DRAFT VALUE/IMPACT STATEMENT

1. BACKGROUND

Among the licenses issued by the NRC are those of limited scope for medical use of byproduct material. In October 1980, the NRC issued Revision 1 of Regulatory Guide 10.8 to provide guidance for preparing applications for these licenses. The guide was prepared for use with application Form NRC-313M, which was superseded in July 1984 by a new application form, NRC Form 313. The NRC has also proposed a complete revision of 10 CFR Part 35, "Medical Use of Byproduct Materials," which was published for comment on July 26, 1985 (50 FR 30616). This proposed revision of Regulatory Guide 10.8 is to provide up-to-date guidance in a format compatible with the new NRC Form 313 and the proposed 10 CFR Part 35.

2. PROPOSED ACTION

2.1 Description

An applicant for a medical use license is required to have a program that complies with NRC regulations and to describe this program in the license application. The proposed action is to issue Revision 2 of Regulatory Guide 10.8 to conform to the new NRC Form 313 and the proposed revision of 10 CFR Part 35 and also to state guidance in a more straightforward manner. There have been no changes in guidance with regard to health and safety requirements.

2.2 Need

Revision 2 of Regulatory Guide 10.8 is needed to provide up-to-date guidance that conforms to the new NRC Form 313 and the proposed revision of 10 CFR Part 35.

2.3 Value/Impact

2.3.1 NRC

The review and approval of applications for the medical use of byproduct material would be facilitated by the instructions and guidance to be provided

in the proposed regulatory guide. The proposed action would clearly detail the regulations to be followed and the information required for licensing and implementing an acceptable program. Staff review time would be shortened because less correspondence would be needed to compensate for the lack of sufficient detail in license applications.

2.3.2 Other Government Agencies

Other government agencies would not be affected unless they are applicants.

2.3.3 Industry

The proposed action would contribute to a reduction in the time required for preparing a license application. An applicant would spend less time trying to interpret NRC regulations and requirements for information. More importantly, the proposed action would provide information for the design and implementation of a more effective radiation safety program, thereby minimizing the exposure of workers to radiation.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Workers

Workers may benefit from the guide through potentially reduced exposure to radiation as discussed in Item 2.3.3.

2.4 Decision on Proposed Action

Revision 2 to Regulatory Guide 10.8 should be prepared because of the benefits previously discussed.

3. TECHNICAL APPROACH

Not applicable.

4. PROCEDURAL APPROACH

4.1 Alternatives

Regulatory Guide 10.8 presently exists. Revision 2 of the guide is necessary because of a change in the application form and the proposed revision of the regulations. The only alternative is to discontinue use of the guide altogether and write individual letters to applicants.

4.2 Discussion

A regulatory guide is the most effective way to transmit information about regulations and licensing requirements. A regulatory guide ensures uniform transmission of information to applicants. Individual letters would be inefficient and, depending on the reviewing official, may not uniformly convey the same information to each applicant. Revision of the guide is the most effective alternative.

5. STATUTORY CONSIDERATIONS

5.1 NRC Authority

Authority for the proposed action is derived from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, and implemented through the Commission's regulations.

5.2 Need for NEPA Assessment

Issuance or amendment of guides for the implementation of regulations in Title 10, Chapter I, of the Code of Federal Regulations is a categorical exclusion under paragraph 51.22(c)(16) of 10 CFR Part 51. Thus, an environmental impact statement or assessment is not required for this action.

6. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps appear to exist.

7. SUMMARY AND CONCLUSIONS

The guide, when disseminated, will assist the NRC and the industry in reviewing and preparing applications that conform to the new NRC Form 313 for the medical use of byproduct material. The regulatory guide should be revised.

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