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PROPOSED RULE PR 40
(67FR 55175)

Secretary, U. S. Nuclear
Regulatory Commission
Washington, D. C. 20555-0001
Attn: Rulemakings and Adjudications Staff

Subject: Comments on 10 CFR Part 40 Proposed Rule Published August 28, 2002

Dear Sir:

The following comments are submitted for your consideration with respect to the subject rule.

1. Under the "Summary" it is stated that the "object of this proposed action is to ensure that the regulations regarding transfers of materials containing low concentrations of source material are adequate to protect public health and safety." This implies that (1) the current rules may be inadequate, and (2) the Commission has determined criteria by which the adequacy of the proposed rule has been or will be determined. Both of these implications should be explicitly addressed by the Commission in its proposal.

2. It appears that there exists the possibility of a specific licensee transferring quantities of source material (SM) to itself that, as a result of the licensee's processing, meet the criteria for exemption. The possibility of a specific licensee also being an exemptee should be explicitly treated in the "Supplementary Information".

3. The question of "disposal options" for exempt SM derived from licensees' specifically licensed material appears under "Supplementary Information" and is subsequently discussed at length. However, it appears that there exists the possibility of the transfer of this exempt SM for other purposes. The possible effect of the Proposed Rule on such transfers should be treated.

4. It is noted in "Supplementary Information" that the proposed rule is limited to SM derived from licensee's specifically licensed material. It is stated that "This is because of the more limited quantities of material handled under general license." However, the radiation doses related to such "more limited quantities" would seem to be the proper parameter for determination of the significance of these materials. This subject should be treated in the "Supplementary Information".

5. The term "essentially at the natural background levels of the surrounding area" is used under "Supplementary Information". However, the "area" to be considered is

not specified. Is this meant to apply to the area of origination? The final destination area; or some intermediate area involved in the process of transferring the material?

6. It is stated under "Supplementary Information" that the NRC "would" make certain determinations in considering the transfer of exempt SM. The use of the word "would", as opposed to the word "will" or "shall" implies that the NRC will make such determinations only if certain, unspecified, conditions (criteria) are fulfilled or met. These conditions or criteria should be explicitly delineated and the manner in which they will be applied described.

7. What are the criteria to be applied by the NRC in making the determinations regarding the transfers mentioned above in Comment 6? How will compliance with the criteria be determined? Will the public be provided notice via the Federal Register of each such determination and be provided with the opportunity to comment? Will the NRC be providing guidance regarding the application of its criteria by its staff? Will the NRC be providing similar guidance for affected members of the public? It appears that the essence of such guidance exists in the results of the "case-by-case decisions" by the NRC with respect to proposed transfers of exempt SM as mentioned under "Supplementary Information".

8. The "occupational exposure" of workers at unlicensed facilities is mentioned under "Supplementary Information". However, the nature and extent of such exposures, their effects, their control, and responsibility for their control apparently have not been determined. Will OSHA be responsible for these matters?

9. Criteria of 25 and 100 mrem/yr doses to a member of the public are mentioned under "Supplementary Information". However, the process and criteria for selection of such a member of the public are not described or provided. For example, the member of the public to be considered could be that member determined to be the most highly exposed; or the most highly exposed member of the cohort determined to be, collectively, the most highly exposed.

10. Will the collective dose(s) to the public and their impact, found to be acceptable as part of the approval process, be considered? It appears obvious that a disposal process or site approved for many transfers where each such transfer approval allows a dose to the public could present a greater risk to the general public than a single approval.

11. Notification of the Commission in those cases where the dose to the general public is estimated to fall between 25 mrem/yr and 100 mrem/yr is mentioned under "Supplementary Information". However, the nature of such notification is not described. Will such notifications be in the form of a formal document addressed to the Commission that will be available to the public via the Federal Register or the Public Document Room? Is it the intent that each such notification be followed by a formal response by the Commission to the staff in the nature of an "approval" document?

12. The proposed rule would apply only to source material resulting from specifically licensed processing. The risk to the public as well as those occupationally exposed is the same whether the material being used resulted from processing by a specific licensee or not. The basis for the Commission's apparent increased concern with respect to doses to "members of the public" from "processed" material meeting the criteria for exemption as opposed to other material that meets the same criteria should be included in the Commission's proposal. (Also, see Comment 13).

13. The mechanism, process, and procedure by which the doses estimated by the specific licensee requesting authority for transfers will be controlled should be described in the Commission's proposal.

    Exempt material from one source i.e., specifically licensed processors, will be subject to the proposed requirements whereas exempt material from other sources is not and will not be. If the proposed requirements are considered appropriate for the material from one source why not all sources?

    Perhaps material meeting the current criteria for exemption should not be exempt. If there is concern about the doses to the public from this material (not to mention the doses to those occupationally exposed to the material and its radiations) perhaps this material should not be released to the environment without some form of continuing control over its effects. (Perhaps this question should be considered in the context of the Commission's "Consumer Product Criteria").

14. A cost/benefit appraisal should be included in the Commission's proposal comparing the benefits (e.g., dose avoidance) associated with the implementation of the proposed rule with the costs to those who will be required to comply with the rule.

    Surely there should be a balance between the Commission's desire to ensure adequate protection of the public's health and safety and the costs of doing so. Estimated doses to the public are included in NUREG-1717. However, the doses (individual and collective) expected to be avoided as a result of the promulgation of the proposed rule are not mentioned in the Commission's proposal.

15. The existence of a criterion for determining the applicability of the proposed requirement for Commission approval for transfers of SM is implied by the phrase "essentially at the natural background levels of the surrounding area" which appears in the "Supplementary Information"? This criterion should be quantified so that both the Commission staff and the public may apply it in their evaluation processes.

16. Although the "Supplementary Information" seems to be concerned with disposal, the proposed rule applies to all licensee transfers of "exempt" material that is derived from specifically licensed material. It appears that transfers of such material that are currently made by licensees for purposes other than disposal will be subject to the proposed rule. This should be clarified and the basis provided for the apparent

determination by the Commission that all such transfers should be subject to the same requirements.

17. The assumption of less risk to the environment and the public for material handled under a specific license as opposed to the handling of material not subject to licensing as stated under "Finding of No Significant Environmental Impact" may not be supported by facts. Material handled under a specific license may be subject to greater regulatory control, but such control does not, necessarily, result in a lower risk. Since dose/risk data for exempt persons exposed to exempt materials and their radiations are not available it appears that such a statement can not be supported.

I hope that these comments will be helpful in the promulgation of an effective, enforceable and understandable rule.

Sincerely,

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