

**CDPH/ORH**  
**Tips for Preparing Regulation Packages &**  
**Responding to Public Comments**

**Initial Statement of Reasons (ISOR):**

*\* Should be written simultaneously with the Regulation Text to ensure consistency.*

*\* Will act as the foundation for the responses to public comments.*

- Shall demonstrate how the necessity standard of the Administrative Procedure Act (APA) has been met.
- Summarize the Program's authority relevant to the proposal (cite state statutes, federal statutes, court decisions, the location of existing regs., if any, and the location in the California Code of Regulations (CCR) of the sections to be adopted, amended or repealed).
- Discuss the provisions of law being interpreted, made specific and/or implemented (can be combined with item above). The authority and reference citations at the end of each regulation section shall be consistent with this discussion.
- Create a context for the regulation, such as a discussion of how a Program currently works, relevant to the proposed regulation text changes; e.g., what will be the intended effect.
- Describe EACH change in every section/subsection and what EACH of the changes (in terms of adoption, amendment, repeal) are, including the necessity for the change and the intended effect of the change. Also, if the provision is controversial, consider restating/reaffirming the legal authority underlying the regulation text.

Explain:

- the "purpose" of the regulations;
  - why the regulation is necessary;
  - why regulate in this area at all;
  - why this is the best alternative;
  - the rationale and necessity for the specific requirements; and
  - how and by whom the regulation is enforceable.
- Language shall be positive and active; don't just duplicate the regulation language.
  - Use parallel construction in sentences and paragraphs; make sure the structure of the ISOR flows and fits together.
  - Don't refer to "underground" documents or manuals.
  - The ISOR can include an "Appendix" if necessary to provide supplemental information.
  - Materials Relied Upon: shall be listed and identified by title, author and date and the relevance of these documents to the rulemaking. Examples include: scientific studies or reports, journal articles, directives from the federal government, legal actions, and letters from

## CDPH/ORH

### Tips for Preparing Regulation Packages & Responding to Public Comments

- interested parties. A listing of these documents can be included at the end of the ISOR [in bibliographic format].
- Discuss any (lawful) alternatives considered, and the reasons why they were rejected (reasons can include fiscal impacts to state, economic impacts to regulated public, etc.).
  - Discuss any potentially adverse statewide economic impacts on all businesses, including small businesses. Also, discuss any economic benefits, qualitatively or quantitatively. See the Statements of Determination description in this document below.
  - Describe any minor grammatical changes made to the regulation text.  
(Ex: “for the verb tenses match”, or for the purpose of “clarity.....” or “consistency.....”)
  - Explain any rearranging of the regulation text with renumbering/re-designation schemes, along with other minor or non-regulatory changes.
  - Incorporations by Reference:
    - Include a formal reference to any forms, standards, manuals, etc. that are being incorporated by reference and a brief reason why they cannot be inserted into the CCR itself (too cumbersome, impractical, or expensive), and if applicable, that the document is available upon request or available from a common source;
    - Each regulatory element of the form or each standard incorporated by reference shall be explained as to necessity;
    - Provide the authority for use of the document/form and the contents requested; and
    - Underline the form name, #, and date in the ISOR.
  - Fees & Rates: Discuss how the specific dollar amount was determined and if the regulation is setting or revising a fee or a rate. In many cases legislation requires fees to be equivalent to the cost of providing the "service," so there needs to be a cost-revenue analysis included here, which will become a part of the rulemaking file. (*This may also be present in the fiscal impact estimate.*)
  - Technology/Equipment: if the regulations mandate the use of technologies/equipment, include a statement of why these mandates are required (alternatives considered).

### Regulation Text

#### Formatting Tips:

- Begin each regulation section at the top of a new page. However make sure all the sections are in one word document.
- Use double spacing and indent the 1<sup>st</sup> line of each Section, Subsection, and Paragraph, 5 spaces.

**CDPH/ORH**  
**Tips for Preparing Regulation Packages &**  
**Responding to Public Comments**

- Each "Printer's Instruction" at the top of the page for each section shall include a unit number i.e. (1), (2), (3) and be followed by the printer's instructions.  
Examples: 1. Amend Section 51215 to read...  
2. Adopt Section 53333 to read...  
3. Repeal Section 58697
- Assure that the existing (base) regulation text is the existing version (Ask ORH for a hard copy of the CCR section(s)).
- Underline new regulation text and ~~strikeout~~ repealed regulation text.
- Keep each section focused on one identified objective. Avoid multi-page regulation sections. Limit sentences to 20 words or less, if possible.
- Definitions:
  1. Unfamiliar words and those that are not commonly understood must be clearly defined in regulation.
  2. Definitions are typically listed alphabetically, each under its own section, under a separate article entitled "Definitions". The definitions under this article would then apply to the other articles under that chapter.
  3. Definitions should not be interspersed throughout regulations. However, in rare instances a definition is imbedded within a regulation section and in this circumstance the definition would apply only to the meaning of the word as used in that section.
  4. In addition definitions:
    - Shall be consistent with existing terms, ideas, and references used within the regulation text;
    - Shall not contain program requirements or standards; and
    - Shall not include the term being defined within the definition itself.
- Arrange subject matter under the sections in the anticipated order that persons will be affected.
- Don't use the letter (a) to designate a subsection if there is no (b); don't use a 1. to designate a paragraph if there is no 2., etc.
- As of 7/07: Include as an Authority NOTE "H&S Code Section 20" – This is due to SB 162 (Dept name change).

General Tips:

- \* *Write the Regulation Text and the Initial Statement of Reasons simultaneously to ensure consistency.*
- Use simple familiar language, active voice, present tense, and third person.

**CDPH/ORH**  
**Tips for Preparing Regulation Packages &**  
**Responding to Public Comments**

- Use correct grammar, short sentences (avoid compounds), to describe mandatory actions.
- Use only necessary words, arrange words carefully, and tabulate when appropriate to simplify ideas.
- Regulations shall be clear to the regulated public and shall leave no room for different interpretations, thus having one meaning.
- Regulations shall contain pertinent information and not be “solely informational material.”
- Words shall be concrete and express objective rather than subjective concepts. Don’t use redundant expressions or “lawyerisms”.
- Ensure that terms, quotations and punctuation are used consistently throughout the regulation text.
- Use parallel construction in the sentences and paragraphs; be sure sentence structure is consistent and flows in each section and that the sections are also consistent with each other.
- Ensure that the content of the regulation text reflects what exists in the State Plan and does not conflict with other existing state or federal regulations or statutes.
- Verify all references made to other sections in the CCR or to other reference locations. Use hard copies of statutes when verifying references/authorities.
- Review other areas of the CCR that may be affected by the proposed revision and may require a revision with the current proposal.
- Regulations shall be consistent with the description of its effect as explained in the corresponding section of the Statement of Reasons.
- Edit the regulation text to remove value words such as "appropriate," "sufficient," and "as necessary." Standards and criteria shall be clear without such modifiers.
- Avoid using the phrase: “including but not limited to.” Instead use the phrases: “including,” “such as”, or “similar to,” if necessary.

Authority and Reference Citations:

*\* Authority exists when the Department is granted “rulemaking authority” (e.g. the ability to adopt, amend or repeal regulations.)*

*\* Reference exists when the Department is empowered to implement, interpret or make specific a California constitutional provision, a California statute, a federal statute or regulation, or a court decision.*

- Are required for each regulation section (even definitions) and are placed at the end of the regulation text.
- Include an underline for new cites and a ~~strikeout~~ for changed or repealed cites.
- Are not repealed when an entire regulation section is repealed.
- Shall be accurate and reflect the existing CCR language and the proposed language changes.

**CDPH/ORH**  
**Tips for Preparing Regulation Packages &**  
**Responding to Public Comments**

**Common Regulation Writing Problems:**

1. Disagreement regarding the objectives of the proposed regulations.
2. Multiple meanings for the regulation text.
3. Insufficient authority (for fees, sanctions).
4. Incorrect references to other sections in the CCR.
5. A desire to “override statute” (state or federal).
6. Informative language, rather than necessary/regulatory language.
7. The use of the terms "may" or "should" (which are permissive) rather than the term "shall" (which is mandatory).
8. Processes getting mixed up in definitions.
9. The use of the same word in the definition as the term or terms defined.
10. Regulating the Department, instead of the public.
11. Not clearly specifying the criteria for approval/compliance/eligibility.
12. Regulation sections that are too long, with too many subsections.
13. Sentences that are too long, with too many dependent clauses or modifiers.
14. The use of the phrases: “notwithstanding...” or “including, but not limited to...”
15. Circular explanations in the statement of reasons for explaining the regulation text (Ex: “we are defining this so the public will know what we mean”).
16. The statement of reasons not aligning/agreeing with the regulation text.

**CDPH/ORH  
Regulation Text Format  
Example**

Each regulation is preceded by a consecutively numbered "printer's order" that specifies the action to be taken, such as:

- (1) Repeal Section 50000.
- (2) Adopt Section 50001 to read:
- (3) Amend Section 50002(b) to read:
- (4) Amend Sections 50003(b) and (e) to read:
- (5) Redesignate Section 50504 as Section 50000 and amend (c) to read:

Regulation text is typed double-spaced on white bond. The DPH-# should be on the upper right corner of each page; below that is the date the regulation text is prepared. Every page is numbered at bottom center. Every section starts on a new page. Changes to existing language are shown as ~~strike-out~~ and new language is underlined. Subsections are broken down in the following numbering sequence -- (a), (1), (A), 1., a., (i). Each subsection or paragraph is indented 5 spaces on the 1<sup>st</sup> line, and each subsequent line is at the left margin.

Every regulation must have an authority and reference citation under the NOTE. The citation is typed single-spaced and begins two lines below the end of the regulation text. The reference citation begins on a new line.

An example of reg text format is on the next page.



**CDPH/ORH  
Regulation Development  
Common Mistakes**

1. Lack of agreement among interested parties regarding the objectives of the regulations.
2. Not considering all options and alternatives to the regulatory action (pursuit of legislation, contracts, etc.).
3. Not identifying and focusing on the goals of the regulatory changes contemplated.
4. Not limiting the goals to those really possible in the current environment (making goals too broad or comprehensive; not recognizing potential sources of opposition).
5. Multiple meanings for the regulation text (providing too much “wobble room”).
6. Not meeting the full requirements for incorporations by reference (Forms, Code of Federal Regulations, etc.).
7. Insufficient authority (statute) as the basis for the regulations (fees or sanctions).
8. Not providing the cost basis (analysis) in the statement of reasons for fee amounts or other fiscal stipulations.
9. Restating statute in the regulations for reasons other than clarity.
10. Attempts to override or go beyond the scope of state or federal statute.
11. Informative language, rather than necessary/regulatory language.
12. Including processes within definitions, definitions within standards, etc.
13. Not clearly specifying a process or the criteria for approval, compliance or eligibility.
14. Use of circular explanations in the statement of reasons.  
 (“It is necessary because it is needed.” “The term is defined so the affected public know the meaning of the term.”)
15. Lack of demonstrated necessity in the statement of reasons. Simply providing a purpose but no reason as to why the regulation supports the purpose.
16. Lack of alignment between the statement of reasons and the regulation text.