UNIVERSITY OF IOWA HEALTH CARE
Changing Medicine. Changing Lives.

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

RE: NUREG-1556 Vol. 9

Dear sir,

I would like to take this opportunity to offer a few comments regarding NUREG-1556 Vol. 9, Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licenses, Revised Draft Report for Comment published March 2002.

Table C.2, page C-4 (p. 164/471 pdf), last row on this page, I-131:
In the second column, specify "I-131 sodium iodide liquid or capsules" instead of "any" because other I-131 radiolabeled therapy products (e.g., antibodies) will likely become available in the near future.
Change "diagnosis and treatment of hyperthyroidism" to "quantities less than or equal to 1.22 gigabecquerels (33 millicuries)" as per terminology in 10 CFR 35.394.
Change "thyroid carcinoma" to "quantities greater than 1.22 gigabecquerels (33 millicuries)" as per terminology in 10 CFR 35.394.
Delete "treatment of cardiac dysfunction" because this term is not specifically identified in 10 CFR Part 35, and will be included in 35.392 and/or 35.394.

Appendix C, Table C-3 on page C-9 (p. 169/471 pdf), Item 7, ANP:
Written certification signed by a preceptor should only be required in addition to the option of description on training and experience. The options of previous license naming the individual as ANP and board certification should be stand-alone criteria which would not additionally require preceptor certification. This differs and is in conflict with criteria stated in 10 CFR 35.55 and described in NUREG-1556, Vol. 9, 8.12, item 7 on pages 8-27 and 8-28 (pp. 69-70/471 pdf).

Appendix C, page C-20 (p. 180/471 pdf), Sample Medical Institution Limited, item 13 Authorized Users:
For Gilbert Lawrence, MD, change "Iodine I-131 for treatment of hyperthyroidism and cardiac dysfunction" to "sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)" to be consistent with 10 CFR 35.392.

Template = ADM-013

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

Appendix C, pages C-21 and C-22 (pp. 181-182/471 pdf), Sample Medical Institution Limited, items 13-15.
Delete leak testing requirements for sealed sources as license conditions because these requirements are already covered in 10 CFR 35.67.

Appendix C, pages C-26 and C-27 (pp. 186-187/471 pdf), Sample Medical-Broad Scope, items 13-14.
Delete leak testing requirements for sealed sources as license conditions because these requirements are already covered in 10 CFR 35.67.

Appendix C, page C-28 (p. 188/471 pdf), Sample Medical-Broad Scope, item 17.
Delete detailed requirements for decay-in-storage as license conditions because these requirements are already covered in 10 CFR 35.92. Also, note that the license condition currently specifies holding waste for at least 10 half-lives, which is not a requirement in 10 CFR 35.92.

Appendix J, page J-1 (p. 231/471 pdf), Model Procedures for Dose Calibrator Calibration:
Change "Repair or replace the dose calibrator if there is an error of greater than 10% for the tests indicated" to "Repair or replace the dose calibrator if there is an error of greater than 10% for constancy or accuracy tests; determine and use mathematical correction factors in situations where linearity or geometry effects exceed 10%." This revision would then be consistent with the wording on page K-7, item A-4 (p. 245/471 pdf) regarding mathematical correction of dosage assays.

Appendix J, page J-2 (p.232/471 pdf), Constancy, # 4:
Change "Using one of the sources, repeat the above procedure for all commonly used radionuclide settings..." to "Perform tests in accordance with nationally recognized standards or the manufacturer's instructions." to be consistent with the wording in Appendix K, page K-7 (p.245/471 pdf). Let me further explain the rationale for this change.
One type of dose calibrator, typically older models, have several potentiometers. For example, our CRC 10R has 9 separate potentiometers – eight are push buttons for specific isotope settings (e.g., Tc-99m, I-131, Tl-201, etc.) and one is a manual ten-turn potentiometer. For this type of dose calibrator, one individual push-button potentiometer for a given isotope setting could go bad while all the others remain OK. Thus, for this type of dose calibrator it is important to perform a daily check on each potentiometer (i.e., each push-button isotope setting) that will be used. The operator's manual for this instrument does in fact instruct the user to perform daily constancy checks on each push-button/potentiometer that will be used.
The other type of dose calibrator, typically new models, has only one potentiometer. For example, our Atomlab 100 has only one potentiometer – the 'push buttons' for specific isotope settings are basically pre-set gain factors for this single potentiometer. For this type of dose calibrator, if the one potentiometer would go bad, all of the 'push-button' isotope settings would go bad, because all of the isotope settings use same potentiometer. Thus, for this type of dose calibrator it is important to perform a daily check on one known setting. The operator's manual for this instrument instructs the user to perform a daily constancy check on one isotope setting.

Appendix J, page J-4 (p. 234/471 pdf), Geometry independence:
A very important test that is not described is a test for geometry effects of different containers (e.g., withdrawing a solution from a glass vial into a plastic syringe). This effect is especially important for radionuclides that decay by Electron Capture and emit low energy X-rays. These low energy X-rays are attenuated less by plastic than by glass, so the assay reading in a plastic syringe is falsely high compared to the assay in a glass vial. Similarly, beta emissions interacting with different containers produce different amounts/energies of bremsstrahlung photons. Therefore, add another section describing a model test for evaluation of geometry effects of different containers; for example,
"After determining the geometry effects for various volumes of a given radionuclide in standard glass vials and in plastic syringes, determine the geometry effects of the different containers by withdrawing various volumes (i.e., over the range of volumes to be used) from the standard glass vial into plastic syringes. For each volume, assay the standard glass vial before and after withdrawal and assay the syringe. Calculate correction factors by the following formula: Correction factor for contents in a plastic syringe = (assayed activity in vial before withdrawal – assayed activity in vial after withdrawal) ÷ assayed activity in syringe. Repeat for each radionuclide to be used."

Table U.1, pages U-5 and U-6 (pp. 329-330/471 pdf):
Delete accelerator/cyclotron radionuclides (e.g., Ga-67, In-111, I-123, Tl-201) because state regulations vary.

Table U.2, pages U-8 and U-9 (pp. 332-333/471 pdf):
Delete accelerator/cyclotron radionuclides (e.g., Ga-67, In-111, I-123, Tl-201) because state regulations vary.

Table U.3, pages U-10 and U-11 (pp. 334-335/471 pdf):
Delete accelerator/cyclotron radionuclides (e.g., Ga-67, In-111, I-123, Tl-201) because state regulations vary.

Appendix X, page X-1 (p. 373/471 pdf), Decay-in-Storage, last sentence which is continued on the next page:
Delete "the radionuclides disposed" because this information is not required in 10 CFR 35.2092.

Thank you for your consideration of these comments.