RESOLUTION OF COMMENTS ON SA-200
"COMPATIBILITY CATEGORIES AND HEALTH AND SAFETY\IDENTIFICATION
FOR NRC REGULATIONS AND OTHER PROGRAM ELEMENTS"

I. Sent to the Agreement States for Comment: October 25, 2002 (SP-02-075)

Comments Dated: Illinois, November 20, 2002
Ohio-Howard, November 29, 2002 email &
letter dated November 21, 2002
Ohio- Snee, e-mail dated 12/10/2002

Response to/Resolution of Comments:

Illinois

Comment 1: The NRC apparently needs to clarify how it resolves compatibility issues. The procedure introduces a new "Compatibility Resolution (CR)" process, which, to our knowledge, appears for the first time there. We are unclear if this term signals a fundamental change in NRC's approach to resolution of compatibility issues. We do not know if the conflict process represents a new process, a revision of an existing one, or merely a new name for something that already exists, for example as provided by Management Directive 5.9.

Response: The procedure was revised to address this comment.

Comment 2: If the compatibility resolution denotes a new or revised activity, then it is unclear, when, and under what conditions NRC would employ it.

Response: The procedure was revised to address this comment.

Comment 3: Although Appendices A and C refer to a couple of compatibility resolutions, the CR documents are not included in Appendix C, nor have we received copies by usual STP communication routes.

Response: Appendix C provides the titles of the CR documents and includes the Adams Accession Number, ML022380136, for retrieval of these documents. In addition, staff will ensure that States receive copies of the CR documents when completed.

Comment 4: We note that the NRC has added tracking numbers from the STP regulation assessment tracking system to Appendix A of the procedure. We welcome this enhancement, which should provide cross-references between SA-201 and SA-200 tables.

Response: No response is needed.

Ohio-Howard

Comment: Ohio compared its regulations to the draft OSP Procedure SA-200. No comments for NRC action were provided.

Response: No response is necessary.

Ohio-Snee

Comment 1: 71.101 - 'C' compatibility for paragraphs (a), (b), (c)(1). There is no (c)(1). 'NRC' for (c)(2). There is no (c)(2).

Response: The procedure was revised to address this comment. The references to (c)(1) and (c)(2) were removed from 10 CFR 71.101.

Comment 2: 71.103 - 'C' compatibility for paragraphs (a), (b), (c) first sentence. The first sentence for (c) doesn't make sense for 71.103. 'C' for paragraph (g). There is no paragraph (g).

Response: The procedure was revised to address this comment. The references to first sentence for (c) and paragraph (g) were removed from 10 CFR 71.103.

II. Sent to the NRC Offices for Comment: October 25, 2002

Comments Dated: STP-Zabko, e-mails dated October 23, 2002; December 20, 2002, and December 26, 2002
Region I, November 12, 2002
Region II, November 13, 2002
Region III, November 26, 2002
OGC, November 25, 2002
NMSS, November 25, 2002
NMSS, Thomas Young, e-mail dated March 19, 2003

STP-Zabko

Comment 1: The definition of Radiographer Certification is missing. This definition appears in Part 34 now and is part of the 1997 amendment:

Response: The procedure was revised to address this comment. The definition "Radiographer Certification" was added to 10 CFR Part 34.3.

Comment 2: In SA-200, we list a definition of Radiography. We also list a definition of Radiographic Operations. The only one that is in Part 34 is Radiographic Operations, this is also the definition that was placed into Part 34 during the 1997 amendment. We need to remove the definition of Radiography from SA-200.

Response: The procedure was revised to address this comment. The definition "Radiography" was removed from 10 CFR Part 34.3.

Comment 3: In Part 20, we still list Appendix F as the Shipping and Manifest reference appendix. Appendix F was removed by amendments 60FR15649 and 60FR25983 in 1995. It was replaced by Appendix G to Part 20. We still have it (App F) as a "B" compatibility item in SA-200. My suggestion is that Appendix F should be removed from SA-200. The States should be referencing Appendix G to Part 20, not F.

Response: The procedure was revised to address this comment. The reference was changed to Appendix G of 10 CFR Part 20.

Region I

Comment 1: The revised procedure includes the regulation assessment tracking system (RATS) number in the comment section of the Appendix A tables. This is a valuable addition, but the table should be modified to include a separate column for the RATS number for each section. Since some sections of the regulations are amended multiple times, having the applicable RATS number(s) will increase the flexibility and use of the table for compatibility reviews by NRC and Agreement State staffs.

Response: We appreciate the comment concerning the RATS number(s) and their inclusion in the table comment section. However, we do not believe it would be appropriate to insert a separate column for this information. As noted in the comment, a regulation section may have multiple amendments; thus, to add this information numerous times would make the SA-200 charts more confusing. In addition, the chronology listing serves the purpose of noting the RATS information.

Comment 2: The Appendix A tables should be modified to include a column for the applicable suggested state regulation (SSR).

