



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

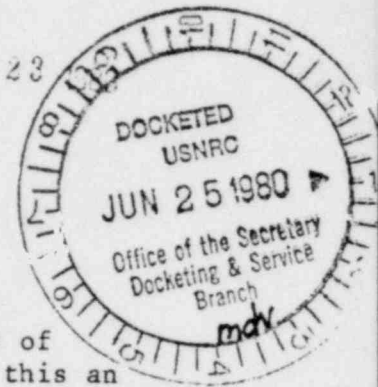
PROJECT NUMBER

PROPOSED RULE

PR-20 (66)
(45 FR 18023)

JUN 23

Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch



Dear Sir:

As stated in your Advance Notice of Proposed Rulemaking (ANPRM) of March 20, 1980 (45 FR 18023), a combination of events has made this an opportune time to consider the total revision of the radiation protection regulations in 10 CFR 20. The passage of over 20 years since adoption should make a reassessment essential. During this time, the attitude of the country with regard to safety and occupational protection has changed significantly. Further during this time period, the use of radioactive materials has also increased dramatically. Because of these aspects, we fully support the need for a reassessment of the radiation protection regulations and their revision as is appropriate.

However, at the same time, there are many constraints as to why such a major reassessment and revision must proceed slowly and deliberately with appropriate input from many segments. These aspects include:

(1) the BEIR-III report, by the National Academy of Sciences, which will provide a basic foundation for future radiation protection standards is not yet available.

(2) the NCRP has scientific committees which are actively considering revisions to the basic radiation protection and internal emitter recommendations.

(3) as noted in the ANPRM (45 FR 18023), the EPA is developing Federal guidance for occupational radiation protection, which has not yet reached the proposal stage.

(4) the new recommendations of the ICRP have been published in Reports 26 and 30 but are not well understood nor accepted in the U.S.

(5) the Radiation Policy Council (RPC) has convened a Task Force to examine the existing Federal approaches to occupational exposure guidance and regulations and develop options to solve existing problems.

(6) there is a second RPC Task Force on low-level radioactive waste, as well as considerable unresolved issues regarding radioactive waste that impact on 10 CFR 20.

(7) the international community as evidenced by the ICRP reports has adopted the International System of Units (SI) for radiation quantities and units; the use of these quantities in the U.S. will require considerable educational efforts.

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Thus, it is obvious that NRC efforts to revise 10 CFR 20 must proceed in concert with these activities if the objectives of the Radiation Policy Council are to be achieved and the revision of 10 CFR 20 is not to be out-of-date upon adoption.

Of the numerous technical and policy issues being considered by the efforts noted above, we would like to emphasize the impact of 10 CFR 20 on radiation protection in the U.S. Because of the dominance of the Atomic Energy program, the provisions of 10 CFR 20 have been recognized as the U.S. standard and have been incorporated, almost verbatim, into the regulations of OSHA and the Suggested State Regulations for Control of Radiation (SSRCR). While such incorporation has facilitated the regulatory development and increased consistency, it has also posed problems because of the different authority and priorities of OSHA and the State agencies. Since the development of the first edition of the SSRCR in 1962, the requirements of NRC that the SSRCR be the same as 10 CFR 20 have frequently resulted in conflicts and prevented desired changes and improvements in the SSRCR for its effective use in the control of all sources of ionizing radiation.

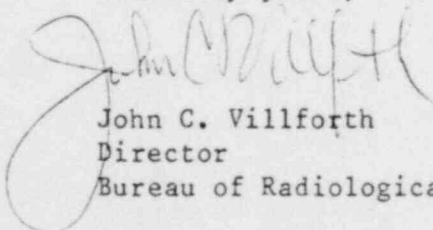
Further, the different historical development of radiation protection in medicine does raise a broad question as to the applicability of 10 CFR 20 for the diagnostic x-ray user. In diagnostic x ray, protection is largely achieved under recommendations of NCRP (and regulations of FDA) through the design of equipment and facilities with a minimum of user regulatory provisions. This approach has recognized the state-of-art technology, the need for protection of patient, worker and the public, and many aspects of the ALARA philosophy. Thus it is not at all clear to what extent the provisions of 10 CFR 20 and its ALARA demands should be imposed on the users of diagnostic x ray.

Because of the above considerations and especially the impact of 10 CFR 20 on the regulations of other State and Federal agencies, it appears imperative that an interagency approach be adopted to revise the radiation protection regulations. This should be done under the aegis of the Radiation Policy Council and include State representation from the Conference of Radiation Control Program Directors.

Members of our staff which reviewed 45 FR 18023 also made various specific comments which are briefly summarized in the enclosure.

We appreciate this opportunity to comment and will be most happy to designate a staff member to provide liaison on the revision of the radiation protection regulations.

