



Air Pollution Control Division

Technical Services Program

APPENDIX P1

Standard Operating Procedure for Amending Quality Management Plans, Quality Assurance Project Plans and Standard Operating Procedures

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1.0 INTRODUCTION

A “Master Copy” of each Quality Management Plan (QMP, Quality Assurance Project Plan (QAPP), and all Standard Operating Procedures (SOPs) shall be maintained by the Quality Assurance Data and Reports Sector of the Technical Services Program (TSP). There are many types of changes that may occur within the network such as instrumentation changes to accommodate new technology and monitoring methods, personnel changes, logistical support changes, changes resulting from policy implementation, and changes in Operating or QA/QC procedures. This SOP is designed to outline the steps to be taken when any proposed changes in the QAPP or SOPs occur.

The three most basic kinds of changes will be addressed here. The first type involves editing corrections. The second involves minor corrections or changes in policy, usually due to revisions in CFR or in response to problem. The third type constitutes major revisions/additions to methodology, which generally occur when new scientific instrumentation or technology replaces the old. The goals behind the strategy provided below are to eliminate confusion, simplify the submittal/update process and to provide a system of document control. Changes not addressed here should be discussed with the QAU or the Quality Assurance Officer (QAO) before proceeding.

2.0 EDITING CORRECTIONS

When typographical or grammatical errors are encountered within a QAPP or SOP the following steps shall occur:

1. A red ballpoint pen shall be used to make the editing change directly into the “Master Copy” of the QAPP. A list of standardized proofreader’s marks can be found in Table EOD-1 or on page 992 of the Second College Edition of *The American Heritage Dictionary*, which is retained by the QA sector.
2. The page number on which the change was made shall be listed on a log sheet posted in the front cover of the QAPP, along with a brief description of the change, the date, and the initials of the person making the change.
3. These changes will be incorporated into the electronic copy of the QAPP only at the time of submittal or update to the EPA, so as not to create referencing problems due to changes in pagination. This process shall occur no less than once every five years.

3.0 MINOR CORRECTIONS

When errors are found within the QAPP which change the meaning or interpretation of its contents, or policy changes occur due to new laws or problem identification and correction, the following steps shall occur:

1. A **non-white** photocopy of the original page or pages that contain the item that needs to be modified shall be made. The purpose for using colored paper is to make identification of changes within the “Master Copy” easy to locate.
2. A red ballpoint pen shall be used to strike through the material needing to be updated. A strike-through consists of a single line drawn through the words, sentences, or figures needing changes. The information under the strike-through should still be readable.
3. The updated information shall be added to the color copy, or if not enough room is available, an additional sheet of colored paper may be used to write or type out the changes. If an additional sheet of paper is used it must be made evident on the colored photocopy exactly where the changes are to be inserted.
4. Each colored page of the proposed changes must be initialed and dated by the QAO.

5. After the QAO has reviewed and approved the changes, they shall be placed into the three-ring binder containing the “Master Copy” immediately preceding the pages that are being revised.
6. An additional copy of these changes must be given to the QA sector. Depending on the nature of the changes, the QAU will submit to the EPA a list of the modifications every three years.
7. These changes will be incorporated into the electronic copy of the QAPP only at the time of submittal or update to the EPA, so as not to create referencing problems due to changes in pagination. This process shall occur no once every three years.

4.0 MAJOR CHANGES OR ADDITIONS

When changes occur that involve modifying an entire section of a QAPP or SOP document, such as new instrumentation or new methodology, the following steps shall be taken:

1. An electronic version of the entire change or addition shall be prepared.
2. The section or method shall then be printed out on **non-white** paper. The signature of the author and date of completion must be written on a cover page.
3. The new procedure shall be submitted to a co-worker within the TSP unit for peer review. Any problems found within the document shall be noted in red ballpoint pen directly on the document or an additional page of comments may be stapled to the front of the document. The reviewer shall initial and date the first page of this new document.
4. The write up shall then be submitted to the QA sector for review. If the change or addition was written by a member of the QA sector, then a different member of the QA sector must review the document. Any problems found within the document shall be noted in red ballpoint pen directly on the document, or an additional page of comments may be stapled to the front of the document. The QA sector reviewer must initial and date the first page.
5. The document shall go back to the author for edits and revisions.
6. Steps 2, 3, and 4 shall be repeated. Both the original copy and the revised copy shall be submitted in steps 3 and 4, so the reviewers can verify the correct changes were made.
7. If the reviewers find more corrections that should be made, then steps 5 and 6 shall be repeated. All of the revisions shall be included for review submittal in steps 3 and 4. If the reviewers are satisfied with the last revision, then the last copy, with no red pen corrections in it, and all the appropriate signatures and initial shall be submitted to the QAO for review and approval.
8. The QAO must sign and date the first page, and return the document to the QA sector.
9. The QA sector will place the colored revision or addition in the three-ring binder containing the “Master Copy” immediately before the section being replaced or in an appropriate “new” location. If it is an addition, the QA sector must also perform edit corrections in the table of contents to reflect positioning of the new document (i.e.- “New SOP” can be found in Appendix CC, or “New Section” can be found between pages 96 and 97). None of the electronic changes will be incorporated into the “Master Copy” of the document at this point. The new write up will temporarily exist as a stand-alone document which is referenced within the “Master Copy”.