Response: We appreciate the comment concerning the Inclusion of the SSR in the Appendix A table. However, we do not believe it would be appropriate to insert a separate column for this information.

Comment 3: Section V.B.2. of the procedure includes a brief description of the program elements table in Appendix B. This section should be expanded to include additional discussion on how the table could be used in conjunction with adequacy and compatibility determinations under Management Directive 5.6.

Response: The procedure was revised to address this comment.

Region II

Comment 1: We liked the H&S comments in Appendix A dealing with the "two or fewer failure test scenarios." However, this failure test concept is not explained in the procedure. The explanation of this concept is covered as a footnote in the Management Directive 5.9 Handbook, so we suggest that consideration be given to either adding the explanation to the SA-200 procedure or provide a reference to the MD 5.9 Handbook. We believe this modification would be more convenient for the States and would add clarification value.

Response: The procedure was revised to address this comment.

Region III

Comment 1: Region III has just one comment on this revision to SA-200. In Section V. Guidance, the concept of a "Compatibility Resolution Process" is introduced. Additional information should be added to explain the need for such a process. Is it primarily used for situations in which NRC and an Agreement State disagree on a regulation compatibility category? Perhaps some history of the process could be included.

Response: The procedure was revised to address this comment.

OGC

Comment 1: p. 4: last paragraph - interim time period between what? Also, I do not think “cognizant” is the appropriate word here - I would suggest “relevant.”

Response: This suggestion was incorporated.

Comment 2: p. 5: Table 1, “Specific Parts of Title 10 of the Code of Federal Regulations that Addresses Areas of Exclusive NRC Authority,” has been omitted from the revised version, but this table is still referenced in the text.

Response: The procedure was revised to address this comment.

Comment 3: p. 5: The first paragraph under A. should reflect that the Statements of Considerations (SOCs) are also part of the analysis in determining categorization.

Response: The procedure was revised to address this comment.

Comment 4: p. 5: Part 0 no longer exists - the reference to it in the table should be deleted.

Response: The procedure was revised to address this comment.

Comment 5: p. 6: 1.c needs to refer also to the SOCs when talking about how categories are determined.

Response: The procedure was revised to address this comment.

Comment 6: p. 7: 1.e says that all C or H&S sections will have a clearly defined essential objective. I do not think this is true for all of the sections.

Response: The procedure was revised to address this comment.

Comment 7: p. 9: D.1 needs to reflect that category designations must also be in accordance with the SOCs.

Response: The procedure was revised to address this comment.

Comment 8: Also need to check page numbering - it currently has “p. 8 of 7", “p. 9 of 7."

Response: The procedure was revised to address this comment.

Comment 9: Appendix A, p. 13: §20.1301,The comments talk about revisions to sections (d) and (e) that were not made in the most recent FRN (67 FR 20250). If you want to leave these explanations in the comments, then there should be a cite to the FRN that made the changes.

Response: The procedure was revised to address this comment.

Comment 10: Appendix A, p. 45: Statement of Considerations (SOCs) say this is “Division 2" - is this consistent with a “C”?

Response: This comment has been addressed by the addition of clarifying language on the new Policy Statement relative to the SOCs.

Comment 11: Appendix A, p. 45: §34.20, again the SOCs label the whole section a “Division 2.” How did (a)(2) become a D?

Response: This comment has been addressed by the addition of clarifying language on the new Policy Statement relative to the SOCs.

Comment 12: Appendix A, 48-49: §34.47, reference should be to 65 FR 63750 (not 63749).

Response: The procedure was revised to address this comment.

Comment 13: Appendix A, p. 51: §34.83, reference should be to 65 FR 63750.

Response: The procedure was revised to address this comment.

Comment 14: Appendix A, p. 107, 108, 111: references should be to 65 FR 63750 (not 63749).

Response: The procedure was revised and address this comment.

Comment 15: Appendix A, p. 117, §40.4, “Uranium Milling,” What is the basis for changing from a “C” to an “A”? There does not appear to be any change to the reg itself.

Response: The change in compatibility designation is to ensure compatibility for those States which regulate uranium milling. This definition is linked to a statutory requirement. Thus, staff determined that Agreement States who have this authority should adopt this definition in an essentially identical manner.

Comment 16: Appendix A, p. 120: §40.32, There has been no change to the regulation, so why do we change the category of (e) from “NRC” to “H&S”?

Response: The compatibility designation was changed for portions of this section from “NRC” to “H&S” for States with uranium mill authority. Previously, all of paragraph (e) was designated a compatibility NRC. Staff reexamined the section and changed the compatibility designation of those portions of the paragraph applicable to uranium mills to “H&S.” The “NRC” designation was retained for those portions of the regulation applicable to uranium enrichment and uranium hexafluoride facilities.

Comment 17: Appendix A, p. 125: I don't understand the reference to "150.15a(b).

Response: The reference was made to 150.15a(b), "Continued Commission authority pertaining to byproduct material," because the requirements in Criterion 11A thru F and Criterion 12 pertain to authority reserved to the NRC.

