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(4)

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

Re: NUREG-1736, Consolidated Guidance About Materials Licenses, Consolidated Guidance: Standards for Protection Against Radiation in 10 CFR Part 20.

Dear Sir or Madam:

I am writing to comment on NUREG-1736, Consolidated Guidance About Materials Licenses, Consolidated Guidance: Standards for Protection Against Radiation in 10 CFR Part 20.

Overall comments:

1. Thank you, I believe this will be a very useful resource and I appreciate the amount of work that went into its preparation. I also look forward to a guidance document on Part 31. It would be able to describe the requirements for General Licensees in planner language.
2. This guide must be written for the Health Physics professional as well as the part time person who was assigned the position of Radiation Safety Officer as part of his other duties. The people in the second group need more help than in the first group, I hope. Therefore redundancy and clarity should be encouraged.

§20.1001 Purpose

The discussion states "The annual dose limits apply to all doses received by the worker, at NRC and . ." This discussion should explicitly state that doses from {non-medical} x-ray exposures are also included as well as from Agreement State regulated radioactive material.

§20.1002 Scope

The discussion states what materials are covered, but should also state that the dose from all radioactive materials and X-rays must be considered.

§20.1003 Definitions

Distinguishable from background. Please add a discussion to this definition that leads the not full-

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time health physicist to a reference for acceptable methods for calculating Minimum Detectable Activity/Concentration (MDA). There is considerable discussion in the literature concerning this concept, and the answer is not readily obvious to many people who work in the health physics field, much less others. MARSSIM is a potential reference. Another that can easily be found is in *Minimum Detectable Activity Regarding Background Counting* by Daniel J. Strom and Paul S. Stansbury in Health Physics September 1992, Volume 63, no. 3 pages 360-361. The formulas for determining when a count is greater than background are clearer in this article than any others I have found. Adding this information will not be difficult, or controversial, and will be a aid to the reader. Another good reference to cite would be NUREG-1505.

§20.1005 Units of Measure

Include in discussion that the SI units are required on manifests, but soon the curie may not be allowed on manifests.

§20.1101 Radiation Protection Programs

(C) annual review of the program

The guidance in this section adds a requirement that is not included in the regulations. Specifically "should be performed by qualified persons **who do not have direct responsibility over the program**" {emphasis added}. Although I agree that this may be the best way to perform audits, this IS NOT included in the regulation. Although the guidance says "should" and the rule says "shall review annually", an obvious interpretation of the reading of this guidance document implies a requirement for an outside audit. This does not appear to have been part of the original intention of the requirement for the audit. The purpose of this document is to provide guidance, not to add additional requirements. The phrase "commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part" is clear and could be applied to the extent of the audit as well as to the extent of the Radiation Protection Program.

§20.1208 Dose to an Embryo/Fetus

Since NUREG-1736 will be used for many purposes, it should perhaps include information that goes beyond Part 20. At a Health Physics Meeting some years ago, a NRC staff member presented a talk on this particular subject (Cynthia Jones, I think). The speaker said that the dose estimates for a fetus and the declaration of pregnancy should NOT be included in any future report of the woman's exposure that is passed onto her next employer. This information should, in effect, be included the baby's exposure history, not in the mothers. Since this is the baby's exposure rather than the woman's exposure this seems rather obvious, until you think how dosimetry information would be filed. If my memory is correct, include this information in the Consolidated Guidance. Including this information may save problems for licensees in the future.

§20.1801 Security of Stored Material and
§20.1802 Control of Material Not in Storage

The sections presenting guidance on these parts did not reference:

"Enforcement Guidance Memorandum Categorizing the Severity Level of Violations Involving Security and Control of Radioactive Material," which was issued on April 24, 1998.

or

Enforcement Manual, NUREG/BR-0195, Rev. 2, (August 1998). Section 8.6.3, "Severity Level of Violations Involving Security and Control of Licensed Material,"

These documents specifically discuss these sections.

The Draft Consolidated Guidance gives the erroneous impression that the NRC is as concerned with the loss of an LSC vial of tritium as with the loss of a used fuel bundle. Although the Guidance Statement as written is true, failing to at least to reference the guidance listed above does not give the full story. Please discuss the graded enforcement and reference the two documents listed above. This information will provide licensees with research facilities to establish similar graded enforcement policies which is the NRC's intent.

§20.1904 Labeling Containers

The discussion states "The removal or defacing of labels **ON** *{emphasis added}* empty containers is of particular importance." NRC Information Notice 97-03 states that the hazard of opening containers to deface containers is probably not worth the risk. "Additionally, these actions would place licensees in violation of the Occupational Safety and Health Administration regulation 29 CFR 1910.1030(d)(1), which requires precautions to prevent contact with blood or other potentially infectious materials, including recommendations not to manipulate used syringes/needles by hand."

Although this information notice is referenced, I think the discussion in this Guidance Document should more explicitly discuss this issue.

§20.2003 Disposal by Release into Sanitary Sewerage

(a)(1) The material is readily soluble (or is readily dispersible biological material) in water

The NRC should make clear in this section that in liquid chemical mixtures of non-radioactive and radioactive labeled molecules, only the molecules with radioactive elements attached need to be readily soluble.

Again for biological research institutions, radiolabeled RNA and DNA are biological material and therefore do not have to be listed as readily soluble.

§20.2003 Disposal by Release into Sanitary Sewerage

(d) Excreta from individuals undergoing medical . . . . are not subject to these limitations.

I believe that excreta from animals which have undergone medical diagnosis or therapy are also exempt from regulation. If I am correct, this fact should also be included in the Guidance.

§20.2005 Disposal of Specific Wastes

The discussion should include a caution the reader that disposal of less than 50 nCi/gram is exempt, but the exemption for shipping requirements in §71.10 only applies at less than 2 nCi/gram.

The discussion should also indicate that this exemption does not apply to animal waste or bedding (I think), and it may not be averaged over multiple animals (I think). Please clarify.

§20.2101 General Provisions

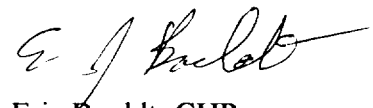
The discussion of this section in the Draft Consolidated Guidance says that "SI or SI and special units, must be used on shipping manifests". A notice of proposed rulemaking July 17, 2000 (page 44359) on changing 10CFR71 into compatibility with ST-1 suggested that special units would not be allowed on shipping papers. Although the Guidance is currently correct, a caution in this section would be appropriate.

§20.2104 Determination of Prior Occupational Dose

Please be more emphatic that no prior history is required for individuals who are not likely to receive 500 mrem per year of exposure. At the university where I work, we frequently receive exposure history requests from locations where the likelihood of receiving 50 mrem is minimal.

Thank you for considering these comments.

Sincerely,



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