

030-02264

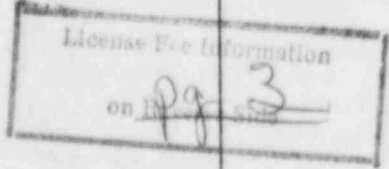
FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557
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INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE Southeast Missouri Hospital 1701 Lacey Street Cape Girardeau, Missouri 63701 TELEPHONE NO.: AREA CODE (314) 334 - 4822	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE Southeast Missouri Hospital 1701 Lacey Street Cape Girardeau, Missouri 63701
2. PERSON TO CONTACT REGARDING THIS APPLICATION Herbert W. Mower, Sc.D. TELEPHONE NO.: AREA CODE (314) 651 - 5544	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. 24-00128-03 c. <input type="checkbox"/> RENEWAL OF LICENSE NO.
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) (No Change)	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.) (No Change)

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE (No Change)					
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
(No Change) 8506110578 850524 REG3 LIC30 24-00128-03 PDR		CONTROL NO. 05706	DEC 14 1981

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8, Rev. 1 Date: October, 1980

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One) No Change	
<input checked="" type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One) No Change	
8. TRAINING AND EXPERIENCE No Change		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One) No Change	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input checked="" type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One) No Change	
10. CALIBRATION OF INSTRUMENTS No Change		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One) No Change	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT No Change		20. THERAPEUTIC USE OF SEALED SOURCES No Change	
<input type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM No Change		<input type="checkbox"/>	Appendix L Procedures Followed; or (Check One)
<input type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL No Change		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133) No Change	
<input type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One) No Change		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS N/A	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached No Change

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	Siemens Gammasonics, Health Physics	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input checked="" type="checkbox"/> FILM	Siemens Gammasonics, Health Physics	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

d. OTHER (Specify)

Applicant... 47/11/40/78
Check No. 47/11/40/78
Amount/Fee Category \$40.00
Type of Fee Amendment
Date Check Rec'd. 12/22/81
Received By BROWN

RECEIVED BY LEMB	
Date 12/22/81	Dec. PG 11 903 III
By BROWN	
Orig. to	
Action: Com. 12/23/81	

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
NAME OF HOSPITAL			c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.
MAILING ADDRESS			
CITY	STATE	ZIP CODE	

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

<p>a. LICENSE FEE REQUIRED <i>(See Section 170.31, 10 CFR 170)</i></p>	<p>b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i></p> <p style="text-align: center;"><i>David Niswonger</i></p>
(1) LICENSE FEE CATEGORY: 7. B. Amendment	(1) NAME <i>(Type of Print)</i> O. David Niswonger
(2) LICENSE FEE ENCLOSED: \$ 40.00	(2) TITLE Administrator
	c. DATE December 7, 1981

CONTROL NO. 05706

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not provided, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

RADIATION SAFETY COMMITTEE

Earl W. Johnson, M.D. (Radiologist), Chairman

G. Ray Ridings, M.D. (Radiation Therapist)

Thomas A. Lovinggood, M.D. (Pathologist)

James R. Dzur, M.D. (Internal Medicine)

Herbert W. Mower, Sc.D. (Radiation Physicist, R.S.O.)

Richard Meyer (Administrator)

Item 7
CONTROL NO. 05706
December, 1981

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____
 Minimum range: _____ mr/hr to _____ mr/hr
 Maximum range: _____ mr/hr to _____ mr/hr
- b. Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____
 Minimum range _____ mr/hr to _____ mr/hr
 Maximum range _____ mr/hr to _____ mr/hr

2. Dose calibrator

Manufacturer's name: _____
 Manufacturer's model number: _____
 Number of instruments available: _____

3. Diagnostic instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
<u>ADD:</u>		
Low Energy Mobile Scintillation Camera	Siemens	006480
<u>DELETE:</u>		
Magnascanner Rectilinear Scanner	Picker	500

4. Other

CONTROL NO. 05706

ALARA Program

For Maintaining Occupational Radiation Exposure

As Low As Reasonably Achievable

I. Management Commitment

- a. We, the management of this medical facility are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the program. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
3. The RSC will ensure that the user justifies his procedures and that the dose will be ALARA (individual and collective).

b. Delegation of Authority

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).

3. The RSC will evaluate our facility's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

- a. Periodic Review and Audit of the Radiation Safety Program for Compliance with ALARA Concepts. Frequent reviews of procedures will be conducted.
 1. The RSO will review annually the effectiveness of the radiation safety program for adherence to ALARA concepts.
 2. The RSO will review at least quarterly the external radiation exposures of authorized users and occupational workers to determine that their exposures are ALARA.
 3. The RSO will review quarterly the radiation levels in unrestricted and restricted areas to determine that their exposures are ALARA.
- b. The RSO's Education Responsibilities for an ALARA Program
 1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
 2. The RSO will assure that authorized users, occupational workers and ancillary personnel will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.
- c. Cooperative efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

 1. The RSO will maintain close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
 2. The RSO will establish procedures for encouraging, receiving, and evaluating the suggestions of individual workers for improving health physics practices.

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d. Reporting and Reviewing Instances of Deviation from Good ALARA Practices

1. The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive approval of, the RSO and RSC before using radioactive materials for a new procedure.
2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept of his commitment to maintain exposures ALARA to all of those he supervises.
2. The authorized user will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Occupational Worker

- a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.
- b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures.

This medical facility hereby establishes Investigational Levels for Occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

Investigational Levels (mrems per calendar quarter)		
	<u>LEVEL I</u>	<u>LEVEL II</u>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table I:

- a. Quarterly exposure of individuals to less than Investigational Level I

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

- b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

- c. Exposure equal to or greater than Investigational Level II

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

- d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed In Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA

practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.