Comment 18: Appendix A, p. 125, why the change of category when there was no corresponding change in the reg?

Response: The compatibility designation was changed for portions of this section from "C" to "A" for States with uranium mill authority. Staff determined that for Agreement States with uranium mill authority, these definitions provide information that is essential to the common understanding beyond the plain dictionary meaning. To be included in Category A, staff determined that these definitions provide a program element that is necessary to understand basic radiation principles for the regulation of uranium mill activities.

Comment 19: Appendix A, p. 156: §71.20, Why is this changed from a D to a [B]? There has been no change in the reg - what has changed?

Response: It was changed to "B" to ensure compatibility between NRC and Agreement States in an area that has significant and direct transboundary implications. During further staff review, it was noted that in accordance with 10 CFR 150.11, an Agreement State can regulate the following fissile materials: U-235 in quantities not exceeding 350 grams, U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams, or any combination of these materials that would not be sufficient to form a critical mass. These requirements would apply to the materials Agreement State regulate. Thus, the compatibility of this requirement was changed to a "[B]," which indicates that if a State has adopted this provision as a part of the State's DOT regulations, then the adoption of this provision is not necessary.

Comment 20: Appendix A, p. 161(§71.101) and p. 162 (§71.103); Why the change from "D" to "C"?

Response: The compatibility designation was changed for portions of this section from "D" to "C" for States which have licensees which use Type B packages. Staff determined that for Paragraphs (a), (b), and (c) are designated Category C and the essential objectives of these provisions should be adopted by those Agreement States which have licensees who use Type B packages. These provisions are designated Category C's because the quality assurance of Type B packages is an activity that is needed in order to avoid a nationwide regulatory gap in the regulation of the transportation of radioactive materials. If these provisions are not adopted, this could result in undesirable consequences in multiple jurisdictions.

NMSS

1. Perform a find and replace action in all the document to correct the term from "retitiled" to "retitled."

   Response: The procedure was revised to address this comment.

2. Page 8, Part 20, §20.1003, definition of "occupational dose."

   In the comment box add the following before the last sentence:

   This amendment reflects that violations to the requirements in §35.75 (patient release criteria) will be cited against §35.75 and not against the 0.1 rem public dose limit in 10 CFR Part 20.

   Response: The procedure was revised to address this comment.

3. Page 9, Part 20, §20.1003, definition of "public dose."

In the comment box add the following before the last sentence:

This amendment reflects that violations to the requirements in §35.75 (patient release criteria) will be cited against §35.75 and not against the 0.1 rem public dose limit in 10 CFR Part 20.

Response: The procedure was revised to address this comment.

4. Page 10, Part 20, §20.1003, definition of "shallow-dose equivalent."

In the comment box add the following before the last sentence:

For a detailed explanation of this change see NRC Regulatory Issue Summary 2002-10, dated July 9, 2002, available in the NRC web site.

Response: The procedure was revised to address this comment.

5. Page 12, Part 20, §20.1201, the section "Occupational dose limits for adults."

In the comment box add the following before the last sentence:

For a detailed explanation of this change see NRC Regulatory Issue Summary 2002-10, dated July 9, 2002, available in the NRC web site.

Response: The procedure was revised to address this comment.

6. Page 13, Part 20, §20.1301, the section "Dose limits for individual members of the public."

In the comment box add the following after the sentence that finishes with: ..and released under §35.75.":

This amendment reflects that violations to the requirements in §35.75 (patient release criteria) will be cited against §35.75 and not against the 0.1 rem public dose limit in 10 CFR Part 20.

Response: The procedure was revised to address this comment.

7. Page 13, Part 20, §20.1301, the section "Dose limits for individual members of the public." In the comment box add the following after "Paragraph (c) was assigned a compatibility category "A."

Paragraph (c) allows a medical licensee to permit visitors to individuals who cannot be released, under §35.75, to receive a radiation dose greater than 0.1 rem if: (1) The radiation dose received does not exceed 0.5 rem (5 mSv); and (2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

Response: The procedure was revised to address this comment.

8. Page 13, Part 20, §20.1301, Unless there has been a recent change, the compatibility table that I have (dated 5/9/02) does not list 20.1301(b) as having a compatibility category at all. This draft version assigns 20.1301(b) as a compatibility category A.

Response: No response is necessary since the 20.1301 compatibility designation was addressed in the proposed final procedure.

9. Page 39, Part 32, §32.72, the section "Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35."

There are two typographical errors in the comment box. Reference to "10.35.960(b)....." should

be corrected to read “34.980(b).....”

Response: The procedure was revised to address this comment.

10. Page 39, Part 32, §32.72, the section “Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.” Under the compatibility category box add: 32.72(b)(1) and 32.72(b)(2)(ii) as both having compatibility category B.

Response: No response is necessary since compatibility designation “B” applies to the entire section.

11. Page 39, Part 32, §32.74, the section “Manufacture and distribution of sources or devices containing byproduct material for medical use.”

