

PLEASE RETURN TO EDO WITH EDITS
BY JUNE 10, 1998

June 5, 1998

NMSS

NOTE TO THE EDO

RE: LETTER TO SENATOR SUSAN COLLINS (EDO 98-0480)

The attached letter is being returned to staff for rewrite to incorporate edits made by the Chairman's office (attached) and to respond to the Senator's request for a summary of the proposed changes to 10 CFR Part 35. Please return the revised letter to SECY for Commission review by Friday, ~~January~~ ^{JUNE} 12, 1998.

Jeanne Shoemaker, SECY
415-1674

I understand that Jim Smith in the Chairman's office talked to Diane Flack or her supervisor regarding this request.

Jeanne

*Not
All Edits were
incorporated -
see attached -
e-mails.
Pink highlights
show where
changes were
made. C. Hays*

9806230311 980519
PDR ORG NRCCO
PDR



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Susan M. Collins
United States Senate
Washington, DC 20510-1904

Dear Senator Collins:

I am responding to your letter dated May 19, 1998, regarding proposed revisions to the U.S. Nuclear Regulatory Commission's (NRC's) 10 CFR Part 35 regulations on medical use of byproduct material.

The NRC staff is scheduled to provide its recommendations on proposed revisions to Part 35 to the Commission in June 1998. The proposed rule is being developed using an increased public participation process that included public workshops; meetings with various medical professional societies (including the American College of Radiology); and the posting of a "strawman" rule text on the Internet for comments. The staff has carefully considered the comments received during these interactions, in preparing the proposal. After Commission approval, a proposed rule will be published in the Federal Register for public comment and forwarded to your office for your information. We expect to hold additional public meetings during the comment period later this year.

The issue of training and experience has received the most comments during the development of the proposed rule. Viewpoints on this issue have varied. The Commission has received comments both supporting reduction in requirements affecting personnel in the diagnostic area, including those from the American College of Cardiology and the American Society of Nuclear Cardiologists, and favoring keeping the presently existing requirements. The staff draft, while reducing the number of hours required for certain medical modalities, also specified a focus on radiation safety and proposed that personnel competency be verified through an examination. This proposal appears to be in keeping with the direction the Commission provided to the staff namely, to develop a risk-informed, and where appropriate, a more performance-based rule and it addressed an objection often expressed by some commenters, that NRC requirements sometimes intruded into the practice of medicine.

The Commission will carefully consider the staff proposal in light of public comments when it is received. The results of that consideration will then be available for additional public comment and discussion.

Sincerely,

Shirley Ann Jackson

The Honorable Susan M. Collins
United States Senate
Washington, DC 20510-1904

OK
ATTACHED IS
THE FR NOTICE...

Dear Senator Collins:

I am responding to your letter dated May 19, 1998, ^{negotiated proposed} which conveyed concerns about revisions in the U.S. Nuclear Regulatory Commission's (NRC's) 10 CFR Part 35 regulations on medical use of byproduct material.

The NRC staff is scheduled to provide its recommendations on proposed revisions to Part 35 to the Commission in June 1998. The proposed rule is being developed using an increased public participation process that included public workshops; meetings with various medical professional societies (including the American College of Radiology); and the posting of a "strawman" rule text on the Internet for comments. The staff ^{has} is carefully considering the comments received during these interactions, in preparing the proposal. After Commission approval, a proposed rule will be published in the Federal Register for public comment. We expect to hold additional public meetings during the comment period later this year.

As requested, a summary of the proposed changes is attached. Of the proposed changes,

the issue of training and experience has received the most comments during the development of the proposed rule. Viewpoints on this issue have varied. The Commission has received comments both supporting reduction in requirements affecting personnel in the diagnostic area, including those from the American College of Cardiology and the American Society of Nuclear Cardiologists, and favoring keeping the presently existing requirements. The staff draft, while reducing the number of hours required for certain medical modalities, also specified a focus on radiation safety and proposed that personnel competency be verified through an examination. This proposal appears to be in keeping with the direction the Commission provided to the staff namely, to develop a risk-informed, and where appropriate, a more performance-based rule and it addressed an objection often expressed by some commenters, that NRC requirements sometimes intruded into the practice of medicine.

The Commission will carefully consider the staff proposal in light of public comments ~~such as~~ ^{your} when it is received. The results of that consideration will then be available for additional public comment and discussion.

Sincerely,

Shirley Ann Jackson

DISTRIBUTION: G980341

NRC File Center

NMSS R/F

EDO r/f

SECY-CRC-98-0480

HThompson

LCallan

PTressler

CPoland

NMSS Dir. Off. r/f

IMNS RF

PDR: ☒ Yes ☐ No

DOCUMENT NAME: A:G980341a *See Previous Concurrence

CP/PROOFED/MAY 28, 1998

| | | | | | |
|--------|----------|-----------|----------|----------|------------|
| OFFICE | RGB | Editor* | IMNS | NMSS DIR | DEDR |
| NAME | DFlack | EKraus | DCool | MKnapp | HLThompson |
| DATE | 5/21/98 | 4/15/98 | 5/28/98 | 6/1/98 | 6/1/98 |
| OFFICE | EDO | OCM | OCA | | |
| NAME | LJCallan | SAJackson | DRathbun | | |
| DATE | 6/1/98 | 6/1/98 | 6/1/98 | | |

"OFFICIAL RECORD COPY"