"Designated Original" PDR

Standard Form 83
(Rev. September 1983)

Request for OMB Review

Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request

U.S. Nuclear Regulatory Commission

2. Agency code

3 1 5 0

3. Name of person who can best answer questions regarding this request

Sterling Bell

Telephone number

(301 427-9026

4. Title of information collection or rulemaking

NRC Form 483 Registration Certificate - In Vitro Testing With Byproduct Material Under General License

5. Legal authority for information collection or rule *(cite United States Code, Public Law, or Executive Order)*

42 USC 2201(o) or

6. Affected public *(check all that apply)*

1 ☐ Individuals or households
2 ☐ State or local governments
3 ☐ Farms
4 ☒ Businesses or other for-profit
5 ☐ Federal agencies or employees
6 ☒ Non-profit institutions
7 ☒ Small businesses or organizations

PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)

___ ___ ___ ___ — ___ ___ ___ ___, or, None assigned ☐

8. Type of submission *(check one in each category)*

Classification

1 ☐ Major
2 ☐ Nonmajor

Stage of development

1 ☐ Proposed or draft
2 ☐ Final or interim final, with prior proposal
3 ☐ Final or interim final, without prior proposal

Type of review requested

1 ☐ Standard
2 ☐ Pending
3 ☐ Emergency
4 ☐ Statutory or judicial deadline

9. CFR section affected

_____ CFR _____

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320? ☐ Yes ☐ No

11. If a major rule, is there a regulatory impact analysis attached? 1 ☐ Yes 2 ☐ No

If "No," did OMB waive the analysis? 3 ☐ Yes 4 ☐ No

Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official — Date

8610300239 861023
PDR ORG EUSOMB
PDR

Signature of authorized regulatory contact — Date

12. *(OMB use only)*

PART III.—Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract—Describe needs, uses and affected public in 50 words or less

"Radioactive Materials, Radiation Safety"
Persons wishing to use radioactive byproduct material for in vitro clinical or laboratory testing under general license must register with NRC by submitting NRC Form 483. The certificate when validated by NRC, serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the material.

14. Type of information collection *(check only one)*

Information collections not contained in rules

1 [X] Regular submission
2 [ ] Emergency submission *(certification attached)*

Information collections contained in rules

3 [ ] Existing regulation *(no change proposed)*
4 [ ] Notice of proposed rulemaking (NPRM)
5 [ ] Final, NPRM was previously published
6 Final or interim final without prior NPRM
A [ ] Regular submission
B [ ] Emergency submission *(certification attached)*

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking *(month, day, year)*: _____

15. Type of review requested *(check only one)*

1 [ ] New collection
2 [ ] Revision of a currently approved collection
3 [X] Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection
4 [ ] Reinstatement of a previously approved collection for which approval has expired
5 [ ] Existing collection in use without an OMB control number

16. Agency report form number(s) *(include standard/optional form number(s))*

NRC Form 483

17. Annual reporting or disclosure burden

1 Number of respondents	250
2 Number of responses per respondent	1
3 Total annual responses *(line 1 times line 2)*	250
4 Hours per response	0.120
5 Total hours *(line 3 times line 4)*	30

18. Annual recordkeeping burden

1 Number of recordkeepers	
2 Annual hours per recordkeeper	
3 Total recordkeeping hours *(line 1 times line 2)*	
4 Recordkeeping retention period	years

19. Total annual burden

1 Requested *(line 17-5 plus line 18-3)*	30
2 In current OMB inventory	30
3 Difference *(line 1 less line 2)*	0
Explanation of difference	
4 Program change	
5 Adjustment	

20. Current *(most recent)* OMB control number or comment number

3150-0038

21. Requested expiration date

3 years from approval date

22. Purpose of information collection *(check as many as apply)*

1 [ ] Application for benefits
2 [ ] Program evaluation
3 [ ] General purpose statistics
4 [X] Regulatory or compliance
5 [ ] Program planning or management
6 [ ] Research
7 [ ] Audit

23. Frequency of recordkeeping or reporting *(check all that apply)*

1 [ ] Recordkeeping

Reporting

2 [ ] On occasion
3 [ ] Weekly
4 [ ] Monthly
5 [ ] Quarterly
6 [ ] Semi-annually
7 [ ] Annually
8 [ ] Biennially
9 [X] Other *(describe)*: One time

24. Respondents' obligation to comply *(check the strongest obligation that applies)*

1 [ ] Voluntary
2 [X] Required to obtain or retain a benefit
3 [ ] Mandatory

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? [ ] Yes [X] No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? [ ] Yes [X] No

27. Regulatory authority for the information collection

10 CFR 31.11(b) ; or ____ ____ FR _____ ; or, Other *(specify)*: _____

Paperwork Certification

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official	Date

Signature of agency head, the senior official or an authorized representative	Date
Patricia G. Norry, Director Office of Administration Patricia G. Norry	10-23-82

☆ GPO : 1984 O - 453-776

Supporting Statement
for
NRC Form 483
Registration Certificate
In Vitro Testing with Byproduct Material
Under General License
(10 CFR 31.11)

Justification

Need for the Collection of Information

Section 31.11(a) of 10 CFR Part 31 provides for a general license for the use of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3, Iron-59, Selenium-75, and mock Iodine-125 by any physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for the purpose of certain *in vitro* clinical or laboratory testing. The general license sets forth the conditions pertaining to possession and use of the byproduct material.

Section 31.11(b) specifies that in order for the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine to use the general license, NRC Form 483, "Registration Certificate - In Vitro Testing with Byproduct Material Under General License," must be completed and submitted to NRC. The licensee must then receive a validated copy of the registration certificate with an assigned registration number to complete the licensing process.