10. Depending on the nature of the revision or addition, the QA sector will submit to the EPA a copy of these modifications no more than once per year and no less than once every three years.
11. These changes will be incorporated into the electronic copy of the QAPP only at the time of submittal or update to the EPA, so as not to create referencing problems due to changes in pagination. This process shall occur once every three years.

Prior to the time of QAPP submittal or update, all three types of modifications will be made to the “Master Electronic Copy” of the document (maintained by the TSP Administrative Staff) and the revision dates will be updated accordingly for the entire QAPP document.

A log of minor corrections and major changes or additions that have been made since the last submittal or update will be kept by the QA sector. A copy of this list will be included in an appendix to the newly revised QAPP for the purpose of tracking modification dates.

The new “Master Copy” will replace the old one in the three-ring binder. The old “Master Copy” will be maintained by the QA sector for a minimum of one year for reference purposes. After this time, the old “Master Copy” will be archived.

5.0 ELECTRONIC FILES

1. An electronic “Master Copy” of each QAPP submitted to EPA shall be kept on CD in a read-only format. A back-up “Master Copy” shall be kept in a read-only format on the CDPHE LAN in a dedicated directory to allow continual back-up via the Department’s ITS group in case there is a failure of the CD. All of the above changes to the QAPP can be accomplished electronically by saving a copy of the original version and making edits in the “Track Changes” section of Microsoft Word. Any changes made must be submitted to the QA group for approval and review.
2. Changes to the QAPP must be authorized by the QAO. When changes are made, they will be made to a copy of the “Master Copy” electronic file using the “Track Changes” feature. The copy will be placed in the dedicated directory and identified as “Draft(DueDate)QAPP.doc”. The Draft(DueDate)QAPP.doc will be a protected file. Only the QAO and designated members of the TSP Administrative Unit will be allowed access.
3. When all changes have been approved by the QAR, the QAR will authorize the printing of a master copy via email. Draft(DueDate)QAPP.doc will be renamed QAPPSubmitted(Date).doc
4. QAPPSubmitted(Date).doc will be written to a read-only file on CD. A back-up copy of QAPPSubmitted(Date).doc will be placed in the dedicated directory.
5. As technology changes, both QAPPSubmitted(Date).doc and all previous versions on-site will be transferred to whatever new media the Department authorizes. Printed copies of the transferred material will be checked against the paper “Master Copy” to verify accuracy and completeness and to identify any copying errors.

PROOFREADER'S MARKS			
Instruction	Mark in Margin	Mark on Proof	Corrected Type
GENERAL			
delete		the best word	the word
delete and close up space		the wo rd	the word
insert indicated material	best	the _{best} word	the best word
let it stand		the <u>best</u> word	the best word
spell out		<u>2</u> words	two words
POSITION AND SPACING			
new paragraph	¶	"Where is it?" [¶] It's on the shelf."	"Where is it?" "It's on the shelf."
flush paragraph		"Where is it?" [¶] It's on the shelf."	"Where is it?" "It's on the shelf."
transpose		the wo <u>rd</u> best	the best word
move left		the word	the word
move right		the word	the word
move down		the word	the word
move up		the word	the word
align		the word the word	the word the word
straighten line	==	the word	the word
insert space	#	theyword	the word
equalize space		the _{best} word	the best word
close up		the wo rd	the word
en space		the word	the word
em space		the word	the word
PUNCTUATION			
period	○	This is the word.	This is the word.
comma	△	words, words, words	words, words, words
hyphen	̄	word [̄] for [̄] word test	word-for-word test
colon	⊙	The following words [⊙]	The following words:
semicolon	△	Scan the words [△] /skim the words.	Scan the words; skim the words.
apostrophe	∇	John's words	John's words
double quotation marks	∇/∇	the word [∇] word [∇]	the word "word"
single quotation marks	∇/∇	the "good"word [∇]	the "good" word"
parentheses	{ / }	The list of words in the dictionary ^{ / } on page 101 ^{ / } is useful.	The list of words in the dictionary (on page 101) is useful.
brackets	{ / }	He read the list of words ^{ / } from the dictionary ^{ / } .	He read the list of words [from the dictionary].
en dash	—	1984 [—] 1992	1984–1992
em dash	—	The dictionary [—] how often it is needed [—] belongs in every home.	The dictionary—how often it is needed— belongs in every home.
asterisk	∇	word [∇]	word*
dagger	∇	word [∇]	word†
section symbol	§	Book [§] Reviews	§Book Reviews
virgule (slash)	/	either [/] or	either/or
three ellipses	/ o / o / o /	the word ^{/ o / o / o /}	the...word
four ellipses	~ o / o / o / o /	the word ^{~ o / o / o / o /}	the word....
STYLE OF TYPE			
uppercase		the word	The Word
lowercase		The word	the word
small capitals		the word	THE WORD
italic		the entry word	the entry <i>word</i>
roman		the entry word	the entry word
boldface		the entry word	the entry word
lightface		the entry word	the entry word
superior	∇	2 [∇] =4	2 ² =4
inferior	△	H ₂ O	H ₂ O

Table EOD-1 Proofreaders' Marks