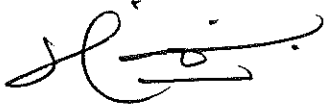


Standard Operating Procedures

V. PREPARING STANDARD OPERATING PROCEDURES (SOPS) AND GUIDELINES

1. Objectives
2. Scope
3. Responsibilities
4. Preparing SOPs and Guidelines Workflow
5. Writing and review of new SOP/Guideline
6. Presentation of new/revised SOP/Guideline to JEPeM
7. Decision of JEPeM USM action on new/revised SOP/Guideline
8. Approval of new/revised SOP/Guideline for implementation
9. Distribution and storage of new/revised SOP/Guideline

Supersedes	Version 06 dated 10 July 2019
Version:	07
Authored by:	Assoc. Prof. Dr. Wong Kah Keng, Assoc. Prof. Dr. Nor Hafizah Selamat, Dr. Husnaida Abdul Manan @ Sulong, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin
Version Date:	30 August 2022
Approved by:	 Professor Dato' Dr. Faisal Rafiq Mahamd Adikan Vice Chancellor, Universiti Sains Malaysia
Approval Date:	22/8/2022

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Document History

Authors	Version	Date	Describe the main change
Mr. Mohd. Bazlan Hafidz Mukrim, Dr. Teguh Haryo Sasongko	01	06-04-2014	First draft
Mr. Mohd. Bazlan Hafidz Mukrim, Dr. Teguh Haryo Sasongko	02	07-09-2015	Second version
Prof. Dr. Nik Hazlina Nik Hussain, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	04	10-05-2017	Fourth version - Minor changes in the SOP. Also update the USM logo in all forms.
Prof. Dr. Nik Hazlina Nik Hussain, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	05	07-01-2019	Fifth version – Adding the page numbers to all the available forms.
Prof. Dr. Nik Hazlina Nik Hussain, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	06	10-07-2019	Sixth version – Minor technical changes in point no. 5, no. 6, no. 7 and no .9.
Assoc. Prof. Dr. Wong Kah Keng, Assoc. Prof. Dr. Nor Hafizah Selamat, Dr. Husnaida Abdul Manan @ Sulong, Mr. Mohd Bazlan Hafidz Mukrim and Miss Siti Fatimah Ariffin	07	30-08-2022	Seventh version – Minor technical changes in the SOP.

1. Objectives

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, amending, and storing JEPeM-USM SOPs and Guidelines.

2. Scope

This SOP applies to any JEPeM-USM SOPs and their amended versions as published and distributed by JEPeM-USM.

3. Responsibilities

The JEPeM-USM committee is responsible for ascertaining the need for new SOPs/Guidelines and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including JEPeM-USM Members. The JEPeM-USM Chair is responsible for designating and appointing an SOP Team, which drafts new SOPs and Guidelines and amends them as needed. The team is responsible for proposing design and format as well as the substantial contents of the SOP or Guideline. JEPeM-USM members are responsible for JEPeM-USM consensus action on the proposed SOP or Guideline, the outcome of which is approved by the Vice Chancellor of USM through the office of Deputy Vice-Chancellor for Research. The USM Vice Chancellor is responsible for the final approval of all SOPs and Guidelines. The JEPeM-USM Secretariat Staff is responsible for storing and distribution.

4. Preparing SOPs and Guidelines Workflow

ACTIVITIES	RESPONSIBILITY
Design SOP/Guideline format, coding, and layout ↓	SOP Team
Write new/review existing SOP/Guideline ↓	SOP Team
Present new/revised SOP/Guidelines to the JEPeM- USM ↓	JEPeM-USM Chair
Decide on JEPeM-USM action ↓	JEPeM-USM Members
Approve new/revised SOP/Guideline ↓	USM Deputy Vice Chancellor of Research and Innovation (R&I), USM Vice Chancellor
Distribute and store new SOP/Guideline	Secretariat Staff

DETAILED INSTRUCTIONS

4.1. Design of the format, coding (using an identifier), and layout

4.1.1. An SOP follows the format:

- **Number and version**, which follows the SOP on coding of SOPs and Guidelines
- **Title**, which is descriptive of contents
- **Objectives**, which defines the purpose and intended outcome
- **Scope**, which defines the extent of coverage of the SOP and its limitations
- **Responsibilities**, which delineates tasking and accountabilities for SOP implementation
- **Workflow** when necessary, which provides a graphic representation of the essential steps to implement the SOP
- **Detailed instructions**, which elaborates the steps outline in workflow
- **JEPeM-USM FORM 5(D): DOCUMENT HISTORY**, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- **Forms**, which are documents to be filled out or accomplished by different parties as required by the SOP, with **a list of forms**
- **References**, which lists the instruments used to draft the Guideline such as other SOPs, guidelines, or policies
- **Appendices** which provide elaborations or clarifications of specific sections including glossary and list of abbreviations

