

MAR 31 1994

Mr. Terry C. Frazee, Head  
Radioactive Materials Section  
Division of Radiation Protection  
Department of Health, LE-13  
Airdustrial Center Building #5  
Post Office Box 47827  
Olympia, WA 98504-7827

Dear Mr. Frazee:

This is in response to your March 10, 1994 letter requesting a review and comments on the draft SSRCR Part G.

The definitions in Section G.2 regarding misadministration requirements are Division 1 category rules. That is, they must be essentially verbatim in order to be compatible with NRC's 10 CFR Part 35 (Part 35). Section G.2 definitions appear to be compatible with the corresponding Part 35 rules. The remaining requirements of the misadministration rule and the quality management program are Division 2 category rules. That is, the basic principles of radiation safety must be addressed, but the States may adopt requirements more restrictive than NRC rules. The use of language identical to that of NRC rules is not necessary provided that the underlying principles are the same.

I would like to offer the enclosed comments for your consideration.

Copies of this draft will be sent to the appropriate NRC offices with the caveat that this is an early pre-concurrence draft.

I appreciate the opportunity to review and comment on this draft. Please let me know if you have any questions on my remarks.

Sincerely,

*/s/*  
Lloyd Bolling  
Office of State Programs

Enclosure:  
As stated

Distribution:  
Dir RF S-64  
RBangart  
PLohaus  
LBolling  
WA File

DCD (SP01) ✓  
PDR YES ✓ NO 4/1/94

OFC	OSP:SA <i>[Signature]</i>	OSP:DD <i>[Signature]</i>			
NME	LBolling/dr	PLohaus			
DTE	03/31/94	03/31/94			

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Comments on Draft SSRRCR Part G (10 CFR Part 35)

1. Variances noted which would affect compatibility:

G.2 Definitions

Misadministration -

(4) (d) delete, " to the treatment site " ...

(5) (a) delete, " by more than 20 percent of " ...

Recordable event -

(3) add, " I-123 and I-125 "...

(4) add, " other than sodium I-125 or I-131 , " ...

Written directive -

(1) add, " I-123, I-125 or I-131 " ...

(2) add, " I-125 or "...

2. We recommend that you add the following in parentheses to the title of Section G.13 : [ QUALITY MANAGEMENT PROGRAM ]

We believe that this will clearly identify this requirement yet allow for a name change if appropriate.

3. Other comments -

Section G.18, b.i. delete " required "...

Section G.19, a. add " 370 kilobecquerels (10 uCi) " ...

Section G.19, b.ii. wouldn't this restriction pose a hardship for small radiopharmacies? Maybe we could accept a letter or other documentation certifying that the particular lot was properly tested.

ENCLOSURE

XXXXXXXXXX  
XXXXXX



STATE OF WASHINGTON

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March 10, 1994

TO: SR-6 Committee Members, Advisors, Resource Persons  
FROM: X Terry C. Frazee, Chair SR-6  
SUBJECT: SSRCR PART G -- MARCH 1994 DRAFT

After many months of waiting for the ROC review to be complete, we are now ready to move on. I have been informed that the Executive Board of the Conference expects to see the NRC's Quality Management rule in this revision of Part G. This is important to Agreement States because the date set by NRC for having compatible "QM" regulations is early 1995. Accordingly, I have added a new section but with a word-engineered slant all my own. First of all, I avoided the term "quality management" because of potential confusion with other QA/QC type programs. I also left out the requirement to barrage the radiation control program with paperwork that doesn't have to be approved before the licensee implements it anyway. Because this is a compatibility issue, we need to have NRC start reviewing this right away. Lloyd - please be sure that a copy of this gets to the right folks to start thinking about NRC concurrence.

Other significant changes in the draft as you now see it are:

G.2 - added definition of "recordable event"

G.27 - "total effective dose equivalent" and "radionuclide" rather than radiopharmaceutical.

G.67 through G.74 - added certifying boards as proposed in the Federal Register notice 58 FR 27953 published May 12, 1993.

This draft will receive widespread distribution: I am resending it to the previous peer reviewers and to several others who have expressed interest (see the distribution list). I am also sending it to the Conference and asking that they send the draft to all states and to the public. I am asking for comments from all of you to reach me by May 2, 1994.

Due to limited funds, Ray Paris has indicated that SR-6 will not meet in conjunction with the annual meeting as we have in the past. Whether we will have any meeting this year depends on the comments received on this draft, and other work which may evolve.