

June 23, 2000

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - SECY-00-0113 - DRAFT FINAL
POLICY STATEMENT ON THE MEDICAL USE OF BYPRODUCT
MATERIAL

The Commission has approved the final policy statement on medical use of byproduct material for publication in the Federal Register subject to the attached changes.
(EDO) (SECY Suspense: 7/31/00)

Attachment: Changes to the Medical Policy Statement in SECY-00-0113

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

Changes to the Medical Policy Statement in SECY-00-0113

1. On page 1, last sentence, remove the extra 's' in "Commission's".
2. On page 3, 1st paragraph, line 5, insert an apostrophe after "Sciences" and remove the comma after "(NAS)".
3. On page 3, 1st paragraph, revise line 12 to read ' ... presented four alternative **proposed revised** versions of the'
4. On page 3, 2nd paragraph, line 4, insert an 's' at the end of "comment".
5. On page 3, 2nd paragraph, line 6, delete "i.e.," at the beginning of the parentheses.
6. On page 3, 2nd paragraph, line 7, insert 'on' after 'Missouri,'.
7. On page 3, 2nd paragraph, line 8, delete 'in' and insert 'on' after 'Maryland,'.
8. On page 4, 2nd paragraph, revise line 5 to read ' ... and **future NRC** involvement with other Federal and'
9. On page 4, 2nd paragraph, revise line 6 to read ' ... policy promotes **a more** ~~the~~ risk-informed approach'
10. On page 6, revise the first word to be '161.i.' .
11. On page 6, 1st full paragraph, line 8, remove the initial parenthesis inside the start of the brackets.
12. On page 6, 2nd full paragraph, line 5, capitalize the 'S' in 'Section'.
13. On page 7, last paragraph, revise line 2 to read ' ... were submitted and **from** the transcripts'
14. On page 7, last paragraph, lines 5 and 6, insert a closing parenthesis after 'professionals' and remove the closing parenthesis after '1998'.
15. On page 8, 2nd paragraph, line 5, remove the extra space after 'commenter'.
16. On page 9, 2nd full paragraph (response section), revise line 3 to read ' ... NRC's regulations, ~~as well as~~ **or** external, ~~factors~~ such as technological'
17. On page 9, revise the last line to read 'Specifically, **one commenter stated** that NRC has never paid'
18. On page 10, 2nd full paragraph, revise line 5 to read ' ... consider developing a **more** risk-informed, performance-based'

19. On page 11, 2nd paragraph (Comment section), line 1, insert a space after 'section'.
20. On page 11, 2nd paragraph (Comment section), revise lines 2 and 3 to read ' ... opinion, NRC's medical use regulations should be'
21. On page 11, 3rd paragraph (Response section), line 2, replace the '162' with '161, 182'.
22. On page 11, 3rd paragraph (Response section), line 5, delete the extra underlining after 'material'.
23. On page 13, 3rd paragraph (Response section), line 1, place "interfere" in quotation marks.
24. On page 13, 3rd paragraph (Response section), line 3, replace 'on' with 'in'.
25. On page 13, 4th paragraph, revise lines 1 and 2 to read ' ... a hospital of a patient ~~who has~~ **to whom radioactive materials have** been administered ~~radioactive materials~~ has long been considered'
26. On page 13, 4th paragraph, revise line 6 to read ' ... ~~who has~~ **to whom radioactive materials have** been administered ~~radioactive materials~~.'
27. On page 14, line 7 from the top, add an 's' to make 'substitutes'.
28. On page 14, line 2 from the bottom, delete the 'e' to correct the spelling of 'judgments'.
29. On page 15, 3rd paragraph, line 2, delete the 'e' to correct the spelling of 'judgments'.
30. On page 15, 4th paragraph, revise line 7 to read ' ... as previously explained, to intrude, **to a certain extent**, into medical'
31. On page 17, last paragraph, revise line 2 to read ' ... pharmacists and physicians, **respectively**, to practice pharmacy'
32. On page 19, 1st full paragraph, revise lines 3 and 4 to read ' ... revise regulatory approach is **more** risk-informed **and more performance-based** and significantly'
33. On page 20, 1st paragraph, revise lines 3 and 4 to read ' ... radiation safety of patients ; ~~primarily on~~ **to** whether the physician's'
34. On page 21, revise line 4 from the top to read ' ... flexibility to **use standards from nationally recognized organizations to** meet the performance'
35. On page 21, 1st full paragraph, line 2, remove the extra 's' in "Commission's".
36. On page 21, 1st full paragraph, revise the 2nd sentence to read '**The NRC's intention is to consider industry and professional standards in developing regulations and guidance for the medical use program, consistent with** ~~This strategy is to increase the involvement of licensees and others in the NRC regulatory development process, based on the~~

concepts in the'

37. On page 22, 2nd paragraph (Response section), line 6, insert a comma after 'appropriate'.
38. On page 22, 2nd paragraph (Response section), last line, include the titles or areas covered in the reports from Task Groups 40, 56, and 59 and Report No. 54.
39. On page 22, 3rd paragraph, line 3, delete the comma after 'positions'.
40. On page 24, revise line 3 from the top to read ' ... goal to develop **regulations that are more** performance-based **regulations.**'
41. On page 24, line 4 from the top, delete 'their'.