4.1.2. Each SOP is alphanumerically coded: **JEPeM-USM SOP XXX/YY-W-ZZZZ**, where **XXX** is a three-digit number corresponding to the chapter, **YY** is a two-digit number identifying the version of the SOP, and **W** is a one-digit number identifying the version of SOP with minor changes in the SOP, and **ZZZZ** refers to the year the SOP was first drafted. **YY** (version) starts from 01 and **W** starts with 0. Thus, the SOP on writing of SOPs is identified with the code **JEPeM-USM SOP 005/01-0-2014**, signifying that this SOP can be seen in Chapter 5, it is the first version (005/01), and has no minor changes, (05/01-0) as of 2014 (when it was first drafted).

4.1.3. A Guideline follows the format:

- **Number and version**, which follows the SOP on coding SOPs and Guidelines
- **Title**, which is descriptive of contents
- **Table of contents**, which lists all major headers and subheadings of the Guideline including the appendices and page numbers on which these appear
- **Introduction**, which includes a summary and explanation of the purpose of the Guideline, a short note on how the Guideline was prepared, and a short note on how to use it
- **Detailed description**, which represents the final text that is short and clear
- **JEPeM-USM FORM 5(D): DOCUMENT HISTORY**, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- **References**, which lists the instruments use to draft the Guideline such as other guidelines or policies
- **Appendices**, which provide elaborations of specific guideline sections including glossary and list of abbreviations

4.1.4. A Guideline is alphanumerically coded in sequence: **JEPeM-USM GL XX**, where **XX** is a two-number that indicates sequence, for example **01** means it is the first guideline issued by the JEPeM. The code is followed by a version number which indicates whether a specific guideline document is a **draft version, final version, final version with minor revisions or final version with major revisions**.

- Draft version is indicated as "Version N.0" followed by the word "draft"; for example **GL 01 Version 1.0 draft** means draft of the first version
- Final version is indicated removing the word "draft"
- Final version with minor revisions is indicated by "Version N.n" followed by the word "final"; for example **Version 1.1 final** means the final version had undergone one round of minor revisions
- Final version with major revisions is indicated by "Version (N+1).0" followed by the word "final"; for example **Version 2.0 final** means the final version had undergone one round of major revisions.

4.1.5. The layout of a typical SOP or Guideline page [**JEPeM FORM 5(A): SOP OR GUIDELINE TEMPLATE**] uses a **header** with the following elements:

- Institutional seal or logo
- Name of institution
- SOP/Guideline code
- SOP/Guideline title
- Effective date
- Page number
- SOP/Guideline content

and a **footer** indicating file name, directory and path included, of the corresponding electronic document, if the file can be accessed through a website or Uniform Resource Locator (URL), or a server

4.1.6. The SOP/Guideline is introduced by a cover page [**JEPeM-USM FORM 5(B): SOP OR GUIDELINE COVER PAGE**] laid out as a typical SOP or Guideline page with the following additional items included:

- Summary content after the title
- Institutional contact details (address, telephone numbers, facsimile number, email address)
- Date of the previous version; if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
- Name of the authors/editors
- Approval information such as approving authorities and offices

5. Writing and review of new SOP/Guideline

5.1. SOPs and Guidelines are issued by the JEPeM-USM in order to facilitate transparent, clear, and systematic implementation of its functions.

5.2. New SOPs and Guidelines may be issued in not less than three-year intervals; unless regulations on which these documents are based have significantly changed in the interim.

5.3. Existing SOPs and Guidelines are reviewed **every three (3) years**; unless regulations on which these documents are based have significantly changed in the interim.

- 5.4. Any amendment or revision must be written and submitted to the JEPeM-USM Chair/Deputy Chair for compilation and processing by respective parties, such as JEPeM-USM Members or USM authorities, in preparation for the next round of SOP or Guideline review.
- 5.5. A request for amendment or revision is accomplished by filling out **JEPeM-USM FORM 5(C): REQUEST FOR AMENDMENT OF AN SOP OR GUIDELINE**. The JEPeM-USM Chair/Deputy Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows:
- The JEPeM-USM Chair requests further information regarding the request of amendment and forward to content expert for opinions
 - Confirm the need for amendment or revision by JEPeM-USM Chair, and forward to SOP Team
- 5.6. When the need for a new SOP or Guideline has been identified and agreed on, the JEPeM-USM Chair/Deputy Chair will organize the writing process whereby a draft will be written by the SOP Team designated by the Chairperson/Deputy Chair. The draft is regarded as a consensus issuance by the SOP Team, and may be a result of consultation with other stakeholders prior to completion.

