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| SOP TITLE: | Format Guidelines for Standard Operating Procedures (SOPS) of The NELAC Institute (TNI) |
| SOP NO.: | 1-100 First Part Numerical Designator: 1 = General Standards Development Program 2 = Consensus Standards Development Program (CSDP) 3 = National Environmental Laboratory Accreditation Program (NELAP) 4 = Proficiency Testing Program (PTP) 5 = Laboratory Accreditation System Program (LASP) 6 = Advocacy Program 7 = Technical Assistance Program 8 = Forum on Laboratory Accreditation 9 = National Environmental Monitoring Conference (NEMC) |
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Format Guidelines for Standard Operating Procedures (SOPS) of The NELAC Institute (TNI)

1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) gives guidelines for preparing SOPs used by The NELAC Institute (TNI) to conduct activities supporting its mission. The guidelines described here apply to all SOPs used by TNI programs and administration.

2.0 Summary

This SOP details the format of the SOPs used by TNI programs. It is itself a model that can be used for drafting other SOPs. This SOP is self-referential and is written in the format and style described in the document

3.0 Related Documents

3.1 SOP 1 – 104, Control of TNI Documents [To be drafted]

4.0 Definitions

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|------------------------------------|--|
| Control Documentation: | Information uniquely identifying an SOP in a page header of standard format. |
| Essential SOP Elements: | Elements that all SOPs must contain. |
| Shall: | Denotes activities, procedures, or elements from which no deviation is allowed and is synonymous with must. |
| Should: | Indicates that an associated element is recommended but not mandatory. |
| SOP: | Acronym for Standard Operating Procedure. A written document of standard format that details in step-by-step fashion how to accomplish an activity or perform a procedure. |
| Supplementary SOP Elements: | SOP elements that must be included in some SOPs, but may be included in others. |

5.0 SOP Elements

5.1 All SOPs shall have the following essential elements:

5.1.1 A cover page.

5.1.2 A title.

5.1.3 An identifying number.

5.1.4 A revision number.

5.1.4.1 The first approved version of an SOP is always revision "0".

5.1.4.2 Substantive revisions to an SOP increase the revision number by an integer. For example, Revision 3 would indicate that an SOP has been revised substantially three times after its original version.

5.1.4.3 Revisions to an SOP made only for editorial reasons or minor clarifications add a decimal number to an existing revision number. For example, Revision 2.4 would indicate that the second substantive revision of an SOP has undergone four editorial revisions.

5.1.4.4 A substantive revision to an SOP with a decimal number increases the SOP's revision number to the next integer. For example, if SOP Revision 2.4 is revised substantially, it would become Revision 3.0 on approval.

5.1.4.5 Editorial changes made in conjunction to substantive revisions increase the SOP's revision number to the next integer. For example, if SOP 7.5 is

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substantially revised and undergoes several editorial changes at the same time, it becomes Revision 8.0 on approval.

- 5.1.5 A header with control documentation for each page other than the cover page.
 - 5.1.6 A footer with page numbers for each page other than the cover page.
 - 5.1.7 A section specifying the SOPs purpose and applicability
 - 5.1.8 A section summarizing the procedure or activity detailed.
 - 5.1.9 Procedural sections of text.
- 5.2 Some SOPs may also contain all or some of the following:
- 5.2.1 A Table of Contents.
 - 5.2.2 A table containing a list of tables and figures.
 - 5.2.3 A section listing related documents.
 - 5.2.4 A “definitions” section.
 - 5.2.5 A section listing references made in the SOP or used in crafting it.
 - 5.2.6 A section summarizing approved changes made to a previously approved SOP.
 - 5.2.7 Tables, figures, diagrams, charts, examples, checklists, or appendices.
- 5.3 All SOPs shall be formatted following a template provided by the Policy Committee. The template specifies paper size, margins, font choice and sizes, and text justification.
- 5.4 All sections and items are numbered using legal style numbering, as done here.
- 5.5 All final SOPs will reference an effective date.
- 5.6 The format of this SOP mirrors the format described in the document and contains most of the elements discussed. The rest of this SOP describes each of these elements in more detail.

