

July 23, 2001

ALL AGREEMENT STATES
MINNESOTA, PENNSYLVANIA, WISCONSIN

PROGRAM MANAGEMENT INFORMATION: DRAFT REVISION OF SA-201: REVIEW OF STATE REGULATORY REQUIREMENTS (STP-01-059)

Enclosed for your review and comment is the draft revision of the Office of State and Tribal Programs (STP) Procedure SA-201: *Review of State Regulatory Requirements*. This procedure describes the process for review and comment on proposed and final State regulations, other generic legally binding requirements and Suggested State Regulations. We have highlighted significant changes in a separate Enclosure. We would appreciate receiving your comments* within one month of receipt of this memorandum.

If you have any questions, please contact me at (301) 415-3340 or the person named below.

POINT OF CONTACT: John Zabko INTERNET: JGZ@NRC.GOV
TELEPHONE: (301) 415-1277 FAX: (301) 415-3502

/RA by Frederick C. Combs, Acting for/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

*This information request has been approved by OMB 3150-0029, expiration 06/30/04. The estimated burden per response to comply with this voluntary collection is approximately 6 hours. Forward any comments regarding the burden estimate to the Information and Records Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0029), Office of Management and Budget, Washington, DC 20503. If a document does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information.

STP-01-059

July 23, 2001

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STP-A-4

HIGHLIGHTS OF THE DRAFT REVISION OF STP PROCEDURE SA-201: REVIEW OF STATE REGULATORY REQUIREMENTS

The discussion below highlights changes to SA-201 to improve efficiency and effectiveness in our review.

Expansion in Scope

The scope has been expanded to explicitly identify generic legally binding requirements, e.g., license conditions and orders, and request that Agreement States provide NRC with copies of such requirements consistent with the approach used currently for proposed and final regulations. Generic legally binding requirements will be reviewed in the same manner as regulations. The scope has also been expanded to include review of Suggested State Regulations submitted by the Conference of Radiation Control Program Directors, Inc. (CRCPD). (See Section II.)

More Specificity in State Guidance

The guidance requests that States, when submitting proposed or final regulations for review, (1) identify the specific regulation sections that are being changed, (2) identify what NRC equivalent regulations are being incorporated into the State's regulation change, (3) identify whether the proposed or final regulations satisfy the compatibility designations of STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, and (4) identify any significant differences between the State's regulation and the NRC's equivalent regulation, and the rationale for the difference. (See Section V.A.3 and Appendix A.)

Enhanced Guidance to STP and RSAO Staff

The Deputy Director, STP, makes assignments for review after receiving the Agreement State regulations or SSR. The Regional State Agreements Officer (RSAO) will usually assume legal responsibility for the review. If, after consultation with the Regional Division Director of Nuclear Material Safety, the RSAO is not available, the review will be assigned to the Agreement States Project Officer (ASPO) or other STP staff. Changes in assigned due dates are to be reviewed and approved by the Deputy Director.

The reviewer conducts a completeness review within three days of receipt of the transmittal letter and regulations, requests any additional information directly from the States, and assures that a realistic due date for completing NRC's review is established through discussion with the State Radiation Control Program Director or designee. The reviewer should meet the State's requested date for comments. However, the normal time to complete a review is 60 days from the receipt of the State's transmittal letter. (See Section V.C.)

To take advantage of word processing software, the reviewer will use standard format and content letters whenever possible. (See Section V.E.2) Finally, STP will maintain a database on the status of the States' regulations using the State Regulation Status (SRS) Data Sheets and information in the Regulation Assessment Tracking System** (RATS). (See Section V.E.4.)

**The RATS Data Sheets will be phased out in lieu of the Revised SRS Data Sheets as Agreement States submit new regulations for review.



STP Procedure Approval

Review of State Regulatory Requirements - SA-201

Issue Date:

Review Date:

Paul H. Lohaus
Director, STP

Date: / /01

Frederick C. Combs
Deputy Director, STP

Date: / /01

John G. Zabko
Procedure Contact, STP

Date: / /01

NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact. Copies of STP procedures will be distributed for information.



Procedure Title:
Review of State Regulatory Requirements
Procedure Number: SA-201

Page: 1 of 8
Issue Date:

I. INTRODUCTION

This procedure describes the process for review and comment on proposed and final State regulations, other generic State legally binding requirements and Suggested State Regulations (SSRs).

