

SEAN sea otter monitoring SOP 11: Revising the protocol package (deliverable SO_A)

Revision History Log:

Previous SOP version	Effective Date	Revised By	Changes Made	New SOP version
-	September 2018	Jamie Womble	Initial version	1.0

Summary

Periodically, changes must be made to the protocol narrative, DQS-QAP, and SOPs to take advantage of better technologies, equipment, and methods. Changes may also be made to support changed staffing levels, correct oversights in previous documents, or redefine and update the forms of deliverable data products.

The Project Leader and Data Manager record desired changes in a running list. The list is periodically examined until it is decided that a revision cycle is appropriate. They review the issues, accept some or all of them by consensus, and draft new language to reflect the accepted changes. One person is chosen to coordinate the new document and be responsible for the new draft. Changes to major key items will trigger an external review of the draft document.

After satisfying both internal and, if judged necessary, external reviewers, the updated protocol documents go through formal validation and acceptance by the Program Manager and Data Manager. If any NRR publication is involved, the IMD publications staff must also approve its content. The accepted Protocol Narrative NRR, DQS-QAP and SOP Set package are widely disseminated under a unique protocol id using the NPS Data Store.

Detailed Steps

1. Network Program Manager tasks
 1. Periodically poll Project Leader and Data Manager on the need for a protocol revision cycle.
 1. Schedule a revision cycle when called for by consensus.
 2. Accepted revisions take effect either well before or after a field survey effort – never part way through.
 2. Obtain a new formal protocol package identifier from Data Manager.
 1. Method for assigning a protocol ID is formally set in SEAN's Data Management Plan, SOP-602 Version Control.
 2. New IDs are required for each protocol package revision because most data collected are tagged with the specific versions they were created under: the mechanism is rigid to ensure data are documented well enough to be correctly used by those outside the immediate project team.
 3. Solicit agenda of issues to address.

4. Initiate kick-off meeting.
2. Project Leader, and Data Manager tasks
 1. Prepare issues lists.
 2. Agree on scope of revisions.
 1. “Minor” revision
 1. Updates detailed processes and definitions.
 2. Requires internal review only.
 3. SOP changes are always minor.
 2. “Major” revision
 1. Updates purpose, objectives, or fundamental design.
 2. Requires out-of-network peer review.
 3. Agree on a coordinator who is responsible for managing assembly of the revised documents.
3. Coordinator tasks
 1. Based on issues list, determine which protocol component documents will be updated in this cycle.
 2. Obtain the most recent Word versions of the currently active protocol documents intended to be updated to serve as the basis for the new document.
 1. Copy the original DOCX files to an editable destination file in [\\sean.glba.nps.gov\data\SEAN_Data\Work_Zone\SO\SO_A\SO-yyyy.n](\\sean.glba.nps.gov\data\SEAN_Data\Work_Zone\SO\SO_A\SO-yyyy.n) where SO-yyyy.n is the new protocol package identifier.
 2. Rename any files to reflect yyyy.
 3. Set the documents for tracked changes.
 4. Globally search and replace to change all existing references to the Protocol Narrative ID and SOP Set ID to their new designators.
 3. Organize possible revisions.
 1. Each team member should take responsibility for sections within their realm of expertise.
 2. If a particular section needs to be addressed to meet multiple needs, it should be worked on serially instead of simultaneously. Get team agreement on the order of attack for issues.
 1. Assign a person to do first revision covering their issues.
 2. Obtain team consensus on this first revision.
 3. Assign people to do subsequent issues and obtain consensus on each.
 4. Assemble revision drafts into coherent documents.
 5. Maintain a document history table at the head of each document to track versioning.
 6. Distribute complete set to Program Manager, Project Leader, and Data Manager for final internal review.
 7. Update document to satisfy internal review comments.
 8. Obtain final consensus of Program Manager, Project Leader, and Data Manager.
 9. Rough format the documents.
 10. Obtain team approval for final review draft.