Add the following sentences in the comment box.

> This section was revised as a result of amendment, “Medical Use of Byproduct Material (67 FR 20250, April 24, 2002) effective October 24, 2002 (RATS ID: 2002-2). The Agreement State implementation date is October 24, 2005. The existing compatibility designations for this section is not affected by this revision. This amendment revised §32.74(a) to correct the reference to ..§35.400 and 35.500..." and substitute it with the reference ..§35.400, 35.500, and 35.600....” Also this amendment revised §32.74(a)(3) to correct the reference to “...§35.57, 35.400, or 35.500..." and substitute it with the reference “...§35.65, 35.400, 35.500, and 35.600...”

Response: The procedure was revised to address this comment.

12. Page 39, Part 32, §32.74, the section “Manufacture and distribution of sources or devices containing byproduct material for medical use.”

Under the compatibility category box add: 32.74(a) and 32.74(a)(3) as both having compatibility category B.

Response: No response is necessary since compatibility designation “B” applies to the entire section.

13. Make the following change in 35.2, Definition of Authorized Nuclear Pharmacist.

> ...and other individuals from ~~“C”~~ “D” to “B” to ensure...

Response: The procedure was revised to address this comment.

14. Make the following change in 35.2, Definition of Mobile Medical Services.

> ~~This~~ The definition of mobile nuclear medicine service was deleted from this section...

Response: No response is necessary since the deletions identified in the proposed procedure were removed from the final procedure.

15. Make the following change in 35.40, Written Directives.

> ...test scenario: If a licensee ~~does not use written directives for therapeutic medical use~~ administers byproduct material that requires a written directive and a misinterpretation.... (Note: Some diagnostic procedures requires a written directive).

Response: The procedure was revised to address this comment.

16. Make the following change in 35.41, Procedures for administrations requiring a written directive.

> The essential objective of this requirement is to ~~assure patient identification and dose verification prior to administration to human beings~~ provide high confidence that byproduct material is administered as directed by an authorized user. (Note: this is the key message of 35.41).

Response: The procedure was revised to address this comment.

17. Make the following change in 35.50, Training for Radiation Safety Officer.

> ...from Section 35.900, Radiation Safety Officer, to Section 35.50. During the two year period after the effective date of the rule, both sections 35.900 and 35.50, will be in effect simultaneously. ~~Two years after the effective date of the final rule,~~After the two year period, Section 35.50 will replace...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.900 or 35.50. After the two year transition period, Section 35.50 will replace Section 35.900 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.50.

18. Make the following change in the strikeout 35.51, Calibration and check of survey instruments.

> The requirements in this section, with some modifications, were moved to Sec. ~~35.60~~ 35.61.

Response: No response is necessary since the deletions identified in the proposed procedure were removed from the final procedure.

19. Make the following change in 35.51, Training for an Authorized Medical Physicist.

> ...from Section 35.961, Training for teletherapy physicist, to Section 35.51. During the two year period after the effective date of the rule, both sections 35.961 and 35.51, will be in effect simultaneously. ~~Two years after the effective date of the final rule~~, After the two year period, Section 35.51 will replace...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.961 or 35.51. After the two year transition period, Section 35.51 will replace Section 35.961 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.51.

20. Make the following change in 35.55, Training for an Authorized Nuclear Pharmacist.

...from Section 35.980, Training for an authorized nuclear pharmacist, to Section 35.55. During the two year period after the effective date of the rule, both sections 35.980 and 35.55, will be in effect simultaneously. ~~Two years after the effective date of the final rule~~, After the two year period, Section 35.55 will replace...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.980 or 35.55. After the two year transition period, Section 35.55 will replace Section 35.980 and licensees will be required to comply with the training and experience requirements in the new 35.55.

21. Make the following change in 35.69, Labeling of vials and syringes.

...then the wrong ~~radiopharmaceutical~~ unsealed byproduct material could be administered... (Note: revised Part 35 no longer uses the term "radiopharmaceutical." It was substituted by "unsealed byproduct material.")

Also delete the example on the last sentence in the second paragraph. The example provided implies that vial shields are required by regulation. Part 35 is a performance-based rule which does not require licensees to used vial shield but instead requires licensees to comply with Part 20 occupational limits. It is up to the licensee to decide whether to use a vial shield or not.

Response: The procedure was revised to address these comments.

22. Make the following change in 35.70, Surveys for ambient radiation exposure rate.

> ....at the end of each day of use, all areas where unsealed byproduct material requiring a written directive is prepared for use or administered, except in areas where patients or human research subjects are confined and cannot be released under 35.75...

Response: The procedure was revised to address these comments.

23. Make the following change in 35.70, Surveys for ambient radiation exposure rate.

> The essential objective of this requirement is to assure that daily radiation surveys are performed in a risk informed manner. ~~areas where therapeutic radiopharmaceuticals are used.~~ (Note: the term "therapeutic radiopharmaceutical" is no longer used in revised Part 35).