II. OBJECTIVES

- A. To provide guidance for recommended use by States and the Conference of Radiation Control Program Directors, Inc. (CRCPD) on preparation and submittal of proposed and final State regulations, other generic legally binding requirements, e.g., license conditions and orders, and SSRs for the Nuclear Regulatory Commission (NRC) staff review.
- B. To establish the procedures to be followed by NRC staff for review of State regulations or other generic legally binding requirements, and SSRs including the scope of review, staff responsibilities, timeliness, and products to be prepared and communicated to the State or CRCPD documenting the results of the review.
- C. To provide guidance to NRC staff on whether there are significant differences identified in State regulations, other generic legally binding requirements, or SSRs.

III. BACKGROUND

- A. Each Agreement State has the responsibility to promulgate legally binding requirements that satisfy the compatibility requirement of Section 274 of the Atomic Energy Act of 1954, as amended. States generally fulfill that responsibility through promulgation of regulations. Because each Agreement State possesses detailed knowledge of its own requirements, Agreement States are best able to determine that their regulations or other generic legally binding requirements are compatible with NRC regulations and where there are significant differences which could affect compatibility.
- B. Agreement States, and all States seeking an Agreement with NRC, are requested to submit for NRC staff review proposed amendments to their regulations or other proposed generic legally binding requirements. Such requests should usually be submitted when they are published for public comment.

Agreement States also are requested to submit final regulations or other final generic legally binding requirements for review. The requested submittal should include requirements satisfying the compatibility and health and safety designation associated with equivalent regulations of the Commission. The Office of State and Tribal Programs (STP) Procedure SA-201 is used as a guide.

- C. To assist States in promulgating compatible regulations or other generic legally binding requirements within three years of the effective date of changes in NRC regulations, NRC staff prepares and publishes semiannually a *Chronology of NRC Amendments*. Included in the chronology is identification of each regulation change, the specific sections modified or established by the regulation change, the effective date of the change, and the compatibility or health and safety designation.

IV. ROLES AND RESPONSIBILITIES

NOTE: In the following, the word, “regulations,” also refers to “other generic legally binding requirements” and the SSRs. The word State also refers to the CRCPD.

- A. The Director, STP, has overall responsibility for the review and determination of the compatibility of State regulations.
- B. The Deputy Director, STP, is designated to receive State regulations and has primary responsibility for coordinating the NRC staff’s review. This includes reviewer assignments, assignment of due dates, and changes to due dates. The Deputy Director also keeps the STP Management Analyst informed when an Agreement State regulation is received so the status of the review can be tracked by the STP Management Analyst through closure.
- C. The State Regulations Review Coordinator (coordinator) is responsible for overall review project management and assuring overall quality control of the review process. In addition, the coordinator: (1) reviews proposed comment letters to help ensure consistency of reviews among reviewers and helps address potential delays or other issues associated with specific regulation reviews, and (2) maintains the *Chronology of NRC Amendments*.
- D. The Regional State Agreements Officer (RSAO) and STP staff are responsible for conducting reviews of State regulations as assigned.
- E. The Management Analyst (analyst) enters information on the regulation review in the STP Action Item Tracking System and the RATS. The analyst also provides information from RATS to the coordinator and reviewer as needed.

V. GUIDANCE**A. The States**

1. States should submit and request comments on proposed and final regulations to the Deputy Director, STP. Regulations must be submitted in hard copy format. In accordance with NRC procedures, all incoming regulations will be entered into the NRC's Agency Wide Documents and Management System (ADAMS). Currently, ADAMS will only accept hard copies for entry.
2. Appendix A to this procedure provides guidance for recommended use by States on the form, content, and process to be followed for preparation and submittal of proposed and final regulations to NRC staff for review.
3. The State, in its transmittal letter, is requested to identify the date comments are requested from NRC (see C.2 for scheduling guidance). The State is also requested to: (1) identify the specific regulation sections that are being changed, (2) identify what NRC equivalent regulations are being incorporated into the State's regulations, (3) indicate whether its proposed/final regulation satisfies the compatibility criteria of STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, and (4) identify any significant difference between the State's regulation and the NRC equivalent regulation and the rationale for the difference.
4. For generic legally binding requirements, the State should provide information demonstrating that they are legally binding and enforceable as law, e.g., license conditions, orders, or statements from Attorney Generals. (NRC Management Directive 5.9, Handbook 5.9, Part VI (D)).

B. Reviewer Assignment

The Deputy Director will normally first assign review of a regulation to the RSAO. If, after consultation with the Regional Director of the Division of Nuclear Materials Safety, the RSAO is not available, the Deputy Director will assign the review to the Agreement States Project Officer (ASPO), other STP staff or evaluate the use of contractor assistance (See Section V.D.). Review assignments should usually be completed within three days of receipt.

