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2002 MAY 13 PM 2:47
Rules and Directives
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April 30, 2002

Chief, Rules and Directives Branch
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

4/5/02
67 FR 16467
(3)

Re: NUREG 1556, Vol. 9, Revised Draft Report for Comment

To whom it may concern:

I have reviewed this draft regulatory guide, and provide the following comments for your consideration.

Page 1-3: One roentgen does not equal 1 rad. They are approximately equal.

Page 8-18:, third paragraph down: Appears to be a typo: The radiation? can be ion implanted...

Page 8-30, 3rd main paragraph:. The reference to 10 CFR 5.310 should be to 35.310.

Page 8-33: Requiring the listing of rooms to be used to house I-131 patients is overly prescriptive. We have never been required to list these rooms on the license before. A commitment to perform the required surveys around any room used for this purpose should be sufficient. This will be a problem if the room that is listed on the license is unavailable, and there is a therapy patient which needs to be treated as an inpatient. The licensee will be required to wait for the lengthy amendment process to add an additional room. Currently, the amendment process takes a full 3 months for very routine matters, even when expedited reviews are requested. The NRC response to a comment on page Z-18 regarding this issue states that this requirement was intended for rooms intended to be used as dedicated treatment rooms, yet the text of the guidance does not state this.

Page 8-42, 3rd paragraph: This implies that dose calibrator calibrations are accomplished by shipping them off to commercial facilities periodically. I do not know of any requirement to be specially licensed to do routine dose calibrator testing. Such testing is routine, and performed by individual licensees according to their procedures. References to these specifically licensed facilities should be removed so that readers are not confused. No such references to these special calibration facilities are made in the regulations.

Page 8-43: This states than an AMP must calculate current activity of Sr-90 applicators, yet it also says there is no AMP specified for brachytherapy sources. Table C1 states that 'Authorized Medical Physicist' is applicable to facilities applying for use of materials in 35.400. Please clarify whether AMP's are required for manual brachytherapy or not.

Page 8-56 & 57 Minimization of Contamination: This new requirement is confusing and unnecessary. It is a new requirement, and this document provides little guidance as to what NRC expects facilities to submit. The practice of nuclear medicine currently produces no waste which requires burial, so the issue with generating excess waste should not be a concern for NRC. There is also no problem for decommissioning, as all materials decay to background within months. Issues of contamination are

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Template = ADM-013

E-RIDS = ADM-03
Add = R. Broseus (RWB)

already adequately addressed in survey and spill procedures. I see no need for this requirement.

Page I-3: This procedure allows for calibration of fewer than two points for each scale or decade, in the case of logarithmic or digital readout instruments, yet the regulations of 35.61 make no such exception. Which is correct?

Page J-3: Typo in the second sentence: "Some sleeves are to used sequentially"

Page J-5: Item 3 under Accuracy: Should require the recording of the current activity. Item 4: Should read "if the test results to not agree, within +/- 10%, with the current activity of the reference sources." The certified activity is only accurate on the day of calibration. Decayed activities must be determined by the licensee, and are not 'certified'.

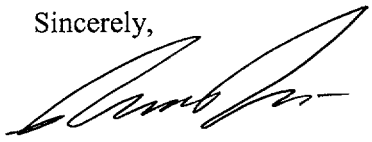
Page Q-2: States that the records of leak tests will be kept in accordance with 35.2067. The suggested procedure states that the record is to include a description of the method used to measure each sample, yet the regulation in 35.2067 does not require this. Why does this procedure require more than the regulation?

Table R-3: The 200 dpm/100 $cm^2$ removable contamination limit for I-131 is too low. The limit in this table was not based on the potential for radiation dose due to the residual contamination. The reasoning for not doing such determinations, as stated in the many replies to comments in appendix Z, is that the NRC did not want this guidance to conflict with previously published guidance. The replies also stated that previously published decommissioning screening values, such as those published in Vol. 63, No. 222 of the Federal Register, did not contain nuclides commonly used in medicine. In NUREG 1500, Working Draft Regulatory Guide on Release Criteria For Decommissioning: NRC Staff's Draft for Comment, screening values are listed for I-131. In Table B-1 of this guide, the screening value for I-131, building occupancy scenario and 3 mrem/year dose limit, is 101,000 dpm/100 $cm^2$, which is more than 500 times higher than the recommended removable contamination limit for unrestricted areas in Table R-3. The I-129 screening value for this same scenario is 1,180 dpm/100 $cm^2$. If this screening value for I-129 is scaled to a dose limit of 25 mrem/year, this gives a screening value of 9,833 dpm/100 $cm^2$, which is actually 3.5 times lower than the I-129 screening value published in Vol. 63, No. 222 of the Federal Register. So, it appears that if I-131 had been listed in the guidance previously published in the Federal Register, the screening value would have been much higher than the values published in draft NUREG 1500, and certainly higher than 200 dpm/100 $cm^2$.
Although facilities are not required to adopt these contamination limits as part of their survey procedures, many facilities will most likely adopt them in an effort to avoid having to justify their decision to deviate from published NRC guidance. Decontaminating rooms used for housing I-131 therapy patients is often a very time consuming process when your removable contamination limit is 200 dpm/100 $cm^2$. At many facilities, the time spent preparing, cleaning, surveying, re-cleaning, and re-surveying these rooms can take up to a day of a technologist's time. In some cases, the technologist does not have adequate time to clean the room, and simply leaves the room unoccupied for many days to allow the radioactivity to decay. This is a waste of hospital resources. I recommend that the contamination limits for I-131 be increased.

Page T-2: Syringe labeling: Requiring all of this information on each syringe is unreasonable, and conflicts with 35.69. In addition, recording of the nuclide should not be required if the radiopharmaceutical is already recorded. The date of calibration activity estimation is also useless unless the time is also recorded, but this procedure only requires labeling with the date. This procedure should be modified to match the regulation of 35.69.

Page T-2: The last item on this page states that licensed materials must be secured if not under constant surveillance of an Authorized User. The reference to authorized users should be removed, or should be reworded to include individuals under their supervision.

Sincerely,



Ronald Frick, M.S., CHP