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[redacted] RULE PR-19,20,30 et al.
(50FR 51992) (89)

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 920
541 Clinical Drive
Indianapolis, Indiana 46223
(317) 264-4797

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May 1, 1986

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attn: Docketing and Service Branch

Gentlemen:

Attached please find my comments of the Proposed Rule of 10 CFR 20. Should you have any questions regarding these comments or clarification is necessary, please do not hesitate to contact this office.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer

Attachments: 1

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PDR PR
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DS10
add: RE Alexander, 1130SS
J Becker, 9604 MNBB
Wm Olmstead, 9604 MNBB

Acknowledged by card ..... MAY 9 1986 ..... pd

COMMENTS TO PROPOSED RULE
FOR 10 CFR 20

20.201(c)(1) - This statement implies to this reviewer that once an individual has received 5 rems (0.05 Sv), he/she may receive an additional 1 rem (0.01 Sv) in each quarter which could conceivably add up to 9 rems for a given year. Is this a correct interpretation or is the additional dose equivalent above 5 rem not to exceed 1 rem for the remainder of the year?

20.204(h)(2) - Utilization of this section in conjunction with Appendix E leads to an over-estimation of the risk in some cases involving the "non-stochastic test". The formula in Appendix E does not correctly test the 50 rems upper limit. When adding the ratio of the external dose equivalent over the external dose equivalent limit to the ratio of the actual intake over the non-stochastic ALI, 50 rem should be utilized as the external dose equivalent limit. For example, assume an individual has an annual deep dose equivalent of 2 rems and inhales 45 uCis of I-125 during the year. I-125 has a non-stochastic ALI of 60 uCis and a stochastic ALI of 200 uCis.

Stochastic Test (Appendix E):

(2 rems/5 rems) + (45 uCis/200 uCis) = 0.625

Non-stochastic Test (Appendix E):

(2 rems/5 rems) + (45 uCis/60 uCis) = 1.15

Utilizing the suggestion above for the non-stochastic test:

(2 rems/50 rems) + (45 uCis/60 uCis) = 0.79

20.208 - It appears that discrimination problems (and possibly legal actions) may be created by this section. I would suggest adding another sub-section as follows: "(d) A pregnant woman who is occupationally exposed may elect to forego any or all specific additional restrictions (i.e. restrictions implemented as a direct result of the declared pregnancy) providing the following conditions are satisfied:

(1) The employee is provided current information (e.g. NRC Regulatory Guide 8.13) regarding the potential risks of radiation exposure to the embryo/fetus; and

(2) The employee verifies in writing that the aforementioned information has been provided, she has had the opportunity to ask questions related to pre-natal radiation exposure, and she elects to forego either all or specific restrictions imposed as a direct result of her pregnancy."

20.303 - The idea of a "reference level" could create legal

problems for licensees. A 100 mrem reference level implies a "standard" and may be construed to mean that levels above this are unacceptable which in turn implies negligence. Rather than invoke an arbitrary "reference level", each licensee should be required to provide information in their license application regarding estimated exposures to the general public from licensed activities and provide assurance that these exposures will be less than 500 mrem.

20.602(a)(2) - Teletherapy facilities are currently required (see 10 CFR 35.25) to be equipped with a radiation monitoring device to visually alert personnel of the presence of a radiation hazard. This section of the proposed rule would apparently require that all teletherapy facilities be retrofitted to include both a visual and audible alarm. Unless there is sufficient evidence to justify this retrofitting, it appears that teletherapy facilities should be excepted from this section with a possible reference to 10 CFR 35.25.

20.903(b) - This section eliminates the posting requirements for patients receiving diagnostic quantities of radioactive materials are located; however, there are some patients undergoing radiopharmaceutical therapy who have not traditionally had to be hospitalized. An example would be patients being treated for hyperthyroidism with < 30 mCis of I-131. In the past, the room of a patient in this category who is hospitalized for some other reason (i.e. not for radiation protection purposes) was typically not required to be posted. I would suggest that the first part of this section be reworded as follows: "(b) In lieu of the previous requirements, rooms or other areas in hospitals shall be posted in accordance with conditions as specified in the medical licensee's byproduct material license/license application."

20.905(b) - The preamble (section XXI. Procedures for Handling Packages) specifically states that the requirement to perform direct radiation measurements at package surfaces is deleted from the proposed rule; however, in the proposed rule it is stated that "Each licensee, upon receipt of a package containing radioactive material, shall monitor the external surfaces of the package for radioactive contamination and radiation levels, and . . ."

The preamble also states that the reason for deleting the surface radiation measurement is because "this requirement increases the occupational radiation exposure of the person performing the measurement and increases the licensee's cost without a corresponding increase in detection of faulty packages." The proposed rule does require that every package containing radioactive material be monitored for radioactive contamination. It can be argued that performing contamination surveys at the surface of every package could easily result in equivalent (if not greater) occupational radiation exposures to personnel performing such surveys. Costs in the form of time and materials would also be significant. Past experience at this

institution soundly illustrates that surveying every radioactive package for removable contamination would be a waste of time. Our current internal procedures (i.e. procedures in addition to the regulatory requirements) include a contamination survey of the inner-most container of all packages which contain greater than 1 mCi of radioactivity. Our results indicate that less than 1% of those surveys exhibited contamination levels of > or = 0.01 uCis and less than 5% exhibited any measureable contamination. Again, bear in mind that these results are from the inner-most container. In addition, over the past 5 years, we have never received a package which has been contaminated on the outside. Based on this information, the requirement to perform contamination surveys on every package is obviously unnecessary. Our suggestion would be to reinstate the exemptions which are included in the current regulations. We would suggest that a section be added as follows: "Any package containing radioactive material which shows evidence of damage and/or leakage shall be monitored for radioactive contamination and radiation levels."

