



EPA Guidelines for Writing Rulemaking Documents

EPA-AA-CD-91-01
Certification Division
Office of Mobile Source Air Pollution Control
U.S. Environmental Protection Agency

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Preface

This document was originally written and designed for the staff of the Certification Division in the Office of Mobile Sources. It was developed as a means to make regulatory documents easier to write and easier to review. Many people aided in the writing process, but special thanks goes to the OBD project team and the Cold Temperature CO project team for helping me learn the "real" way things get done.

Kathy E. Carter

About This Guide

This guide is to help in writing and organizing three documents, the preamble to a *Notice of Proposed Rulemaking*, a *Response to Comments on the _____ NPRM*, and the preamble to a *Final Rulemaking*. It provides information about what should be included in each document and a structure to follow in organizing it. You may not be writing the entire document, but only one section. By following these guidelines and structuring your section as indicated, the editing and review process will be simplified.

Note this is a "guide," not a set of rules. It gives you a starting point, something to put on that blank sheet of paper. However, you will find each rule will require changes and adaptations to the outline provided. Make those changes or adaptations, but remember to follow the basic tenets of this document—keep it simple and keep it logical to the reader.

To help you find information, read this overview of what is in each section.

You will find the information divided into several sections. The first section has some general information related to writing rulemaking documents. Then there is a special section for the NPRM, the Response to Comments, and the Final Rule.

In the three special sections, the information is set up so that the right-hand page contains an example of the text of the document. The left-hand page contains an explanation and tips for writing that portion of the text.

Throughout the guide you will see references to the *Document Drafting Handbook*. This means the *Federal Register Document Drafting Handbook*, revised April 1986 (the version with the blue cover). Additional copies may be obtained by calling the Office of the Federal Register at 523-5240.

The example text is available on floppy disk or on the LNS network at MVEL in Microsoft Word™, Wordperfect™, and OfficeWriter™ formats. It can be accessed via the network from zone "Cert # 2" on CD38-Carter (Macintosh-MS Word format).
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Section 1. Background and Planning

General Background

Before writing the preamble, you will have done research and collected information. You will have decided what type of rule you are writing:

- substantive (legislative)—issued by an agency pursuant to statutory authority to implement the statute...has the force of law
- interpretive—rules or statements advising the public of the agency's construction of the statutes and rules which it administers
- statements of policy—issued by an agency to advise the public prospectively of the manner in which it proposes to exercise discretionary power

You will also have decided the classification of the rule as major, significant, or minor. A major rule is one which is likely to result in

- an annual effect on the economy of \$100 million or more; and/or
- a major increase in costs or price for consumers, individual industries, Federal, States or local government agencies or geographic regions; and/or
- significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A significant rule is one that does not meet criteria for major rules, but may

- have significant adverse impact on the public, or
- raise important health or intermedia issues, or
- have broad geographic effects

A minor rule is one that does not meet criteria of major or significant rules.

What about public participation

An important part of the rulemaking process is public participation. The Administrative Procedures Act states that for any Federal rulemaking, the public must be informed, the opinion of the public must be sought, and the issuing agency is accountable for insuring public participation. Public participation should not wait until after the rule has been proposed, but should begin during the research and information gathering stage. Early participation can garner full public and private sector support, making acceptance of the rule easier and stronger. This involves designing a rule around what the public tells the agency. Public participation can be sought through a variety of methods:

- advanced notice of proposed rulemaking (ANPRM)
- public hearings

- request for information (in Federal Register)
- letters to interested parties (up to 9 requests for information do not need prior OMB approval)
- meetings with affected parties prior to the NPRM
- articles in trade/professional publications delineating information needs
- meetings with public interest groups prior to the NPRM
- public comment period
- consultants

Once all the information is gathered and the research is done, you will start making decisions about what is to be proposed in the rule. As you begin writing, you should remember your goal is writing clearly, in plain English, and to present your information succinctly and coherently.

Some steps to writing and recognizing clear, coherent text:

1. Develop an outline.¹ Use those provided, but fill in the specific topical headings appropriate for your rulemaking.
2. List all the ideas you want to present (this doesn't have to be in complete sentences and probably shouldn't be). List the ideas under the appropriate sections in your outline.
3. Chunk the ideas into related groups. Decide if your related groups will remain single sentences or will be expanded into paragraphs or subsections needing headings.
4. Create your headings and subheadings and insert them into your outline. You should not have more than three levels of headings [main headings (I., II.,...), subheadings (A., B.,...), and sub-subheadings (1., 2., ...)]
5. Write 1-2 sentences for each of the headings or subheadings which summarizes the focus of that particular chunk of the document. These sentences should answer the questions "What's the point?" and "So what?"
6. Decide on the tables or figures you want to use and create them, if not already done. (You may add others later, but if you assemble the ones you anticipate using first, it makes writing about them easier.)
7. Now, starting from the beginning of your outline, write the text. Write as though you were talking to someone and be as clear as possible. Don't force the reader to make inferences, spell out the facts (but this doesn't mean giving every detail, just the basic facts.)
8. If possible, put your writing away at this point. Come back the next day and review your original outline and your document. Delete (or

