

APP C2
REVIEW CHECKLIST
RESEARCH

COMMAND: _____

PERMIT NUMBER: _____

TYPE OF ACTION: _____

NAVY AND MARINE CORPS PUBLIC HEALTH CENTER

REVISED NOVEMBER 2007

REVIEWER: _____

SECOND REVIEW: _____

**GUIDELINES FOR PREPARATION OF NAVAL RADIOACTIVE
MATERIALS PERMIT APPLICATIONS FOR RESEARCH ACTIVITIES**

The enclosed Naval Radioactive Materials Permit (NRMP) Application For Medical Department Activities Form (NRMP Application Form) 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.

Below is a guide to aid you in your permit application. However, it is your responsibility to read the appropriate NUREG, Code of Federal Regulations, and Naval instructions to ensure all pertinent items are answered in your permit application. For research activities, most information required is located in NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," dated December 1999, (NUREG-1556, Volume 7).

See NRMP Application Form. Item numbers below correspond to those on the NRMP Application Form.

For information on filling out the form, see NRC NUREG-1556, Volume 7, Section 8, Contents of an Application. The applicable sections of the NUREG will be the same section numbers as in the NRMP Application Form, preceded by an 8 (for Permit Application Form Items # 1- 11).

ITEMS 5 through the last item on the page (unnumbered, the CO signature) should be submitted as an enclosure for new applications, renewals and terminations. The NRMP Application Form may have changes noted on it for a simple amendment.

A cover letter, signed by the CO (or OIC), serialized and dated is required to be submitted with the NRMP Application Form.

Item 1. Mark the appropriate block, whether new, amendment, renewal, or termination of permit.

Item 2. Name and mailing address of command requesting a permit, include building numbers.

Item 3. ADDRESSES WHERE RADIOACTIVE MATERIAL USED OR POSSESSED

Specify the street address of the location of use if the address differs from the one given in Item 2. If use is to be at more than one location, give the specific address of each location. Include building numbers, clinics, and/or room numbers where radioactive material is used or stored.

Item 4. POINT OF CONTACT ABOUT THIS APPLICATION

Person to be contacted concerning this application. Include name and title, phone (both DSN and commercial) and fax numbers, and e-mail address. This should typically be the RSO named on the permit.

Item No.	Suggested Response	Description Attached
5.	RADIOACTIVE MATERIAL	
	Unsealed and/or Sealed Sources	
	For unsealed materials:	
--	<p>Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit.</p> <p>For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.</p> <p>Include all calibration sources, such as liquid hydrogen-3.</p>	
	For sealed materials:	
--	<p>Identify each Radionuclide (element name and mass number) that will be used in each source.</p> <p>Include all calibration sources, such as solid iodine-129..</p>	
--	Provide the manufacturer's (distributor's) name and model 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 NRC or an Agreement State.	
	--	Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.	
		Provide an Emergency Plan (if required).	
6.		PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED	
		List the specific use or purpose of each radioisotope. State, which isotopes listed in item 5, will be used for in vitro studies, animal use, as calibration sources, etc. See NUREG-1556, Volume 7, Section 8.6, pages 8-12 to 8-13, Purposes For Which Licensed Material Will Be Used, for specific information and sample formats.	
7.		INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE	
7.1		RSO	
		a) Submit the name and information demonstrating training, and experience of your Radiation Safety Officer (RSO) using NRC Form 313A, Training and Experience and Preceptor Statement, Appendix B from NUREG-1556, Volume 9. b) Certify that the RSO has been trained and tested in accordance with 49 CFR 172.702.	
7.1.1		OCONUS COMMANDS	

	<p>a) Copy of command license from the host country AND the English translation.</p> <p>b) Copy of any host country certifications of personnel (badges, class certificates, etc.).</p> <p>c) Copy of host country waste disposal agreements, radioactive material transfer logs, Memorandum of Understanding, Status of Forces Agreement, etc.</p>	
7.2	AUs	
	<p>a) Name of each proposed AU with the types and quantities of licensed material to be used. Types of material include in vitro, animals, irradiator, etc.</p> <p>b) Information demonstrating that each proposed AU is qualified by training and experience to use the requested materials.”</p>	
8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)	
	Submit a description in table format of the radiation safety-training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. See NUREG-1556 Volume 7 and 49 CFR 172.704 for required frequency of training and general information on topics.	
9.	FACILITIES AND EQUIPMENT	
	Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to	

facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.

