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Radionuclides

February 20, 2001

Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

65 FR 70742
11/27/00
(5)

**RE: Draft NUREG-1736 – Consolidated Guidance: Standards for Protection
Against Radiation in 10 CFR Part 20**

Gentlemen:

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications.

CORAR appreciates the attempt NRC has made to provide a document that provides consolidated for licensee use. This type of guidance contained in a single reference can be potentially very valuable to licensees with limited resources who are confronted with radiation protection regulations that are complex and prescriptive, and at times unclear and ambiguous.

GENERAL COMMENTS

1. While it is the objective of NRC to provide a single, comprehensive source of guidance concerning 10 CFR 20 by combining the multitude of guidance information previously available in a variety of formats, the draft has not effectively achieved this purpose. The draft consolidated guidance could be vastly improved if it integrated the text of the numerous guidance references (e.g. Q&As, HPPOS and circulars), wherever possible, into the text of the discussion of the consolidated guidance. The volume of text in the Q&A documents is usually very brief and could easily be inserted if not condensed into the relevant discussion

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C. BROWN (CXB)

sections of the NUREG. This would provide the opportunity to edit and update the guidance as needed. Limiting the list of references to more lengthy and detailed guidance that could not be practically integrated such as other NUREGS or Regulatory Guides would result in a more comprehensive guidance document that would serve as the definitive handbook to Part 20 compliance.

An alternative to the production of a printed document would be an electronic version on the NRC web site that could still include the lists of implementing guidance where links to individual documents, also available on the web site, would be provided.

2. In some parts of the NUREG, the terms “dose” and “exposure” are used indiscriminately in discussions such as those regarding surveys and monitoring, monitoring of occupational dose, determination of prior occupational dose, and records of individual monitoring results. This sometimes occurs in the same sentence (see the discussion on page 3-168). This can be confusing and should, at least for the sake of technical consistency, be addressed throughout the guidance document.
3. There is a similar problem with use of the terms radioactive “waste” and “materials” as they are used in discussion regarding records of waste disposal, disposal of specific wastes, transfer for disposal and manifests, method for obtaining approval of proposed disposal procedures and the general requirements in 3.20.2001. A more fundamental problem is the fact that nowhere in this NUREG is there a definition of “waste” nor is there any guidance that can help licensees determine the distinction between material to be transferred for potential reuse or recycling from those materials that are transferred directly to a disposal site.

Appendix G contains detailed guidance on the content and format of manifests that includes definitions for waste collector, waste description, waste generator and waste processor. However, there is no definition for waste itself. This leaves any guidance in this NUREG relevant to disposal of radioactive material incomplete and open to subjective interpretation. This definition is lacking not only in this guidance but also everywhere else in NRC regulation and guidance documentation. We strongly recommend that this need be addressed in this comprehensive guidance document.

SPECIFIC COMMENTS

1. 3.20.1002 Scope

Guidance in this section should address the situation where radioactive material could be either by-product material or NARM or both.

2. 3.20.1003 Definitions

The discussion on page 3-17 states that “ ‘Reference Man,’ also called ‘Standard Man,’ is a set of standardized physical parameters...”. This is incorrect. Reference Man has replaced Standard Man and it was the physical parameters of Reference Man that were used in ICRP 26 and 30 dose modeling as the basis of 10 CFR 20 standards for radiation protection. The reference to Standard Man should be removed, as it is obsolete.

The discussion on page 3-19 concerning stochastic effects states that “according to the linear-no-threshold hypothesis, the risks resulting from doses below the regulatory limit for the effective dose equivalent are not zero.” It would be appropriate to state after this that the linear-no-threshold model (rather than hypothesis), considered conservative by most experts in the field, is applied as a prudent measure even though it may in fact overstate risk. The effects predicted by this model have never been observed in populations exposed to levels of radiation within occupational limits.

The discussion at the top of page 3-21 includes a statement that deterministic effects resulting from acute exposures are commonly known as “radiation sickness”. This statement is incorrect and misleading. There are deterministic effects resulting from acute doses other than “radiation sickness” which include erythema, induction of cataracts, impairment of fertility and tissue degeneration from fractional dose.

The statement that “the rem is defined using the quality factor for cancer as the end point of interest” is confusing because it implies that there is just one quality factor when in fact the quality factor is dependent on the type of radiation, dose-rate and the tissue exposed.

Also the shallow-dose equivalent (H_s), when applied to small areas (i.e. $<30 \text{ cm}^2$) of skin exposed due to local contamination or hot particles, is designed to protect against potential deterministic effects which have thresholds that are factors of 30 or 100 or more above the U.S. NRC limit. In this case, both the limit and the unit are inappropriate and need to be changed and discussed.

3. 3.20.1201 Occupational Dose Limits for Adults

In the discussion on page 3-38, it says, “the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases.” We disagree with this statement. While the “scientific community” generally accepts that exposures to ionizing radiation should be reduced to levels as low as reasonably achievable, many among this group believe that there is no likelihood of increased risk from stochastic effects below a certain threshold. This threshold may be above the occupational limits as the effects, predicted by the model projecting an increase in effects as the dose increases, have never been observed in populations exposed at these levels.

On page 3-40, the discussion concerning the relation between doses recorded on the abdomen and the back should consider the guidance in NCRP Report Number 122.

4. 3.20.1202 Compliance with Requirements for Summation of External and Internal Doses

The guidance statement on page 3-43 should address the situation where an individual receives a DDE close to 5.0 rem and an intake $< 10\%$ which is not required to be measured but may be greater than zero to the extent that the TEDE exceeds 5.0 rem.

5. 3.20.1301 Dose Limits for Individual Members of the Public

The list of public doses not subject to this regulation on page 3-66 should include those that come as a result from exposure to radioactive materials legally in transport and members of the public who provide support to a nuclear medicine patient.