¹Many people do not start the writing process with an outline and I am not implying this is the beginning of the writing process. If you think through your ideas by writing your thoughts and notes together, by all means continue. DON'T MAKE THE MISTAKE of using this random collection of thoughts as your rough draft. Once your research is done, your data analyzed, and your thoughts generated, begin writing your rough draft by developing an outline and following the steps above.

minimize) any information unrelated to the central concepts. (You may want to have a colleague review the document.)

Your text structure should be clear and coherent. Now it's time to look at your sentence structure.

9. Work on individual sentences, deleting useless words and phrases, tightening constructions, and polishing the overall text. Check spelling, word usage, grammar questions, and any format guidelines you need to follow.
10. Again, put your writing away. This is also another good time to get someone else to read it, preferably someone who is not familiar with the topic and might represent the intended reader. Can they identify the main issues? Do they understand why EPA chose this option? Then you've probably accomplished your objective.

Some things to remember about the *Federal Register*

Some things to remember about writing for the *Federal Register*:

Indentation: Headings and subheadings are not indented from the margin. Instead a variety in type style is used to indicate the different levels.

Underlining: Only underline—

- what will be in **bold** typeface [i.e., section headings in the regulatory text and main headers (I., II., III.,...) in the preamble].
- what will be in *italic* typeface [i.e., paragraph headings in the regulatory text and subheadings headers (A., B., C.,...) in the preamble; scientific terms; ordering statements; and court cases].
- all dates to be computed by FR staff.

DO NOT underline anything else.

Formatting: Double-space on one side of each page. See page 61 of *Document Drafting Handbook* for margins and other specifics.

Some planning steps

After the NPRM is complete and sent to the Federal Register for publishing, plans should be made for the next steps. Too often preparations are not made until after the public hearing or comment period. Planning ahead helps to make deadlines for the Final Rule easier to meet. Just because a deadline may be set for the preamble, doesn't mean that is done first. Do tasks in the order that is most efficient and will produce the best final product.

Plan who will be involved with preparing the *Response to Comments* and the preamble to the Final Rule. Assemble the team and notify them of important dates and involve them in the planning. Use the timetable provided to set your schedule.

One of the points to note in this timetable is that preparation of the Response to Comments does not have to wait for the end of the comment period to begin, especially if your team is organized and assignments are made early. Also, changes to the regulatory language can begin to be made by team members as soon as their analysis of comments is complete.

A second point to notice is that the Response should be near completion as the Preamble to the Final Rule is begun. This is a very important point. In order to write the preamble, EPA must have decided its position and why that position is appropriate. A great deal of discussion usually takes place in order to come to a position. This discussion can be much more focused when all participants have a copy of the summary of the comments on the particular issue and know exactly what the NPRM said on the issue. Meetings can go much more smoothly when someone has already examined the NPRM for what was said and time does not have to be spent trying to remember what was said (and memories might be faulty) and everyone knows what comments were made. And once the decisions are made and the Response drafted, the Preamble can be written in a few days. When you try to do the preamble first, most of the time spent on the Preamble is actually time spent deciding the issues. So just decide the issues, then write the Preamble.

Proposed Timetable for Drafting Final Rule

What's Due	Date Due	Description
NPRM published	Week 1, Day 1	
Public Hearing held	Week 5, Day 30	
Team Meets	Week 6	Discuss what are the major, significant, and minor issues/make assignments to each member to track
Transcript and Comments Arrive	Week 7-8	Team members read as received and prepare a list of the comments on their assigned topic (or other way to track the comments)
Public Comment Period ends	Week 9, Day 60	Continue above
Statement of Proposal and Summary of Comments	Week 10	Team members examine NPRM for what it says and summarize the comments on the issues raised
Statement of Proposal and Summary of Comments completed	Week 11	Team begins meeting to analyze and respond to the comments, copies of each summary are distributed
Discussion of Comments and EPA Position	Week 12-15 (or longer)	as each issue reaches conclusion, the position statement is prepared
Preamble Drafted—rough draft	Week 12	Prepare Background and boilerplate sections of Final Rule preamble/as issues resolved and decisions made, prepare appropriate discussion sections
Reg. Lang.—draft changes	Week 13	For their respective topics, have team members prepare list of changes or a draft of Reg. Lang.
Preamble—Complete Draft ready for internal review Response to Comments on NPRM complete	Week 16	All position statements complete in summary and all discussion statements complete in preamble
Reg. Lang.—finish changes	Week 17	Change appropriate sections of Reg. Lang. as need

Section 2. Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking (NPRM) is the first published version of the regulations. It includes a preamble supplying the background and support for the regulations and the regulatory language. For a detailed explanation of the preamble and regulatory language requirements, refer to the *Document Drafting Handbook*.

