

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

ATTACHMENT

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

On page 1, last sentence, remove the extra 's' in "Commission's".

On page 3, 1<sup>st</sup> paragraph, line 5, insert an apostrophe after "Sciences" and remove the comma after "(NAS)".

On page 3, 1<sup>st</sup> paragraph, revise line 12 to read ' ... presented four alternative proposed revised versions of the ....'

On page 3, 2<sup>nd</sup> paragraph, line 4, insert an 's' at the end of "comment".

On page 3, 2<sup>nd</sup> paragraph, line 6, delete "i.e.," at the beginning of the parentheses.

On page 3, 2<sup>nd</sup> paragraph, line 7, insert 'on' after 'Missouri,'.

On page 3, 2<sup>nd</sup> paragraph, line 8, delete 'in' and insert 'on' after 'Maryland,'.

On page 4, 2<sup>nd</sup> paragraph, revise line 5 to read ' ... and future NRC involvement with other Federal and ....'

On page 4, 2<sup>nd</sup> paragraph, revise line 6 to read ' ... policy promotes a more the risk-informed approach ....'

On page 6, revise the first word to be '161 .i.' .

On page 6, 1<sup>st</sup> full paragraph, line 8, remove the initial parenthesis inside the start of the brackets.

On page 6, 2<sup>nd</sup> full paragraph, line 5, capitalize the 'S' in 'Section'.

On page 7, last paragraph, revise line 2 to read ' ... were submitted and from the transcripts ....'

On page 7, last paragraph, lines 5 and 6, insert a closing parenthesis after 'professionals' and remove the closing parenthesis after '1998'.

On page 8, 2<sup>nd</sup> paragraph, line 5, remove the extra space after 'commenter'.

On page 9, 2<sup>nd</sup> full paragraph (response section), revise line 3 to read ' ... NRC's regulations, as well as or external , factors such as technological ....'

On page 9, revise the last line to read 'Specifically, one commenter stated that NRC has never paid ....'

On page 10, 2<sup>nd</sup> full paragraph, revise line 5 to read ' ... consider developing a more risk-informed, performance-based ....'

On page 11, 2<sup>nd</sup> paragraph (Comment section), line 1, insert a space after 'section'.

On page 11, 2<sup>nd</sup> paragraph (Comment section), revise lines 2 and 3 to read ' ...

opinion, NRC 's medical use regulations should be ....'

On page 11, 3<sup>rd</sup> paragraph (Response section), line 2, replace the '162' with '161, 182'.

On page 11, 3<sup>rd</sup> paragraph (Response section), line 5, delete the extra underlining after 'material'.

On page 13, 3<sup>rd</sup> paragraph (Response section), line 1, place "interfere" in quotation marks.

On page 13, 3<sup>rd</sup> paragraph (Response section), line 3, replace 'on' with 'in'.

On page 13, 4<sup>th</sup> 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 ...'

On page 13, 4<sup>th</sup> paragraph, revise line 6 to read ' ... who has to whom radioactive materials have been administered radioactive materials.'

On page 14, line 7 from the top, add an 's' to make 'substitutes'.

On page 14, line 2 from the bottom, delete the 'e' to correct the spelling of 'judgments'.

On page 15, 3<sup>rd</sup> paragraph, line 2, delete the 'e' to correct the spelling of 'judgments'.

On page 15, 4<sup>th</sup> paragraph, revise line 7 to read ' ... as previously explained, to

intrude , to a certain extent, into medical ....'

On page 17, last paragraph, revise line 2 to read ' ... pharmacists and physicians , respectively, to practice pharmacy ....'

On page 19, 1<sup>st</sup> full paragraph, revise lines 3 and 4 to read ' ... revise regulatory approach is more risk-informed and more performance-based and significantly ....'

On page 20, 1<sup>st</sup> paragraph, revise lines 3 and 4 to read ' ... radiation safety of patients , primarily on to whether the physician's ....'

On page 21, revise line 4 from the top to read ' ... flexibility to use standards from nationally recognized organizations to meet the performance ....'

On page 21, 1<sup>st</sup> full paragraph, line 2, remove the extra 's' in "Commission's".

On page 21, 1<sup>st</sup> full paragraph, revise the 2<sup>nd</sup> 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 ....'

On page 22, 2<sup>nd</sup> paragraph (Response section), line 6, insert a comma after 'appropriate'.

On page 22, 2<sup>nd</sup> 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.

On page 22, 3<sup>rd</sup> paragraph, line 3, delete the comma after 'positions'.

On page 24, revise line 3 from the top to read ' ... goal to develop regulations that are more performance-based regulations.'

On page 24, line 4 from the top, delete 'their'.