C. The Reviewer

1. Conducts a completeness review within three days of receipt of the transmittal letter and regulations. If the State did not include the information requested in Section V.A.3, the reviewer should contact the State Director or designee to determine whether it can be made available to the reviewer.
2. After conducting a completeness review, notifies the State by telephone or E-mail as to whether the staff expects to be able to meet the State's requested date for comments; if not, the reviewer should establish a revised date that is acceptable to the State. Regulation reviews will be scheduled to meet State requested due dates. However, the normal review time is 60 days from the receipt of the State transmittal letter.
3. Conducts a comparison of the intent of the State's regulation with the equivalent NRC regulation to determine if the State's regulation is "essentially identical" (Category A and B) or meets the "essential objectives" (Category C and H&S) as defined in the glossary of Handbook 5.9. Differences that are identified, which either significantly change or affect the intent of the regulation, should be analyzed further and a determination made whether the regulation meets (or does not meet) the compatibility or health and safety objective of the equivalent NRC regulation. Guidance to assist in determining when a difference is significant and should be included as a comment on the State's regulation is set out in Appendix B, Handbook 5.9, and STP Procedure SA-200.
4. Limits review to those portions of a State's regulation that are being added or amended by the State's rulemaking action. The reviewer should also limit review to those parts or sections of the regulation that are either required for compatibility or health and safety, as set out in STP Procedure SA-200 (i.e., Categories A, B, and C or H&S).
5. Consults, as necessary, for State regulations and in all cases for SSRs and for a State seeking an Agreement with NRC with the Office of Nuclear Material Safety and Safeguards (NMSS) or other NRC offices to support completion of the review based on issues raised during the review and their significance. If requested, NMSS and the OGC, or other NRC offices, review State regulations according to their own internal procedures. The reviewer will also schedule meetings with the Deputy Director and commenting offices to resolve differing views, or significant issues.
6. Prepares the comment letter to the State and updates the State Regulation Status (SRS) Data Sheet (see Appendix G). The letter and updated SRS Data Sheet may be sent to the coordinator electronically.

7. Follows any comments returned by the State on the subject regulations to examine how the State addressed the comments.

D. Contractor Assistance

A request for consultant or contractor assistance in review of proposed or final State regulations can only be initiated by the STP technical monitor of the consultant or contractor, but requires the concurrence of the Director, STP. When using such assistance, the coordinator should:

1. Prepare a cover letter and attach the regulations package for forwarding to the consultant or contractor following the instructions of the technical monitor, including the instruction to follow this procedure to conduct the review.
2. Evaluate the comments as the basis for development of a comment letter to the State upon return of the consultant's or contractor's review report.

E. Communication of Review Results

1. Before a formal comment letter or "no comment" letter to the State is prepared, the reviewer should informally discuss proposed comments with the State to assure the comments will be clearly understood and to receive any information from the State that is helpful in explaining the comments.
2. The reviewer should prepare a formal comment letter or "no comment" letter to the State documenting the results of the review. The letter should be addressed to the State Radiation Control Program Director, unless State staff has specified otherwise, and should normally be prepared for signature by the Deputy Director. The standard format and content for the letter are set out in either Appendix C (proposed regulations) or Appendix D (final regulations). The reviewer should not use past letters as a word processing basis to prepare a new comment letter for the review. A clean blank comments letter should be used in all cases. Form letters that are partially completed are available on S:\Regulations\State Regulations\ in Read-Only. (Regions may have these letters on the H:drive.) Save the letter before entering data. (Note: Only the Deputy Director's secretary is authorized to modify the form letters on the S: drive.) All letters should use the Regulatory Information Distribution System (RIDS) codes SP (05-08), corresponding to NRC Regions I-IV, on the concurrence sheet.

3. Comments resulting from the review should be set out in an enclosure to the letter and should contain, as a minimum, the following information:
 - a. Citation of the part or section of the State regulation reviewed or SSR;
 - b. Citation of the equivalent NRC regulation or SSR;
 - c. RATS ID;
 - d. Compatibility or H&S category assigned to that section or part of the regulation;
 - e. Description of the difference identified by the Reviewer between the State (or SSR) and NRC regulation, including the significance of the difference (e.g., why it does not meet the assigned compatibility category), and description of at least one course of action the State could take to address the comment.
 - f. A blank comment table for reviewer use in summarizing comments is attached to the sample comment letters for proposed and final regulations (Appendices C and D on S: drive). The reviewer may draft the table in either electronic or handwritten form. However, to expedite word processing, completion of the table to be attached to the letter will only be prepared by secretarial staff.
4. A SRS Data Sheet should be updated to reflect the current review and included as an enclosure to the comment letter.
5. The reviewer should concur in the comment letter and forward it to the coordinator. The coordinator reviews and concurs on all letters within one week of receipt. All letters should also be reviewed and concurred in by the Deputy Director, STP, prior to being sent out for office concurrence.
6. All offices participating in the review should be on concurrence. For reviews conducted by the RSAO, the concurrence of the Regional Counsel may be required in accordance with Regional procedure or practice. The concurrence of OGC is always required. (Note: OGC requests that two weeks be provided for their concurrence.)
7. Concurrence in the comment letter by NMSS, the Regional Office and OGC should

be requested in all cases when the regulation has been submitted by a State seeking an Agreement with NRC.

