June 20, 1997 SECY-97-131

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: SUPPLEMENTAL INFORMATION ON SECY-97-115, "PROGRAM FOR REVISION OF 10 CFR PART 35, 'MEDICAL USES OF BYPRODUCT MATERIAL,' AND ASSOCIATED FEDERAL REGISTER NOTICE"

PURPOSE:

To provide the Commission with supplemental information and an alternative program for the revision of 10 CFR Part 35.

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

BACKGROUND:

On June 5, 1997, in SECY-97-115, the staff requested Commission approval of: (1) its proposed program for revising 10 CFR Part 35, associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary; and (2) a Federal Register notice (FRN) of proposed rulemaking, for publication, to solicit public comments about restructuring Part 35 into a risk-informed, more performance-based regulation.

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On June 13, 1997, the staff briefed the Commission on its proposed program for revising Part 35 as described in SECY-97-115. In addition, the staff and the Commission discussed an alternative approach to revising the regulation. The Commission requested that the staff supplement SECY-97-115 with a description of the alternative approach, as well as with the estimated resources to complete the rulemaking, if this alternative were implemented.

DISCUSSION:

Attachment 1 describes the staff's alternative approach for revising Part 35 and the associated guidance documents. Under the alternative, the staff would immediately begin preparing proposed rule language and alternatives using a "modality" approach (Attachment 2). The alternative differs from the program recommended in SECY-97-115 in several respects. First, there would be no formal public opportunity for comment at the beginning of the process. The staff would consider comments and rule language alternatives beginning immediately, but the first more formal opportunity for public interactions would be during facilitated public meetings in the fall of 1997. The staff would, under the alternative, provide a proposed rule; associated documents such as the regulatory analysis, environmental assessment, and finding of no significant environmental impact; and the Office of Management and Budget clearance package to the Commission in May 1998[1]. At that same time, the staff would expect to provide the Commission with draft guidance documents for each of the proposed rule modalities, and its recommendations regarding the need for any changes to the 1979 Medical Policy Statement. Following Commission approval, the proposed rule and draft documents would be published for public comment. The legal minimum time for public comment on a proposed rulemaking is 75 days. The staff would expect to provide a final rule, associated documents, and final guidance documents for Commission approval in May 1999.

Under the alternative, there would be more public interactions than the usual rulemaking and comment process of the Administrative Procedure Act, in the following respects. First, public input would begin immediately and continue throughout the development of the rule alternatives and facilited public meetings in the fall of 1997. Consideration of comments would be cut off at a point approximately two-three months before providing the material to the Commission for approval. Rulemaking alternatives and drafts would be made publicly available on an ongoing basis, including posting them on an INTERNET page, and the staff would make available the comments received, both in the PDR, and to the extent possible, electronically in the INTERNET. If the alternative revision program described in this supplemental information is approved, staff would revise the Federal Register notice in SECY-97-115 to notify the public of the approved program and the availability of documents on the INTERNET. The staff would continue, as proposed in the original program outlined in SECY-97-115, to solicit comments and specific rule text proposals from various professional societies. The staff would also continue its proposal to use both consultants, and a working group and steering group approach to the development of the documents. The staff would particularly look into obtaining consultants or other information sources that can provide an indication of the current trends in medical practice, in addition to vigorously using the Advisory Committee on the Medical Uses of Isotopes.

[1]As the staff proceeds with this rulemaking, the staff will be alert to issues or areas where more immediate rulemaking is appropriate.

RESOURCES:

Resource projections associated with revising Part 35 and associated documents for fiscal years (FY) 1998, FY 1999, and FY 2000 were provided to the Commission in SECY-97-115. Staff does not anticipate any change in the resources needed, in FY 1998 and FY 1999, to complete the rulemaking effort by May 1999. The primary resource needs are based upon development of the rule, associated documents, and corresponding guidance. Since this task is unchanged, the resource estimates are unchanged. Since the rulemaking effort would be completed in FY 1999, the resources identified in SECY-97-115 for FY 2000 would be used in other areas of the medical program.

RECOMMENDATION:

That the Commission approve the Part 35 revision program described in the attachment to this document.

COORDINATION:

The Office of the General Counsel reviewed this paper and has no legal objection. The Chief Financial Officer and Chief Information Officer have no objection to this paper.

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. Alternative Program for Medical Revision
2. Modality Outline for 10 CFR Part 35

ALTERNATIVE PROGRAM FOR MEDICAL REVISION

The following is an alternative program for the revision of 10 CFR Part 35, as discussed with the Commission on June 13, 1997.

The alternative consists of the following program elements.

1. The staff would immediately initiate development of draft language and rule alternatives, and make these materials publicly available on an ongoing basis, including posting them on an INTERNET page, and would consider comments, suggestions, and other alternatives that result from these interactions. Public input would begin immediately and continue throughout the development of rule alternatives, facilitated public meetings in the fall of 1997, and development of the proposed rule. The staff would interact with professional societies and the public to solicit, on an informal basis, comments and rule text. In addition, staff would prepare a Federal Register notice to notify the public of the approved Part 35 program and the availability of documents on the INTERNET.

2. Per Management Directive 6.3, the staff proposes to conduct this rulemaking using a group approach. Development of rule text alternatives, including draft guidance documents, would use a working group (or groups) and steering group approach. The staff proposes to enhance the State participation in the process through the inclusion of State individuals in both the working group and the steering group. This participation would facilitate the Conference of Radiation Control Program Directors' (CRCPD's) development of corresponding rules in its suggested State regulations, and would allow the State staff to focus on potential impacts of Nuclear Regulatory Commission draft language on the regulation of non-Atomic Energy Act materials used in medical diagnosis, treatment, or research in the States.

