



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

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MEMORANDUM FOR: William Walker, Chief
Material Licensing Branch, NMSS

FROM : William A. Mills, Chief
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SUBJECT: COMMENTS ON DRAFT REVISION OF PART 35

I am struck by the detailed requirements placed on the licensee by the present draft revision. Subpart C on General Technical Requirements contains significantly more operational and administrative requirements than is in the current 10 CFR Part 35. I understand that the reason for this is to codify current suggestions (Regulatory Guide 10.8) on calibration of equipment, storage, measurements, etc. With codification, the licensing process is intended to be shortened in time and other "modernization" of the regulations attained. I assume that the "Statement of Consideration" for the proposed rule will adequately address the need for these increased requirements by drawing upon NRC's licensing and inspection experiences as well as the experiences of the Agreement States. It appears that a significant loss in licensee flexibility will take place if the present draft becomes final.

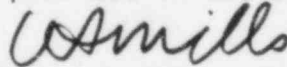
Specific Comments

1. Define "dose" as it is used on page 6 to mean the amount of material administered. Likewise radiation dose needs to be defined because on page 8 the ALARA program requires consideration of "individual and collective dose".
2. On page 8, provide the title for form NRC-313-AR.
3. Section 35.30(b)(4) (top of page 9). If you require an active ALARA program and monitoring of that program by the Committee, the establishment of "investigational levels for occupational" exposures seems unnecessary. Investigational and reference levels tend to become lower standards; rely on the Committee and the RSO to provide the radiation protection needed. Does the requirement mean that NRC will pass judgement on the selection of the levels?
4. Section 35.31(b). Should this requirement not be at the end of the requirements for the Committee?
5. Section 35.32. Why is the RSO charged to establish "policy for disposal"? Is this not a responsibility of the Committee? In (c) and (d) the requirements to "establish" are unnecessary.

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6. Section 35.34. Regarding the "visiting physician" requirements, should not (a)(1) and (a)(2) be an "either-or"? In line 2 of (3), "physician" I assume refers to the "visiting physician". With references to visiting physicians could not Section 35.17 (b)(c) and (d) be combined into a requirement that says get a license amendment when the designated RSO and the listing of authorized users, including visiting physicians, is changed.
7. Section 35.630. Is there agreement on the alternative of an intercomparison check between 1 1/2 and 2 1/2 yrs as a substitute for the present ≥ 2 yrs as a response to the AAPM petition? Are there reasons why a longer period of time would not be adequate based on NRC's experiences? Does the alternative address the broader problem of the need for comparison to a primary NBS standard? Perhaps a viable alternative is to rely solely on the calibration factor not changing by more than 2 percent without a mandated time for recalibration.
8. Page 35,(d), line 3. Substitute "radioactive" for "physical".
9. Subpart J. Is it really necessary to mandate what the training consists of, e.g. discussion groups on the subject areas with the number of hours in each? In 35.910(c), for example, what is lost by deleting all details beyond the first complete sentence that requires 200 hours of training. Will NRC reject as an authorized user a physician with only 24 hours of training in radiation protection? I suspect not.

I recognize the large effort devoted by a competent task group to draft a revision of Part 35 that provides adequate radiation protection and is meaningful in its implementation. To fully satisfy these goals NRC should make sure that needed changes are warranted and again reasons provided in the Statement of Considerations.



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