8. On the date that the letter is signed by the Deputy Director, the STP secretary should enter the NRC review date into the enclosed RATS Data Sheet for the amendments marked by a star.
9. The coordinator should ensure that a copy of the letter is provided to the STP Management Analyst so that the results of the comment letter are entered into the RATS Data Base and the action is closed in the tracking system.

VII. APPENDICES

Appendix A - Guidance for Recommended Use by Agreement States and CRCPD for Submitting Regulations for NRC Staff Review

Appendix B - Criteria for Comparing Regulations and Identifying Differences

Appendix C - Sample Comment Letter for Proposed State Regulations

Appendix D - Sample Comment Letter for Final State Regulations

Appendix E - Instructions for Completing SRS Data Sheet

Appendix F - Document Review Flow Chart

Appendix G - SRS* Data Sheet

*The RATS Data Sheets will be phased out in lieu of the Revised SRS Data Sheets as Agreement States submit new regulations for review.

VIII. REFERENCES

1. STP Procedure SA-201, *Review of State Regulatory Requirements*, supersedes STP Procedure SA-201, *Review of State Regulations*, November 10, 1998.
2. STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*.
3. NRC Regulations Title 10-Chapter 1, *Code of Federal Regulations*, published by the Division of Freedom of Information and Publications Services, NRC, codified and reissued periodically.
4. The latest *Chronology of NRC Amendments* provided electronically to the States by All Agreement States Letter and posted on the STP website. Links are provided to the Federal Register notice.
5. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*, and associated Handbook 5.9.
6. Suggested State Regulations (that have received final approval by NRC) published by the Conference of Radiation Control Program Directors, Inc.
 - Part E - Radiation Safety Requirements for Industrial Radiographic Operations, February 1999.
 - Part O - Decommissioning, August 2000.
 - Part T - Transportation of Radioactive Material, February 1999.

Appendix A

GUIDANCE FOR RECOMMENDED USE BY STATES AND CRCPD FOR SUBMITTING REGULATIONS (OTHER GENERIC LEGALLY BINDING REQUIREMENTS) FOR NRC STAFF REVIEW

I. INTRODUCTION

This guidance to Agreement States, States seeking an Agreement, and the CRCPD, pertains to the submittal of proposed and final State regulations to NRC staff for review to confirm that they are compatible with equivalent regulations of the NRC. NRC's goal is to conduct a single review for proposed regulations and a single review for final promulgated regulations. Although many States base their regulations on Suggested State Regulations (SSRs), until the SSRs are updated and reviewed with regard to compatibility and approved by NRC, the State should not assume that State regulations based on SSRs are necessarily compatible. The NRC review process compares all State regulations with the equivalent regulations of the NRC and NRC-approved final SSRs, when the State uses them for a model.

Other generic legally binding requirements consistent with State administrative law may be applicable to more than a few licensees. However, since the appropriate approach to such issues will depend on the types and numbers of licenses involved, the State's approach will be reviewed on a case-by-case basis. (NRC Management Directive 5.9, Handbook 5.9, Part VI (D))

II. STATE SUBMITTAL GUIDANCE

A. For proposed regulations at the draft stage or, preferably, the public comment stage, but not both, the Radiation Control Program Director, or designee, or CRCPD (Director), in preparing and submitting proposed regulations, is requested to identify by line-in/line-out text, or similar identification, the changes to NRC's regulations that are being incorporated into the State's regulations. The Director is requested to identify at what point in the State's regulatory process NRC's review would be of most benefit to the State, i.e., either at the draft stage or the public comment stage (or peer review stage for SSR's), and to have NRC complete the review at that stage. It is important that when the proposed regulations are finalized, that the final regulations are also submitted to NRC. For final promulgated regulation changes, the Director is requested to identify by line-in/line-out text, or similar identification, the changes made between the proposed regulation submitted above and the final regulation. The Director is requested to discuss how the State has addressed or incorporated NRC's comments on the proposed regulation. The Director is requested to submit preferably an electronic version of the cover letter and regulation, whenever possible, using a word processing software that is compatible with "WordPerfect 6.1" or higher. A sample submittal letter is shown in Attachment 1.