What to include in the preamble to the NPRM

Headings	ENVIRONMENTAL PROTECTION AGENCY 40 CFR Part xx Subject (content of document)
AGENCY:	Environmental Protection Agency
ACTION:	Notice of proposed rulemaking.
SUMMARY:	Action summary which answers three questions: <ul style="list-style-type: none">• What action is being taken?• Why is this action necessary?• What is the intended effect of this action? Should not exceed one page (about 1-2 paragraphs). See example on next page.
DATES:	Includes all dates essential to rulemaking. <u>Underline</u> the notes asking <i>Federal Register</i> staff to compute the date.
ADDRESSES:	Includes all addresses any participant needs to know (mailing, hand delivering, public hearing, examining public material).
FOR FURTHER INFORMATION CONTACT:	Name and telephone number of contact person (principal project officer).
SUPPLEMENTARY INFORMATION	Provides the rationale for your proposed rule. Should not exceed 50 double-spaced manuscript pages.

The following provides guidelines for what to include in your preamble and how to organize it. The text is provided where the same text is always used or used with only slight modifications. This text is available over the LNS network—MS Word version on CD38 in Zone "Cert #2."

Example

SUMMARY: Today's action proposes on-board diagnostic (OBD) system requirements for light-duty vehicles and light-duty trucks commencing in the 1994 model year. Under the Clean Air Act Amendments of 1990, EPA is required to promulgate final OBD rules by May 15, 1992; this action is an initial step in that process. This proposal will require manufacturers to install systems which will monitor the functioning of emission control components and alert the vehicle operator to the need for repair. In addition, when a malfunction occurs, diagnostic information must be stored to assist the mechanic in diagnosis and repair. Also proposed are requirements which would make available to the repair industry information necessary to perform repair and maintenance service on on-board diagnostic systems and other emission-related vehicle components.

Answers the three questions—what, why, effect—and no more.

Table of Contents (TOC)

- At the beginning of the preamble, provide a Table of Contents. Use your document outline, listing the first and second level of headings. In some cases you may also want to show the third level of heading also. (Example shows only first and second levels.)
- On working drafts, you may want to supply page numbers.
- Do this section after the first draft is reviewed or document organization is fairly complete.
- Having a TOC not only makes it easier to find things in the draft, but helps readers to understand your organization when it is published in the *Federal Register*.

Summary

- This section provides an executive summary of the proposal (a summary of the preamble as opposed to a summary of the regulation). Answers the question "What does the action involve?"
- This is different from the action summary at the beginning of the document (which is more a summary of the regulation). DO NOT include the exact same information.
- Answers the question "What is the point?" of your whole preamble in just three to four sentences.
- Picks up where the action summary left off: give one to two statement summary of the proposed regulation (Section IV.A.), one sentence summary of why this option was chosen (Section IV.B.), and one to two sentence summary of issues or other options (Section V or VI).
- Write this section LAST or at least after most of preamble is complete.
- An executive summary helps to make sure everyone gets your main idea, and allows them to do so without reading every word first.

Authority

- provides a complete statement of statutory authority
- mention all applicable sections and a statement of the authority provided

Background

- Answer the questions "What led to making this proposal?" and/or "What went on before and while developing this proposal?" Include in this section any or all of the following:
 - a brief statement of current procedures (if being changed)
 - prior research or decisions on another rule which pertains to this rule
 - pending Congressional actions pertaining to this rule
 - prior legal decisions pertaining to this rule
 - anticipated future needs/changes
 - related rulemaking documents
 - magnitude of pollution problem this rule affects
 - pollution abatement and controls already in effect
- Describes the problem for which the rule is the solution.
- This section should just state the facts, clearly and succinctly, not provide great detail; i.e. state your point, but don't comment on it.
- For more detail, refer to supporting documents, but do not repeat detailed analysis which appears in support documents.

- This section can have subheadings (i.e.; Air Quality, Legislative Action, etc.) if the topics listed previously require more than several sentences each.
- It is not necessary to include information which was in the action summary at the beginning of the document. However, it is preferable to have the details in this section and not in the action summary.

