

**SUGGESTED STATE REGULATION (SSR)
PROCESS DEVELOPMENT**

THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
Approved by Board of Directors
(Approved 3/25/03)

SSR COMMITTEE CHAIR PROCESSES

This document contains an outline of the process that an SSR Committee Chair should follow, with pointers to enable you to meet the timelines established by the Board. This document should be used in conjunction with the CRCPD Operations Handbook for working groups.

Your first task:

- Review the charges and look at the SSR Process Flow Chart in Appendix E. Your charges should have due dates established by the Board. If not, contact your council chairperson.
 - Work backward from your due date and fill out the outline and timelines on the Process Outline and Timetable chart (Appendix B).
 - Based on the SSR committee you are chairing, insert the initial list of individuals/agencies/groups that you would like to use for peer review.
 - Add the dates for your 6-month reports that are due to the council chairperson to your outline.
- Provide this information to the council chairperson. You both then have an outline of how you think you will be able to meet your due dates. If a change needs to be made to the deadline on a charge, the committee chair needs to go to the council chair with the new deadline and justification for change.
- A copy should also be made available to the other committee members, advisors and resource persons once it has received council chairperson approval. *(Note: The council chair is responsible for providing this timetable to the OED staff person who is assigned as staff support to the SSRCR project.)*
- When committee members or advisors are needed for a working group, the SSR chair will provide the OED with a call for volunteers that is to include an overview of the tasks and due dates. OED will email this request to the membership, post to the web, and include it in the *Newsbrief* if timely. This should ensure that the members and advisors who respond have current interest and time available to serve.

The Board supports the parallel rulemaking concept by working with the appropriate federal agencies, such as DOT, EPA, FDA and NRC. As it relates to NRC rule development, CRCPD, in cooperation with the Organization of Agreement States, will continue to work with the NRC to ensure that the appropriate individuals are assigned to the NRC rule development groups.

The Executive Board reiterates the need for working group chairs to involve the advisors and resource persons in the working group activities. It is particularly important that chairs provide members, advisors and resource persons with as much lead time as possible when planning a meeting.

Step 1 - Identify Need

The need for the development of a new SSR, or the revision of an existing SSR, can come from a number of sources. The CRCPD Board, a committee member or chair, a state initiative, petition for rulemaking from a federal agency, or the SSRCR chair (or combined chairs at annual meeting) can initialize the need for SSRCR development. A change in federal regulations can also initialize the need for development or revision. If the need for rulemaking has already been established through the parallel rulemaking process with a federal agency, the SSR committee chair may want to volunteer to be a member of the federal committee in order to take advantage of research, language, and any compatibility designation in order to increase efficiency in completion of the SSR Part. The chair may also want to look at other federal agency rulemaking plans so that the SSR Part can be coordinated with the federal counterpart. You may also want to talk to other committee chairs that are actively working on an SSR part to ascertain the impact of that rulemaking with the charge given to your committee (e.g. cross references, new federal rule that may cause a portion of your part to be rewritten).

The Board approves all members for each SSR committee. Usually the committee chair submits requests for additions or changes to their committee. If additional members are needed to deal with the breadth of the work, the chair can recommend to the council chair that additional members be added. Also, check with the council chair to see if the CRCPD liaison to a professional group needs to be added to advise the group or if there is a person in one of these professional groups that could be used as a resource person.

The Board has created an Emerging Issues (EI) group for the Suggested State Regulations. Members, advisors, and resource persons are encouraged to monitor bulletin boards, such as Rad Rap, Rad Safe or others, and provide any potential emerging issues to the attention of the SSRCR Emerging Issues Chairperson. The EI group will consider and forward the issue(s) to the Board if appropriate.

Step 2 - Research and Development

What issues would you consider when planning research? Use this list as inspiration:

- Are committee members going to complete pieces of the research?
- Will they be assigned the same section of rules as they were assigned for research?
- Look to the states that perform SS&D reviews within the subject area of your part.
- Monitor the electronic bulletin boards for emerging issues that may need to be included in your rulemaking. The Board will assign the appropriate charges once they have considered the recommendation of the Emerging Issues chair.
- Identify relevant pre-decisional documents from federal agencies.
- Identify problem among licensees.

