GENERAL OPERATING PROCEDURE

PROCEDURE TITLE: Numbering and Formatting of Standard Operating Procedures (SOPs)

APPLICABILITY: All personnel at the Upper Midwest Environmental Sciences Center (UMESC), La Crosse, Wisconsin

PURPOSE: To standardize the numbering and format systems used in the development and revision of SOPs

PROCEDURES:

NUMBERING SOPS

A. Each SOP has a three-part identification code that **is assigned by the Quality Assurance Unit (QAU).** This code signifies (1) the area to which the SOP applies, (2) the type of the SOP and (3) the version of the SOP.

1. One of the following three-letter designations will signify the area to which the SOP applies.

   a. GEN-General SOPs. These apply to activities in all of the UMESC and override CAP, AS, and TS SOPs if there is a conflict.

   b. CAP-Chemistry and Physiology SOPs. These apply to activities only in the Branch of Chemistry and Physiology

   c. AS-Aquatic Sciences SOPs. These apply to activities only in the Branch of Aquatic Sciences.

   d. TS-Terrestrial Sciences SOPs. These apply to activities only in the Branch of Terrestrial Sciences.

2. A three-digit number that follows the three-letter designation signifies the type of SOP.

   a. General Operating Procedures are numbered 001-200.

   b. Instrument Operating Procedures are numbered 201-400.

   c. Technical Operating Procedures are generally numbered 401-999.

3. A number that follows the type number signifies the version of the SOP. A decimal point will separate the type number and the version number.

4. EXAMPLE: GEN 005.1

   area to which SOP applies type of SOP version number

   CAP 214.0

5. Each form that is part of an SOP is identified by the same three-part identification code as the SOP except that the word "Form" will precede the code and a small letter of the alphabet will be used as a suffix to the code. The first form within an SOP will be "a", the second "b" and so forth.

   EXAMPLE: Form AS 511.2a Form AS 511.2b

   These codes identify the first and second forms that are part of AS 511.2

6. The identification code for a deleted SOP cannot be reused for a newly developed SOP.

FORMATTING SOPS

A. SOP Page Headers

1. Header for the **FIRST PAGE ONLY** of an SOP

   a. The complete UMESC name and address are in the upper left corner of the page. See d. for examples.

   b. The SOP identification code; the effective date; the effective date of the former version of the SOP, (only if the SOP is being revised to replace a former version); the identification code of the SOP being deleted and its effective date, (only if the SOP will replace an SOP being deleted); and "Page 1 of (number of pages in SOP)" are in the upper right corner of the page. See d. for examples.

   c. The SOP type (General Operating Procedure, Instrument Operating Procedure or Technical Operating Procedure) is centered on the page below the information given in Steps a. and b. See d. for examples.

   d. Examples

   This is the first-page header for a revised SOP. Note that the effective date follows "Date:" and effective date of the former version follows "Replaces".

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This is the first-page header for an SOP that will replace an SOP that will be deleted. Note that the identification code in addition to the effective date of the SOP being deleted follows "Replaces".

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TECHNICAL OPERATING INSTRUCTION

This is the first-page header for a new SOP. Note that there is no "Replaces" information because it is the first version of this operating procedure.

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TECHNICAL OPERATING PROCEDURE	

2. Headers for pages following Page 1 of an SOP

   a. The SOP identification code and the page number and total number of pages of the SOP are in the upper right corner of the page.

   Example:

   SOP No. GEN 003.1
   Page 2 of 3

   b. All pages of a form that is part of an SOP have the header explained in a. and a second header (below the first) that identifies the form and gives the page number and total number of page **OF THE FORM.**

   Example:

   SOP No. AS 511.2
   Page 3 of 4

   Form AS 511.2a
   Page 1 of 1

B. Text of the General Operating Procedure

1. **PROCEDURE TITLE**-Use a specific, descriptive, and concise title of the subject to be covered in the SOP.

   EXAMPLES: Laboratory Data Books and Recording of Data
   General procedure for Cleanliness of Lab Work Areas

2. **APPLICABILITY**-Define the specific work area or areas affected. This could be a subgroup (e.g., Fish Culture), the entire Branch (Chemistry and Physiology), or the entire UMESC.

3. **PURPOSE**-Give the reason for the SOP.

4. **PROCEDURE**-Explain the subject simply, concisely and clearly, preferably in chronological order. Present in a modified outline form: the title **PROCEDURE**, followed by an outline of the procedure beginning with the "A" level.

5. **REVIEWED BY/APPROVED BY**-The dated signatures of the Center Director, and as appropriate, the Quality Assurance Officer (QAO), the Radiation Safety Officer, or the Animal Care Chairman signify approval of a General Operating Procedure.

6. EXAMPLE: See Form GEN 004.7a.

C. Text of the Instrument Operating Procedure

1. **INSTRUMENT-**State the accepted name of the instrument. Do not include the model or manufacturer in the name.

2. **MANUFACTURER**-State the manufacturer of the instrument.

3. **MODEL**-State the model number of the instrument.

4. **SERIAL NUMBER** - State the manufacturer's serial number given on the instrument.

5. **MODE** (Optional)-If the instrument is operated in more than one mode, state the types of modes of operation with the principal mode of operation given first (e.g., pH vs selective ion electrode mode).