Appendix A (Continued)

- B. The Director is requested to submit proposed regulations to the Deputy Director, STP. The regulations are requested to be submitted at least sixty days before the State needs comments, or concurrently with the State publication of the proposed regulations for public comment. The Director is requested to identify the date by which the State needs comments from NRC in the transmittal letter. Final regulations as officially adopted by the State are requested to be submitted to the Deputy Director, STP, for review after the regulations are published, and no longer than two months following their promulgation as an effective regulation.
- C. With both proposed or final regulation, the Director is requested to document whether the Agreement State believes its regulation satisfies the compatibility and health and safety component criteria in *Handbook 5.9* and the assigned compatibility and health and safety component designations set out in STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*. The staff reviews State regulations based on this guidance and the guidance set out in Appendix B to this procedure. If the regulation does not satisfy the compatibility and health and safety designation, the Director is requested to identify those sections and to describe the State's rationale for promulgating a regulation that is not compatible with NRC's regulation. The Director is requested also to describe any constraints that prevent the State from promulgating a rule that satisfies the compatibility or health and safety designation and whether the program is examining removal of the constraints.
- D. The State or CRCPD may be requested to submit additional relevant information, as necessary, such as a copy of the State regulations package, public proceedings, advisory committee comments, and public comments that influenced the text of the final regulations. The State has the responsibility of demonstrating that the requirements adopted other than by regulation are legally binding on the licensee, e.g., license conditions, orders, or statements from Attorney Generals.

III. THE STATE REGULATION STATUS (SRS) DATA SHEET

The SRS Data Sheet (Appendix G) is used by NRC staff to track the status of Agreement State regulations. If information is missing, the Agreement State should add the missing information and forward the revised SRS Data Sheet to the regulation coordinator. The regulations assessment tracking system (RATS) is an internal program used by STP to track the progress of State regulation review requests.

Attachment 1

(Date: preferably 60 days before comments are due or concurrently with the State publication of the proposed regulations for public comment)

Mr./Ms. *(Name)*
Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr./Ms. *(Name)*:

Enclosed is a copy of the proposed *(or final)* revisions to the *(State)* Radiological Health Rules *(identify the regulations using the title or description and date of regulations)*. *(For proposed regulations)* The proposed revisions were made available for public comment on *(date)* with a request for comments by *(date)*. We request NRC's comments by *(date)*. The proposed *(or final)* regulations are identified by line-in/line-out text *(or similar identification)* and correspond to the following equivalent amendments to NRC's regulations. *(Please identify the specific NRC equivalent regulations from the Chronology of NRC Amendments or the SRS Data Sheet. An optional table for your use which captures this information is also attached.)*

(If there are issues) The following are two issues that we would like the NRC to address:

1. *Description of issue.*
2. *Description of issue.*

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

(If the regulations do not satisfy the compatibility and health and safety designation, identify those sections and describe the State's rationale for promulgating a regulation that is not compatible with NRC's regulation. Describe any constraint that prevents the State from promulgating a regulation that satisfies the compatibility and health and safety category and whether the program is examining removal of the constraints. For other legally binding requirements, the State should demonstrate that they are legally binding.)

If you have any questions, please feel free to contact me at *(telephone number)* or *(name of State contact)* of my staff at *(telephone number)* or *(e-mail address)*.

Sincerely,

*(Name of Radiation Control Program Director or designee),
(Director or title of designee) (Radiation Control Program)*

Enclosures:
As stated

Optional Table

Proposed Revisions of (State) Regulations that
Incorporate Equivalent NRC Amendments into State Regulations

NRC Regulation	FR Notice (State Due Date)	RATS ID	State Regulation★	Final State Regulation (or SSR) (Effective Date)†
Resolution of Dual Regulation of Airborne Effluents-Part 20	61 FR 65119 (1/9/00)	1997-1	4.1	
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662 (2/27/00)	1997-2	3	
Criteria for the Release of Individuals Administered Radioactive Material- Parts 20, 35	62 FR 4120 (5/29/00)	1997-3	4.1.07	

★For generic legally binding requirements, mark Legally Binding Requirements with the effective date.

†The last column is used only when the regulations are final.

Appendix B

CRITERIA FOR COMPARING REGULATIONS AND IDENTIFYING DIFFERENCES

I. DIFFERENCES THAT ARE NOT SIGNIFICANT

In most cases, the following differences between State and NRC regulations are not significant and do NOT affect compatibility or the health and safety objectives of the regulation. These differences do not need to be identified or commented on.

