

January 29, 2003

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA, WISCONSIN

DRAFT REVISION OF STP PROCEDURE SA-201: REVIEW OF STATE REGULATORY REQUIREMENTS (STP-03- 010)

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*, which incorporates comments received from the States on an earlier draft sent to you on July 23, 2001. 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 the date 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) 415-2308	FAX:	(301) 415-3502

/ RA /

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-03-010

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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. Comments received from the States and other NRC offices have been incorporated into this revision where applicable.

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 for review, consistent with the approach used currently for proposed and final regulations. Generic legally binding requirements will be reviewed in the same manner as regulations. (See Section V.A.4)

More Specific State Guidance

The State should submit regulations to the NRC at least 60 days prior to the date by which comments are needed by the State. Before a regulation review can commence all of the required information needs to be supplied to STP. The State, in its transmittal letter, is requested to: (1) identify the specific regulation sections that are being changed using line-in/line-out text or equivalent format, (2) identify which amendment(s) the State is submitting regulations to cover using the name or RATS ID number. Sample transmittal letters are shown in attachments 1 and 2 to appendix A of the document. (3) indicate whether the 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.

(See Section V.A.3 and Appendix A.)

Enhanced Guidance to STP and RSAO Staff and the Incorporation of a Timeliness Metric for Regulation Review

The guidance for review documentation has been expanded and a new documentation method (Review Summary Sheets) has been added. (See Section V.D.2)

An acceptance review has been incorporated into the procedure. STP will perform an acceptance review of packages within three days of receipt of the transmittal letter and regulations from the States, to ensure each package is complete and in the correct format. (See Section V.A.5 and V.C.1) A final comment letter will be sent to the State within sixty days from the receipt of a complete package from the State. The STP Operating Plan goal is to complete 85% of State regulation review packages within 60 days of receipt of a complete package, and 100% within 120 days of receipt of a complete package. (See Section II.D)

The roles and responsibilities of the STP Regulation Review Assistant have been defined (See Section V.B)



DRAFT

STP Procedure Approval

Review of State Regulatory Requirements **SA-201**

Issue Date:

Review Date:

Paul H. Lohaus
Director, STP

Date: / /03

Josephine M. Piccone
Deputy Director, STP

Date: / /03

John G. Zabko
Procedure Contact, STP

Date: / /03

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 9

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 (LBR) and Suggested State Regulations (SSRs).

II. OBJECTIVES

- A. To provide guidance for 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 LBR (e.g., license conditions and orders), and SSRs, for the U.S. 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 LBR, 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 the significance of differences between State regulations, other generic LBR, or SSRs and NRC regulations.
- D. To meet the following performance objectives: 1) The acceptance review of incoming packages should be completed within three days of receipt at the Office of State and Tribal Programs (STP). 2) Packages that have been determined to be complete should be assigned to the reviewer within three days of the acceptance review. 3) The regulation review should be completed within fourteen days of review assignment. 4) Any concurrence from other offices such as the Office of Nuclear Material Safety and Safeguard (NMSS) or the Office of the General Counsel (OGC) should be completed within two weeks of the request for concurrence. 5) A final comment letter will be sent to the State within sixty days from the receipt of a complete package from the State. The STP Operating Plan goal is to complete 85% of State regulation review packages within 60 days of receipt of a complete package, and 100% within 120 days of receipt of a complete package.

III. BACKGROUND

A. Each Agreement State has the responsibility to promulgate LBR 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 LBR 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 LBR. 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 LBR for review. The requested submittal should include requirements satisfying the compatibility and health and safety designation associated with equivalent regulations of the Commission. The STP Procedure SA-201 is used as a guide.

C. To assist States in promulgating compatible regulations or other generic LBR within three years of the effective date of changes in NRC regulations, NRC staff prepares and publishes 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,” “license conditions” 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 managing and coordinating the NRC staff's review. This includes reviewer assignments, assignment of due dates, and changes to due dates. The Deputy Director also keeps State Regulation Review Coordinator (SRRC) and Regulation Review Assistant informed when an Agreement State regulation is received so the status of the review can be tracked through closure.
- C. The SRRC is responsible for overall review project management and assuring overall quality control of the review process. As part of this responsibility, the SRRC: (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 is responsible for conducting reviews of State regulations as assigned.
- E. The Regulations Review Assistant enters information on the regulation review in the STP Action Item Tracking System and the Regulation Action Tracking System (RATS). Information from RATS is provided to the coordinator, reviewer and other Staff as needed.