The guidance statement on page 3-70 should address the use of passive dosimeters at the perimeter of a site and other methods to demonstrate compliance with the external dose limit of 2 mrem in an hour if results of these devices indicate the total annual dose from external exposure and from airborne releases do not exceed 100 mrem.

6. 3.20.1500 Subpart F – Surveys and Monitoring

Although the meaning of the “survey” is clarified on page 3-19, it would be helpful to also include in the guidance statement on page 3-14 the fact that the performance of surveys in the field with a survey instrument without assess the resulting data would not be considered having satisfied the requirement to perform an adequate survey. The important distinction made on 3-19 might otherwise be missed if one consults the guidance in 3.20.1500.

7. 3.20.1801 Security of Stored Material

The guidance statement on page 3-133 states that “only active measures” would be sufficient to demonstrate compliance with the need to secure material from unauthorized materials. The implication is that material needs to be stored under lock and key. This guidance needs to take into account situations, such as those at manufacturers and distributors of radiopharmaceuticals and life science radiochemicals, where unit containers may be stored on shelves or bins in areas where trained employees can access them, keeping in mind that the access to the facility or the storage area would have positive restrictions to unauthorized access.

During U.S. NRC workshops on the topic of securing licensed material the general consensus was that small quantities < 100 ALI do not need to be secured behind locked doors, but can be treated like non-radioactive hazardous chemicals commonly

found in research laboratories.

8. 3.20.1902 Posting Requirements

Guidance in this part should address situations where there may be a large number of labeled containers in an enclosure, such as a refrigerator or an autoclave and how the requirements in 20.1905 relate to those for posting these enclosures or areas where they are located. The concern that needs to be considered is the avoidance of excessive posting and labeling.

9. 3.20.1904 Labeling Containers

On page 3-141 the requirement to include "radiation levels" on the label is redundant because licensees should be required to have instruments that can directly measure radiation fields in the vicinity of a container. This prescriptive provision could also be counter productive, particularly for short lived radioactive materials, because the routine measuring and labeling of the vial will incur more dose than is likely to be avoided. Also warning of significant radiation fields are adequately provided by the requirement to post radiation areas.

The discussion at the bottom of page 3-141 implies that it is necessary to accurately determine the quantity of radioactive material and radiation fields. However, only order of magnitude assessments in containers are needed to provide adequate protection.

Some additional guidance on page 3-142 would be helpful on appropriate methods for defacing labels on containers prior to disposal.

10. 3.20.1906 Procedures for Receiving and Opening Packages

The paragraph on the bottom of page 3-147 explains how a limit of 22,000 dpm would apply to the wipe of an area on a package of 100cm². This discussion should include a statement that this would apply to a beta, gamma, or low toxicity alpha emitting contaminant. In addition, in practice the area will be greater than 100cm² if all sides of a package are wiped. This should be considered in the guidance.

A common problem is that licensees receiving packages will use inappropriate contamination monitoring instruments to measure the near surface radiation levels and TI. U.S. NRC should recommend the use of an energy compensated side window GM detector, with the window closed, or equivalent instruments.

11. 3.20.2001 General Requirements

If the intent of U.S. NRC regulations is to limit decay in storage to 5 years it would greatly simplify compliance if the NRC specified this or a 180 day half life as a limit

for decay in storage. The U.S. NRC and Agreement State regulator could still impose more restrictive license conditions if appropriate.

The U.S. NRC definition of “effluent” to exclude releases to the sanitary sewer is bizarre and confusing. We would recommend that the term is defined as in common usage to include sewerage released (via the sewer) to the environment.

12. 3.20.2003 Disposal by Release into Sanitary Sewerage

The guidance statement on page 3-155 should explain the proper handling of excreta from employees at licensed facilities who, as patients, have also been administered licensed material. In other words, should this material be accounted for in liquid releases when there are other examples in the NUREG where material that is otherwise unregulated becomes regulated at licensed facilities?

13. 3.20.2103 Records of Surveys

The second sentence in the discussion section on page 3-165 needs to be reworded as, in its current condition, does not read well and its meaning is unclear.

14. Appendix B

The introduction on page B-1 contains the statement, “...an activity median aerodynamic diameter (AMAD) of 1 *m*...”. The AMAD should be 1 *micron*.

On page B-9 the statement that HT and T₂ oxidize in air and in the body to HTO is misleading. In practice the conversion is very slow and gas is only retained long enough for a fraction of a percent to convert to HTO. There should be a separate category for HT and T₂ gas with ALI and DAC that are about four orders of magnitude higher than for HTO. Also airborne effluent concentration limit for HT and T₂ gas should be at least 100 times higher than for HTO in a rural environment where bacterial conversion in soil is the critical pathway and up to four orders of magnitude higher in an urban environment where there is no soil.

This technical error has been reported to the U.S. NRC on numerous occasions without effect.

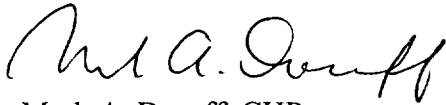
Also the tables concerning ¹⁴C compounds should include other low risk radiochemicals in the categories containing carbon monoxide and carbon dioxide such as methyl iodide, methane, nitromethane and ethane etc.

15. Appendix G

We strongly recommend that a definition of radioactive waste be provided in this section.

CORAR appreciates the need for comprehensive and consolidated compliance guidance that this NUREG intends to fulfill. These comments are provided for consideration of ways in which the guidance can be improved. Please contact us if there should be any questions or if any additional information concerning these comments is needed.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark A. Doruff". The signature is fluid and cursive, with the first name "Mark" and last name "Doruff" clearly distinguishable.

Mark A. Doruff, CHP
Council on Radionuclides and Radiopharmaceuticals