Writing, Approving and Updating SOPs, SOGs, and Other Controlled Documents

1. Purpose
This procedure describes how the EHS Office will manage the development and maintenance of the Standard Operating Procedures (SOPs), Standard Operating Guidelines (SOGs), and other controlled documents. These documents are typically created to standardize a process to reduce noncompliance or quality errors or to prevent adverse outcomes.

2. Scope
This procedure applies to all personnel in the MIT’s EHS Office and to any MIT personnel using EHS documents. This procedure describes how the EHS Office will:
- Identify the need for SOPs, SOGs and other documents;
- Develop new SOPs, SOGs and other documents;
- Review and Approve documents;
- Maintain and Update SOPs, SOGs and other documents; and
- Communicate SOPs, SOGs and other documents to users.

3. Prerequisites
N/A

4. Procedures

4.1. Identifying a Need
The EHS Office Director determines the need to revise an existing or develop a new EHS-related SOP, SOG, or other controlled document. This need may be triggered from a variety of sources including, but not limited to:
- Inspection/ Investigation,
- Audits,
- Questions/ Requests,
- Regulations,
- Corrective Actions,
- Incidents,
- New Equipment or Processes, or
- PI Registration Process.

4.2. Development Process
When the need for a new document is identified, the EHS Office Director will determine which program within EHS will be the lead for that document. The relevant EHS Program Deputy Director (DD) will assign responsibility for developing and writing this document to a Subject Matter Expert (SME). The Subject Matter Expert may be a staff member in the EHS Office or in a DLC. The EHS Office Director, the Document Coordinator, the Program Deputy Director, and the SME may all be involved in identifying stakeholders. The EHS Office Director will determine stakeholders to be engaged.

Prior to drafting the document, the SME will interview the stakeholders, gather input and develop the timeline. The SME will then write the document using the current version of the appropriate EHS SOP/SOG/Document template.

After the preliminary draft of the document is completed, it will be submitted to the EHS Program Deputy Director to initiate EHS review.
4.3. Initial Review Process

The EHS Program DD and/or the Services Team Leader (STL) perform the initial content review following creation of the document. Once the document has been reviewed and approved for release by the appropriate EHS DD/STL, the document is ready for external (“public”) review and comment. The document is posted on EHSNET by the EHS Document Coordinator under the “Documents for Review” heading and a comment period is specified. Specific individuals may be solicited directly for review.

After the closing of the review period, the SME considers each comment. The document may or may not be changed as a result of the comments provided. After the SME addresses each comment, the Program DD and/or STL again grants approval of the changed document, at which time it is either finalized by sending it on to the Document Coordinator for final editing and posting or, if the comments were substantial, the SOP may be re-posted for review.

Revisions will be identified by a revision number modification and the date issued. Changing the second digit, e.g. 1.x, can identify minor revisions. A major change can be identified by an upgrade to the 1st digit, e.g., 2.0. The document will be finalized and approved after the reviews have been completed and all issues addressed.

4.4 Approval of SOPs, SOGs, and Other Documents

Following the creation, review, and approval by the Program DD and/or the Services Team Leader(s), the Director, EHS Office approves SOPs, SOGs, and other documents. The Deputy Director of one or more of the Programs within the EHS Office (i.e., Biosafety, Environmental Management, Industrial Hygiene, Radiation Protection, or Safety) may also co-approve such documents.

The EHS Director approves these documents following several levels of involvement and review by the stakeholders of the SOPs, SOGs, and other documents. The development of all SOPs, SOGs, and other documents generally require the involvement of an individual, group, DLC, or other body whose role is affected by the nature and scope of the document. The different levels of scope and approvals for consideration are below. The EHS Office Director decides which level of involvement is required.

Scope
1. All of MIT (Policy)
2. Multiple DLCs
3. One specific DLC
4. EHS Office Only
5. EHS Program(s) only

Involvement of:
1. Academic Council
2. Working Committee, Ad Hoc
3. DLC EHS Committee
4. EHS Director, Managing Director, Associate Directors, EHS Programs
5. Program Deputy Director(s)

4.5. Maintaining and Updating Documents

All SOPs/SOGs and other documents are reviewed annually by the SMEs and others for relevance, accuracy, and grammatical correctness and updated as necessary. The annual review will begin in January and end the last day of February each year. EHS Coordinators and others, as appropriate, will be involved in the review and approval process. The EHS Document
Coordinator is responsible to ensure that all reviews are completed. SOPs/SOGs and other documents that have been created within the last 6 months of the prior calendar year; need no review for that year.

4.6 Communicating Documents
The approved documents will be posted on the EHS website for a review / comments period. Notification will be sent to all EHS Coordinators, by the Documents Coordinator, that the SOP, SOG, or other documents are available for review and comment. Upon final approval, SOP’s are posted on the EHS Web site.

5. Roles & Responsibilities
- **EHS Office Director** will have the responsibility for determining whether a controlled document is needed and what is the priority for completing the document.
- **EHS Associate Director or Program Deputy Director** respectively will assign responsibility to: a) develop the document, b) review a draft document and c) initiate internal and/or external review. The EHS Program Deputy Director will also ensure the full implementation of the final document.
- **Subject Matter Expert (SME)/document Owner** - a staff member in the EHS Office or in a DLC with expertise in the document area who writes the document and initiates review of its contents on an annual basis. The annual review will begin in January and end the last day of February each year.
- **EHS Document Coordinator** - a staff member in the EHS Office who will maintain the master list of all EHS documents, will assign a number to the new / revised document and facilitate the production and annual updating of all documents. The EHS Document Coordinator posts documents for the review period and posts final SOP’s on the EHS Web. On an annual basis in December, the EHS Document Coordinator will notify owners of SOP’s, SOG’s or other Controlled documents about the provisions of this SOP and the need for a review to be conducted prior to the end of the following February. When a new or revised SOP, SOG or Controlled Document is generated, the EHS Document Coordinator will inform DLC EHS Coordinators.
- **DLC Reviewers** - DLC EHS Coordinators and/or other DLC staff members will review the documents that affect their DLC’s operations. These reviewers are chosen based on the subject matter of the document and whether or not their DLC is affected.

6. Training
If training is required, the SME will schedule, conduct and document the training and /or may elect to use assistance from the EHS Office Training Services Team Leader

7. Monitoring Requirements
N/A

8. Records Management
All documents addressed under this SOP are retained as specified in the EHS Office Records Retention SOP and EHS Office Records Retention Program.