Example

I. Table of Contents

Summary of Proposal

Authority

Background of Proposed Rule

Proposed Regulations

A. Proposed Requirements

B. Rationale (or Discussion)

Discussion of Issues

A., B., etc.

Environmental and Health Benefits

A., B., etc.

Economic Impact

A., B., etc.

Cost-Effectiveness

Public Participation

A. Comments and the Public Docket

B. Public Hearing

Administrative Requirements

A. Administrative Designation

B. Reporting & Recordkeeping Requirements

C. Regulatory Flexibility Act

II. Summary of Proposal

III. Authority

Authority for the actions proposed in this notice is granted to EPA by section XXX(x) of the Clean Air Act as amended [42 U.S.C. 7521(a)]....

IV. Background of Proposed Rule

Requirements

- Discusses in detail EPA's proposed course of action.
- May have topical subheadings (but not necessary to have them).
- Include any or all of the following:
 - Part A.
 - standards
 - test procedures
 - compliance procedures
 - effective dates
 - leadtime/phase-in
 - enforcement
 - other topical headings
 - Part B.
 - benefits of this option
 - impact of this option (usually the economic effects, but costs may be something besides money)
 - why benefits outweigh costs
- Part A should always be included. Part B might be included in VI. Discussion of Issues instead of here.
- Part A answers the question "What do I do to obey this rule?"
- Part A explains the proposed regulation requirements in layperson's language, but doesn't get into "why" this is being proposed.
- Make the rationale (Part B) separate from the statement of the regulations; i.e. don't try to explain why you chose this option in the same paragraph you tell them what to do.
- Part B answers the question "Why did EPA choose this option?"
- Part B is a succinct statement of overall benefits/costs using positive language. Save the detailed analysis for other sections.

Discussion of Issues

- Discuss the issues *or* the options. Issues are more general (i.e. what temperature to use, what level of standard, etc.). Options are the combination of decisions on issues that present different ways to meet the goal. If you are discussing options, then **you are only discussing the ones EPA chose not to use in this rulemaking.**
- If you discuss both issues and options, separate them into two sections (see VI. Other Topical Headings)
- Should summarize, not repeat, information in support documents entered in the public docket.
- If you find the information in this section overlapping the info in III. B. Rationale or VI. Other Topical Headings, then cut one of these sections or combine these sections.
- State the topic, or point, of each section or subsection at the **BEGINNING** of the section. The point of a section can come at either the beginning or the end, but in this type of writing, the reader will be looking for your point at the beginning.

Example

V. Requirements of the Proposed Rule**A. Proposed Requirements**

(optional subheadings)

B. Rationale (or topical headings if appropriate)**VI. Discussion of Issues** (or Options)**A. Topical Subheadings** (make these descriptive, not just "Option No. 1" but "Regulatory Approach," "Technical Feasibility," "Enforcement," etc.)

Other Topical Headings

- If there are major headings not covered in one of the other sections, make them separate sections. For example, if you had several alternative approaches or courses of action and want to briefly discuss them, you might have a heading such as "Other Actions Considered" and then describe each option.
- You will probably find everything should fit into one of the other sections. If not, make sure this info is crucial to the preamble or could it just be presented in a support document.

Environmental and Health Benefits

- This is an extremely important part of a proposed rule. It should receive importance and may appear earlier in the preamble.
- Since our rules focus specifically on providing environmental benefits, go into detail on the benefits. Provide information about specific impacts on health. This is a risk assessment in terms of the public health and welfare, the ecological system, and wildlife.
- Write about the anticipated benefits. Do not use numbers and data as though they were absolute or the final word.
- Note that the optional subheadings say basically the same thing in three different ways. Choose one version (or one of your creation) and use it as the model for wording all your subheadings. Don't use all three versions in the same document. Be consistent.

Economic Impact

- Should summarize, not repeat, information in support documents entered in the public docket. This does not repeat, nor is it the same, as section XI. C. Regulatory Flexibility Act.
- State the topic, or point, of each section or subsection at the BEGINNING of the section. The point of a section can come at either the beginning or the end, but in this type of writing, the reader will be looking for your point at the beginning.

Cost Effectiveness

- Benefits vs. Cost
- State the topic, or point, of each section or subsection at the BEGINNING of the section. The point of a section can come at either the beginning or the end, but in this type of writing, the reader will be looking for your point at the beginning.

Public Participation

- Use as written, with addition of appropriate names, dates, and addresses.