Response: The suggested wording was not incorporated because the phrase "a risk informed manner" may not be understood in this context as it relates to surveys and could lead to misinterpretation by the Agreement States in their adoption of the concept. The wording was revised as follows:

The essential objective of paragraph (a) is to assure that daily radiation surveys are performed in areas where unsealed byproduct materials requiring a written directive are used.

24. Make the following change in 35.75, Release of individuals containing....

> The essential objective of this requirement is to assure that 0.5 rem TEDE is not exceeded by ~~any individual~~ a member of the public from an individual released under 35.75, and that written instructions are provided ~~so that a breast-feeding infant/child does not receive an exposure exceeding 0.1 rem TEDE~~ to the released individual to maintain doses ALARA if the TEDE to any other individual is likely to exceed 0.1 rem.

Response: The procedure was revised to address these comments.

24. Make the following change in 35.80, Provision of mobile medical service.

> ...are used and that radiation surveys are performed in areas ~~where therapeutic radiopharmaceuticals are used~~ to ensure compliance with Part 20 dose limits. (Note: revised Part 35 no longer uses the term "radiopharmaceutical." It was substituted by "unsealed byproduct material.")

Response: The procedure was revised to address these comments.

25. Make the following change in 35.100, Use of unsealed...

> Delete the term “radiopharmaceuticals” which is referenced two times and substitute it with unsealed byproduct material. (Note: revised Part 35 no longer uses the term “radiopharmaceutical.” It was substituted by “unsealed byproduct material.”)

Response: The procedure was revised to address this comment.

27. Make the following change in 35.190, Training for uptake...

> ...from Sec. 35.910, Training for uptake, dilution, and excretion studies, to section 35.190. During the two year period after the effective date of the rule, both sections 35.910 and 35.190, will be in effect simultaneously. After the two year period, Section 35.190 will replace 35.910. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.190 or 35.910. After the two year transition period, Section 35.190 will replace Section 35.910 and licensees will be required to comply with the training and experience requirements in the new 35.190.

28. Make the following change in 35.200, Use of unsealed...

> Delete the term “radiopharmaceuticals” which is referenced two times and substitute it with unsealed byproduct material. (Note: revised Part 35 no longer uses the term “radiopharmaceutical.” It was substituted by “unsealed byproduct material.”)

Response: The procedure was revised to address this comment.

29. Make the following change in 35.204, Permissible molybdenum-99...

> ... The essential objective of this requirement is to assure that ~~5.55 kBq is not exceeded~~ a licensee does not administer more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m.
>
> Delete the second paragraph. Failure to comply with the requirement in 35.204 will not trigger a medical event.

Response: The procedure was revised to address these comments.

30. Make the following change in 35.290, Training for uptake...

> ...from Sec. 35.920, Training for imaging and localization studies, to section 35.290. ~~Note, 2 years after the effective date of the final rule, Sec. 35.290 will replace the requirements in Sec. 36.920, Training for imaging and localization studies.~~ During the two year period after the effective date of the rule, both sections 35.920 and 35.290, will be in effect simultaneously. After the two year period, Section 35.290 will replace 35.920. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.920 or 35.290. After the two year transition period, Section 35.290 will replace Section 35.920 and licensees

will be required to comply with the training and experience requirements in the new Sec. 35.290.

31. Make the following change in 35.300, Use of unsealed...

> Delete the term “radiopharmaceuticals” which is referenced two times and substitute it with unsealed byproduct material. (Note: revised Part 35 no longer uses the term “radiopharmaceutical.” It was substituted by “unsealed byproduct material.”)

Response: The procedure was revised to address this comment.

32. Make the following change in 35.310, Safety instruction.

> ... The essential objective of this requirement is to assure that medical personnel caring.... test scenario: If the medical personnel caring for patients...

Response: The procedure was revised to address this comment.

33. Make the following change in 35.390, Training for use of unsealed...

> ...from Sec. 35.930, Training for therapeutic use of unsealed byproduct material, to section 35.390. During the two year period after the effective date of the rule, both sections 35.930 and 35.390, will be in effect simultaneously. After the two year period, Section 35.390 will replace 35.930. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.930 or 35.390. After the two year transition period, Section 35.390 will replace Section 35.930 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.390.

34. Make the following change in 35.392, Training for the oral administration...

> ...from Sec. 35.932, Training for treatment of hyperthyroidism, to section 35.392. During the two year period after the effective date of the rule, both sections 35.932 and 35.392, will be in effect simultaneously. After the two year period, Section 35.392 will replace 35.932. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.932 or 35.392. After the two year transition period, Section 35.392 will replace Section 35.932 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.392.

35. Make the following change in 35.394, Training for the oral administration...

> ...from Sec. 35.934, Training for treatment of thyroid carcinoma, to section 35.394. During the two year period after the effective date of the rule, both sections 35.934 and 35.394, will be in effect simultaneously. After the two year period, Section 35.394 will replace 35.934. To be included.