V. GUIDANCE

- A. The States
 - 1. States should submit and request comments on proposed and final regulations to the Deputy Director, STP. States are encouraged to submit regulations electronically. In accordance with NRC procedures, all incoming regulations will be entered into the NRC's Agencywide Document Access and Management System (ADAMS).
 - 2. Appendix A to this procedure provides guidance for 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 should submit regulations to the NRC at least 60 days prior to the date by which comments are needed by the State. Before a regulation review can commence, all of the required information needs to be supplied to STP. The State, in its transmittal letter, is requested to: (1) identify the specific regulation sections that are being changed using line-in/line-out text or equivalent format; (2) identify which amendment(s) the State is submitting regulations to cover using the name or RATS ID number. (Sample transmittal letters are shown in Attachments 1 and 2 to Appendix A); (3) indicate whether the 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. LBR or license conditions that a State proposes to adopt to meet the requirements of an NRC rule, should be submitted for review using the same procedures as a State regulation review. In its submittal letter the State should explain how the LBR or license condition meets the requirements of the NRC rule.
5. The sixty-day review period will begin following confirmation by the SRRC that all of the required information has been provided. The States should be aware that missing information may lead to delays in the review. The States are encouraged to contact the SRRC prior to submitting a package for review to ensure all required items have been addressed.

B. Regulation Review Assistant

1. Tracks the status of regulation review packages from receipt through closure.
2. Conducts a completeness review of incoming State transmittal letters and regulation packages within three days of a receipt of a review request. Enters all information supplied by the State into ADAMS. If the State has not included the information requested in Section V.A.3, will contact the State Director or designee to request the missing information.

3. Tracks the progress of review packages through office concurrence and performs technical editing based on input from office review.
4. Once the finished review letter is signed by the Deputy Director STP, enters the NRC review date into the enclosed State Regulation Status (SRS) Data Sheet for the amendments reviewed and enters the review results into the RATS data base.
5. Transmits a copy of the final letter to the State with the results of the NRC review and closes the action in the tracking system. Updates ADAMS to reflect the final package changes.

C. Reviewer Assignment

1. The Deputy Director will normally assign review of a regulation to the Regional State Agreement Officer (RSAO). If the RSAO is not available or able to meet the projected due date because of competing priority work assignments, the Deputy Director will assign the review to the Agreement States Project Officer (ASPO), other STP staff or evaluate the use of contractor assistance. Reviews will normally be assigned within three days of receipt of a complete State package by STP. Reviews are generally to be completed within two weeks but allowances will be made for large regulation packages or scheduling conflicts.

D. The Reviewer

1. Conducts a comparison of the State's regulation with the equivalent NRC regulation to determine if the State's regulation is compatible. 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 the reviewer in determining when a difference is significant and should be included as a comment on the State's regulation can be found in Appendix B of this document, Management Directive 5.9 and STP Procedure SA-200.

2. Prepares a review summary sheet to document the review, showing all areas where the State regulation differs from the NRC regulations and documenting the reviewer's reasoning for generating or not generating a comment on the difference. An example review summary sheet is shown in Appendix G. This summary sheet shall be provided to OGC for their review.
3. 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).
4. Consults, as necessary, for State regulations and SSRs, with NMSS or other NRC offices to support completion of the regulation review based on issues raised during the review and their significance. If requested, NMSS or other NRC offices, review State regulations according to their own internal procedures. When reviewing the regulations for States seeking an Agreement with the NRC, the reviewer shall follow STP Procedure SA-700 for coordination with NMSS. All regulation review packages shall be provided to OGC for review and concurrence (no legal objection) within 14 days.
5. 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.
6. The reviewer should prepare a formal comment letter or "no comment" letter to the State documenting the results of the review and update the SRS Data Sheet. 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). 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.) All letters should use the Regulatory Information Distribution System (RIDS) codes SP (05-08), corresponding to NRC Regions I-IV, on the concurrence sheet. A sample concurrence block is shown in Appendix C.