- Identify rules from states dealing with these issues.
- Consensus standards that may have information helpful to the rulemaking process.
- There are several websites that may be useful for searching federal documents:

Federal Register

< www.access.gpo.gov/su_docs/aces/aces140.html >

Code of Federal Regulations

< www.access.gpo.gov/nara/cfr/cfr-table-search.html >

One site provides a link to the *Federal Register*, *Code of Federal Regulations*, *Congressional Record*, and public laws <www.access.gpo.gov>

NRC website - <www.nrc.gov>

The beginning of a draft will vary based on whether it is a new rule developed for the first time or an existing rule that is being revised. It is important for the chair and members to keep their focus on the subject that initiated the rule change. The Board must approve any amendment to the existing charge(s). If there has been a demonstrated need for the rewriting of an entire Part, the SSR chairperson must provide justification to the council chairperson. The council chairperson may seek Board approval provided he/she agrees with the recommendation. It is also important that committees coordinate their work with other committees whose work may be impacted by the rule change or whose product may impact the rule change. The SSR council chairperson will conduct a mid-year conference call with all SSR chairpersons and the OED staff assistant to facilitate this discussion and to summarize the changes needed to other Parts as a result of their rule writing. On behalf of the council chairperson, the OED technical staff will routinely monitor the *Federal Register* for federal agency notices that identify other affected Parts. This information will be provided to the council chairperson for appropriate action.

Relevant federal regulations are researched at this point. Draft language begins at this time. It is important that the SSR group seek the advice of other expert advisors and resource persons who are not currently serving on the working group.

The Part will be marked draft on each page in the heading (see Style Guide, Appendix A). For existing Parts, proposed new language will be displayed using the red double underlining feature. Language that is proposed for deletion will be displayed using the red strike out feature. OED will keep the official copy that tracks all changes. The SSR committee chair has final say on all proposed changes up until the time it is submitted to the Board for approval. From this point forward, the Board has the final say over additional changes to the Part. Only the SSR committee chair may authorize the draft to be distributed in any way to anyone not on the committee. For clarification, the OED will not release a draft copy unless specifically directed by the SSR committee chairperson. OED serves only as a mailing service for the SSR committee chairperson. If a Part is being substantially changed, the committee may decide to do a complete

rewrite instead of marking up the old Part (see above discussion regarding task focus). This is particularly useful if the committee wishes to change the overall organization of a Part. This results in a draft that looks new but may still be based on an older SSR. This information should be clearly reflected in the rationale.

Step 3 - First Draft

The decision on how the first draft is developed lies with the SSR chairperson. The draft can be developed either by the chair based on material submitted by the committee, or it can be a collaborative effort coordinated by the chair. This is a question of style and depends on the chair. All drafts are submitted to OED and maintained by OED. The draft shall include the Part and the rationale. A new rationale must be developed for each Part revision. The rationale shall address the reader directly as to what changes have been made and why. If this Part has references to other Parts, regulations, or standards, or there are other Parts that reference sections of this Part, the committee chair shall include any new references or changed references in the draft to OED. A cross-reference chart (Appendix D) should be

created to enable all reviewers to quickly see if all issues have been addressed. This is also helpful to states as they go through their rule-making process. Continue making revisions to this chart if changes are made during the process. This chart is to be addressed in the rationale, provided to the federal agencies when submitted for peer review, and published with the rule and its rationale.

The committee chair should check the progress of committee members on a pre-determined schedule (weekly, monthly) to assure that the committee will meet established milestones. OED staff, on behalf of the SR Council chair, will also periodically monitor the working groups' progress. The committee member drafts should be e-mailed back to the chair as they are finished so the complete package can be compiled and a conference established to discuss the proposed changes.

Step 4 - Committee Convenes and Revises Draft

The committee chair, in consultation with the council chairperson, should first determine if an online meeting can be held or whether a face-to-face meeting is needed. The next step is to poll the members, advisors, resource persons, and OED staff to determine the best date and time for the meeting. The chair should submit the meeting request form (*ref: Operations Handbook*) to the council chairperson for approval of the meeting, with a copy to the OED so that funding availability can be verified. Once approved, the OED will notify the committee chair that the meeting has been approved and then follow up with either the information on how to access the conference call, or issue travel authorizations. The committee chair is to confirm the meeting with members, advisors, resource persons and the OED staff. A tentative agenda and the revised draft package should be included with this notice.