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will

have the option of complying with either the training requirements in Section 35.934 or 35.394. After the two year transition period, Section 35.394 will replace Section 35.934 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.394.

36. Make the following change in 35.406, Brachytherapy sources accountability.

> ... The essential objective of this requirement is to assure the accountability of sources ~~after use~~ in storage and in use at all times.

Response: The procedure was revised to address this comment.

37. Make the following change in 35.410, Safety instruction.

> ... The essential objective of this requirement is to assure that medical personnel caring.... test scenario: If the medical personnel caring for patients...

Response: The procedure was revised to address this comment.

38. Make the following change in 35.415, Safety precautions.

> ... ~~The revises reflect that posting requirements in Part 20 were determined to be not adequate~~ The posting requirements in 35.415 are in addition to the posting requirements in Part 20 to ensure that individuals entering the room would be aware of the presence of radioactive material in the room.

Response: The procedure was revised to address this comment.

39. Make the following change in 35.432, Calibration measurements of brachytherapy sources.

> ...are performed before the first medical use of the source or source /applicator configuration after the effective date of the final rule... test scenario: a licensee does not perform ~~full~~ calibration... (Note: term full calibration is used exclusively for gamma knifes, teletherapy and remote afterloader units).

Response: The procedure was revised to address this comment. However, the wording "after the effective date of the final rule..." was not inserted because it creates confusion by combining the essential objective with the rule finalization date.

40. Make the following change in 35.457, Therapy-related computer systems.

> ...operating properly~~, and~~ a medical event could occur~~s~~.

Response: The procedure was revised to address this comment.

41. Make the following change in 35.490, Training for use of manual...

> ...from the Sec. 35.940, Training for use of brachytherapy sources, to section 35.490. During the two year period after the effective date of the rule, both sections 35.940 and 35.490, will be in effect simultaneously. After the two year period, Section 35.490 will replace 35.940. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.940 or 35.490. After the two year transition period, Section 35.490 will replace Section 35.940 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.490.

42. Make the following change in 35.491, Training for ophthalmic use of Sr-90.

...from the Sec. 35.941, Training for ophthalmic use of strontium-90, to section 35.491. During the two year period after the effective date of the rule, both sections 35.941 and 35.491, will be in effect simultaneously. After the two year period, Section 35.491 will replace 35.941. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.941 or 35.491. After the two year transition period, Section 35.491 will replace Section 35.941 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.491.

43. Make the following change in 35.500, Use of sealed sources for diagnosis.

Delete the first two sentences in the paragraph since they are not related to section 35.500. Move the following sentence that is located in the middle of the text to the beginning of the paragraph "This section requires the use of sealed sources in the SS&D Registry by all specific licensees." Retain the remainder of the text.

Response: The procedure was revised to address this comment.

44. Make the following change in 35.590, Training for use of sealed sources...

...from the Sec. 35.950, Training for use of sealed sources for diagnosis, to section 35.590. During the two year period after the effective date of the rule, both sections 35.950 and 35.590, will be in effect simultaneously. After the two year period, Section 35.590 will replace 35.950. To be included...

Response: The suggested wording was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.950 or 35.590. After the two year transition period, Section 35.590 will replace Section 35.950 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.590.

45. Make the following change in 35.615, Safety precautions...

...is to assure that controls are implemented, to ~~require the physical presence~~ establish the requirements for physical presence and immediate availability of the authorized user...

Response: The procedure was revised to address this comment.

46. Make the following change in 35.630, Dosimetry equipment.

...calibrated in accordance with ~~national standards~~ protocols accepted by nationally recognized bodies...

...test scenario: If a licensee does not calibrate and check dosimetry equipment in accordance with ~~industry standards~~ accepted protocols, and an equipment failure...

Response: The procedure was revised to address this comment.

47. Make the following change in 35.632, Full calibration measurements...

...test scenario: If a licensee does not perform full calibration measurements on teletherapy units in accordance with ~~industry standards~~ accepted protocols, and an equipment failure...

Response: The procedure was revised to address this comment.

48. Make the following change in 35.633, Full calibration measurements...

> ...test scenario: If a licensee does not perform full calibration measurements on remote afterloaders in accordance with ~~industry standards~~ accepted protocols, and an equipment failure...
>
> It is stated in the compatibility category box that paragraph (i) is compatibility category D while the rest of the text is H&S. If your read the comment it states that Handbook 5.9 assigns a category of H&S to paragraphs (a) through (f), but nothing is mentioned about paragraph (g) and (h). The reader will not know for sure what compatibility category is paragraph (g) and (h).

Response: The procedure was revised to address this comment.

49. Make the following change in 35.635, Full calibration measurements...

...test scenario: If a licensee does not perform full calibration measurements on gamma stereotactic radiosurgery units in accordance with ~~industry standards~~ accepted protocols, and an equipment failure...

Response: The procedure was revised to address this comment.

50. Make the following change in 35.647, Additional technical requirements...

> ...Section E, paragraph(a) was designated a H&S for those Agreements States...