4. Program Manager tasks
 1. If scope is major, coordinate external review.
 1. Pass document to regional I&M coordinator for consideration.
 2. Distribute resulting review comments to Program Manager, Project Leader, and Data Manager.
 3. Revise protocol components in light of review comments.
 4. Coordinate revisions among team.
5. Coordinator tasks
 1. Declare the exact date the new protocol package will go into effect (i.e., the date in which data records are to begin getting stamped with the new protocol IDs).
 2. Publish the protocol narrative NRR, if this has been changed.
 1. Edit the effective date and protocol package id into the narrative NRR document's title.
 2. Have copy editor format narrative document as a natural resource report.
 3. Coordinate technical NRR review with publications staff.
 4. Obtain a TIC document number from NRSS.
 5. Make final technical revisions.
 6. Publish to Data Store using the current WASO process.
 7. Activate the reference but keep access internal.
 3. Publish any revised DQS or QAP document.
 1. Edit the effective date and destination protocol package ID into the DQS/QAP document.
 2. Final review of document by team.
 3. Publish to Data Store using the current WASO process.
 4. Create Data Store reference of type "Published Report". This may be drafted by NRSS publication staff,
 1. Reference title must include the effective date.
 2. Reference subtitle must include the protocol package ID.
 3. Publish to Data Store using the current WASO process.
 4. Activate the reference but keep it internal.
 5. Upload a PDF created from the final Work_Zone DOCX file to the reference.
 4. Publish the revised SOP Set.
 1. Edit the effective date into any revised individual SOP documents.
 2. Team performs final review.
 3. Enter any altered individual SOPs into Data Store as new references of type "Standard Operating Procedure" by cloning their most recent previous references.
 1. Do not use the "versioning" facility in Data Store, which would imply previous versions of the SOP are obsolete and inaccurate. Previous SOP documents are, in fact, authoritative documentation of data collected in the past and are needed to fully understand the nature of historic data.
 2. Be sure the reference title includes the effective date.

3. Upload a PDF created from the final Work_Zone DOCX files of the appropriate new SOP.
 4. Activate the reference but keep it internal.
4. Create a new Data Store reference of type “Assemblage” to hold the revised protocol package.
 1. Clone the most recent existing SO protocol package reference as a starting point.
 2. The assemblage title should clearly indicate the effective date.
 3. Update Data Store links in the assemblage to point to the latest Narrative, PIP, and QAP or DQS.
 4. Activate the reference but keep it internal.
5. Update the Data Store reference titled “SEAN Sea Otter protocol packages (SO_A)”
 1. Add a link to the new assemblage holding the protocol package.
 2. Activate the reference but keep it internal.
6. Submit the revised protocol package parts by email to the Data Manager for validation.
 1. Indicate if the protocol narrative NRR was updated.
 2. Indicate if a DQS or QAP was updated.
 3. Indicate which, if any, SOPs were updated.
 4. Don’t attach files to the email – the data manager will know where to find them.
6. Data Manager Tasks
 1. On receipt of the submission, assign the next formal submission number to this package.
 1. Use the Update Submission Log web tool on the NPS network at http://sean-dm.glba.nps.gov/0_submission_update.aspx.
 2. Complete Submission_Log details up through the Submission_Date column.
 3. Treat the package as one submission – not as multiple submissions – regardless of how many documents were involved.
 2. Save the revised holding files from the references into the staging area for validation at [\\sean.glba.nps.gov\data\SEAN_Data\Staging\SO\SO_A\ssss](http://sean.glba.nps.gov/data/SEAN_Data/Staging/SO/SO_A/ssss), where ssss is the submission number.
 1. Find them by traversing the “SEAN Sea Otter protocol packages (SO_A)” links.
 2. Do not include unchanged documents, such as some SOPs.
 3. Validate the files according to current criteria listed in Appendix SOP-11.A.
 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:
 1. The submission number assigned
 2. The deliverable ID
 3. The protocol package ID.
 4. Documentation listing all the specific mandatory criteria failed
 6. If submission passes mandatory criteria, reply with a “success email” that includes:
 1. The submission number assigned.
 2. The deliverable ID.

