Instructions for calibration of survey and dosage measuring instruments (see Section 8.16 and 8.17).</p> <p>(g) Periodic spot checks of therapy device units, sources, and treatment facilities (see Sections 8.18).</p> <p>(h) Instructions for radioactive waste management (see Section 8.28).</p> <p>(i) Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunctions and/or damage, (c) permitted material spills, (d) theft or loss of permitted material, or (e) any other incidents involving permitted material (see Section 8.25 and 8.44).</p> <p>(j) Steps for source retrieval and access control of damaged source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.21).</p> <p>(k) Steps to take if a therapy patient undergoes emergency surgery or dies.</p> <p>2) The permittee should consider the following:</p> <p>(a) Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);</p> <p>(b) Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).</p> <p>(c) When developing the procedures described above, the permittee is reminded that 10 CFR 20.1101(b) requires that the permittee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.</p> <p>(d) When receiving and using byproduct material, the permittee is reminded that it must be permitted to possess the byproduct material and that the radioactive material must be secured (or controlled) and accounted for at all times.</p> <p><u>Material Receipt and Accountability</u></p> <p>1) Permitted materials must be tracked from “cradle to grave” to ensure accountability, identify when permitted material could be lost, stolen, or misplaced, and ensure that possession limits listed on the permit are not exceeded.</p> <p><u>Ordering and Receiving</u></p> <p>1) Permittee must ensure that the type and quantity of permitted material possessed is in accordance with the permit. Additionally, permittees must ensure that packages are secured and radiation exposure from packages is minimized. (Appendix O, NUREG 1556 Volume 9 contains model procedures that are one method for ordering and receiving permitted material.)</p>	
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	<p><u>Sealed Source Inventory</u></p> <p>1) According to 10 CFR 35.67, the permittee must conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in 10 CFR 35.67(g). However, the permittee must maintain records of GSR source receipt, transfer, and disposal, under 10 CFR 30.51, to indicate the current inventory of sources at the permittee's facility.</p> <p><u>Records of Dosage and Use of Brachytherapy Source</u></p> <p>1) Permittees are required to make and maintain records of each dosage and administration prior to medical use. The records must include:</p> <ul style="list-style-type: none">(a) Radiopharmaceutical;(b) Patient's or human research subject's name or identification number (if one has been assigned);(c) Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq;(d) Date and time of dosage determination; and(e) Name of the individual who determined the dosage. <p><u>Recordkeeping</u></p> <p>1) The permittee must maintain certain records to comply with NRC regulations, the conditions of the permit, and commitments made in the permittee application and correspondence with NRC. Operating procedures should identify which individuals in the organization are responsible for maintaining which records.</p> <p>2) A table of recordkeeping requirements appears in Appendix X, NUREG 1556 Volume 9.</p> <p><u>Reporting</u></p> <p>1) Information Notice 2002-01: Notifications and Reports for Reportable Events discuss the proper procedure for notifying OPNAV, BUMED and NEHC.</p> <p><u>Leak Tests</u></p> <p>1) Permittees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with 10 CFR 35.67.</p> <p>2) Appendix Q, NUREG 1556 Volume 9 provides model procedures that are one way to perform leak testing. 10 CFR 35.67 requires permittees to perform leak tests at six-month intervals or at other intervals approved by NRC or an Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurements of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.</p> <p><u>Safety Procedures for Treatments When Patients Are Hospitalized</u></p> <p>1) Section 8.46 NUREG 1556 Volume 9 page 8-69, discusses the required information that should be included in your safety procedures for treatments when patients are hospitalized.</p>	
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	<p><u>Additional procedures to be included in the SOP</u></p> <ol style="list-style-type: none">1) Procedures for calibrating radiation-monitoring instruments (Item 9 above).2) Procedure used for calibrating dose calibrator and other measuring equipment (Item 9 above).3) Procedures for calibrating sealed sources and therapy units (Item 9 above).4) Safety procedures and instructions for remote afterloader units, teletherapy units and gamma Stereotactic Radiosurgery unit, if applicable (Item 10 above).5) Procedures for an Occupational Dose Program (Item 10 above).6) Procedures for area surveys (Item 10 above).7) Procedures for safe use of unsealed permitted material (Item 10 above).8) Procedures for a spill (Item 10 above).9) Procedures for waste management (Item 11 above).	
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Authorized User	Approved for what?	Approved by whom?	Basis for Approval