Response: The procedure was revised to address this comment.

51. Make the following change in 35.655, Five-year inspection...

This section replaces the ~~previous~~ requirements ~~contains the requirements~~ for inspections that were in the previous Sec. 35.647...

Response: The procedure was revised to address this comment.

52. Make the following change in 35.657, Therapy-related computer...

> The first sentence in the first paragraph is incomplete and has no meaning. Information apparently was deleted unintentionally. Originator of document should correct.
>
> ...treatment planning systems are operating properly, ~~and~~ a medical event could occur~~s~~.

Response: The procedure was revised to address these comments.

53. Explanation of Section 35.690, Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, is missing from the draft document. Explanation should include the following.

The training and experience requirements for an Authorized User of teletherapy units were moved, with some modifications, from the Sec. 35.960, Training for teletherapy, to section 35.690. Also Sec. 35.690 was expanded to include the training for Authorized Users of remote afterloaders and gamma stereotactic radiosurgery units. During the two year period after the effective date of the rule, both sections 35.960 and 35.690, will be in effect simultaneously. After the two year period, Section 35.690 will replace 35.960. To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from “C” to “B” to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.

Response: The section was changed as suggested except for the following wording, "During the two year period after the effective date of the rule, both sections 35.960 and 35.690, will be in effect simultaneously." This language was not taken because it appeared to imply dual regulation and was not consistent with the statements in the Federal Register notice. The section was revised to read:

During the two year transition period, October 24, 2002 through October 24, 2004, licensees will have the option of complying with either the training requirements in Section 35.960 or 35.690. After the two year transition period, Section 35.690 will replace Section 35.960 and licensees will be required to comply with the training and experience requirements in the new Sec. 35.690.

54. Add the following sentences at the end of the paragraph in the comment box of Subpart J, Training and Experience Requirements

> ~~This section~~ Subpart J will be retained for 2 years after the effective date of the final rule (October 24, 2002). ~~A two year "Transition Period" has been established starting on the effective date of the revised Part 35. The Subpart J addressing training and experience requirements will be accepted along with the revised requirements.~~ During the 2-year transition period, licensees will have the option of complying with either the training requirements of Subpart J, or the revised requirements in Subparts B and D through H.
>
> Only two changes were made in Subpart J after revised Part 35 went into effect. The title in Sec. 35.960, "Training for teletherapy", was changed to "Training for use of therapeutic medical devices", and the title in Sec. 35.961, "Training for teletherapy physicist", was changed to "Training for authorized medical physicist." In addition, reference to "teletherapy physicist" was changed to "authorized medical physicist."

Response: The procedure was revised to address these comments.

55. Make the following change in 35.900, Radiation Safety Officer.

> This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

56. Make the following change in 35.910, Training for uptake...

> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

57. Make the following change in 35.920, Training for imaging...

> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

58. Make the following change in 35.930, Training for therapeutic use...

> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

59. Make the following change in 35.932, Training for treatment of hyperthyroidism.

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

60. Make the following change in 35.934, Training for thyroid carcinoma.

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

61. Make the following change in 35.940, Training for use of brachytherapy...

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

62. Make the following change in 35.941, Training for ophthalmic use...

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

63. Make the following change in 35.950, Training for use of sealed sources...

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

64. Make the following change in 35.960, Training for teletherapy.

As a result of the amendment, one change has been made in this section...

... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

65. Make the following change in 35.961, Training for teletherapy physicist.

> As a result of the amendment, one change has been made in this section...
>
> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

66. Make the following change in 35.980, Training for an authorized nuclear...

> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

67. Make the following change in 35.981, Training for experienced...

> ... This section will be retained for 2 years after the effective date of the final rule. ~~at which time~~ After the 2-year transition period licensees will be required to comply with...

Response: The procedure was revised to address these comments.

68. Make the following change in 35.3045, Report and notification of a medical event.

> ...radiation control program and ~~in order~~ to assess the effectiveness...
>
> Add the following sentence at the end of the paragraph. The term "misadministration" used in old Part 35 evolved into the new term "medical event." The new term recognizes wrong treatment site, patient intervention and dose to skin.

Response: The procedure was revised to address these comments.

69. Make the following change in 35.3047, Report and notification of a dose to an embryo/fetus or a nursing child.

> ... The essential objective of this requirement is to assure that unintended doses to the embryo/fetus or nursing child greater than the doses allowed in Sec. 35.3047 are reported to the radiation control program.

Response: The procedure was revised to address these comments.

70. On page 3 of the text, Table 1 is missing and Table 2 is mislabeled as Table 1.

Response: The procedure was revised to address these comments.

71. The description of the Regulation Table indicates (on page 5) that the Comment column provides rationale for compatibility designations. This is done only in limited cases; it is not clear why the rationale is included in the cases that it is and not for others.

Response: The procedure was revised to address these comments.