Suppliers of byproduct material to other persons are required to determine that the person receiving the material is authorized to receive it. The validated certificate, maintained by the licensee, serves as evidence for the supplier that a physician, clinical laboratory, hospital, or veterinarian in the

practice of veterinary medicine is a general licensee authorized to receive the byproduct material.

Section 31.11(e) requires that a licensee under this section report in writing any change in a previously validated registration certificate. The licensee must report the change to the NRC within 30 days after the effective date of such change.

Agency Use of the Information

The information derived as a result of the submission of the registration form provides NRC with the name of each physician, clinical laboratory, or hospital using byproduct material under the general license. The registration certificate contains the terms and conditions of the general license and provides a means of assurance to the NRC that the general licensee is aware of those terms and conditions prior to receipt of byproduct material.

A registration certificate is usually validated within seven days of its receipt. A validated copy is returned to the general licensee, who may then use it to obtain byproduct material from a supplier.

Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. Registrants may use electronic information processing systems to prepare and submit the required information.

Effort to Identify Duplication

The Federal Information Locator System was searched to determine NRC and other Federal agency duplication. None was found.

Effort to Use Similar Information

There is no similar information available to the NRC.

Effort to Reduce Small Business Burden

The majority of the registrants who use byproduct material are small businesses. The health and safety consequences of improper use or handling of radioactive byproduct material are the same for large and small entities. The burden of providing the small amount of information required on the registration form is only nominal. The Registration Certificate is only submitted once. Therefore, it is not possible to reduce the burden on small businesses by less frequent or less complete submittal.

Consequences of Less Frequent Collection

NRC Form 483 is only submitted once, for initial registration.

Circumstances Which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

Consultations Outside the Agency

There have been no outside consultations since the previous clearance.

Confidentiality of Information

None.

Sensitive Questions

None.

Estimate of Compliance Burden

Approximately 250 registration certificates are received annually from persons who wish to be general licensees. The time required for completion of Form 483 is approximately seve minutes. All that is necessary is filling in the name and address, checking one of the categories of licensees, signing and dating the registration certificate. The total burden for all general licensees is approximately 30 hours annually. Since preparation of the form is essentially a clerical function, the cost is estimated to be approximately $25 per hour. The total cost for preparation of the 250 certificates would be approximately $750.

Estimated Annual Cost to the Federal Government

The average time needed for processing of a registration certificate is approximately 15 minutes. At a rate of $60 per hour, the annual cost to the Federal government based on 62.5 hours of effort is $3,750.

NRC Form 483
(12-81)
10 CFR 31

U.S. NUCLEAR REGULATORY COMMISSION

Approved by OMB
3150-0035

REGISTRATION CERTIFICATE—IN VITRO TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with registration number.

3. I hereby apply for a registration number pursuant to §31.11, 10 CRF 31 for use of byproduct materials for *(please check one block only)*
   - ☐ a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine.
   - ☐ b. The above-named clinical laboratory.
   - ☐ c. The above-named hospital.
   - ☐ d. Veterinarian in the practice of veterinary medicine.
4. To be completed by the Nuclear Regulatory Commission.

Registration number:

(If this is an initial registration, leave this space blank — number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)

INSTRUCTIONS

1. Submit this form in triplicate to:
   Office of Nuclear Material Safety and Safeguards
   ATTN: Material Licensing Branch
   U.S. Nuclear Regulatory Commission
   Washington, D.C. 20555

2. Please print or type the name and address (including zip code) of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed. Position the first letter of the address below the left dot and do not extend the address beyond the right dot. (At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

5. If place of use is different from address in Item 1, please give complete address:

6. Certification:

I hereby certify that:

a. All information in this registration certificate is true and complete.

b. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CRF 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

c. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change.

d. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the Nuclear Regulatory Commission.

Date _____ By _____

Printed name and title or position of person filing form

WARNING— 18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§31.11 General license for use of byproduct materials for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron 59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.005 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) No person shall receive, acquire, possess, use or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed NRC Form 483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and received from the Commission a validated copy of NRC Form 483 with registration numoer assigned or until he has been authorized pursuant to §35.14(c) of this chapter to use byproduct material under the general license in this §31.11. The registrant shall furnish on NRC Form 483 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) The location of use; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with byproduct materials as authorized under the general license in paragraph (a) of this section, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the byproduct materials.

(c) A person who receives, acquires, possesses or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine 125, iodine 131, selenium-75, and/or iron 59 in excess of 200 microcuries.

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State,[1] nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources decribed in paragraph (a)(7) of this section as required by §20.301 of this chapter.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of §32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59 or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:[2]

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

.....

Name of manufacturer

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," NRC Form 483. The report shall be furnished within 30 days after the effective date of such change.[3]

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20 and 21 of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §20.301, 20.402 and 20.403 of this chapter.

NOTES

[1] A State to which certain regulatory authority over radioactive material has been transferred by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

[2] Material generally licensed under this section prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[3] A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, an "Application for Byproduct Material License," NRC Forms 313I, 313M, or 313R should be filed to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Material Licensing Branch, Division of Fuel Cycle and Material Safety.

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 522a(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 NRC Form 483. 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 criteria set forth in 10 CFR Parts 30-36 to determine whether the application conforms to the requirements of the Atomic Energy Act of 1954, as amended, and the regulations of the NRC, for the issuance of a registration certificate authorizing the use of in vitro testing.

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 purposes of their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, or local agencies in the event 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 an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION It is voluntary that you furnish the requested information. If the requested information is not furnished, however, the registration certificate, 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.