



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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April 29, 1998

MEMORANDUM TO: Catherine Haney
Medical, Academic and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

FROM: Brenda Jo. Shelton, Chief *Brenda J. Shelton*
Records Management Branch
Office of the Chief Information Officer

SUBJECT: CONCURRENCE IN THE REVISION OF 10 CFR PART 35, MEDICAL USE
OF BYPRODUCT MATERIAL, PROPOSED RULE

The Office of the Chief Information Officer has reviewed the subject rule and concurs in it providing you make the following changes to the rule:

Change the Paperwork Reduction Act Statement (PRAS) to Attachment 1.

Change Section 35.8, Information collection requirements: OMB approval to Attachment 2.

In addition, we have the following comments on the rule:

The preceptor formats required by the rule and the guide are not official NRC Forms. We suggest that the requirement for the forms be included in the rule and that they be included as NRC Forms 313A and 313B in section 35.12. We have accordingly included them in that section in our attached PRAS. Please include a statement in the preamble to the rule addressing the collections in that section, stating that "The information collections contained in NRC Form 313A, "Training and Experience," and NRC Form 313B, "Preceptor Statement," have been submitted to OMB for review. Also, please submit a request to Beverly Martin, T-6 F34, Publishing Services Branch, for assistance in creating the official NRC forms and also provide her with a contact for any changes made to the forms.

The aforementioned preceptor formats contain information collections that must receive OMB approval. We understand that the preceptor forms required by the rule will be a revision of the currently used preceptor forms. The current forms do not have OMB clearance and are therefore an unauthorized collection. Please submit a request to the Rules and Guidance Branch, IMNS, to obtain clearance immediately for the forms, so that we may include the clearance approval numbers in the final rule.

We have discussed this issue with both OGC and with the OMB Desk Officer. The OMB Desk Officer has indicated that it is imperative that this noncompliance issue be resolved immediately, but he has orally agreed that, even if he receives comment, not to consider the bootleg forms as an issue in his review of the revision to Part 35. A revised

OMB clearance may need to be prepared for the revised forms that will be included in the new Part 35.

Some sections are referenced in the guide that are not included in the rule. Although most of them are probably section renumberings that haven't been caught in the guide, one of them, section 35.900, "Emerging Technologies," appears to be missing entirely in the rule, unless this is section 35.1000, and has also been retitled.

Section 35.75(b)(2) indicates that the licensee shall provide the release individual with information on the potential consequences, if any, of failure to follow the guidance. However, on page 240/7 it states that guidance should be provided in addition to indicate that there are no consequences. The rule and guidance should be consistent.

Please change "Form NRC-313" to "NRC Form 313" throughout the rule.

We have reviewed NUREG-1556, Vol 9, "Consolidated Guidance About Materials Licenses," and have the following concerns:

The OMB clearance number for Part 35, 3150-0010, in the Paperwork Reduction Act Statement on page 13, is missing and should be included.

Not all of the requirements described in Items 5 through 10 are contained in the "Regulations" paragraph. For example, in Section 8.31, on page 101, the "Regulations" paragraph should also include §35.2204, and in Section 8.40, on page 116, it should also include §35.2404.

Our greatest concern is that much of the guidance appears to require licensees to have procedures to ensure that the requirements in numerous sections are met. However, we do not find any regulatory citations for the procedure requirements listed in the guidance. Therefore, we cannot determine if the requirement for the procedures is included in the regulations or whether it is an implied requirement to ensure that the Part 35 requirements are met. If the requirements for the procedures are included in the regulations, we suggest that you cite the regulatory citation in the "Regulations" paragraph at the start of each guidance section. If, on the other hand, these are implied requirements, at a minimum, you need to include in your OMB clearance package the burden to develop and maintain the procedures for each referenced Part 35 section, and indicate the page in the guide that states the licensee should have the procedure. However, we suggest that if you intend licensees to develop and maintain these extensive procedures, and they are not included in the regulations, that you include them. Otherwise, they are not enforceable.

The guidance refers to information collection requirements that are contained in license conditions. This burden has not received OMB clearance approval. However, we will allow publication of the guide, because NMSS has agreed to prepare an OMB clearance package for the Standard License Conditions.

Many model procedures included as appendices do not appear to be referenced in the basic guide at all, e.g., appendices I, J, S, V, and X. You may wish to include a reference to the appendices in the guide.

Many sections that are cited in the guidance are not in the rule, e.g., sections 35.69(g), 35.294, 35.315(a)(4) & (7), 35.612, 35.634, 35.650, 35.741, 35.747, and 35.2069. In addition, there are other section references that are incorrect, e.g., the reference to 35.900 which is listed as "Medical Use of Byproduct Material in Emerging Technologies" on pages 46 and 49 of the guide, which is RSO Training in the rule.

Supplement A and B forms, included in Appendix G, must receive official NRC form numbers. We suggest that they be named NRC Forms 313A and 313B. Please contact Beverly Martin on 415-5877 to create official NRC forms.

The specific procedures included in the guidance to ensure that access to therapy treatment rooms and exposure rates from therapy treatments are maintained ALARA, on page 119, are not included in section 35.610. We suggest that the specific procedures be included in the regulations.

The references to recordkeeping requirements are inconsistent in that sometimes they reference the materials requirements sections that state that "a record must be kept in accordance with section ..." and sometimes they reference the records sections in Subpart L. We suggest that they consistently reference records sections in Subpart L unless the details of the record are included in the materials requirements sections, in which case, they should reference both.

We have placed the rule on hold with the Office of Administration pending OCIO approval of the OMB clearance package. We will continue to work with you and cognizant staff to finalize the submittal.

We appreciated the opportunity to discuss with you and Diane Flack in a April 28, 1998, meeting these issues and numerous minor editorial comments on both the guide and rule that we have not included in this memorandum. Should you have any questions on our comments, please contact Beth St. Mary on 415-5878 or e-mail BCS.

Attachments:
As stated

cc: D. Meyer, ADM
D. Flack, NMSS
D. Cool, NMSS
R. O'Connell, NMSS
F. Cardile, NMSS
L. Moorin, OCIO
P. Lanzisera, Region I

PAPERWORK REDUCTION ACT STATEMENT

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by ___ hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010), Office of Management and Budget, Washington, DC 20503. The information collections contained in NRC Forms 313A and 313B, that are required by section 35.12, are at OMB for its review and approval. Should you have comments on these forms, please reference the forms numbers in all communications.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

§35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.57, 35.60, 35.61, 35.62, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.204, 35.290, 35.292, 35.310, 35.315, 35.390, 35.404, 35.410, 35.415, 35.432, 35.490, 35.604, 35.605, 35.610, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645, 35.647, 35.652, 35.655, 35.690, 35.2024, 35.2026, 35.2040, 35.2045, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2605, 35.2630, 35.2632, 35.2633, 35.2635, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3046, 35.3047, 35,3067, and Appendix A.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In §35.12, NRC Form 313 is approved under control number 3150-0120, NRC Form 313A is approved under control number 3150-[to be inserted upon OMB approval], and NRC Form 313B is approved under control number 3150-[to be inserted upon OMB approval].

(2) [Reserved]