72. In the Regulation Table:

As the whole of 10 CFR 31.5 has been changed from compatibility designation C to B, indicating only what has changed in the specific provisions is not appropriate. There needs to be some comment about the whole section as some jurisdictions did not have comparable provisions at all before. In addition to the statement about the change of

compatibility designation, it should include at least the same comment as there is for 10 CFR 31.3, but possibly more as this is a significant change. Also, in the discussion of 31.5(c)(13), delete the words, "and referencing the fee requirement in Section 170.31," as this is not an appropriate detail to include.

Response: The procedure was revised to address these comments.

73. On 10 CFR 31.6, the comment should be changed to delete only the second sentence (not the first) and revise the added text to say: "The compatibility designation for this section was changed from Category C to Category B as a result of amendment, "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," (65 FR 79162; December 18, 2000) effective February 16, 2001 (RATS ID: 2002-1). The Agreement State implementation date is February 16, 2004." Note, section 31.6 was not revised, only the compatibility designation.

Response: The procedure was revised to address these comments.

74. On 10 CFR 32.52, the implementation date for rulemaking is February 16, 2004, as stated. However, there was a 6-month implementation date to use some method to require updated reports; should this be noted also?

Response: Since Agreement States are required to adopt their compatible regulations within three years, a noting of the 6-month implementation date is not necessary.

75. On 10 CFR 32.52, in the note about NRC Form 653, replace the words, "will be provided" with "is available."

Response: The procedure was revised to address these comments.

76. On 10 CFR 32.52(c), as the records requirement is also there as a backup for verifying reports made to NRC, why are we giving flexibility to the States on the retention period? Is it so as not to force the same reduction from 5 years to 3 years? We should require a minimum of 3 years.

Response: The area of record keeping is not an area that requires strict compatibility.

77. In the Program Element Table: On Reciprocal recognition of licenses, as transboundary implications are noted, compatibility classification "B" should be referred to rather than "A."

Response: The procedure was revised to address these comments.

78. P.45, §34.13:

A. Line 6: Delete "(g)" after "§34.43."
B. Line 10: Add "as described in §34.45" after "emergency procedures."
C. Line 15: Replace "teasing" by "testing."
D. Line 17: Delete "methods of sample collection" and replace "analyzing" by "collecting the."
E. Line 18: Add "analytical" before "instruments."
F. Line 20: Replace "not" by "as well as."
G. Line 23: Add "d" after "prescribe."

Response: The procedure was revised to address these comments.

79. P.45, §34.20: Line 4: Add "for" after "shall be used."

Response: The procedure was revised to address these comments.

80. P.49, §34.47:

A. Line 12: Delete "by this section."
B. 5th line from bottom: Add "and maintain records" after "radiation."

Response: The procedure was revised to address these comments.

81. On page 117, the change of the §40.4 “uranium milling” definition from compatibility designation “C” to “A” is appropriate because it is necessary to implement the NRC regulations and the Atomic Energy Act (e.g., Section 84), not just to understand basic radiation principles.

Response: The procedure was revised to address these comments. However, the wording “to implement the NRC regulations and the Atomic Energy Act” was not taken because Agreement States do not implement NRC regulations or the Atomic Energy Act. Agreement States implement compatible State regulations not NRC regulations and their State statutes.

82. On page 125, the comment on Part 40, Appendix A, Criteria 11 and 12 apparently should refer to 10 CRF 150.15a(b), not 150.a(b). Since this regulation reserves Commission authority over minimum standards regarding reclamation, as well as for long-term surveillance and ownership, other Appendix A criteria such as 4 and 6 should be compatibility designation “A” instead of “C.”

Response: The procedure was revised to address these comments.

NMSS, Thomas Young

83. The section, SA 200, Section 34.13, page 47, suggested revision:

Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), this section is designated as a Category C which requires the Agreement State to adopt the essential objective of the rule. The essential objective of this rule is that Agreement States should establish basic requirements for approval of industrial radiography license applications which address the following: (a) general requirements in §30.33; (b) procedures for verifying and documenting the certification status of radiographers and ensuring that the certification of individuals acting as radiographers remain valid; (c) written operating and emergency procedures; (d) the program for inspections of the job performance of each radiographer and radiographer’s assistant at intervals not to exceed six months as described in §34.43 (e); (e) overall organization structure as it applies to the radiation safety responsibilities in industrial radiography, including delegation of authority and responsibility; (f) qualifications of the individual designated as the radiation safety officer as described in §34.42; (g) if the applicant intends to perform leak teasing of the sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test–methods of sample collection; qualifications of person analyzing samples; instruments to be used; and method of analyzing the samples. In addition, for the purposes of further clarification, §34.13(h)(3) refers to the qualifications of the individual who analyzes the samples, not the person taking the samples; (For additional information, see Appendix C, CR-02-02) (h) if the applicant intends to perform calibrations of survey instruments, the applicant describe methods to be used and the experience of the person(s) who will perform the calibrations prescribe in §34.25; (i) locations of all field stations and permanent radiographic installations; and (j) the storage location of all required records.

Response: The procedure was revised to address these comments.