- A. Differences that do not result in Agreement State licensees being subject to a requirement different from the equivalent NRC requirement;
- B. Differences that result from the State regulation being made applicable to sources of radiation not covered by the Atomic Energy Act (e.g., x-rays, naturally-occurring and accelerator-produced radioactive materials);
- C. Differences between the ordering of the subdivisions of the NRC and the State regulations;
- D. The substitution of terms with the same meaning (where the use of essentially identical terms is not required) according to the editorial style of the State, i.e., "shall" or "must," "rule" or "regulation," "Commission" or "agency," "device" or "equipment;"
- E. The omission of any portion of the text of an NRC regulation that provides an example, contains supplementary material, or provides a reference to another regulation for the convenience of the reader;
- F. The incorporation, as a requirement in the State regulation, of any portion of the text of an NRC regulation that provides an example, contains supplementary material, or provides a reference to another regulation for the convenience of the reader;
- G. Modifications to punctuation that do not change the meaning of the text, i.e., changing a semicolon (";") to a conjunction followed by a comma ("and,");
- H. Any difference that results from the use of SI units for record keeping and reporting; and
- I. Typographical and minor editorial or punctuation errors.

Appendix B (Continued)

II. DIFFERENCES THAT ARE SIGNIFICANT

In some cases, the difference in the wording between State and NRC regulations may significantly change or affect the intent of the regulation and may, therefore, affect compatibility or the health and safety objectives of the regulation. For regulations with Category A and B compatibility designations, the differences or changes are significant if licensee actions to satisfy the NRC equivalent regulation are not the same as those actions required to satisfy the Agreement State regulation for all phases of the licensee's operations. For regulations with a Category C compatibility designation or a health and safety designation, the changes or differences in an Agreement State regulation are acceptable only if an Agreement State licensee must take the same action needed to satisfy the NRC-equivalent regulation, or must take actions in addition to those required to satisfy the NRC-equivalent regulation.

A conclusion that the text of the State regulation leads to a different interpretation than the text of the equivalent NRC regulation, for regulations designated Category A or B, would result in a finding that the regulation does not meet the Category A or B designation. The reviewer should describe why the State's regulation leads to a different interpretation.

A conclusion that the regulation does not reflect either the essential objective of the NRC regulation or the State's regulation creates a conflict, duplication or a gap would result in a finding that the regulation does not meet the Category C or Health and Safety designation. Please see Section VII of *Handbook 5.9* for definitions of essential objective, conflict, duplication, and gap.

Appendix C

Sample Comment Letter for Proposed State Regulations (or Other Generic Legally Binding Requirements)

Note: *Italicized text* is guidance for determining text to be entered.

Name, Title
Address

Dear Mr. (Ms.) Name:

As requested, we have reviewed the proposed regulations (*identify the regulations using the same title or description given by the State*), (*give date of regulations and cover letter date*). The proposed regulations are in response to the (*number*) amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. [*In the event the preparation of the SRS Data Sheet is delaying the issuance of the comment letter, substitute: The proposed regulations are in response to RATS ID (list year and number)*]. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Part __ (*section number*). We also discussed our review of the regulations with (*name of State person contacted*) on (*date*).

As a result of our review we have (*no*) or (*number of comments*) comments (*that have been identified in the enclosure*). Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if your proposed regulations were adopted (*incorporating the comments and*) without (*other*) significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the “as published” regulations be provided to us for review. As requested in STP Procedure SA-201, *Review of State Regulatory Requirements* (current date in 2000), please highlight the final changes and provide a hard copy to STP.

We have also summarized on the SRS Data Sheet our knowledge of the status of other (*State*) regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet is posted on the STP website: <http://www.hrsd.ornl.gov/nrc/rulemaking.htm>. [*In the event the preparation of the SRS Data Sheet is delaying the issuance of the comment letter, delete this paragraph and substitute: We shall be sending the SRS Data sheet that summarizes our knowledge of the status of other (State) regulations under separate cover.*]

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or (*give name of reviewer or other contact*) of my staff at (*staff telephone*) or (*staff ID*)@NRC.GOV.

Sincerely,

Deputy Director
Office of State and Tribal Programs

Enclosure(s):
As stated

Distribution:

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Director, STP
Management Analyst
Agreement State Project Officer (ASPO)
[*Other staff as needed*]
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STP-AG-[State]

Appendix D

Sample Comment Letter for Final State Regulations (or Other Generic Legally Binding Requirements)

Notes: *Italicized text* is guidance for determining text to be entered. Where appropriate, substitute Other Generic Legally Binding Requirements or SSR for regulations.

