U.S. EPA New England

Office of Environmental Measurement and Evaluation

Document Control

Standard Operating Procedure

The controlled version of this document is the electronic version viewed on-line only. If this is a printed copy of the document, it is an uncontrolled version and may or may not be the version currently in use.

Prepared for: The Office of Environmental Measurement and Evaluation (OEME), U.S. EPA New England

Prepared by: A R. J/l — 18 FEB 2004
Ann Jefferies, Quality Assurance Chemist, QA Unit, OEME — Date

Approved by: Gerard Sotolongo — Feb. 18, 2004
Gerard Sotolongo, Quality Assurance Unit Manager — Date

Approved by: Carol Wood — 02/18/04
Carol Wood, Director (Acting), OEME — Effective Date

Office of Environmental Measurement and Evaluation (OEME)

Document Control

Standard Operating Procedure

1.0 Summary – Document control ensures documents are able to be located; reviewed periodically and revised; approved; available as the current revision at the locations needed; and removed when obsolete and archived. Controlled documents are legible, dated (with effective date of revision), readily identifiable, maintained in an orderly manner and retained for a specified period. Document control helps ensure that documents are created and maintained in a manner sufficient to implement the management systems at OEME including the Environmental Management System, Health & Safety program, laboratory and field operations, and Quality System.

2.0 Purpose – The purpose of this SOP is to introduce and establish a unified, electronic system of document control for OEME. It describes procedures and responsibilities for the creation and modification of controlled documents.

3.0 Scope and Application – This procedure applies to controlled documents across all OEME units. Typically, controlled documents are those used on an ongoing basis, reviewed and revised regularly, and approved for release. Controlled documents may include manuals, plans, policies, guidance, quality assurance project plans, SOPs, forms, and any other documents used to implement the management systems.

The electronic document control system is a Lotus Notes database named "Lab SOPs". Controlled documents are accessible to all OEME personnel as portable document format ("PDF") files. Write access for entering, editing, and archiving controlled documents is limited to designated Document Control Contacts.

A master list of controlled documents including the current status is available from the database.

4.0 Procedure

4.1 Database Structure and Organization – The document control database is organized according to:

DOCUMENT VIEW
DEPARTMENT and
CATEGORY/SUB-DEPARTMENT

4.1.1 DOCUMENT VIEWS – Document views are listed on the far left side of the Lab SOPs database. Each document view has its own input form and three letter abbreviation. The following document views are included:

- **Archived Documents** (all abbreviations apply)
- **Standard Operating Procedures (SOP)**
- **Forms (FRM)**
- **Plans (PLN) & Policies (POL)**
- **Guidance (GUI)** – to be added
- **Quality Assurance Project Plans (QAP)** – to be added
- **Single Analysis** – laboratory only
- **Multi Analysis** – laboratory only

4.1.2 DEPARTMENT – The following departments are included within each document view:

Biology
Chemistry
EMS (Environmental Management System)
Field Sampling
Health & Safety
Investigations
Miscellaneous
QA (Quality Assurance)

4.1.3 CATEGORY/SUB-DEPARTMENT – Each department may be divided into Categories or Sub-Departments. The current listing of categories/sub-departments includes:

AIR
BIOLOGY
CONTRACTOR
ESAT
FACILITY
FIELD
GC
GCMSBNA
GCMSVOA
HPLC
INORG
MICROBIOLOGY

MISC
MISC–ORG
QC
SAMPLE CONTROL
SUBCON

4.2 Unique Identifier Convention – Each controlled document is given a unique identifier (document number) in the form of an abbreviated title. The convention for identifying controlled documents is:

(Unit Code)(Document Type)–(Abbreviated Title)(Revision #) 20 character maximum

e.g., **EIASOP-AIRCAN7**

The original document is Revision 0. Subsequent revisions are numbered sequentially as integers. A maximum of twenty characters total is used for each identifier.

4.3 Header – For document types where headers are appropriate, such as SOPs, the following minimum information should be included in the header:

UNIQUE-IDENTIFIER
Title of Document
Revision number (if desired)
Date of Current Revision
Page # and Total Pages in Document

e.g.,
EIASOP-AIRCAN7
Air Toxics by GC/MS
08/09/02
Page 1 of 26

4.4 Effective Date – Each controlled document must have the effective date of that revision. The effective date is the last management approval date unless otherwise specified.

4.5 PDF Files – To ensure that one, and only one, version is maintained, controlled documents are entered in the document control database as PDF files. Documents may be converted to PDF files by scanning the document on the Canon *Imagerunner 400E* scanning equipment in the Ecosystem Assessment Unit (ECA) photocopy area. Scanning

a document allows inclusion of an approval signature page and other non-text elements in the controlled electronic version. Alternatively, documents may be written as PDF files and signed electronically (*First M. Last /s).*

4.6 Unit-Specific Document Control Procedures – Each unit is responsible for determining which of its documents are controlled; what procedures are used for developing, reviewing, approving, revising and archiving these documents; and the frequency of review for controlled documents.

4.7 Document Control Contacts – Each unit designates a Document Control Contact(s) who has write access to the electronic document control database. The Document Control Contact is responsible for entering, editing and archiving the unit's controlled documents. The current Document Control Contacts are:

UNIT	CONTACT
EAA	Scott Pellerin
EAF	Dave Coveney
ECA	Greg Hellyer
EIA	Agnes Van Langenhove
EQA	Denise DePierro, Ann Jefferies
OARM System Manager	Phil Warren

5.0 Location and Control of Documents – The current version of each controlled document resides in the electronic document control system. Printed copies of controlled documents may be maintained at workstations and other appropriate areas for easy access. Printed copies, however, are uncontrolled versions. The only controlled version of a document is the electronic version viewed on-line.

5.1 Disclaimer – The following disclaimer, or a similar statement, should appear on the first page of each controlled document:

"The controlled version of this document is the electronic version viewed on-line only. If this is a printed copy of the document, it is an uncontrolled version and may or may not be the version currently in use."

Use of the disclaimer statement eliminates the need for a distribution list. It is the user's responsibility to check the document control database and verify that he/she is using the current, controlled version.

5.2 Archives – When a new version of a document becomes effective, the unit's document control contact replaces the old version with the new one in the document control database. The status of the previous version is changed from "approved" to "archived" on the input form. The archived documents are maintained in a separate document view of the database named "Archived Documents."

6.0 References

6.1 BS EN ISO 14001 : 1996 *Environmental Management Systems - Specification with Guidance for Use*, British Standards Institution, ISBN 0 580 26708 3, September 1996.

6.2 *National Environmental Laboratory Accreditation Conference Constitution, Bylaws, and Standards*, Approved May 2001 – Effective July 2003.

6.3 *National Environmental Laboratory Accreditation Conference Constitution, Bylaws, and Standards*, Approved July 2002 – Effective July 2004.

6.4 U.S. Environmental Protection Agency. 2002. *EPA Guidance for Quality Assurance Project Plans (QA/G-5)*. EPA/240/R-02/009. Washington, DC.

6.5 Van Langenhove, Agnes. 1998. *Guidance for the Development of Standard Operating Procedures*. EPA Region 1, Investigations and Analysis Unit, OEME.

6.6 Wilson, W. Gary. 2000. EMS Implementation Workshop, U.S. EPA Region 1 Regional Laboratory. Environmental Science & Engineering, Inc.