3. Facilitated public round table meetings in the fall of 1997 would be used to focus discussion on specific rule text and alternatives. Discussions would also be held in meetings with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and with the Organization of Agreement States. The exact timing of the meetings would depend on the process to convene and facilitate these meetings, but it is expected that the meetings could be conducted in the late September to November 1997 timeframe.

4. Based on the informal and formal public interactions, the staff, using the working group and steering group approach, would develop the proposed rule and associated documents including the regulatory analysis, environmental assessment, finding of no significant environmental impact, and Office of Management and Budget clearance for Commission review and approval. The staff would also develop draft guidance documents for each medical modality of the proposed rule, for publication as drafts for comment, in parallel with the proposed rule, and would provide for Commission consideration, any recommendations regarding changes to the 1979 Medical Policy Statement. During the development process, the staff would continue to make drafts publicly available, but would need to cut off consideration of comments at a point approximately two-three months before providing the material to the Commission for approval. Comments received after that time would be considered as part of the

ongoing interaction process, and as part of the comments received during the formal public comment period on the proposed rule after Commission approval.

5. Following Commission approval, the proposed rule and draft documents would be published for public comment. The legal minimum time for public comment on a proposed rulemaking is 75 days. The staff would make the drafts available on the INTERNET, and would accept comments electronically. The staff would also hold two public meetings, during the formal comment period, to facilitate comments.

6. Development of the final rule, associated documents, and final guidance would be through the working group and steering group. The staff would continue to make draft documents available, but would not be able to consider further external input beginning approximately four months before the submission of the final documents for Commission approval. The staff would discuss the final documents with the ACMUI, and with the Agreement States, prior to submission to the Commission. The staff would expect to provide the final documents for Commission approval in May 1999.

MODALITY OUTLINE FOR 10 CFR PART 35

In developing the revisions to 10 CFR Part 35, the staff proposes to move the rule to an entirely modality based approach, as discussed with the Commission on June 13, 1997. This approach is described briefly below.

Part 35 is currently a mixture of modality specific requirements, and generally applicable requirements. The staff proposes to reexamine the current divisions, and, based on risk, develop a set of requirements that are specific to each modality. At this time, the staff anticipates that the following modalities would be addressed:

1. low-dose unsealed materials (diagnostic nuclear medicine);
2. high-dose unsealed materials (nuclear medicine therapy);
3. low-dose sealed source applications;
4. teletherapy;
5. high-dose-rate remote afterloaders;
6. gamma stereotactic surgery; and
7. emerging technologies.

The above list is not viewed as all-inclusive. Additional categories may be developed, depending on the breadth of the areas to be covered, and the similarity of requirements in a given area.

The modality approach envisioned would place all requirements for a given type of treatment into a single section of the regulation, including who or what organization is licensed; what type of license is issued; the necessary technical requirements, such as surveys and calibration; the training and experience requirements; the event recording and reporting requirements; and the quality improvement and management objectives. Thus, requirements can be tailored more specifically for each modality (as listed above), with those posing lower risks having fewer or simpler requirements, and those posing higher risks having correspondingly more stringent requirements.

The advantage of organizing Part 35 to be entirely modality-driven is that the rule can be modified to incorporate new modalities by simply adding a new subpart to address the activity. The staff envisions that new approaches would initially be licensed under the emerging technologies modality, where the rule requirements would be general in nature, and the specifics would be contained in license conditions. As experience was gained in the regulation of that modality, a rulemaking to add a new subpart to address the specific modality could then be undertaken, and there would be no need to revise the regulations for the other modalities.

The downside of the modality approach is that there would need to be some repetition between the subparts, since some of the requirements would be similar for at least some of the modalities. However, the staff believes at this time that this type of organization would make for a more flexible and usable regulation.

The following is a set of questions that have been developed for determining the contents of each modality section. This list is not intended to be all-inclusive.

1. Who and/or what (e.g., facility) should be licensed?
2. What type of license (e.g., is registration a possibility)?
3. What terms should be defined?
4. Should there be an operational definition of "adequate protection," such as performance criteria or a "safety goal"?
5. What are the "technical issues" that should be addressed (e.g., surveys, calibration, access controls, etc.)?
6. What training and experience (T&E) is necessary for what types of personnel involved in the modality?

    a. Should T&E include not only physicians and radiation safety officers, but associated professional personnel (e.g., medical physicists)?
    b. Should the focus of T&E be radiation safety or extend to medical or other credentials? Is it sufficient to simply require the requisite licensure and credentials required by the State, for the medical specialty being practiced?
    c. Are there needs to maintain qualifications and undertake periodic requalifications?

7. What duties and responsibilities should be set forth, and for which personnel?

8. What reports of "safety significant" medical events or "precursor" events should be required?

9. What should be the necessary Quality Management objectives that are essential for patient safety? Are there any additional specifications needed in addition to the basic objectives?

10. What records should be kept?

11. What provisions relative to enforcement should there be?

12. What provisions for amendments, renewals, exemptions, etc., should be included in the rule?

13. What, if any, provisions are needed for the protection of human research subjects?

14. Are there industry guides and standards available that either the regulation or guidance can rely on?

15. What interactions are there with other regulations, particularly 10 CFR Parts 20, 30, 32, and 33?