DOCKET NUMBER
PROPOSED RULE PR-Misc. Notice
(Reg. Guide)

The University of Texas Medical Branch at Galveston

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Medical School
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing

Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals at Galveston

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September 18, 1985

NUCLEAR MEDICINE DIVISION
RADIOLOGY DEPARTMENT
(409) 761-2921

Secretary of the Commission
US Nuclear Regulatory Commission
Attn: Docketing and Service Branch
Washington, DC 20555

Attached are comments on "Proposed Revision 2 to Regulatory Guide 10.8", Task FC415-4, published August 1985. These comments are mine as an individual and do not necessarily represent the views of organizations in which I hold positions of responsibility.

Anthony R Benedetto

Anthony R. Benedetto, Ph.D.

ARB/skb

Attachment: Comments on Task FC415-4

DS09
Add: Ed Hill, 113055

1/1

Acknowledged by card SEP 24 1985

page 2, para 1.3: Since this is a medical Regulatory Guide, it would seem reasonable to also mention guide 8.18.

page 7: This section has the same problems as 10CFR35.15(e), i.e., Agreement States should be identified so that an applicant doesn't waste time filing an NRC application, only to find out he didn't need to.

page 9, Item 3, para 2: Much of this material doesn't belong here, but rather is more appropriate in Item 10 and others.

page 21, Section 4: The qualified therapy calibration expert (QTCE) should also be mentioned here.

page A-1, para 3, line 2: Should read "....certification, etc; site-specific training must be provided to all workers."

page B-1, para 1, line 1: How do I (or NRC) know if my contractor follows this guidance? Perhaps NRC should require applicant to have a letter from contractor on file stating this.

page B-1, Model Procedure 3: What sources does NRC consider acceptable for calibrating meters used for I-125, Xe-133, Tc-99m, and I-131? No long-lived isotopic sources are commercially available at these low energies.

page B-2, 8c: Can be combined with 8b.

page B-4, para 12c(1-3): Why is all of this required if the meter falls within ±10%?

page C-1, Procedure 1b: Quarterly linearity checks of dose calibrators are not technologically justifiable. Annually is sufficiently frequent.

page D-1, Program (1): Define "promptly". I suggest within one week after receipt.

page D-1, Program (3): This is only needed for people working with large activities on a routine and frequent basis.

page D-1, Program (4): I've been looking at these dosimetry results for 12 years and can't recall anybody ever getting a dose large enough to justify all of this expense and hassle.

page E-2, para 1b: Flood images should be performed with collimator removed. Floods with collimator mounted require high activity sheet sources or high activity point sources many meters away from the camera; counting times are too long. People won't put this much effort into it.

page F-2, para 2: Add reference to QTCE.

page H-2, para 4a: Many people don't know how to determine whether their detector can measure 0.005 uCi. Suggest you add an example of this calculation.

page H-3, para 4d: Should not be necessary to calculate microcuries if net sample count rate is within three standard deviations of the mean background count rate. Should be OK to enter "B" or "bkgd" or something similar.

page I-1, Rule 3: Suggest you change wording to read: "...area with a sensitive survey meter". A Geiger counter is adequate for this purpose. A gamma camera is not a good choice since it can't be operated in integral mode and thus each window would have to be checked. The collimator would have to be removed if a camera were used.

page K-1: This whole procedure is too slow and totally impractical for radiopharmaceuticals because of the perishability of the drugs. In almost every instance an RSO would delegate total purchase authority for radiopharmaceuticals to the Nuclear Medicine Clinic, completely bypassing RSO.

page L-2, para 2c: Define "usual". Might be better to either extract the pertinent sections of 10CFR35.205(b-c) or at least refer to them.

page M-5, Procedure 6: The use of the 0.07 action level protects you only to six hours. I recommend changing this to require calculation of the clock time at which the 0.15 level would be reached.

page N-2, para 1d: Add: "A continuously operating laboratory monitor should be permanently located close to these areas to alert other workers when sources are being removed from or replaced in the safe and to alert workers to misplaced sources."

page O-1, para 2: There are still leaks around mouthpieces and masks, and occasionally patients rip masks and mouthpieces out.

page O-3, para 1c: A 20% loss rate seems excessively conservative.

pages P-1 and Q-1, Procedure (1): A private room is interpreted by most people as a room with only one bed. The wording should be changed to indicate that the room will be occupied by only one person, regardless of the number of beds.

page P-3, para 9, first sentence: This is ridiculous. Dosages are administered with large quantities of water, so this should never be a problem.

page P-3, para 12: The 30mCi (6 MR/hr) limits used by NRC have been inconsistent with NCRP 37 for years now. What good reason can NRC have to continue being at variance? An ionization-type meter isn't necessary if a high-range GM meter is available.

page Q-2, para 8: A survey of the room should also be performed to check for occult dislodged sources.

page R-2, last para: Add a note that most cocktails are toxic and can't be flushed down a sewer.

page R-3, para 1: I don't know of anyone who separates needles and syringes. This operation simply increases the risk of contamination from extra handling.

page U-1, Subpart E.2: High-range GM survey meters should be acceptable here and for all of the other subparts.

page U-5, para 2: Calibration with a velometer or anemotherm is preferred and should at least be mentioned here. Some of our tissue paper is so stiff and rough that a hurricane wouldn't bend it!

page V-5: The "loose-leak" notebooks should not leak. Add: "6. US NRC Rules and Regulations", subscription.

Exhibit 3.2: The following "conditions" are now rare and should be eliminated to make room for others:

I-131/125	liver and fat studies
P-32	eye tumor
Se-75	pancreas
Tc-99m	salivary and placenta

Add the following:

Tc-99m	hepatobiliary (disofenin)
Tc-99m	gastric (reflux, emptying)
Tc-99m	kidney (pentetate, gluceptate, succimer)
I-131	adrenal (NP-59)

Since Appendix V is willing to discuss NARM, recommend you consider adding Tl-201 chloride (myocardial prefusion), In-111 DTPA (CSF), Ga-67 (abscess/tumor), In-111 chloride (abscess), I-123 (thyroid), Xe-127(pulmonary). Many places use these nuclides, and experience with them ~~is equally good~~ for clinical and safety training ~~as~~ is equivalent to experience gained with byproduct materials.

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