Federal resource persons should participate in this meeting also. Traditionally this meeting was in person, but with some state budgets not allowing travel, virtual or online

meetings will become more prevalent. By using an online meeting, OED can make available the revised draft on the CRCPD website. As changes are identified, OED can make the necessary corrections and allow the participants to view the changes on an ongoing basis. This should make the final drafting faster. OED provides staff assistance at most face-to-face and online meetings. At the end of this meeting, the draft should be complete and for OED technical staff review.

Approval for peer review should be in place so there are no delays at the step labeled Peer Review. The peer reviewer list must be submitted to the council chairperson in advance for Board approval. The committee is encouraged to seek input from the regulated community as well as the regulators and other technical experts. The Board of Directors may choose to add additional individuals/groups to the SR committee recommended list. The Board, the federal liaisons, the Director Members and the OED technical staff are automatically included as part of the peer reviewers.

Step 5 - OED Technical Review and Formatting

The finished draft that results from the meeting in Step 4 is then forwarded to OED for Technical Review. At this stage OED also confirms all cross references to other SSRs referenced in the draft. OED technical staff will provide written feedback to the SSR chair within 30 days if there are issues that need further consideration prior to releasing the document for peer review.

Step 6 - Peer Review

Once Step 5 is finished, which will include formatting the Part as indicated in the Style Guide, OED will distribute the draft SSR to the Board approved list of peer reviewers. The draft will include the rationale and the cross-reference chart. The list of peer reviewers will automatically include the Board members, the federal agency liaisons, state director members, and the OED technical staff. A cover letter is developed that indicates the review period of 60 days and gives a due date for the return of comments to the chair, preferably in electronic format. This would allow the chair to cut and paste responses into the comment template. The letter will also advise the peer reviewers that the Board has directed the committees to move forward with the process once the 60 days have expired, or sooner if all peer review comments have been received.

Each federal agency is provided a copy of the SSR at this time along with an official request for peer review. This official request will strongly encourage the federal agency to take whatever steps are necessary to have the appropriate individuals within the agency to review and ensure compatibility and consistency of message, approach and interpretation. The goal is to address any issues at this stage that have generally not been identified until the federal concurrence comment period.

Step 7 - Review Comments

Once all comments are received, the chair must prepare responses to the comments. The committee must decide what changes to make to the SSR Part based on the perceived merits of the comments. This can be done at a meeting or through conference calls. Set the date and time as you did for the draft completion meeting. Each member of the committee will need a copy of the most recent rule draft and the completed comment template for reference at the time of the meeting. During any meeting regarding resolution of comments, any changes to the rationale, rule references or compatibility designation must be recorded.

Responses should be prepared using the Analysis of Comments template (Appendix C) or similar document containing this format. The form is a table so you can add lines as needed for the number of comments you received. The format allows the Board to see what the comments were and how the committee resolved the comments.

Do not include name or agency in the Analysis of Comments. Comments are to be judged based on the content, and therefore the name and/or agency should not enter into the decision of the committee.

Comments may be grouped together or summarized. Examples of a response include but are not limited to the following: comments implemented; comments considered but not changed; comments moved to Matters for Future Consideration; or comments partially implemented to include specific change.

Step 7a - OED Technical Review (Feedback to the Council/Committee Chair)

On behalf of the SR Council Chair, the OED technical staff will review any revision to the draft SSR that resulted from peer review. To assist the OED technical staff with this review, the committee chairperson shall forward to the OED technical staff the revised draft, the rationale, and the Analysis of Comments (Appendix C) and the Cross-Reference chart (Appendix D) at the same time as the information is provided to the SR Council Chair. On behalf of the SR Council Chair, the OED technical staff will also review the comments received, and cross check to ensure that the actions taken by the committee are adequately reflected in the proposed draft and accompanying documents. The purpose of this step is to identify areas that can be corrected prior to official submission to the Board. If there are problems identified, the SR Council Chair can direct the SR Committee Chair to revise the appropriate documents for formal submission to the Board for approval. This process should take no more than 30 days provided there are no major revisions needed. The Board should then be able to review the information in a more efficient manner.