6. **CALIBRATION FREQUENCY-**State the required frequency of calibration for the instrument.

7. **PRECAUTIONS**-Explain potential interferences and provide safety information.

8. **PROCEDURE**-Give concise and clear step-by-step instructions on how to start, standardize, calibrate, operate and shut down the instrument. Present in a modified outline form: the title **PROCEDURE,** followed by an outline of the procedure beginning with the "A" level. Identify difficult operating situations. Make specific recommendations for actions to be taken when problems arise. Give instructions for recording calibration results in the Instrument Use, Calibration and Maintenance Log Book.

9. **MAINTENANCE**-List all required maintenance and schedules for maintenance. Give instructions for recording performance of maintenance in the instrument calibration and maintenance log. Present in a modified outline form: the title **MAINTENANCE,** followed by an outline beginning with the "A" level.

10. **REFERENCES**-List instrument instruction manuals or other references.

11. **ORIGINAL AUTHOR**-If the originator of the SOP is known, put it in this location.

12. **REVIEWED BY/APPROVED BY**-The dated signatures of the Branch Chief and the Quality Assurance Officer signify approval of an Instrument Operating Procedure.

13. EXAMPLE: See Form GEN 004.7b.

D. Text of the Technical Operating Procedure

1. **PROCEDURE TITLE**-Use a specific, brief title of the technique to be covered in the SOP.

   Example: Quantitative sampling of mussels in medium-sized rivers

2. **APPLICABILITY**-Define work areas to which the procedure applies. Identify any conflicts or overlapping of this procedure with similar procedures in other areas. For example, the glassware-washing procedures in Radio-chemistry differ from those in other areas by requiring that the glassware be soaked in a special surfactant solution before it is washed. Define when the procedure is applicable and when it is not.

3. **PRINCIPLE**-State the technical basis for the method of the analysis. Equations or symbols can be included. Provide sufficient information to allow a trained individual to determine whether the method is suitable for other applications.

4. **PRECAUTIONS**-Explain potential interferences and provide safety information.

5. **PROCEDURE**-List steps in "cookbook" fashion to allow major elements to be easily identified. Use a logical sequence of events to allow the researcher to determine all elements of the method and any special requirements/needs. Present in a modified outline form: the title **PROCEDURE**, followed by an outline of the procedure beginning with the "A" level.

6. **REFERENCES-**Cite the reference document on which the procedure is based and any additional references if the procedure was modified.

7. **ORIGINAL AUTHOR**-if the originator of the SOP is known, put it in this location.

8. **REVIEWED BY/APPROVED BY**-The dated signatures of the Branch Chief and the Quality Assurance Officer signify approval of a Technical Operating Procedure.

9. EXAMPLE: See Form GEN 004.7c.

E. The QAU will ensure that SOPs are in the proper format before being approved.

REVIEWED BY: _____ DATE: _____

Quality Assurance Officer

APPROVED BY: _____ DATE: _____

Center Director

SAMPLE FORMAT

Upper Midwest Environmental Sciences Center
2630 Fanta Reed Road
La Crosse, Wisconsin 54603

SOP No. GEN XXX.X
Date: _____
Replaces: _____
Page ____ of ____

GENERAL OPERATING PROCEDURE

PROCEDURE TITLE:

APPLICABILITY:

PURPOSE:

PROCEDURES:

REFERENCES:

REVIEWED BY: _____ DATE: _____

QAU or see SOP 005

APPROVED BY: _____ DATE: _____

Center Director

SAMPLE FORMAT

Upper Midwest Environmental Sciences Center
2630 Fanta Reed Road
La Crosse, Wisconsin 54603

SOP No. XXX yyy.y
Date: _____
Replaces: _____
Page ____ of ____

INSTRUMENT OPERATING PROCEDURE

INSTRUMENT: **MODEL:**

MANUFACTURER: **SERIAL NUMBER:**

CALIBRATION FREQUENCY: **MODE:**

PRECAUTIONS:

A. Potential Interferences
B. Safety

PROCEDURE:

A. Start-Up
B. Calibration (including Instrument Use, Calibration and Maintenance Log Book use if needed.
C. Routine Operation
D. Shutdown
E. Record Keeping

MAINTENANCE:

A. Routine
B. Service Agreements
C. Malfunction/Repairs
D. Record Keeping

REFERENCES:

ORIGINAL AUTHOR: (if known)

REVIEWED BY: _____ DATE: _____

Quality Assurance Officer

APPROVED BY: _____ DATE: _____

Branch Chief

Unofficial Copy

SAMPLE FORMAT

Upper Midwest Environmental Sciences Center
2630 Fanta Reed Road
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SOP No. XXX yyy.y
Date: _____
Replaces: _____
Page ____ of ____

TECHNICAL OPERATING PROCEDURE

PROCEDURE TITLE:

APPLICABILITY:

PRINCIPLE:

PRECAUTIONS:

A. Potential Interferences

B. Safety

PROCEDURE:

REFERENCES:

ORIGINAL AUTHOR: (if known)

REVIEWED BY: _____ DATE: _____

Quality Assurance Officer

APPROVED BY: _____ DATE: _____

Branch Chief