Example

VII. Other Topical Headings (Optional) (such as: Other Actions Considered)

VIII. Environmental and Health Benefits (optional subheadings)

- A. Reduction of NO_x*
- B. CO Emissions Benefits*
- C. Effect on HC Emissions*

IX. Economic Impact (optional subheadings)

- A. Developmental Costs*
- B. Variable Costs*
- C. Fixed Costs*
- D. Cost to Government*

X. Cost-Effectiveness

XI. Public Participation

A. Comments and the Public Docket

EPA welcomes comments on all aspects of this proposed rulemaking. Commenters are especially encouraged to give suggestions for changing any aspects of the proposal that they find objectionable. All comments, with the exception of proprietary information, should be directed to the EPA Air Docket Section, Docket No. A-XX-XX (see "ADDRESSES").

Commenters who wish to submit proprietary information for consideration should clearly separate such information from other comments by

- labeling proprietary information "Confidential Business Information" and
- sending proprietary information directly to the contact person listed (see "FOR FURTHER INFORMATION CONTACT") and not to the public docket.

This will help insure that proprietary information is not inadvertently placed in the docket. If a commenter wants EPA to use a submission labeled as confidential business information as part of the basis for the final rule, then a nonconfidential version of the document, which summarizes the key data or information, should be sent to the docket.

Public Participation

Continuation of example text

Administrative Requirements

- Use as written, with addition of appropriate names, dates, and addresses.

Part A.

- Two first paragraphs are provided. Choose the one appropriate for the rule being proposed. Second paragraph same in both versions.
- Pertinent info from the RIA should be included in VIII. Economic Impact. NOTE: RIA is different from Regulatory Analysis.

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR Part 2. If no claim of confidentiality accompanies the submission when it is received by EPA, the submission may be made available to the public without notifying the commenters.

B. Public Hearing

Anyone who wants to present testimony about this proposal at the public hearing (see "DATES") should, if possible, notify the contact person (see "FOR FURTHER INFORMATION CONTACT") at least seven days prior to the day of the hearing. The contact person should be given an estimate of the time required for the presentation of testimony and notification of any need for audio/visual equipment. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling those who have not notified the contact earlier. This testimony will be scheduled on a first-come, first-serve basis to follow the previously scheduled testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advance copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date. This is to give EPA staff adequate time to review such material before the hearing. Such advance copies should be submitted to the contact person listed.

The official records of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the Air Docket, Docket No. A-XX-XX (see "ADDRESSES").

_____, is hereby designated Presiding Officer of the hearing. The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceeding.

XI. Administrative Requirements

A. Administrative Designation

Under Executive Order 12291, EPA must judge whether a regulation is a "major" rule and, therefore, subject to the

Administrative Requirements

Part B. Always included.

Part C. If a significant impact was found, then change the text to indicate this here, but provide more information in IX. Economic Impact or X. Cost-Effectiveness.

requirement that a Regulatory Impact Analysis (RIA) be prepared. Since EPA has determined that this regulation is not major, an RIA has not been prepared.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.
OR

Under Executive Order 12291, EPA has determined that this regulation is major. A Regulatory Impact Analysis (RIA) has been prepared and is available from the address provided under "FOR MORE INFORMATION CONTACT."

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.

B. Reporting & Recordkeeping Requirement

All of the information collection requirements contained in this proposed rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB Control Number XXXX-XXXX. The information collection provisions relating to [insert reference to the data/forms to be collected] have been submitted for approval to OMB.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that the regulations proposed today will not have a significant impact on a substantial number of small entities. This regulation will affect only [insert appropriate businesses], a group which contains few small entities. [May insert additional reasons why small entities not affected.]

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this regulation does not have a significant impact on a substantial number of small entities.

Section 3. Response to Comments

Federal Guidance on Writing a *Response to Comments*

No formal guidelines are provided on the content or structure. Instructions provided in the Regulatory Development Notebook indicate the following:

- The law requires that the Agency provide a written response to all significant comments. You should respond to major comments in the preamble to the final rule. For most rules of any size, the Agency usually prepares a *Response to Comments* document that presents a more complete response to the comments received.
- No guidelines for distinguishing a major issue from a significant issue are provided. Only major issues need be discussed in the preamble to the final rule.
- Organize this document carefully to prevent responding to the same comment repeatedly. Cutting up the comments and grouping them together by issue and then writing one response often works best.
- Responses should be thoughtful, reflecting that you took the comment seriously; it should indicate whether the Agency has changed the final rule in response, and if not, why not.

What to include in the *Response to Comments on the* ----- *NPRM*

The *Response to Comments* document presents the entire discussion of EPA's response to comments received at a public hearing on the NPRM or during the comment period. It should be as exhaustive as necessary to make your case. It is not necessary to repeat all the comments or to repeat technical discussions or analysis found in the public docket.