Name, Title
Address

Dear Mr. (*Ms.*) Name:

We have reviewed the final (*name of State*) regulations (*identify the regulations using the title or description given by the State*), which became effective on (*effective date of the regulations*). The regulations were sent on (*date*). The final regulations are in response to the (*number*) amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. [*In the event the preparation of the SRS Data Sheet is delaying the issuance of the comment letter, substitute: The final regulations are in response to RATS ID (list year and number)*]. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Part __ (*section number*). In addition, we reviewed our (*date*) letter to you that addressed the proposed regulations. We also discussed our review of the regulations with (*name of State person contacted*) on (*date*).

(If there are comments, use the following:)

As a result of the NRC review we have identified (*number of comments*) comments, as enclosed. These comments must be addressed to meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

(If there are no comments, use the following:)

As a result of the NRC review, we have determined that the (*name of State*) regulations, as adopted, meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

We have also summarized on the SRS Data Sheet our knowledge of the status of other (*State*) regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet is posted on the STP website: <http://www.hrsd.ornl.gov/nrc/rulemaking.htm>. [*In the event the preparation of the SRS Data Sheet is delaying the issuance of the comment letter, delete this paragraph and substitute: We shall be sending the SRS Data sheet that summarizes our knowledge of the status of other (State) regulations under separate cover.*]

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me or (*give name of reviewer or other contact*) of my staff at (*staff telephone*) or (*staff ID*)@NRC.GOV.

Sincerely,
Deputy Director
Office of State and Tribal Programs

Enclosure(s):
As stated

Appendix D (Continued)

COMMENTS ON (PROPOSED or FINAL) *(State name)* REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

State Regulation ¹ or SSR	NRC Regulation or SSR ²	RATS ID	Category	Subject and Comments
4.1-14	20.2006 (excluding Appendix F)	1995-3	B	<p>Transfer for Disposal and Manifests</p> <p>Paragraph E was omitted from Appendix G, 10 CFR 20 (60 FR 25983).</p> <p>Unless the missing paragraph is adopted, the regulation would not meet the compatibility category.</p>
5.10	34.25	1995-4	C	<p>Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources</p> <p>RH 5.10 requires the labeling of exposure devices, while the equivalent NRC regulation in 10 CFR 34.25(e) requires the labeling of sealed sources not fastened to or contained in exposure devices. Regulatory requirements for the labeling of exposure devices are found in 10 CFR 34.20(b) and the equivalent State regulation RH 5.5.2. As a result, the State regulations do not meet the compatibility category with respect to the requirements for labeling of sealed sources not fastened to or contained in exposure devices.</p> <p>Consequently, RH 5.10.5 should be amended to incorporate the essential objectives of the text of 10 CFR 34.25(e) with respect to labeling of sealed sources not fastened to or contained in exposure devices.</p>

¹For other generic legally binding requirements, change State Regulations to LBR.

²Use NRC regulation when the review is conducted against the equivalent NRC regulation. Use SSR when the review is conducted against the SSR equivalent which NRC has concurred.