See NUREG-1556, Volume 7, Section 8.9, pages 8-19 and 8-20. The required response is on page 8-20.

10. RADIATION SAFETY PROGRAM

10.1 AUDIT PROGRAM

Requirement in permit condition.

10.2 RADIATION MONITORING INSTRUMENTS

- a) For each radiation detection instrument, list the manufacturer's name and model number, the number of instruments available, and the type of use. Serial numbers are not required.
- b) If the command's radiation survey instruments are calibrated by a Navy RADIAC Calibration Facility, state on the application: "All radiation survey instruments are calibrated by (name of facility)."
- c) 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).
- d) 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. See Appendix M.

	e) A statement that: ““We will use the instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG-1556, Volume 7, dated Dec 1999. We reserve the right to upgrade our survey instruments as necessary.”	
	OR	
	A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Further, the statement “We reserve the right to upgrade our survey instruments as necessary.” should be added to the response.	
	f) 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).	
10.3	MATERIAL RECEIPT AND ACCOUNTABILITY	
	a) Develop and maintain procedures for ensuring material accountability,	
	AND	
	b) State that “Semi-annual physical inventories, not to exceed 6 months, of all radioactive material, sealed sources and devices including unsealed sources and wastes received and possessed under this permit, will be conducted and signed by the Radiation Safety Officer.”	
	See NUREG-1556, Volume 7, Section 8.10.3, pages 8-25 through 8-31 and Appendix N.	

	<p>Note: see Table 8.4 of NUREG-1556, Volume 7, pages 8-26 and 8-27, for package monitoring requirements.</p> <p>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>	
	OR	
	A description of the procedures for ensuring that no sealed sources have been lost, stolen or misplaced.	
10.4	OCCUPATIONAL DOSE	
	<p>See NUREG-1556, Volume 7, Section 8.10.4, pages 8-31 through 8-34.</p> <p>a) State that TLD's will be sent to the Naval Dosimetry Center for processing every 6-7 weeks in accordance with NAVMED P-5055. If personnel dosimetry will not be used, the applicant should submit calculations or documentation from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 10 CFR Part 20. Personnel dosimetry is not required for individuals utilizing only hydrogen-3.</p> <p>1) Note any extremity dosimetry use.</p> <p>2) Note if dosimetry use not required.</p> <p>b) Bioassays: If you are required to perform bioassays, submit bioassay procedures to include:</p> <p>1) The instrument used, the counting time and the geometry used (standard and subject).</p>	

	<p>2) The MDA of the system. Show the efficiency calculation for I-131 and identify the standard used and its activity.</p> <p>3) The trigger level and the actions to be taken if exceeded. NUREG-1556, Volume 7 lists various regulatory guides concerning internal dose and bioassays on page 8-34. Monitoring frequency for bioassay is given in Appendix Q, pages Q-9 and Q-10.</p>	
10.5	PUBLIC DOSE	
	<p>See NUREG-1556, Volume 7, Section 8.10.5, pages 8-35 and Appendix O.</p> <p>a) State how you will evaluate the yearly dose to the public as required by 10 CFR 20.1301.</p> <p>b) 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>c) 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>d) 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>	[]
10.6	SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES	
	<p>Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed.</p>	

OR

A statement that: "We will follow the model procedures in Appendix P, NUREG Guide 1556 Volume 7."

See NUREG-1556 Volume 7, Section 8.10.6, pages 8-37 through 8-42 and Appendix P, General Topics for Safe Use of Radioisotopes and Model Emergency Procedures.

Also, see Model Rules for the Safe Use of Radioactive Material (RAM), at the end of this document.

Additional items are requested:

a) Security of Radioactive Material: Describe your methods for securing all radioactive material from unauthorized removal or access when not under constant surveillance by personnel. See NUREG-1556, Volume 7, page 8-39.

b) Submit Radionuclide-Specific Protocols: See attached example.

1) Each protocol should be less than one page but contain all the information needed to understand that the experiment is being conducted safely from a radiological point of view.