3. The protocol package ID.
 4. Documentation listing any specific optional criteria failed.
 5. Request to certify deliverable as accepted.
7. Project Leader tasks
 1. On receipt of a failure email:
 1. Make corrections so the deliverable meets mandatory criteria.
 2. Make another submission with the corrected deliverable candidate.
 2. On receipt of a success email, review any failed optional criteria.
 1. If these are acceptable to Program Manager, Project Leader, and Data Manager reply with an “acceptance email” stating the deliverable is accepted and may be disseminated.
 2. If these are unacceptable:
 1. Reply with a “withdrawal email,” stating the deliverable is withdrawn.
 2. Take remedial action to obtain a corrected deliverable.
 3. Resubmit updated version to Data Manager for review.
8. Data Manager tasks
 1. On receipt of a withdrawal email:
 1. Mark the withdrawal in the Submission_Log’s Status column using the web tool.
 2. Terminate the process.
 2. On receipt of an acceptance email:
 1. Due to its nature, deliverable SO_A contains no sensitive information.
 2. Create a new protocol package assemblage using the new package identifier and link it to the parent SO_A assemblage (currently Data Store reference 2248281). This may be made simply by cloning the previous protocol package assemblage and changing its package identifier to the new one.
 3. Edit each underlying Data Store reference so it is accessible to Public and activated.
 4. Update the protocol package assemblage so that the full set of current documents that now define the monitoring program are represented.
 1. Those that are carried over from the previous cycle should already be present.
 2. Update reference links for any documents that have been revised during this cycle.
 3. There should be one narrative reference, one QAP or DQS reference, and 20 SOP references.
 5. Update the annual deliverable tracking spreadsheet showing date of completion for SO_A. Note: if revision work spans calendar years, use the SO_A column for the year work began.
 6. Mark the acceptance in the Status column in Submission_Log using the web tool.
 7. Update the Staging database table SEAN.TBL_PROTOCOL to include the new protocol package ID and citation. These will be used in automated validation processes.
9. Program Leader tasks

1. Determine whether the content of any revised data deliverables is no longer consistent with the products created under previous protocol packages.
2. If an inconsistency is present, initiate a project to handle this, possible by recasting prior data into the new form.

Appendix SOP-11.A: Protocol package – detailed deliverable definitions

Purpose of Deliverable

A protocol package defines SEAN's Sea Otter monitoring program at a particular point in time. It completely documents the detailed methods, parameters collected, locations, deliverable data products, data formats, data limitations, quality control processes, and analytical techniques used to produce population estimates that inform park management decisions. Components may include Narrative, Quality Assurance Plan, Data Quality Standards, and multiple Standard Operating Procedures.

Frequency Produced

As needed. It is preferable to have a package complete and accepted well in advance of the field season in order to allow adequate preparation time for implementation.

Prerequisites

An existing protocol package must already be available in order to produce this deliverable.