Sincerely yours,



John C. Villforth
Director
Bureau of Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
Rockville, Maryland 20857

June 13, 1980

Brief Specific Comments on
Standards for Protection Against Radiation, 10 CFR 20; Advance
Notice of Proposed Rulemaking, 45 FR 18023, March 20, 1980

General Aspects

1. The noting of "women in general" and "fertile women" as susceptible groups may be a rather poor choice of terminology. Apparently, the intent is with regard to the protection of the embryo/fetus and not that the fertile woman is more susceptible. If, however, the concern is for genetic risks, then one must also consider the "fertile male."
2. Reference is made to protection of the population in general. However, perhaps the future dose commitment to world population should be considered for large releases, e.g., from uranium mill tailings and carbon 14, and long lived radionuclides.
3. Continuing education should be required of all occupationally exposed workers. Course content should include information on biological effects of radiation and the long-term risks of their own radiation exposure (Note: Libassi Report Summary, pages 82-83). Hopefully, some of this perspective would spill over into the community at large.
4. The revision should consider the problem of multiple facilities discharging effluent in the same area.
5. The expansion of record keeping requirements of item e.(1) of the Notice could be the basis for inclusion of medical exposure records. This issue must be examined carefully with regard to the real value of such records.
6. The numerical limits for ALARA, if adopted, should be based on solid scientific and technical justification which shows practicality and an actual benefit.
7. If a dose-response function other than linear-no-threshold is accepted, the collective population dose concept may have little meaning.
8. In view of the fact that our society is resource-limited, exposure and maximum concentration limits should be set, taking into account economic and social factors.
9. In the revision of Part 20, it is suggested that all definitions be included in one section (e.g., Sec. 20.3) and not spread throughout several

sections as is currently done (e.g., Sec. 20.4, 20.5, 20.201, 20.202, and 20.203). It is preferable for all definitions to be included alphabetically. Definitions can also be kept in alphabetical form when amendments are made by referring to them throughout the regulations by section only.

10. Improvement of Part 20 by presenting the underlying protection principles adopted by NRC in terms understandable to laymen (a.(1) on page 18025 of FEDERAL REGISTER, Vol. 45, No. 56) is an excellent goal. However, it will be made more difficult by the adoption of the International System of Units (f.(1) on page 18025 of FR, Vol. 45, No. 56). The use of S.I. units should be phased in gradually over a period of years. A special education program may be necessary to make the revised standards understandable to the laymen.

11. It is suggested that the dose limits for occasionally exposed individuals shown in Table 6 of NCRP Report No. 39 be included in the revision of Part 20.

Specific Comments

1. 10 CFR 20.3(a)(12): In the definition of "Radiation," change "alpha rays" and "beta rays" to "alpha particles" and "beta particles" and add at the end of the definition "or any nonionizing radiation."
2. 10 CFR 20.3(a)(13): In this definition, it is suggested that the following words be included between "Radioactive material" and "includes:" "means any material (solid, liquid, or gas) which emits radiation spontaneously and."
3. It is suggested that the title to Section 20.101 be changed to "Radiation Dose to Individuals in Restricted Areas" since the terminology "dose" and "rems" is used throughout Section 20.101.
4. It is suggested that the title to Section 20.104 be changed from "Exposure of Minors" to "Dose to Minors" since reference is made in paragraph (a) of Section 20.104 to "the limits specified in the table in paragraph (a) of Section 20.101" and the unit, "rems", for the quantity, dose equivalent, is used for expressing the limits in the table of 20.101(a). It is also suggested that dose be used, as appropriate, in the text of Section 20.104.
5. Add a subparagraph (3) to paragraph (b) of Section 20.105 to limit radiation levels such that individuals in unrestricted areas could not receive a dose to the whole body in excess of 0.5 rem in any one year. As presently written, 20.105(b)(2) would allow "radiation levels which, if an individual were continuously present in the (unrestricted) area could result in his receiving a dose... of 100 millirems in any seven consecutive days." It is also suggested that "and" be used in place of "or" between the final two subparagraphs of 10 CFR 20.105(b) so that it is clear that the licensee must meet the requirements of all subparagraphs and is not free to choose which one of the subparagraphs to comply with. To allow a choice of which subparagraph to comply with could result in a dose several times greater than desired.

6. In 10 CFR 20.204(a), it is suggested that "radiation level" be replaced with "dose rate" or "dose equivalent rate" in order to be consistent with millirem, the special radiation unit for dose equivalent, used in the same sentence.
7. Comments received on the SSR/R have indicated that the time requirement given for the wipe testing and survey of incoming shipments of radioactive material in 20.205(b)(1) may be too restrictive. The 18-hour requirement for shipments received during off-duty time would require special personnel call arrangements for weekend receipts. Further, the specifications as regards the types of packages to be wipe tested and/or surveyed are confusing and users may misinterpret the requirements and fail to take proper action (e.g., due to differences in exemption statements, some packages - such as 150 mCi of Tc-99m - will require wipe testing, but need not be surveyed). Consider the following suggestion: (a) Relax the time limit for packages received during off-duty hours to require wipe testing and survey within 3 hours of the next workday. (b) Rewrite the requirements to call for both wipe test and survey of all packages as specified in 20.205(b)(1), but with the deletion of the exemption condition in 20.205(b)(1)(v). This would mean that almost every shipment of radioactive material to a nuclear medicine laboratory would require both procedures, a practice that is in the best interest of radiation safety.
8. In the title of Section 20.303, it is suggested that the word "sewerage" be replaced with "sewage" to read as follows: "Disposal by release into sanitary sewage systems." "Sewerage" is redundant as used, and changing to "sewage" would eliminate this redundancy.
9. It is suggested that Section 20.304 be changed to read substantially the same as Section 20.305 - i.e., the disposal of radioactive material by burial in soil be allowed only as specifically approved by the Commission.
10. In Section 20.402, it is noted that the phrase "... any theft or loss of licensed material in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas" is rather indefinite and should be quantified as to what constitutes a "substantial hazard."