

SOP 10: Protocol Revision (KM_H creation)

Version 1.0

Revision History Log:

Previous Version #	Revision Date	Author	Changes Made	Reason for Change	New Version #
	November 2012	S. Hoekman, W. Johnson, B. Moynahan, C. Sergeant	Initial version		1.0

Summary

Periodically, material changes must be made to the protocol to take advantage of new or different technologies, equipment, and methods. Changes may also be made to correct significant errors in the document or to refine and update the data reports.

The Program Manager, Project Leader, and Data Manager jointly build a list of desired changes. They review the issues, accept some or all of them by consensus, and draft new language to affect the accepted changes. One person shall be chosen to coordinate the new document and be responsible for the new draft. Changes to key items will trigger an external review of the draft document. Reviews will consider impacts including but not limited to those caused by changes in equipment, data collection methods, and data processing methods.

After satisfying both internal and external reviewers, the updated protocol will go through formal validation and certification by the Program Manager and Data Manager. The certified protocol will be widely disseminated.

Detailed Steps

A. Program Manager (PM) Tasks

1. Periodically poll Project Leader (PL) and Data Manager (DM) on the need for a protocol revision cycle.
2. Schedule a revision cycle when called for by consensus.
3. Obtain a new formal protocol ID number from Data Manager.
 - a. Method for assigning a protocol ID is formally set in SEAN's Data Management Plan SOP-602 Version Control.
 - b. A new ID is required for each revision because most data collected are tagged with the specific protocol they were created under: the mechanism is rigid.
4. Solicit agenda of issues to address.
5. Initiate kick-off meeting.

B. Program Manager, Project Leader, and Data Manager Tasks

1. Prepare issues lists.
2. Agree on overall scope of revision.

- a. "Minor" will have internal review.
 - b. "Major" will have peer review.
3. Agree on a "coordinator" who is responsible for managing assembly of the revised document.
4. Obtain the most recent Word version of the current protocol from the DM to serve as the basis for the new document.
 - a. The original DOCX file is copied to an editable destination file.
 - b. The document is set for tracked changes.
 - c. A global search and replace is done to change all existing references to the protocol ID to the new designator.
 - d. The DM provides a link allowing access of the DOCX file by the three team members through a browser.
 - e. The actual final product will be made available on the web only as read-only PDF in order to minimize the chance of multiple conflicting documents being built.
5. Draft possible revisions.
 - a. Each team member should take responsibility for sections within their realm of expertise.
 - b. If a particular section needs to be addressed to meet multiple needs, it should be worked on serially.
 - i. Get team agreement on the order of attack for issues.
 - ii. Assign person to do first revision covering first issue.
 - iii. Obtain consensus on the first revision.
 - iv. Assign person to do second revision covering second issue, etc.

C. "Coordinator" Tasks

1. Assemble revision drafts into a coherent document.
2. Maintain a document change table in the SOP document to track internal versioning.
3. Distribute to PM, PL, and DM for internal review.
4. Update document to satisfy internal review.
5. Obtain consensus of PM, PL, and DM.
6. Format the document.
7. If scope is major, coordinate external review.
 - a. Pass document to Regional I&M Coordinator for consideration.
 - b. Distribute resulting review comments to PM, PL, and DM.
 - c. Revise protocol in light of review comments.
 - d. Coordinate revisions among team.
8. Assemble document.
9. Obtain final team approval.
10. Format document as a Natural Resource Report (NRR).
 - a. Coordinate technical/formatting NRR review
 - b. Obtain a "TIC" document number from NRPC.
 - c. Make final technical revisions.

11. Notify team of completion.

D. Program Manager Tasks

1. Generate a PDF file from the original Word document.
2. Submit both the PDF and DOCX files via email attachment to the Data Manager for validation.
 - a. Specify in the message body it is deliverable KM_H, as defined in protocol KM_2012.1.

E. Data Manager Tasks

1. On receipt of the submission, assign the next formal Submission Number to this file, as found in the master Submission_Log table.
 - a. Use the "Update Submission Log" web tool at http://165.83.57.239/0_submission_update.aspx.
 - b. Complete Submission_Log details up through the Submission_Date column.
2. Save the attached file into the staging area for validation at [\\inpglbafs03\data\SEAN_Data\Staging\KM\KM_H](\\inpglbafs03\data\SEAN_Data\Staging\KM\KM_H).
3. Validate the two files according to current criteria.
4. Record validation summary data in the Submission_Log using the web tool.
5. If submission fails mandatory criteria, reply with a "failure email" that includes:
 - a. The submission number assigned
 - b. The deliverable ID
 - c. The protocol ID
 - d. Documentation listing all the specific mandatory criteria failed
6. If submission passes mandatory criteria, reply with a "success email" that includes:
 - a. The submission number assigned
 - b. The deliverable ID
 - c. The protocol ID
 - d. Documentation listing any specific optional criteria failed
 - e. Request to certify deliverable as complete

F. Program Manager Tasks

1. On receipt of a failure email:
 - a. Make corrections so the deliverable meets mandatory criteria.
 - b. Make another submission with the corrected deliverable candidate
2. On receipt of a success email, review any failed optional criteria:
 - a. If these are acceptable to PM, PL, and DM:
 - i. Reply with a "certification email" stating the deliverable is certified and may be disseminated.
 - b. If these are unacceptable:
 - i. Reply with a "withdrawal email", stating the deliverable is withdrawn.
 - ii. Take remedial action to obtain a corrected deliverable.
 - iii. Restart the process from the beginning.

G. Data Manager Tasks

1. On receipt of a withdrawal email:
 - a. Mark the withdrawal in the Submission_Log's Status column using the web tool.
 - b. Terminate the process.
2. On receipt of a certification email:
 - a. Due to the nature of these data NO sensitive information is in the deliverable.
 - b. Copy the two submitted files to test environment at AUXREP\KM\KM_H\
 - i. Name them <protocol_ID>.PDF and <protocol_ID>.DOCX.
 - c. Create web page link to the new PDF but not the .DOCX, which remains hidden.
 - d. Retire the old protocol so it becomes accessible from the Historical Protocol link.
 - e. Mark the certification in the Status column in Submission_Log using the web tool.
 - f. Using a database editing tool such as SSMS, insert the new protocol ID into the Staging database table SEAN.TBL_PROTOCOL.
 - g. Propagate from test to production environment.
 - h. Update the annual deliverable tracking spreadsheet showing date of completion for KM_H.
 - i. Record in the tracking spreadsheet for the year reflected in the protocol_ID, which may not be the current year.
 - ii. An entirely new row will need to be added to the sheet, as this is not a scheduled deliverable already accounted for.
 - i. Submit the final document to NRInfo Portal.
 - j. Update the I&M protocol database to reference the new protocol.
 - k. Revise web sites to accommodate any altered information structure set in the new protocol.

Update the scope of the formal metadata so it includes the new date and versioning information