January 6, 2014

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /RA/

SUBJECT: STAFF REQUIREMENTS – SECY-13-0084 – PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63)

The Commission has approved publication of the proposed rule for public comment subject to the comments and changes noted below.

The staff should include another question in the *Federal Register* to request specific comments on whether the application of the proposed medical event definition for normal tissue based on the absorbed dose to the maximally exposed 5 contiguous cubic centimeters during permanent implant brachytherapy is appropriate for all potential treatment modalities, or whether it may result in unintended consequences for tissues or organs adjacent to the treatment site.

The staff should eliminate the proposed reporting requirements for manufacturers and distributers of failed molybdenum/technetium and strontium/rubidium generators. The staff should update the NRC's Memorandum of Understanding with the U.S. Food and Drug Administration to ensure that our respective regulatory responsibilities are effectively carried out and that appropriate information is effectively shared between our agencies to enable prompt evaluation and action.

The staff should extend the comment period from 90 to 120 days.

The proposed rule should solicit generally for public comment on whether any of the proposed changes are likely to discourage licensees from using certain therapy options or otherwise adversely impact clinical practice and if so, how.

The Compatibility Category for medical event reporting should be changed from C to B.

The staff should consider and solicit comment on whether a 180 day effective date for the final rule is sufficient to communicate these changes to all practitioners, revise procedures, train on them, and implement the changes.

The staff should provide the revised *Federal Register* notice for the proposed rule to the Commission for review a minimum of five business days prior to its transmittal to the Office of the Federal Register.

The staff should provide a voting paper to the Commission that describes the staff's recommendation on whether to update the policy statement on Medical Uses of Byproduct Material.

The staff has indicated that no teletherapy units are licensed in the United States for medical uses. The staff should include a question in this rulemaking to confirm this and, if so, the staff should indicate their plans to remove the requirements associated with these units in Part 35.600 in the final rulemaking.

The proposed reporting requirement for breakthrough of Mo-99, Sr-82, and Sr-85 should be modified from 24 hours to 30 days.

The staff should ensure timely assessment of licensees' reports on generator failures such that staff can identify and address multiple events caused by one manufacturer or one type of generator.

The following specific changes should be made to the FRN:

a. Page 1, last line, add a comma after "…part 35,…"

b. Page 7, add new item: "XIX. List of Subjects" to the end of the Table of Contents.

c. Page 11, 1st full ¶, last line, add a comma after "…SECY-12-0053, …"

d. Page 13, line 7, add a comma after … "alternative pathway,"…

e. Page 16, line 5, add a comma after "letters," ; line 19, add a comma after "procedures,"

f. Page 19, 1st full ¶, line 9, add a comma after "ME reporting,"

g. Page 20, line 13, revise to read: "…SECY-05-0234."

h. Page 21, line 5, revise to read: "…patient unavailability after treatment."

i. Page 23, 1st full sentence, revise to read: "Based on ACMUI input and information gained at public workshops, the NRC understands that the final WD documentation related to these § 35.40 permanent implants must ~~allow for~~ reflect ~~final WD documentation based on~~ the medical situation encountered during the surgical procedure. "

j. Page 23, 2nd full sentence, revise to read: "Therefore, in defining an ME involving the treatment site for permanent implants, the NRC based the criterion for an ME ~~is based~~ on the percentage of implanted sources that are outside of the treatment site as documented in the post-implantation portion of the WD ~~that is outside of the treatment site, and not~~ rather than defining an ME based on a comparison…"

k. Page 24, last line, revise to read: "…individuals was ~~superfluous~~ not needed."

l. Page 27, ¶ d., lines 5 - 8, revise to read: "…specified concentrations~~.~~ ; ~~Although~~ however, a generator can be eluted several times to obtain Tc-99m for formulating

radiopharmaceuticals for patient use~~, current regulations require licensees to measure the Mo-99 concentration only the first time the generator is eluted~~."

