Standard Operating Procedure (SOP) – Revising a Protocol

Version 1.0 (July, 2007)

The following table lists all changes that have been made to this Standard Operating Procedure since the original publication date. Any recommended or required changes added to the log must be complete and concise and promptly brought to the attention of the Project Leader. The Project Leader will review and incorporate all changes, officially complete the revision history log, and change the date and version number on the title page. For complete instructions, please refer to Section II of this SOP.

Revision History Log:

New Version #	Previous Version #	Revision Date	Author (full name, title, affiliation)	Location in Document and Description of Change	Reason for Change

The following Master Version Table tracks the relationships between the protocol narrative and the associated Standard Operating Procedures, as discussed in Section II. C. of this Protocol.

Master Version Table: NCBN Ocean Shoreline Position Monitoring Protocol and Standard Operating Procedures												
Date of Revision	Protocol	Narrative	SOP #1	SOP #2	SOP #3	SOP #4	SOP #5	SOP #6	SOP #7	SOP #8	SOP #9	SOP #10
8/16/2007	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

I. Scope and Applicability

Due to the long-term nature of the NCBN monitoring program, revisions to the Protocol Narrative and to individual Standard Operating Procedures (SOPs) will be necessary from time to time (O'Ney, 2005). Careful documentation of changes to the Narrative and its related SOPs, along with a library of previous versions, are essential for maintaining consistency in the collection, summary, analysis, and reporting of data.

The Revision History Logs found at the beginning of the narrative and each SOP list all edits to that section since the original publication date. Information entered in these logs should be complete and concise. The logs track the previous version date and number, date of revision and new version number, author(s) of revision, location of changes within the document, description

Draft

of change, and the reason the change was made. Author information must include full name, title, and affiliation.

The Master Version Table found in SOP #10 – Revising the Protocol tracks the relationships between the narrative and the associated SOP's. The use of this table is discussed in detail in Section II.C. below.

II. Instructions for Recording Revisions

Protocol users must promptly notify the Project Leader about recommended and/or required changes. The Project Leader will then review and incorporate all changes, update the Revision History Log and Master Version Table, and change the date and version number on the title page of the master document as well as any SOPs the revisions apply to.

A. Minor Revisions

Minor revisions are those that *do not* represent a change in the underlying methods or procedures used to generate data values for the protocol's existing data set. Minor revisions include small changes in, or clarification of procedures. Version numbers for minor revisions increase incrementally by hundredths (1.01, 1.02 . . .).

B. Major Revisions

Major revisions are those that involve changes in methodology that could influence the resulting data values and the ability to compare newly-collected data with data collected using a previous version, such as:

- addition of monitoring objectives
- changes to the sampling design
- changes to reporting requirements
- addition of new variables

Major revisions are designated with the next whole number in the sequence (2.0, 3.0, 4.0...).

C. Coordinating Narrative and SOP Versions

In order to track the most current version numbers of all SOPs associated with a particular protocol version, the Project Leader will also maintain the Master Version Table, which immediately precedes the narrative's Revision History Log. A new entry must be made each time the narrative and/or any SOPs are modified. In cases where the narrative and/or one or more SOP have undergone only minor revisions (Section II A above), the overall protocol version number will itself increase incrementally by hundredths. In cases where the narrative and/or one or more SOP have undergone a major revision (whether or not other sections have undergone minor revisions), the overall protocol version number will increase incrementally by whole numbers (Fig. S10.1).

Draft

This Master Version Table tracks the relationships between the Protocol Narrative and the associated Standard Operating Procedures, as discussed in Section II. C. of SOP #10 – Revising the Protocol.

Master Version Table: NCBN Ocean Shoreline Position Monitoring Protocol and Standard Operating Procedures												
Date of Revision	Protocol	Narrative	SOP #1	SOP #2	SOP #3	SOP #4	SOP #5	SOP #6	SOP #7	SOP #8	SOP #9	SOP #10
1/1/2007	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
6/1/2007	1.01	1.01	1.01	1.00	1.00	1.00	1.01	1.00	1.00	1.00	1.01	1.01
8/2/2007	2.00	1.01	1.01	1.00	1.00	2.00	1.01	1.00	1.00	1.00	1.01	1.01
1/10/2008	3.00	2.00	1.01	1.00	1.01	2.01	1.02	1.00	1.00	1.01	1.02	1.01

Fig S10.1. Example of a Master Version Table reflecting possible revision scenarios and associated numbering of the protocol.

The Project Leader will also update all associated field forms to reflect the change in protocol version. Users noting discrepancies in versions between the protocol, SOPs, data values, and field forms should notify the Project Leader so that corrections can be made and documentation kept current.

III. Reviewing suggested protocol revisions

All suggested edits require review by the Project Leader for clarity and technical soundness. Small changes or additions to existing methods will be reviewed by NCBN staff. However, if a significant change in methods is recommended, additional expert review may be required.

IV. Communicating changes to investigators / users

Once changes have been made, the updated document is posted on the NCBN web site (http://www.nature.nps.gov/im/units/ncbn/) and is added to the National Vital Signs Monitoring Protocol Database (http://science.nature.nps.gov/im/monitor/protocoldb.cfm). All previous versions are archived in the NCBN information system and can be obtained by contacting the Data Manager. Each time an SOP is revised, the Project Leader ensures that all known users obtain a current copy of the SOP and receive the necessary briefing material and/or training to understand and incorporate the change(s). Users are encouraged to visit the network web site and/or contact the Project Leader at least once per season to check for updates associated with the monitoring protocol.

V. References

O'Ney SE. 2005. Standard operating procedure #11: Revising the protocol, Version 1.0. In: O'Ney, S.E. 2005. Regulatory water quality monitoring protocol. Version 1.0. Bozeman (MT): National Park Service, Greater Yellowstone Network.

Draft