Step 8 - Board Approval Process

Once the committee has completed the response to comments, and OED has provided feedback to the Council/Committee Chairpersons (Step 7 A), an SSR approval package is submitted to the Board by the OED on behalf of the SSR committee chair. The Board must

approve the proposed part before it can be submitted for federal concurrence. For clarification, the Board has final say over all changes or Part developments

The Board package, that is also provided to the Federal Liaisons, must include: a cover letter submitting the Part to the Board; the new or revised SSR Part with all changes indicated in red; OED technical review documentation; a new rationale including the Cross-Reference chart (Appendix D); and the Analysis of Comments template (Appendix C) that includes the committee's response to each comment.

The cover letter should request that the Board submit preliminary comments to the committee within 30 days, so that final Board approval can still be obtained within 60 days. A 30-day approval is possible provided there are no additional changes needed to the proposed part or supporting documentation. The OED will facilitate a conference call between the Board members, OED staff and the committee chair in order to solicit preliminary comments to the committee. The SSR chairperson will be available on the call should the Board have questions or need further clarification. This again should help speed the process along. If additional changes are needed, the committee chair is responsible for seeing that the changes are made and resubmitted to the OED technical staff for verification of the proposed changes. OED will forward the revised information to the Board for approval within the 60-day time period.

Once Board approval is obtained, the Executive Director/Administrative Officer will provide written confirmation to the OED staff person who is responsible for preparing the Part for federal concurrence. The OED staff will remove the word "draft" from the subsequent Part, and the section numbers will be placed in the headings. This document is final pending negotiations with the federal agencies that may require additional changes. As noted previously, the Board is responsible for directing any changes to be made to the Part. From Board approval until publication, this final document may only be released to others outside of the federal agencies when approved by the SR Council Chair.

Step 9 - Federal Concurrence Process

Once a Part has been approved by the Board, federal concurrence is sought. OED submits a copy of the Part, its rationale, the Cross-Reference chart (Appendix C), and Analysis of Comments (Appendix D) to each Federal agency (EPA, FDA, and NRC). Although concurrence is not requested on the rationale, comments identified by the Federal agencies will be considered by the working group and provided to the Board for information.

The cover letter will include a 60-day comment period, and a request that the Federal agencies submit preliminary comments to the Board within 30 days so that Federal concurrence can be obtained within 60 days.

- ***Feedback to Board - SSR Committee Makes Changes Resulting from Federal Concurrence***
 - The Board will consider any comments submitted by the Federal agencies within the 60-day comment period and determine whether or not to request the committee to make further changes, to consider the comments during the next rewrite of the Part, or publish as written. If the Board requests the committee to make additional changes, the OED technical staff person will verify the changes and submit to the Board for approval. Since some of the Federal agencies may have provided a response based on an earlier draft, CRCPD must seek reaffirmation from the Federal agencies based on the revised changes. At this point, the Board has several options to consider: (1) Direct OED to provide the revised information to the Federal agencies with a request for a rapid review and reaffirmation of their response; or (2) Direct OED to facilitate a conference call between CRCPD and the federal agencies whereby the revisions will be reviewed and agency positions reaffirmed or modified. The overall goal is to accomplish this within the 60-day period so that OED can prepare the document for publication.

Step 10 - Publish

The final stage is publication. The Executive Director/Administrative Officer, on behalf of the CRCPD Board of Directors, will provide written notification to the OED staff person that the Part has been approved for publication. The OED is responsible for preparing the document for publication and for distributing the revised Part to all program directors. The Part is also placed on the CRCPD Website and is included in all printed copies of the SSRs.

Additional Information

When the SR Working Group Has Finished Their Task(s)

In keeping with the Board approved working group initiative, the SSR working group's membership will be terminated when their tasks are complete. When the tasks are completed and membership terminated, or if a chair resigns their position prior to the tasks being completed, the working group chair is requested to prepare a final report addressing the items below for inclusion with the files. These files are to be turned over to OED when tasks are completed and membership is terminated, or to the new chair if the chair resigned or was removed from this position, and there are still tasks to be completed.