The document can be organized into three basic sections as described on the following pages.

About This Summary

Write your introduction to the overall summary, providing information about each chapter and how it is organized. Much of this will be boilerplate language, which can be copied from a previous document or use the sample provided. Successful introductions usually cannot be written until the document is complete or near completion.

Executive Summary of Comments

This section should be written after the completion of the rest of the document. You will then be able to summarize the comments made on significant issues into a short paragraph or two and give EPA's position on these issues. This section should provide an overall view of the positions without necessarily mentioning each specific comment and commenter by name. It also does not go into every comment or issue. Here you are summarizing what the substantive issues were which could influence rulemaking decisions. Positions which were unchanged do not need to be discussed in this section.

Discussion of Comments by Issue

Here is the detailed summary and analysis of comments and EPA's position for the final rule. All significant and major comments must be addressed. Since it is an arbitrary decision what is significant and what is major and what is neither, err on the conservative side. It is a matter of discretion whether or not to mention every comment made; however, there is no need to deal with every comment. Those comments which had no impact on the decision-making process or which repeat issues discussed in documents which proposed the rule are not significant comments.

Favorable comments do not need a response, but a mention that they existed is recommended, especially where they enhance our choice among options or our position on an issue.

Group all comments by issue. Each issue should have four types of information given:

- a concise statement of what the NPRM said on this issue. Give a 1-2 sentence synopsis of what the proposed rule says or the position being debated. Do not give the rationale for why the NPRM said this. This is a key starting point from which to base all discussions of the issue. Unless compelling reasons and evidence was provided to justify a change, we intend to finalize what we proposed.
- a summary of the comments. A summary, by definition, means to cover the main points succinctly. This is not a list of the actual comments, but a summary of them (remember the full text is part of the docket). Indicate *who* made the comment (the entity's name, not the individual's name). When several commenters take the same position, indicate this agreement and who agreed. This can be done in several ways, depending on the nature of the comment. The use of company names

Example

Chapter 1. About This Summary

On [give date], the Environmental Protection Agency (EPA) published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) for [title-description]. EPA also held a public hearing on this proposal on [give date] and accepted written comments for 30 days following the conclusion of the hearing. EPA received [give number] written statements from the public on the NPRM. All of the written comments submitted to EPA and a transcript of the public hearing are contained in EPA's [name of docket (docket #)]. A list of all commenters speaking at the public hearing and writing to the public docket is provided in the appendix to this document.

The purpose of this document is to summarize and respond to the comments submitted by the public. Included in the document are responses to issues raised both at the public hearing and in the written comments sent to EPA. Comments were grouped by issue and responded to as a group. The issues discussed in this document are [give list].

[OPTIONAL PARAGRAPH] Comments on [give list] are not addressed in this document. The reader is referred to the final rule published in the *Federal Register* for a detailed discussion of this (these) issue(s).

Chapter 2. Executive Summary contains a synopsis of the comments received and EPA's position on each issue in order to provide a quick overall view of the issues.

Chapter 3. Discussion of Comments by Issue is broken into sections corresponding to the issues given above. Each section begins with a brief description of the EPA proposal followed by a summary of the comments received, and then EPA's response to these comments and the final position taken.

Chapter 2. Executive Summary of Comments

Chapter 3. Discussion of Comments by Issue

3.1. *First Issue*

Statement of Proposal
Summary of Comments
Discussion of Comments
EPA Position

3.2. *Second Issue*

Statement of Proposal
Summary of Comments
Discussion of Comments
EPA Position
etc.

Appendix 1. List of Commenters

summary of comments continued--

should be avoided except where it makes more sense to be specific rather than general, as when one commenter varies greatly from all the other comments. When a large number of commenters make a similar comment, it is not necessary to provide all of their names.

Examples: Several manufacturers indicated..., Two environmental groups agreed that..., Only Ford and Toyota commented that..., All state and local areas said..., etc.

If opposing comments were received, indicate who was opposed and the support for each side.

Tell *what* was said, the basic thrust of the comments, summarizing the commenter's position in 1-2 sentences. Repeating large portions of information which is in the public docket is not necessary. Careful analysis is required to interpret the comments correctly and to state the main point of the comments succinctly. You will find times when it is difficult to truly understand what the commenter means, making your interpretation all the more important.

If evidence was presented to support a comment, summarize this evidence. If no evidence was presented, then you might indicate no evidence was presented to support the comment. This is especially important on a comment where commenters disagree with EPA or with each other and the use of evidence is needed to support a position. **The summary of comments section is vital because of the influence your interpretation may have on the rationale EPA uses to make a final decision.**

- **a discussion and full analysis of the comments.** This is our response to the comments made and our analysis of them. When responding, consider whether we have new data unavailable when the NPRM was written. Also consider whether commenters raised points inconsistent with prior positions they have taken. Use the following questions to help you think about our response:

How have the comments influenced our thinking?

Do the comments simply raise issues or arguments we anticipated and refuted in the NPRM?

Is there any new data or arguments we didn't deal with in the NRPM?

Is a change from the proposal warranted? If not, why not?

If a change is warranted, what options should we consider for changing the final rule?

Are there any new CAA requirements which require us to change or influence us to change from the proposal? If so what options should we consider?

Each comment must be acknowledged and treated seriously, even if the law prescribes the action they are commenting about. When the law very clearly prescribes an action, all that is needed is a statement that EPA is aware of the comments made and the argument presented, but they are not pertinent because of the law. When the law is being *interpreted* as prescribing an action, then it is best to still respond to each comment so future changes in interpretation will not necessarily change the analysis.

You do not need to acknowledge each individual commenter, however, just each position taken.

References may be made to the Regulatory Support Document or other documents in the docket, but detailed analyses from these documents do not need to be repeated. However, where new analysis has been done, a full explanation is needed.

Discuss the pros and cons of the options raised. Relevant comments may be mentioned, but keep this to a minimum, since they should be in the summary given previous to this section. The response should show the logic EPA used to get to its final position.

- the position taken on the issue and why. Organize this section by first stating the position EPA is taking for the final rule, followed by the rationale or process EPA used to reach this position. This should essentially summarize in a few sentences the detailed explanation of the logic and process presented in the discussion and full analysis. For example, in the case of a prescribed action, you indicate EPA is aware of the comments, but cannot act on them because the law precludes such action.

The language used is often of concern. For positions in the NPRM, EPA "believes." In the *Response to Comments*, EPA has "determined" or "believes." In the Final Rule, EPA has "decided." Avoid the use of the term "recommended." Our statements are the law unless significant reason for change exists, so do not use language which implies possible change.

Appendixes

One appendix should exist which lists all the commenters at the hearing and from the docket. It is also suggested that this list be coded to indicate which issues each commented on. This can be done by simply listing after the name the issue as numbered in the discussion section. For example, after MVMA, the numbers 3.4, 3.5, and 3.8 might appear, indicating MVMA provided comments on those three issues.

All tables, figures, and other information should be included in text as it is referred to. However, if the same information is referred to frequently, it may be more advantageous to put it into an appendix at the end of the summary.

Number each appendix in the order it is referred to in the text. This means the list of commenters should always be Appendix 1 since it is referred to in the first paragraph of "About This Summary" at the beginning of the document.

Section 4. Notice of Final Rulemaking

The Notice of Final Rulemaking is the last published version of the regulations before going into the Code of Federal Regulations (CFR). It includes a preamble supplying the background and support for the regulations and the regulatory language. For a detailed explanation of the preamble requirements, refer to the *Document Drafting Handbook*).

What to include in the preamble to the Final Rule:

Headings	ENVIRONMENTAL PROTECTION AGENCY 40 CFR Part xx Subject (content of document)
AGENCY:	Environmental Protection Agency
ACTION:	Final rule.
SUMMARY:	Action summary which answers three questions: <ul style="list-style-type: none">• What action is being taken?• Why is this action necessary?• What is the intended effect of this action? Should not exceed one page (about 1-2 paragraphs). Can be repeated from NPRM as appropriate.
EFFECTIVE DATE:	Unless dates other than the effective date are given, use this heading and give the date. Underline the notes asking <i>Federal Register</i> staff to compute the date.
ADDRESSES:	Optional, but frequently gives the docket address.
FOR FURTHER INFORMATION CONTACT:	Name and telephone number of contact person (principal project officer).
SUPPLEMENTARY INFORMATION	Provides background and basis for final rule. Should not exceed 50 double-spaced manuscript pages.

The following provides guidelines for writing your preamble. The text is provided where the same text is always used or used with only slight modifications. This text is available over the LNS network—MS Word version on CD38 in Zone "Cert #2."

Table of Contents (TOC)

- At the beginning, provide your document outline using the first and second level of headings. In some cases you may also want to show the third level of heading also. (Example shows only first and second levels.)
- On working drafts, you may want to supply page numbers.
- Do this section after first draft is reviewed or document organization is fairly complete.
- May start out with just the first level of headers and add subheads as text is written and organized.
- Having a TOC helps the reader to understand your organization and to find things in the text.