2) A radioactive material protocol includes:

- a) Name of protocol
- b) Authorized user
- c) List of supervised users under this authorized user
- d) Description of protocol
- e) Isotopes to be used

- f) Maximum quantity or activity of each isotope stored in the laboratory
- g) Room number where radioisotope stored
- h) Room number where radioisotope used
- i) Activity or amount used in the protocol
- j) Physical/chemical form
- k) Contamination control measures
- l) Waste management

c) Bioassay sample collection. See page 8-40 for requirements.

d) Animal Handling

- 1) Submit procedures for use of RAM in animals.
- 2) Submit procedures for use by animal handlers.
- 3) Submit procedures for cleaning and decontaminating animal cages.

10.7

SURVEY

State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.

Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate.

Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide

	leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."	
	OR	
	<p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999.</p> <p>Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate.</p> <p>Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."</p>	
10.8	MINIMIZATION OF CONTAMINATION	
	The applicant does not need to provide a response to this item under the following condition. NAVENVIRHTLCEN will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."	N/A

11.	WASTE MANAGEMENT	
	State that: “We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999.”	
	OR	
	“We will use the (specify either (1) Decay-In-Storage, (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix T to NUREG - 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999.”	
12	TRANSPORTATION	
	<p>See NUREG-1556, Volume 7, Section 8.10.8, pages 8-47 and 8-48 and 10 CFR 20.1101, 10 CFR 30.51, 10 CFR 71, 49 CFR 171-173.</p> <p>a) List the Areas Of Ram Transportation Safety below which apply to your command:</p> <p>1) Receipt of Packages</p> <p style="margin-left: 40px;">a) Reference 10 CFR 20.1906</p> <p style="margin-left: 40px;">b) NRC NUREG-1556, Volume 7, Section 8.10.3</p> <p style="margin-left: 40px;">c) Note: This may apply to supply personnel if they receive and/or handle RAM packages</p> <p>2) General Safety and Awareness</p> <p style="margin-left: 40px;">(a) Reference 10 CFR Part 20</p> <p style="margin-left: 40px;">(b) Reference 49 CFR Parts 171 and 172</p> <p>3) Transportatation of RADIACS</p>	

Comment [D1]: OK for Cairo

Comment [D2]: OK for Cairo

Comment [D3]: OK for Cairo

- (a) Reference SE700-AA-MAN-100/RADIAC, RADIAC Policy and Procedures Manual Volume I, dated 1Sep96, Section 6
- (b) Note: Applies to shipment as well as vehicular transportation of RADIACS for calibration.
- (c) NAVICP MECHANICSBURG PA msg of 15 Apr 98, Subj: Shipment of Source Bearing RADIAC (SBR)

4) Return of Sources to Manufacturer

1) Reference 49 CFR Parts 172 and 173

2) Note: In some cases manufacturers or distributors may provide instructions for preparing packages, but it remains the responsibility of the RSO to verify that these procedures are in compliance with applicable DOT regulations.

b) Submit separate procedures used for each area in 12.a. above (Areas 1-4, note type of package shipment or receipt). For outgoing packages, include the preparation, labeling, marking and documentation of the shipment.

c) State that the RSO or a qualified designee will review each transfer of RAM to ensure compliance with Department of Transportation regulations.

Comment [D4]: *DOES NOT APPLY TO Cairo*

13

RECORDS

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:

- 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,

	<p>f) The radiation level measured at the surface of each waste container and g) The name of the individual who performed the survey.”</p>	
14	AUTHORITY FOR THE RADIATION PROTECTION PROGRAM	
	Submit your command’s instruction describing the RSC’s membership and responsibilities (if applicable).	
15	Application signed by the Commanding Officer (or Officer in Charge). Blank for signature, name and date. Mandatory.	

MODEL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (RAM)

1. Wear laboratory coats or other protective clothing at all times in areas where RAM is used.
2. Wear disposable gloves at all times when handling RAM.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low background area.
4. Do not eat, drink, smoke or apply cosmetics in any area where RAM is used or stored.
5. Do not store food, drink or personal effects in areas where RAM is used or stored.
6. Wear whole-body TLDs or finger ring TLDs as prescribed by the RSO when using RAM. When not being worn to monitor occupational exposures, store TLDs in a low-background area.
7. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
8. Never pipette by mouth.
9. Wipe test RAM use, preparation and storage areas as directed by the RSO for contamination. If necessary, decontaminate or secure the area for decay.
10. Refrigerators shall not be used jointly for foods and RAM.
11. Confine RAM in shielded containers that are clearly labeled.
12. Secure all RAM when not under the constant surveillance and immediate control of the authorized user.