DOCKET NUMBER PROPOSED RULE PR-30,31,32 et al (50 FR 30616) (17)

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DOCKETED OCT 28 1985 DOCKETING & SERVICE BRANCH SECY-NRC

October 24, 1985

Secretary of the Commission
United States Nuclear Regulatory
  Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Dear Sir:

In response to the Federal Register Notice on the proposed revision of 10 CFR Part 35 "Medical Uses of Byproduct Material", the following comments are offered:

1. The concept of incorporating radiation safety requirements into one coherent document is fully supported.

2. Section 35.36 allows the licensee to make changes in the radiation safety program without regulatory review. This approach is not supported.

   Many licenses do not have the expertise needed to make an adequate safety review of changes to the radiation safety program, and under this proposal, the agency will no longer have the opportunity to circumvent ill advised changes. A field inspection is an inappropriate place to both review current practices and determine that procedural changes since licensure/last inspection are adequate to confirm compliance. In addition, unintentional degradation of a safety program could go undetected for years resulting in potential overexposures to workers and the public.

   The "minor" threshold includes many health and safety components that should be considered "major". Inclusion of many procedural changes in the "major" category, i.e.; leak test, surveys, changes in area of use effecting xenon-133 use, instrument calibration, etc. would make this approach more palatable.

   Alternatively, the commission should continue to require licensees to submit all radiation safety program changes for agency approval.

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Acknowledged by card OCT 31 1985

3. Misadministration reporting and record keeping requirements for diagnostic misadministrations is felt to be too stringent for the benefit gained. It is our experience that diagnostic misadministrations seem to be reported only by the more conscientious licensees and of the diagnostic misadministrations reported, very few seem to be generic and correctable. Enforcement action should not be taken for diagnostic misadministrations, however, the current level of regulatory control seems appropriate for therapeutic misadministrations.

4. Section 35.51 requires possession of a survey instrument with a scale reading up to 1000 milliroentgens, and that two readings on each scale be calibrated.

   It seems ludicrous to require a licensee who uses only unit doses (maximum 20 millicuries) to have a survey instrument with a scale reading up to 1000 milliroentgens. Given that this example licensee has this instrument, it appears that it could be calibrated at two minutely separated readings at the low end of each scale.

5. Section 35.90 requires storage of radioactive gases in a fume hood or "in a container with two barriers against release".

   Several individuals were asked for interpretation of what "two barriers" indicated and what would be adequate to confirm compliance. All had different answers. This statement should be clarified or expanded.

6. Section 35.200 allows the use of xenon-133 as a gas without specific license authorization.

   The use of virtually unlimited amounts of xenon-133 without agency review of ventilation/area of use changes is inappropriate and is not seen as a benefit for workers or the public.

7. Section 35.310 requires oral and written radiation safety instruction for all personnel "caring for" the patient.

   This requirement does not appear to include ancillary personnel such as housekeeping and security, etc.

8. Section 35.315 requires thyroid burden measurement within 3 days after administration of a therapeutic dosage of iodine-131.

Requiring thyroid burden measurements on an individual administering a millicurie iodine-131 capsule once or twice a year seems unduly restrictive.

9. Section 35.420 requires possession of a survey instrument with a full scale deflection of one Roentgen per hour: 35.620 requires possession of a survey instrument with a full scale deflection of not more than 1 milliRoentgen per hour by teletherapy licensees. Certainly this cannot be the intent.

   It appears that by regulation one could survey for a lost iodine-125 seed with a CDV 700 survey instrument with a questionable lower level detectability of 0.1 mR/hr, and a teletherapy licensee could perform surveys with an instrument having a maximum full scale deflection of 1 milliRoentgen.

10. Section 35.500 does not include the use of gadolinium-153 for bone mineral analysis. Is this an oversight or intentional?

Voluminous specific comments have been offered repeatedly over the past 3 years, many of which still apply, however, NRC staff does not concur with many of the comments therefore repetition does not seem productive.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Mary L. Blazek

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