Data Flow

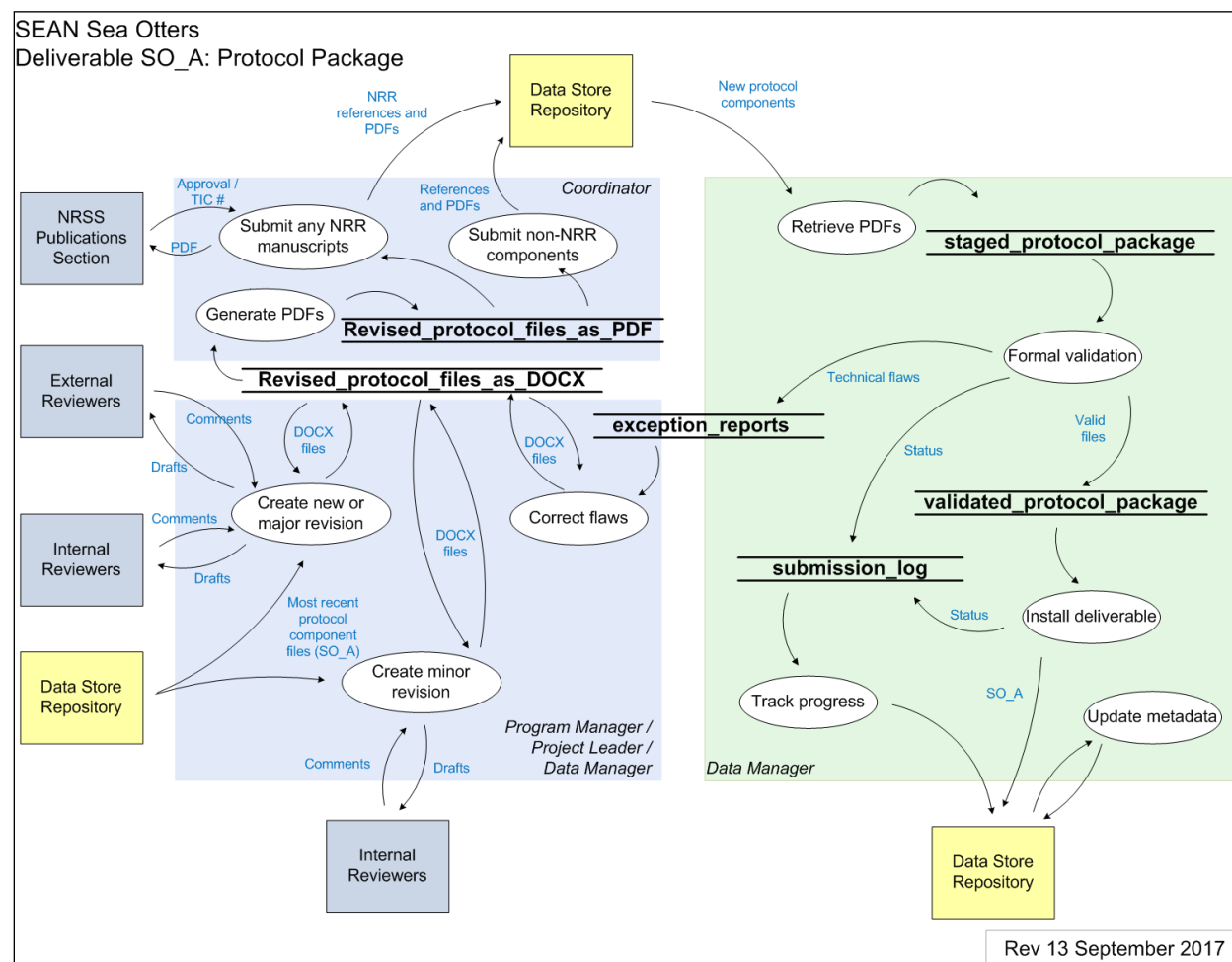


Figure SOP-11.A.1. Data flow required to generate deliverable SO_A Protocol Package.

Deliverable Definition Forms

Form A: Non-tabular Information Deliverable

<i>Vital Sign:</i> SO Sea Otters	<i>Deliverable ID:</i> SO_A	<i>Deliverable Title:</i> Protocol Package
<i>File Format:</i> DOCX and PDF	<i>Associated Software and Version:</i> Microsoft Word 2106, Adobe Acrobat DC 12 or greater	<i>Revision Date:</i> 10-20-2017
<i>Expected Frequency:</i> As needed	<i>Submission Unit:</i> Not applicable	<i>ID of first protocol this applies to:</i> SO-2017.1
<i>What purpose does this deliverable serve?</i> The document package defining SEAN's sea otter monitoring program. Protocol Narrative, Quality Assurance Plan (QAP), and Data Quality Standards (DQS) are published as NRR reports. Standard operating procedure (SOP) sets are individual documents housed in Data Store using reference type "SOP". Each component of the package is always stamped with a unique package identifier indicating when it originally went into effect.		
<i>Summary of content:</i> Protocol narrative, DQS or QAP, and applicable SOP set.		
<i>Mandatory validation criteria:</i> 1. Narrative, QAP, and DQS must successfully pass the NRR review process. 2. All components must successfully open using Adobe Reader DC or greater.		
<i>Optional validation criteria:</i> None		
<i>Deliverable ID of any other SEAN data products required to create this product</i> The package consists of numerous components. When a new package is generated at least one of the components must be updated. Components that were not revised are represented in the package using those from the prior protocol package.		
<i>Description and source of any outside data required to create this product:</i> The only outside input to this deliverable are the collected peer review comments and responses.		