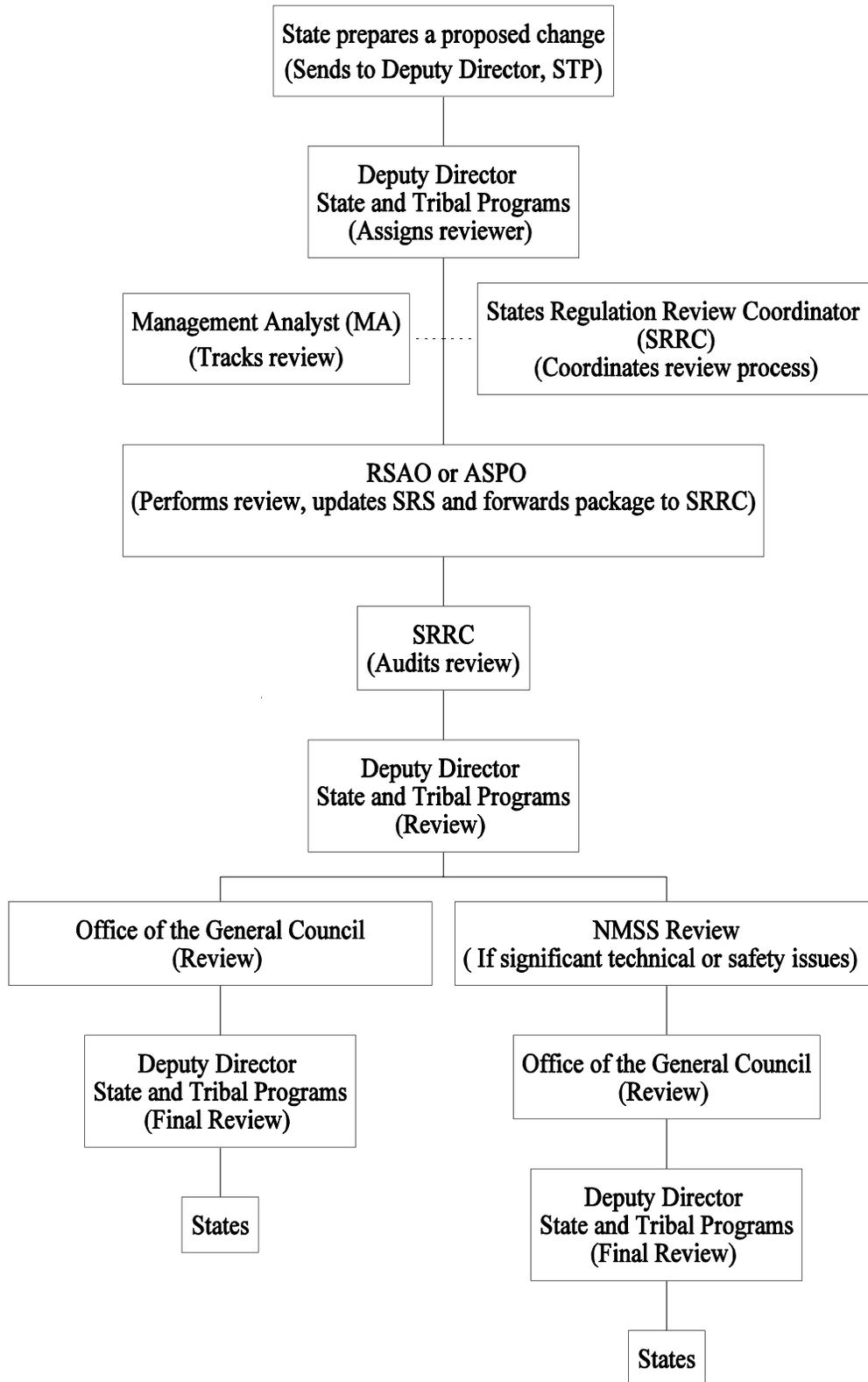
Appendix E

Instructions for Updating State Regulation Status (SRS) Data Sheet or RATS Data Sheet

- A.** If the State has a current SRS data sheet on the website:
1. Obtain the ML number for the SRS sheet. This ML number can be found on the most recent SRS data sheet which is posted on the Office of State and Tribal Programs (STP) web site under “regulations,” arranged by State. This number appears directly under the review chain block.
 2. Using the ADAMS system, under the “tools” pull down menu, go to “ADAMS find.” Enter the ML number in the “accession number” block and conduct search.
 3. When Adams finds the document, right click on the document. Do not open it yet, this is the (.pdf) version, and unusable for modification. In the properties menu, go to “versions.” Select the WordPerfect version, usually the second document listed (.wpd format).
 4. Save this version to the local drive (desktop or any local folder). This version allows changes to be made to the SRS sheet.
 5. Delete the “*” designators from the last review and place new “*” next to the regulations that are being changed during this review.
 6. Fill in the remainder of the blocks as appropriate for each “*” regulation you have entered.
 7. Forward the updated SRS data sheet electronically with the comment sheet to the Regulations Coordinator at STP.
- B.** If the State has a current RATS data sheet on the website:
1. Obtain a blank SRS data sheet from on the “S” drive on the computer.
 2. Download a copy to the local drive with a new file name.
 3. Fill in the line items for the regulations that were reviewed. It is not necessary to fill out any information for regulations that were not reviewed. Forward the updated SRS data sheet electronically with the comment letter to the Regulations Coordinator at STP. STP will create a complete SRS data sheet and post it on the state website.
 4. States with RATS data sheets will be updated to SRS data sheets each review process until all states have SRS Data Sheets on the website.

Appendix F

Document Review Flow Chart



Appendix G
STATE REGULATION STATUS

State: Date Page Update:
[Number of proposed/final amendments (date) reviewed are Tracking Ticket Number:
identified by a ★ at the beginning of each equivalent NRC regulation.] Date:

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3			
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4			
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1			
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1			
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2			
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3			
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5			
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6			
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3			
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1			
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2			
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3			
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948; (6/27/00)	1997-5			
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6			
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7			
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55525 (2/2/03)	1999-3			
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address.
N means "No," there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number