DRAFT OMB SUPPORTING STATEMENT FOR 10 CFR PART 33 SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL (3150-0015)

CLEARANCE EXTENSION

Description of the Information Collection

The NRC regulations in 10 CFR Part 33 specify requirements for applying for and being granted licenses authorizing broad scope use of byproduct material. Three types of licenses may be issued: Type A, Type B, or Type C, with Type A being the largest program. The types of licenses are defined by Section 33.11. Applicants and licensees are primarily medical institutions, colleges, universities, government agencies, and large private companies engaged in broad educational, research, and development activities.

A. Justification

1. Need for and Practical Utility of the Collection of Information

Section 33.12 specifies that an applicant for a broad license must complete NRC Form 313, "Application for Material License." The NRC Form 313 has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden, and cost data.

Sections 33.13, 33.14, and 33.15 specify the information which must be included in an application in order for the NRC to issue a license based on a finding that the public health and safety will be adequately protected.

Section 33.13 specifies the requirements for the issuance of a Type A broad license. It requires that an applicant have equipment and facilities adequate to protect health and minimize danger to life or property, have personnel with adequate training and experience, and have adequate administrative controls and procedures, including a radiation safety committee and radiation safety officer. The applicant must describe the program for meeting these requirements when the applicant submits a license application, in order to establish that radioactive material can be used safely.

The burden and cost associated with this requirement are incurred in connection with the submission of the application, NRC Form 313. The use of NRC Form 313 has been previously approved by OMB under clearance number 3150-0120, which should be referred to for information collection burden and supporting data.

Section 33.14 specifies the requirements for the issuance of a Type B broad license. The requirements are similar to those specified in Section 33.13, except that the applicant need not demonstrate as extensive experience in use of radioactive materials as is required for a Type A broad license, and need not have a radiation safety committee. The application submitted by the applicant must demonstrate that he can meet these requirements.

The burden and cost associated with this requirement are incurred in connection with the submission of the application, NRC Form 313. The use of NRC Form 313 has been previously approved by OMB under clearance number 3150-0120, which should be referred to for information collection burden and supporting data.

Section 33.15 specifies the requirements for the issuance of a Type C broad license. It requires that an applicant have equipment and facilities adequate to protect health and minimize danger to life or property, have personnel meeting certain training and experience requirements, supervise use of radioactive material, and have adequate administrative controls and procedures to assure safe use of radioactive material. The application submitted by the applicant must demonstrate that he can meet these requirements.

The burden and cost associated with this requirement are incurred in connection with the submission of the application, NRC Form 313. The use of NRC Form 313 has been previously approved by OMB under clearance number 3150-0120, which should be referred to for information collection burden and supporting data.

2. Agency Use of Information

The NRC reviews the information submitted in order to determine whether the applicant's training, personnel experience, equipment, facilities, and procedures for the use of byproduct material are adequate to protect the public health and safety as required by the Atomic Energy Act, as amended, and the Energy Reorganization Act of 1974, as amended, so that the Commission may determine whether to issue, amend, or renew a broad scope license.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. There are no current information technology applications that would reduce the burden of these information collection requirements. Consequently, the current percentage of electronic submission is zero.

4. Effort to Identify Duplication and Use Similar Information

The information is not a duplication of other information the affected licensee must submit for other purposes. The nature of the information being requested is unique to licensed activities at the facilities, and is necessary so that the Commission may determine whether to issue, amend, or renew a broad license.

5. Effort to Reduce Small Business Burden

While a number of the licensees are considered small businesses, under the NRC's current definitions, the health and safety consequences of improper use of radioactive material are the same for large and small entities. There is a minimum amount of information that must be provided in order for the Commission to determine if an applicant's facilities, equipment, and procedures are adequate to protect the public health and safety. Therefore, it is not possible to reduce the burden on small businesses by less frequent submission or less complete applications.

6. <u>Consequences to Federal Program or Policy Activities if the Collection is Not</u> Conducted or is Conducted Less Frequently

Applications on NRC Form 313 for a new license are submitted only once, while applications for renewal of a license are submitted every 10 years. Amendments are submitted as needed by the licensee. This is the minimum frequency necessary to assure that licensees will continue to conduct programs in a manner that will assure adequate protection of the public health and safety. If the information is not collected, the NRC will have no way to determine the adequacy of licensees' programs to protect the public health and safety.

7. Circumstances which Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultations Outside the NRC

The opportunity for public comment on the information collection requirements has been published in the Federal Register .

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the Information

None.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Industry Burden and Costs

All of the Information Collection in Part 33 are captured under OMB clearance number 3150-0120 for NRC Form 313.

13. Estimate of Other Additional Cost

Part 33 has no additional costs.

14. Estimated Annualized Cost to the Federal Government

It is estimated that the NRC cost to review and other efforts attributable to an application for broad scope use of byproduct material would be incurred with the submission of the application, NRC Form 313, previously approved by OMB under clearance number 3150-0120.

15. Reasons for Changes in Burden or Cost

There are no changes in burden or responses. All burden is captured under NRC Form 313, previously approved under OMB clearance 3150-0120.

16. Publication for Statistical Use

There is no information that will be published for statistical use.

17. Reason for Not Displaying the Expiration Date

The requirement is contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become out of date, would confuse the public.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.