The time requirement for performing package surveys (within 3 hours if received during normal working hours or within 3 hours from the beginning of the next working day) should only be required for packages which are not excepted per the current regulations.

This section should also state how long package receipt/survey records should be maintained.

20.1003(a)(1) - This deviates from the current regulations which include materials which are "soluble or dispersible" in water. Was this simply an inadvertant omission or is there some reason for prohibiting materials that are dispersible in water? A very specific example of how this could affect some licensees is in regard to animal carcasses containing small amounts of radioactivity. Some licensees have the capability of grinding up these animal carcasses thus rendering them dispersible and disposing them via the sanitary sewer.

The sewerage disposal monthly concentration levels specified in Table 3, Appendix B are obviously lower based upon the fact that they are related to the 0.5 rem non-occupational limit. Even though this reduction may not have a significant impact on licensees, is there any evidence that this reduction is warranted? The rationale that most licensees would not be adversely affected is not in itself a valid reason to reduce a given regulatory limit. If there is hard evidence that contamination has been detected in wells which are located downstream from a sewerage treatment facility, then reduction of the current sewerage limits should be considered providing that the source of such a problem can be shown to have been in compliance with the current limits.

20.1005 - Why not include H-3 and C-14 dry solid waste of < 0.05 uCis/gm in this category, also? The benefit from such an

exemption would be tremendously beneficial to research/academic licensees and would also extend the lifetime of present and future radwaste disposal sites. The increased amount of H-3 and C-14 which would be introduced into the environment would most likely be insignificant.

20.1104(b) - This section appears to be unclear as to how the "period of exposure" is defined. Do the results from each monitoring period need to be listed (e.g. monthly or quarterly) or does this section allow the information to be collectively summarized during the period of employment? Realistically, with the exception of the current calendar year, one is only interested in the lifetime occupational radiation dose to ascertain restrictions for future "planned special exposures".

20.1106(d)(2)(ii) - Many licensees typically utilize the dosimetry report provided by the personnel monitoring vendor to meet the NRC-5 recordkeeping requirement. This section implies that dose equivalents resulting from the intake of radioactive material are required to be recorded on the same form. This could involve maintaining routine bioassay records and then transcribing them onto the NRC-5 (or equivalent) form. It is understood that each licensee must evaluate and record collectively both internal and external exposures to verify compliance with 20.202; however; it is the opinion of this reviewer that requiring the recording of the information on the same form is too specific.

20.1201(a)(ii) - This section appears to be overly restrictive. For example, ten times the Appendix C quantity for I-125 would be 10 uCis. I-125 may be purchased in 10 uCi amounts (with possession of up to 200 uCis) as a generally licensed quantity under 10 CFR 31.11; however, the General Licensee is exempt from the requirements in 10 CFR 20. A General Licensee could conceivably lose (or have stolen) up to 200 uCis of I-125 and would not be required to file a report. I would suggest that this section be changed to one hundred times the Appendix C quantity. I do feel that it is important that licensees investigate all losses (or thefts) of byproduct material including those which are less than 100 times the Appendix C quantity; therefore, I would suggest that in addition to the aforementioned change, the following section be added as 20.1201(f): "(f) In the event of theft or loss of byproduct material which is less than 100 times the Appendix C quantity, the licensee shall investigate said theft or loss. Documentation of the results of the investigation shall be maintained for future inspection and shall include the same information specified in 20.1201(b)(1)."

20.1205 - The comments regarding "reference levels" (20.303) are also related to this section. This section is essentially requiring a report to the NRC when no real limit has been exceeded. At most, the licensee should have to investigate exposures exceeding a reference level which could be established

as a license condition. If that investigation indicates that the 500 mrem limit has been exceeded, then a report would be required. Results of such investigations would be maintained for review during routine inspections.

GENERAL COMMENTS

It is my understanding that the main benefit of this "Proposed Rule" is to update the regulations in such a way as to make them compatible with the recommendations of the ICRP and to also begin the transition to the S.I. system of units. I feel that it is the responsibility of all individuals associated with the implementation of radiation safety programs to periodically review and update policies and procedures to reflect the most currently accepted radiation safety practices. With this philosophy in mind, I support a revision of 10 CFR 20.

I believe most Health Physicists would agree that the current regulations do provide a more than adequate margin of safety for individuals exposed occupationally and those individuals exposed as a result of the use of byproduct material. Many of the specific comments on the previous pages relate to the fact that even though many of the current regulations are totally acceptable, the authors of the proposed rule have introduced new requirements such as "reference levels" which are apparently meant to make "safe" levels "safer".