6.0 Cover Page Format

- 6.1 The cover page of an SOP shall include in this order:
- 6.1.1 A descriptive title.
 - 6.1.2 An identifying number that follows the indexing system described in Section 18.0 of this SOP.
 - 6.1.3 The revision number of the SOP. The first final version of an SOP is always ‘Revision 0’.
 - 6.1.4 The identity of the committee preparing the SOP and the committee’s approval date. If a committee has not drafted the SOP, the entries are completed with the initials NA, not applicable.
 - 6.1.5 The identity of the program board preparing or approving the SOP and the approval date. If a program board has not drafted or approved the SOP, the entries are completed with the initials NA, not applicable.
 - 6.1.6 The date on which the TNI Policy Committee completed its review of the SOP for consistency with TNI’s mission and other approved documents.
 - 6.1.7 The date on which the TNI Board of Directors endorses the SOP.
 - 6.1.8 The effective date of the SOP.
 - 6.1.9 A footer with:
 - 6.1.9.1 The words “**The NELAC Institute**” in bold.
 - 6.1.9.2 The mailing address of TNI.
 - 6.1.9.3 The website address of TNI.

7.0 Page Header and Footer Format

- 7.1 All pages other than the cover page have a header with a standard format. The header contains the following information in the format shown on this SOP:

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- 7.1.1 The words “TNI Standard Operating Procedure”.
 - 7.1.2 The SOP number.
 - 7.1.3 The date on which the SOP became effective.
 - 7.1.4 The revision number of the SOP.
 - 7.1.5 The title of the SOP.
- 7.2 All pages other than the cover page have a footer with a standard format. The footer contains the following information in the format shown on this SOP:
- 7.2.1 The acronym “TNI”.
 - 7.2.2 The page number of the SOP in “Page X of Y” format for all pages except the table of content pages.
 - 7.2.3 The Table of Contents page numbers will be in lower case Roman numeral format, where the last number is the total number of pages in the table of contents (e.g.: i of iv, ii of v, iv of xii), for SOPs that have a table of contents. (See Section 12.0)

8.0 Purpose and Applicability Section Content

The first two sections of an SOP shall briefly explain the purpose of the document and its applicability. Applicability can be conveyed by listing the parties or activities covered or excluded by the SOP.

9.0 Summary Section Content

This section should describe briefly the content of the SOP. If desired, special features of a procedure can be highlighted in this section.

10.0 Procedural Sections

- 10.1 Procedural sections constitute the core of the SOP, describing in text and in detail the procedure or activity that is the object of the SOP.
- 10.2 The text can be divided into as many sections as is necessary to completely describe a procedure.
- 10.3 Although procedural sections can contain diagrams, graphs, charts, or tables if including them in the body of the SOP is essential for clearly understanding a step in a process, non-textual information is usually placed at the end of SOPs, after the reference section.
- 10.4 These sections should be written in sufficient detail to allow someone with basic knowledge to complete or reproduce the referenced activity.
- 10.5 SOPs shall be written in English, using grammar and style suitable for formal business documents.

11.0 Using Supplementary Elements in SOPs

- 11.1 Some SOPs will require additional sections to completely describe a procedure or to make the procedure clear to those that are not completely familiar with the process described. The writer and the person approving the SOP should discuss the need for including supplementary elements.
- 11.2 Sections 12 – 17 describe supplementary elements and indicate when it is appropriate to include them in an SOP.

12.0 Table of Contents Section

- 12.1 SOPs longer than 15 pages shall have a table of contents. A table of contents is optional for SOPs with fewer than 15 pages.
- 12.2 The table of contents should indicate the page number of the principal sections of an SOP, those with a zero decimal, in the format of the table of contents of this SOP.