m. Page 27, 2nd to last line, revise to read: "The Mo-99 breakthrough ~~measurements~~, which exceeds the permissible concentration in § 35.204(a), may cause…"

n. Page 28, 2nd full ¶, line 7, add a comma after "performance standard,"

o. Page 29, 2nd full ¶, lines 3 – 5, revise to read: "…require a licensee to report to the NRC and the manufacturer or distributor of medical generators within 24 hours any measurement that exceeds the limits specified in § 35.204(a) ~~within 24 hours~~."

p. Page 29 – 30, delete the last sentence starting on page 29: "~~The NRC believes… prompt action as needed.~~" And the first full sentence on page 30: "~~This new reporting requirement… radiation exposure to patients~~."

q. Page 32, line 2, add a comma after "amendments,"

r. Page 33, ¶ "3)", revise to read: "3) Do other (NRC, Agreement State, or other agency)…"

s. Page 34, line 4, revise to read: "…some of which are Agreement State-regulated."

t. Page 34, line 15, revise to read: "…reports to the NRC ~~only~~ include…"

u. Page 35, line 6, add a comma after "Category C,"

v. Page 35, 1st full ¶, last sentence, revise to read: "…activity-based criteria is the "failure of dose-based criteria to sensitively and ~~to only~~ specifically capture clinically significant 'misadministrations' [or MEs] in permanent implant brachytherapy."

w. Page 37, item viii, line 2, revise to read: "…Subsection C. and D. of Section IV…"

x. Page 37, item viii, line 3, revise to read: "… Agreement State Compatibility…"

y. Page 43, line 5, revise to read: "… redundant ~~of~~ with…"

z. Page 44, line 1, delete vertical line preceding "~~l~~implantation"

aa. Page 46, "*Paragraph (b)(2)*", delete the 2nd sentence: "~~The requirement… alternate pathway.~~"

bb. Page 51, "*Paragraph (a)(4)*", revise to read: "This paragraph would be renumbered…"

cc. Page 54, "*Paragraph (b)*", line 2, revise to read: "… measured ~~in~~ after each…"

dd. Page 63, "Section 35.400" last sentence, revise to read: "The NRC has determined this latitude ~~is under~~ should be afforded to physicians to use at their discretion in the practice of medicine.

ee. Page 65, *Paragraph (b)(1)(ii)*, line 6, revise to read: "…an organization practices ~~has~~ more than one medical discipline…"

ff. Page 68, *Paragraph (a)*, lines 3 – 4, revise to read: "…SSDR or ~~in~~ for research ~~in these units~~ in accordance with…"

gg. Page 68, last line, revise to read: "…SSDR or ~~in~~ for research…"

hh. Page 69, last sentence, revise to read: "…safety of patients~~,~~ by eliminating the potential for ~~as postponing the~~ training of new staff to be delayed until the required annual training, which could lead to…"

ii. Page 71, *Paragraph (b)(1)(ii)*, line 6 - 7, revise to read: "…an organization practices ~~has~~ more than one medical discipline…"

jj. Page 73, Section 35.2655, add a period at the end of the sentence.

kk. Page 79, line 16, add a comma after "essential objectives,"

ll. Page 95, 2nd full ¶, line 5, revise to read: "…recommendations ~~which~~ that the staff…"

mm. Page 102, "Public Protection Notification", if this is supposed to be a title, it should be added to the index and the remaining titles should be renumbered.

nn. Page 103, item "b)", revise to read: "~~How~~ If the proposed regulation…"

oo. Page 104, add "XIX" in front of heading "List of Subjects"

pp. Page 125, line 2, add a comma after "October 24, 2005,"

qq. Replace "which" with "that" in the following locations:

i. page 116, last line

ii. page 120, ¶ "(a)", line 3

iii. page 121, ¶ "(a)", line 2

iv. page 127, ¶ "(a)", line 3

v. page 128, last line

vi. page 132, 2nd to last line

vii. page 134, ¶ "(a)", line 4

viii. page 139, ¶ "(a)", line 3

ix. page 142, line 4

x. page 144 last line

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR