

INSTRUCTIONS FOR THE DRAFTING, SUBMISSION AND ASSIGNMENT OF NCIMS PROPOSALS

In order to provide for the most efficient and satisfactory deliberation of proposals, the following instructions are provided. Proposals may request actions, studies, pilot projects or ideas that need thoughtful consideration for development as possible recommendations to the next NCIMS conference or as actions to be completed within a shorter time period. The conference has a number of standing committees that proposals may be assigned to for action or *ad-hoc* committees may be established to work on a specific proposal.

DRAFTING INSTRUCTIONS FOR CONFERENCE PROPOSALS:

A properly prepared proposal may be found on the NCIMS website at www.ncims.org located on the link for the 2023 Conference.

Please prepare your proposal using Microsoft Word and save your submission as a Word document with the file extension “.docx” only.

With each proposal, the text for the proposed solution should include enough or all of the text required for the reader to understand the proposed changes to the identified conference document without having to refer to the conference document being changed. Citing only the page number or a single sentence from the text of the conference document being changed is not enough text for the reader to be able to understand the issue in most cases. It is strongly recommended that the submitter incorporate the changes into all of the conference documents text, where applicable, for consideration by the conference delegates. It is vitally important for the text to include every section of all of the conference documents the change will affect. Conference documents may be downloaded from the NCIMS Website at www.ncims.org.

A. Use the following guidelines for the body of the text for citing all revisions to PMO provisions and NCIMS conference documents within the Proposed Solution Section of all submitted proposals:

1. Type the documents in conventional uppercase and lowercase format. **Do not use colored font, underlining or highlighting** as these will not appear in the printed versions.
2. Underscore new proposed text. Use the single line form of underlining. **Do not use “words only” underlining.**
3. ~~Strike through language to be deleted.~~ Text proposed to be deleted is struck through.
4. Always insert proposed new text *after* stricken proposed deleted text.

EXAMPLES

Underscore:

2. The owner shall install, calibrate, maintain, and operate a device to continuously measure the temperature of the flue gas stream at the inlet of each particulate matter control device.

Strikethrough:

~~3. 12 VAC 5-590-420—Treatment technique requirements.~~

Strikethrough, then underscore:

~~7. 9. For any request application made under subdivision A 2 of this section, for a treatment technique variance, the applicant must also include a statement that the owner will perform monitoring and other reasonable requirements prescribed by the division commissioner as a condition to the variance; will be performed.~~

5. Do not use the “revision mode” or “track changes” mode for creating a document for submission. Such word processing modes provide opportunities for accepting and rejecting revisions that allow language to be inadvertently deleted or changed without showing the changes.

In **Microsoft Word**, use the “strikethrough” and “underline” features located under Format - Font.

6. Do not use the automatic numbering feature when creating a list. This occasionally inserts codes that are difficult to remove later and causes numbers or letters to disappear when applying paragraph styles.

In **Microsoft Word**, the automatic numbering feature can be disabled at Tools – AutoCorrect Options - AutoFormat.

7. Use underscoring only for indicating new proposed text. **Do not use underscoring for emphasis, for the names of books, or for foreign phrases.** Use quotation marks for the names of books, journals, articles, and similar items.

8. Do not strike a part or portion of a word or number. First, strike through the entire word or number, then insert the new proposed word or number and underscore to indicate that it is new proposed text.

EXAMPLES

To change a word from plural to singular or vice versa:

INCORRECT
parking decks
applications

CORRECT
parking ~~decks~~ deck
~~applicati~~ applications

9. Avoid the use of illustrations whenever possible. However, if required, please provide clear illustrations that will reproduce well for incorporation into printed and electronic publications.

10. Proposals are effective for rating and enforcement purposes one year after the publication of the IMS-a by FDA for States that can legally enforce the IMS-a upon its issuance or one year after the issuance of the electronic version of the conference document for the remaining States. The IMS-a document is normally published sometime in October or November after each NCIMS conference, and the conference documents are normally published after the first of the year following the NCIMS conference.

You may propose an effective date earlier than one year after publication of the IMS-a, however, the effective date cannot be earlier than the meeting of the NCIMS Executive Board during which FDA's concurrence with Conference actions is finalized.

If you wish to propose an earlier or later effective date, that date shall be cited in each proposal.

Note: Per Article V of the Constitution, amendments to the Constitution become effective at the close of the Conference at which they are adopted.

PROPOSALS THAT DO NOT AMEND CONFERENCE DOCUMENTS; BUT SEEK ASSIGNMENT TO A NCIMS COMMITTEE:

For proposals that result in assignment to NCIMS committees, the Conference procedures require the Chair of the NCIMS Executive Board to assign those passed proposals to an NCIMS standing committee, special committee, or ad hoc committee as approved by the NCIMS Executive Board. The NCIMS Executive Board has requested that all proposals that will result in assignments to NCIMS committees be formatted to begin with the statement:

“(Insert the name of the Submitter, Council, Committee, Organization, etc. making the request) request the Chair to assign this proposal to an NCIMS standing committee, special committee, or *ad hoc* committee as approved by the NCIMS Executive Board.”

The request should also include what the expected outcome is, i.e., proposal to be developed for the next conference; report to Executive Board; etc. and timeline for completion, i.e., next conference or a specific date, etc.

FDA/NCIMS 2400 FORMS:

All proposals for new laboratory test methods or changes to approved laboratory test methods will be assigned to the NCIMS Laboratory Committee for deliberation and recommendation to Council II. Council II will deliberate each proposal and make a recommendation to the voting delegate of either “no-action”; “passed as submitted”; or “passed as amended”. During the delegate voting session, FDA/NCIMS 2400 Forms will not be discussed. Conference procedures require that all of the FDA/NCIMS 2400 Forms be handled as a block. First the FDA/NCIMS 2400 Forms recommended for “no-

action” will be voted on; then the FDA/NCIMS 2400 Forms recommended to be “passed” will be voted on.

If passed the forms will be sent back to the NCIMS Laboratory Committee to work with the manufacturer and FDA until all parties agree on a finished FDA/NCIMS 2400 Form for each method that can be recommended to the NCIMS Executive Board. The NCIMS Laboratory Committee then recommends to the NCIMS Executive Board for their approval each FDA/NCIMS 2400 Form that has been finalized. After the NCIMS Executive Board approves individual FDA/NCIMS 2400 Forms they are officially accepted and published by FDA.