13.0 Related Documents Section

- 13.1 Some SOPs are intimately linked to others. When information contained in more than one document is necessary to complete a task, it is useful to include a cross-reference section in each document.
- 13.2 When necessary, this section should be placed between the “Summary” and “Definitions” sections, or when the latter section is not necessary, between the “Summary” and the first procedural section.

14.0 Definitions Section

- 14.1 This section defines any terms that are not universally understood or establishes the sense in which a term that can be defined in more than one way is used in an SOP.
- 14.2 When terms that are not universally understood by TNI members or that have more than one sense are used in an SOP and these terms can be found in a glossary, it is not necessary to include definitions of those terms in an SOP.
- 14.3 Since SOPs should strive for clarity, it is sometimes appropriate to include definitions in an SOP even when the same definitions can be found in a common glossary.
- 14.4 Uncommon acronyms should be fully spelled in the “Definitions” section. They do not need to be defined if the terms comprising the acronym are well-understood.

15.0 References Section Format

- 15.1 This section shall list any sources quoted, cited, or used in preparing an SOP.
- 15.2 References should be listed alphabetically by source title or author’s last name, as appropriate.

16.0 Approved Changes Made to the SOP

- 16.1 This section details in chronological order substantive changes made and approved to a previously approved SOP. The first approved and effective version of an SOP does not require this section.
- 16.2 This section is included as the last one before any tables, figures, diagrams, charts, examples, checklists, or appendices.
- 16.3 The entries in this section shall reference the specific section of the SOP where the change occurred.
- 16.4 Editorial changes need not be itemized, but may be referenced in general terms in this section. For example a statement such as “several sections of the SOP were rewritten to correct grammar and punctuation errors and to improve its clarity” may be included in this section.

17.0 Tables, Figures, Diagrams, Charts, Examples, Checklists, and Appendices Format

- 17.1 Some SOPs will need tables, figures, diagrams, charts, examples, or checklists to completely describe a procedure or to make it more understandable.
- 17.2 Generally, non-textual information is added at the end of an SOP after the “References” section, but this information can be part of a procedural section if this improves the SOP’s clarity or is more convenient.
- 17.3 Some SOPs will make reference to other documents and at times, these should be included as Appendices. When documents referenced are not readily available and reading them is essential to performing a procedure, such documents must be included with the SOP as appendices.
 - 17.3.1 Appendices are identified by capital letters in ascending order.
 - 17.3.2 The pages of appendices composed as parts of SOPs are numbered in the “Page X of Y” format where the “X” is preceded by the letter identifying the appendix and the last number is the total number of pages in the specific appendix (e.g.: Page D3 of 7).

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17.3.3 Documents conceived independently of an SOP can be included as appendices in their original format.

18.0 SOP Indexing System

- 18.1 All SOPs are indexed by a two part numerical designator
- 18.2 The first part of the designator corresponds to a specific TNI program or effort. The second part of the designator is a three digit number assigned sequentially as SOPs are drafted.
- 18.3 The first part numerical designators are assigned as:
 - 18.3.1 General Procedures and Administration — 1
 - 18.3.2 Consensus Standards Development Program (CSDP) — 2
 - 18.3.3 National Environmental Laboratory Accreditation Program (NELAP) — 3
 - 18.3.4 Proficiency Testing Program (PTP) — 4
 - 18.3.5 Laboratory Accreditation System Program (LASP) — 5
 - 18.3.6 Advocacy Program — 6
 - 18.3.7 Technical Assistance Program — 7
 - 18.3.8 Forum on Laboratory Accreditation — 8
 - 18.3.9 National Environmental Monitoring Conference (NEMC) — 9

19.0 References

- 19.1 Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents. EPA QA/G-6. EPA/600/R-96/027; US EPA, Office of Research and Development.

20.0 SOP Approved Changes

| Prev. SOP No. | New SOP No. | Date of Change | Description of Change |
|---------------|-------------|----------------|-----------------------|
| | 1-100 | 1/31/08 | New Document. |
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