7. Comments resulting from the review should be set out in an enclosure to the letter and should contain, as a minimum, the information as listed in a-e below. A blank comment table with sample comments for reviewer use is shown in Appendix E.
 - a. Citation of the part or section of the State regulation or SSR reviewed;
 - b. Citation of the equivalent NRC regulation;
 - 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.
8. A SRS Data Sheet should be updated to reflect the current review and included as an enclosure to the comment letter.
9. The reviewer should concur in the comment letter and forward it to the SRRC. The SRRC will conduct a quality assurance review and will concur on all letters within three days of receipt and will provide to the Deputy Director, STP, for review and concurrence prior to being sent out for other office concurrence.
10. All offices participating in the review should be on concurrence. The concurrence of OGC is always required.

11. Responds to questions or issues raised by OGC or other offices.
- E. The States Regulation Review Coordinator (SRRC)
1. Upon completion of the review, conducts a quality assurance review of the comment letter and comments, serves as liaison between the State, the reviewer, the Office of General Council (OGC), and Nuclear Material Safety and Safeguards (NMSS) throughout the review process. Facilitates preparation of a final letter and comment sheet.
 2. Schedules meetings with the Deputy Director and concurring offices to resolve review issues not resolved by reviewer and concurring offices. Acts as point of contact for questions on the review process.
 3. Follows any generic comments returned by the State on the subject regulations to examine how the State addressed the comments. Schedules meetings with the Deputy Director and other offices to develop answers to any State concerns, involving generic or SSR issues.
 4. If necessary, the SRRC shall coordinate the request for consultant or contractor assistance in review of proposed or final State regulations. Contractor assistance can only be initiated by the STP technical monitor of the consultant or contractor, and requires the concurrence of the Director, STP. When using such assistance, the SRRC should:
 - a. 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.
 - b. 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.

VII. APPENDICES

Appendix A - Regulation Submission Guidance 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 - Sample Comment Chart

Appendix F - Document Review Flow Chart

Appendix G - Sample Review Summary Sheet

Appendix H - State Regulation Status** Data Sheet

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*.
6. STP Procedure SA-700, *Processing an Agreement*

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

APPENDIX A

REGULATION SUBMISSION GUIDANCE FOR NRC STAFF REVIEW (Includes License Conditions and Other Generic Legally Binding Requirements)

I. INTRODUCTION

This guidance to Agreement States, States seeking an Agreement, and the Conference of Radiation Control Program Directors, Inc., (CRCPD) pertains to the submittal of proposed and final State regulations to the U.S. Nuclear Regulatory Commission (NRC) staff for review. The NRC goal is to conduct a single review for proposed regulations and a single review for final promulgated regulations to confirm they are compatible with equivalent NRC 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.

II. STATE SUBMITTAL GUIDANCE

- A. When regulations are at the draft stage or, preferably, the public comment stage, the Radiation Control Program Director, or designee, or CRCPD (Director) should submit the regulations to the Deputy Director, STP. In preparing and submitting proposed regulations, the Director should 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. 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 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 Attachments 1 and 2.
- B. With both proposed or final regulations, the Director is requested to document significant differences between the State rule and the equivalent NRC rule and whether the Agreement State believes its regulation satisfies the compatibility and health and safety component criteria in *Management Directive 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. 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 H) 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 SRRC. The regulation assessment tracking system (RATS) is an internal program used by STP to track the status of State adoption of amendments equivalent to those made to the NRC regulations.

Attachments:

1. Sample Transmittal Letter for Proposed State Regulations
(Includes License Conditions and Other Generic Legally Binding Requirements)
2. Sample Transmittal Letter for Final State Regulations
(Includes License Conditions and Other Generic Legally Binding Requirements)

Attachment 1

SAMPLE TRANSMITTAL LETTER FOR PROPOSED STATE REGULATIONS

(Includes License Conditions and Other Generic Legally Binding Requirements)

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

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

Dear Mr./Mrs.(Name):

Enclosed is a copy of the proposed revisions to the (State) Radiological Health Rules (*identify the regulations using the title or description and date of regulations*). The proposed revisions were made available for public comment on (date) with a request for comments by (date). The proposed regulations are identified by line-in/line-out text (*or similar identification*) and correspond to the following equivalent amendments to NRC's regulations. (RATS ID #, *Please identify the specific NRC equivalent regulations from the Chronology of NRC Amendments or the SRS Data Sheet you are submitting for review.*)

(*If there are significant differences between the States rule and the NRC rule*) - The following are items that we would like the NRC to consider:

- 1) *Description of difference. (Such as a State not incorporating all of an amendment or using a different method of incorporation to achieve compatibility)*

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 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

ATTACHMENT 2

SAMPLE TRANSMITTAL LETTER FOR FINAL STATE REGULATIONS (Includes License Conditions and Other Generic Legally Binding Requirements)

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

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

Dear Mr./Mrs.(Name):

Enclosed is a copy of the final revisions to the (State) Radiological Health Rules (*identify the regulations using the title or description and date of regulations*). The final regulations correspond to the following equivalent amendments to NRC's regulations: (RATS ID #, *Please identify the specific NRC equivalent regulations from the Chronology of NRC Amendments or the SRS Data Sheet.*) *Please choose from paragraph A or B below to add here.*

A (*If there were NRC comments on the proposed State regulations*) - We have incorporated the comments cited in your letter dated (*date*) regarding our proposed version of these regulations (*with the exception of those noted below*).

(*If there are comments the State did not address*) - For the following comments (*State*) proposes a different solution to meet compatibility: 1. *Description of solution. (Such as the State chose to meet compatibility using a legally binding requirement instead of altering the State regulation)*

B (*If there were no comments on the proposed State regulations*) - The proposed regulations are being submitted as final regulations without change.

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 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

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 *Management Directive 5.9* for definitions of essential objective, conflict, duplication, and gap.

APPENDIX C

SAMPLE COMMENT LETTER FOR PROPOSED STATE REGULATIONS (Includes License Conditions and Other Generic Legally Binding Requirements)

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

*Name, Title
Address*

Dear Mr./Mrs. Name:

As requested, we have reviewed the proposed regulations (*identify the regulations using the same title or description given by the State*), (*give the 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. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Part __ (*section number*). We 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.

The SRS Data Sheet summarizes 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>.

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

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NAME	RSAO/STP STAFF		<i>Coordinator</i>							
DATE	03/ /03		03/ /03		03/ /03		03/ /03			

Appendix D

Sample Comment Letter for Final State Regulations (Includes License Conditions and Other Generic Legally Binding Requirements)

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

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. 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 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.

The SRS Data Sheet summarizes 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>.

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 E

COMMENTS ON (*PROPOSED* or *FINAL*) (*STATE NAME*) REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

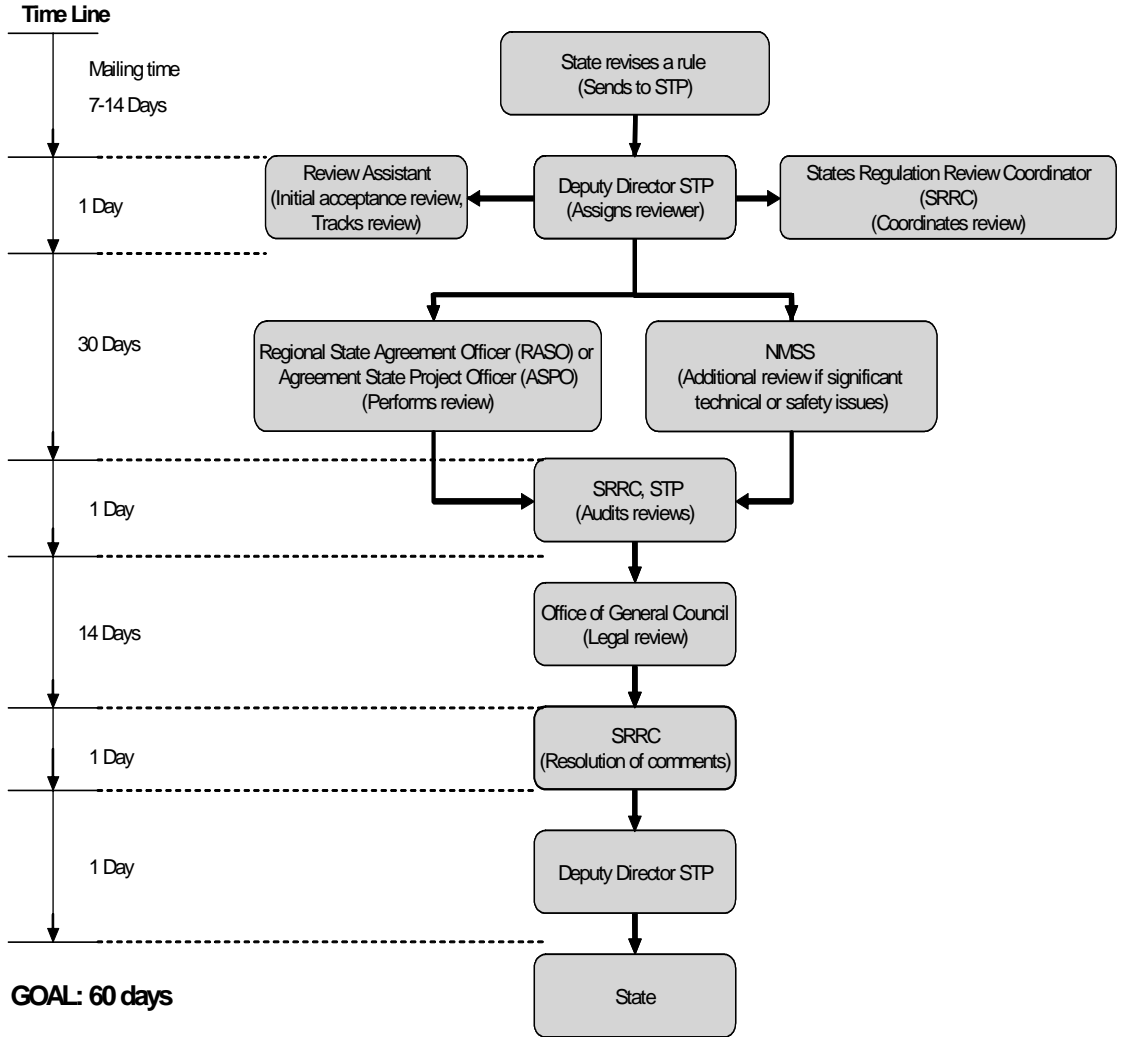
Note: *Italicized text* is guidance for determining text to be entered.