Authority

- provides a complete statement of statutory authority
- mention all applicable sections and a statement of the authority provided
- can probably take from NPRM, plus any new actions

Requirements

- Discusses and explains EPA's final requirements as will be written into code. Include any or all of the following:
 - standards
 - test procedures
 - compliance procedures
 - effective dates
 - leadtime/phase-in
 - enforcement
 - other topical headings
- Explain in layperson's language.
- Answers the question "What do I do to obey this rule?"
- May have topical subheadings (but not necessary to have them).

Summary of Changes

- Provide a list of exactly what in the regulatory language has been changed from the NPRM.
- Do not give any background or rationale for these changes, but just make reader aware of the changes.
- Often may be giving minor changes made to accommodate procedures or new statutes and may not be discussed anywhere.

Example

I. Table of Contents

Authority

Requirements of Final Rule

Summary of Changes to Proposed Rule

Background and Development of Rule

Discussion of Comments and Issues

A., B., etc.

Administrative Requirements

A. Administrative Designation and RIA

B. Reporting & Recordkeeping Requirements

C. Regulatory Flexibility Act

II. Authority

Authority for the actions in this notice is granted to EPA by section XXX(x) of the Clean Air Act as amended [42 U.S.C. 7521(a)]....

III. Requirements of Final Rule

IV. Summary of Changes to Proposed Rule

Background

- Answers the question "What lead to making this rule?" and/or "What went on before developing this rule?" Include in this section any or all of the following:
 - highlights from the background section of the NPRM (but does not repeat the entire background section of the NPRM)
 - highlights of the activities provided for public participation
 - related legislative or judicial action occurring since NPRM published
- It is not necessary to include information which was in the action summary at the beginning of the document.
- This section should just state the facts, clearly and succinctly, not provide great detail; i.e. state your point, but don't comment on it.
- This section can have subheadings if the topics listed above require more than several sentences each (will probably have a section for *Public Participation*).

Discussion

- This section should begin with a paragraph indicating a complete analysis of all comments has been done and where it can be obtained. This section then only describes the *major* issues. All significant and minor issues are dealt with only in the *Response to Comments*.
- Decide which are the major issues and so must be dealt with in the preamble.
- Major issues can be identified by determining if policy hinges on these issues, if they are so controversial we must explain our rationale, or if

the resolution of the issue affects the stringency of the standards.

- All the discussion contained in the *Response to Comments* on a major issue **does not** need to be repeated in the preamble. Only the action to be taken, an abbreviated summary of comments, and a summary of the discussion and analysis are needed. (Answer the questions: What's the final outcome? What was the comment made? and Why did or didn't we change our position?) These can be lifted from the *Response to Comments* when it is completed.
- None of the discussion on significant and minor issues needs to be in the preamble. A statement indicating what other issues were raised and what decisions were made is sufficient for significant issues. Minor issues do not need to be mentioned.
- Organize by the issues raised in the comments, not by the commenter.

Administrative Requirements

- Use as written, with addition of appropriate names, dates, and addresses.

Part A.

- Two first paragraphs are provided. Choose the one appropriate for the rule being proposed. Second paragraph same in both versions.

V. Background and Development of Rule**VI. Discussion of Comments and Issues**

A full discussion of all comments received is available in the *Response to Comments on the _____ NPRM*. A copy may be obtained by contacting _____. A summary of the discussion on several issues of major importance is provided here.

A. Topical Subheadings (make these descriptive, not just "Issue No. 1" but "Regulatory Approach," "Technical Feasibility," "Enforcement," etc.)

VII. Administrative Requirements**A. Administrative Designation**

Under Executive Order 12291, EPA must judge whether a regulation is a "major" rule and, therefore, subject to the requirement that a Regulatory Impact Analysis (RIA) be prepared. Since EPA has determined that this regulation is not major, an RIA has not been prepared.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.
OR

Under Executive Order 12291, EPA has determined that this regulation is major. A Regulatory Impact Analysis (RIA) has been prepared and is available from the address provided under "FOR MORE INFORMATION CONTACT."

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.

Administrative Requirements

Continuation

Part B. Always included.

Part C. If a significant impact was found, then indicate this here and summarize info from the NPRM.

B. Reporting & Recordkeeping Requirement

All of the information collection requirements contained in this proposed rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and have been assigned OMB Control Number XXXX-XXXX.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that the regulations proposed today will not have a significant impact on a substantial number of small entities. This regulation will affect only [insert appropriate businesses], a group which contains few small entities. [May insert additional reasons why small entities not affected.]

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., I certify that this regulation does not have a significant impact on a substantial number of small entities.