Prepare a final report addressing:

- Whether any issues impacted progress.
- The timeline, if rulemaking isn't finished (showing where in the timeline you stopped).
- Suggestions you would give a new chair.
- Any suggestions you would give the council chair that would assist the council chair to make the whole rule-making process move faster and more efficiently.

Need for a guidance document in support of the rule?

If a guidance document is deemed necessary, the SSR committee chair may recommend development to the SSR Council Chair. The SR Council Chair will consider the request and forward to the Board for their consideration.

OED's Responsibilities - Staff support to the Board, Council Chairperson and SSR chairpersons. Specific tasks include:

- Coordinate and track all changes to the SSRs.
- Provide technical review for the committee and the Board that includes cross-reference checks with other SSR parts relative to citations and verification. *(OED recommends that a report be included that lists the other parts where citations need to be changed – January 03.)*
- Distribute draft SSR for peer review, board approval, and federal concurrence.
- Assure that Board approved changes that result from federal concurrence are implemented. *(For clarification, Federal agencies will be given an opportunity to review any additional approved changes, and the opportunity to modify their agency position relative to concurrence.)*
- Print and distribute final approved SSR parts.
- On behalf of the council chairperson, track progress of the committees against the deadlines established by the Board.
- On behalf of the council chairperson, review *Federal Register* relative to a SSR part having direct impact on other SSR Parts.

**Appendix B
Process Outline And Timeline**

OUTLINE OF PROCESS

PLANNED
START DATE

PLANNED
COMPLETE
DATE

ACTUAL
COMPLETE
DATE

STEP 1 - IDENTIFY NEED

STEP 2 - RESEARCH & DEVELOPMENT

(work on language)

STEP 3 - FIRST DRAFT & RATIONALE

(created by the members at their HQ & complete by due date)

OUTLINE OF PROCESS
(continued)

PLANNED
START DATE

PLANNED
COMPLETE
DATE

ACTUAL
COMPLETE
DATE

**STEP 4 - COMMITTEE CONVENES &
FINISHES DRAFT**
*(Either virtual meeting or face to face
based on committee needs)*

**STEP 5 - OED TECHNICAL REVIEW
& FORMATTING** *(Feedback to Committee)*
(Add any committee action based on review)

STEP 6 - PEER REVIEW
*(Recommended reviewers in addition
to Board, Federal Liaisons and Director Members)*

OUTLINE OF PROCESS
(continued)

PLANNED
START DATE

PLANNED
COMPLETE
DATE

ACTUAL
COMPLETE
DATE

**STEP 7 - SSR CHAIR RESPONDS TO
COMMENTS & COMMITTEE REDRAFTS
IF NECESSARY**
(Notes on redraft)

STEP 7 A - OED Technical Review
*(Feedback loop to Committee/Council Chair.
Add any committee action based on review)*

**Step 8 - BOARD APPROVAL OF
FINAL PART**
(Notes on any additional action)

OUTLINE OF PROCESS
(continued)

PLANNED
START DATE

PLANNED
COMPLETE
DATE

ACTUAL
COMPLETE
DATE

STEP 9 - FEDERAL CONCURRENCE
(Notes on any additional action)

**STEP 9 A - SSR COMMITTEE MAKES _
CHANGES RESULTING FROM FEDERAL
CONCURRENCE PROCESS**
(Outline of change process)

OUTLINE OF PROCESS
(continued)

PLANNED
START DATE

PLANNED
COMPLETE
DATE

ACTUAL
COMPLETE
DATE

STEP 9 B - OED Technical Review
*(Feedback loop to Committee/Council Chair.
Add any committee action based on review)*

STEP 10 - PUBLICATION
(Notes for publication)

FINAL REPORT FOR SSR FILES
*(Refer to SSR Committee Chair Processes
for details)*

Appendix C
Analysis of Comments Template

Instructions: Add as many lines and pages that you need to include all comments and part reference. Do not include information pertaining to the name/agency who made the comment(s).

PART NUMBER	COMMENTS	COMMITTEE ACTION

**Appendix D
Cross-Reference Table**

Instructions: Add as many lines and pages as you need.

SSR REFERENCE	CFR	REQUIRED Y/N OR NRC COMPATIBILITY	EXPLANATION OF DIFFERENCES