State Regulation** or SSR	NRC Regulation	RATS ID	Category	Subject and Comments
4.1-14	20.2006	1995-3	B	<p><i>CFR Title</i></p> <p><i>Description of comment</i></p> <p><i>Action State must take to meet compatibility</i></p> <p><i>(See below for example)</i></p>
5.10	34.25	1995-4	C	<p><i>Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources</i></p> <p><i>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.</i></p> <p><i>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.</i></p>

** For other generic LBR, change State Regulations to LBR or License Condition.

APPENDIX F

Document Review Flow Chart



The Regulation Review Process

APPENDIX G
Sample Review Summary Sheet

Note: The *italicized text* represents sample entries and is guidance for determining text to be entered.

NRC Section	Section Title	State Section	Compatibility Category	Summary of Amendment Change	Is There a Difference Between State Text and NRC Yes/No	Is the Difference Significant Yes/No	Comments: If Difference Exists, Why or Why Not Is The Difference Significant.
20.1003	Definitions	53.2 (1)	A	<p>In Sec. 20.1003 the definition of Shallow-dose equivalent (Hs) is revised to read as follows:</p> <p>Shallow-dose equivalent (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²)</p>	NO		
20.1701	Use of process or other engineering controls	4.1.2	H&S	<p>Section 20.1701 is revised to read as follows:</p> <p>The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.</p>	YES	NO	<i>The State uses a different word order, but the essential objectives are met. Not a compatibility issue.</i>
39.49	Uranium sinker bars	4.2.3 (b)	C	<p>Section 39.49 is revised to read as follows:</p> <p>The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words “CAUTION--RADIOACTIVE-DEPLETED URANIUM” and “NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND.”</p>	YES	YES	<p><i>The State has omitted this requirement</i></p> <p>Comment Prepared</p>

APPENDIX H

STATE REGULATION STATUS (SRS) DATA SHEET

State:

[Number of amendments reviewed are identified by a ★ at the beginning of each equivalent NRC regulation.]

Tracking Ticket Number:

Date:

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) Rule ¹ / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
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			
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			
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
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1			
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			SECY-95-112 ⁴
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	1995-1			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) Rule ¹ / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
	60 FR 322; (1/1/98)				
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			
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 28724 (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			
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			
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			
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5			
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (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			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) Final (F) Rule¹ / ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			
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			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (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 63750; (1/8/04)	2000-2			
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1			

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 #