6. Presentation of new/revised SOP/Guideline to the JEPeM-USM

- 6.1. The draft version is submitted by the SOP Team to the JEPeM-USM Chair/Deputy Chair.
- 6.2. The JEPeM-USM Chair/Deputy Chair organizes a JEPeM-USM forum, which is expected to be attended by majority of the JEPeM-USM members.
- 6.3. The JEPeM-USM Chair/Deputy Chair presents the new/revised SOP or Guideline to the JEPeM-USM during this forum and presides over deliberation.

7. Decision of JEPeM-USM action on new/revised SOP or Guideline

- 7.1. The JEPeM-USM members will deliberate on the proposed draft and arrive at a consensus action. *Favorable action by consensus* requires representation of all JEPeM-USM panels by way of the presence of at least the Chairperson/Deputy Chair.
- 7.2. If a consensus cannot be achieved, the matter is put to a vote. *Favorable action by voting* requires representation of all JEPeM-USM members, with a vote of **two-thirds plus one** of the members present in the meeting.

- 7.3. Action can be deferred if recommendations for further amendments or revisions are lodged during the forum, in which case, the JEPeM-USM Chair/Deputy Chair will supervise the documentation of requested amendments or revisions and call for a subsequent meeting, no more than **thirty (30) calendar days** from the date of this forum.

8. Approval of new/revised SOP/Guideline for implementation

- 8.1. Upon favorable action by JEPeM-USM, the SOP team will seek for approval from the JEPeM-USM Chair/Deputy Chair to the USM Vice Chancellor through the Deputy Vice-Chancellor of Research & Innovation (R&I) for final approval.
- 8.2. The approval is indicated by the dated signature of the USM Vice Chancellor on the cover page of the document.
- 8.3. The effective date of the document is reckoned as the date when the USM Vice Chancellor signs the document. However, in the interest of continuity of JEPeM-USM work, SOP and Guideline documents may be regarded as functionally approved as of the date of favorable action by JEPeM-USM (see section 8.1 above).

9. Distribution and storage of new/revised SOP or Guideline

- 9.1. The printed copy of the approved SOPs will be distributed to JEPeM-USM Members within **thirty (30) calendar days** of approval by the USM Vice Chancellor
- 9.2. An electronic copy of the SOP or Guideline will be published as soon as possible in the JEPeM-USM website.
- 9.3. One (1) complete originally signed set of current SOPs is maintained by the JEPeM-USM Secretariat Staff, which can be reproduced as needed.
- 9.4. In case of amended or revised SOP or Guideline documents, the old version will undergo archiving procedures by the Secretariat Staff. The word "SUPERSEDED" is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.
- 9.5. Superseded versions are indicated in the **JEPeM-USM FORM 5(D): DOCUMENT HISTORY** of the new version by Secretariat Staff prior to storage.

Reference:

<http://www.jepem.kk.usm.my/index.php/references>



Standard Operating Procedures

XX. YYYYYYYYYYYY

1. Content 1
2. Content 2
3. Content 3

Supersedes	<version number>
Version:	<version number>
Authored by:	TITLE, NAME
Version Date:	dd/mm/yyyy
Approved by:	Vice Chancellor, Universiti Sains Malaysia
Approval Date:	dd/mm/yyyy

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Request for Revision of an SOP or Guideline

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit to the JEPeM-USM Coordinator for processing.

SOP or Guideline Code	SOP or Guideline TITLE
Reason for request (citing details of problems or deficiency in current document):	
Description of requested changes	
Revision Requested by: (Name and signature)	Date: (dd/mm/yyyy)

<i>Recommendations by JEPeM-USM Coordinator</i>	
<input type="checkbox"/> Revision requirement confirmed, forward to SOP Team <input type="checkbox"/> Request further information (state) <input type="checkbox"/> Forward to content expert for opinion	
Name of JEPeM-USM Coordinator	<Title, Name, Surname>
Signature	
Date	<dd/mm/yyyy>

Document History

Author	Version	Date	Describe the main change
<i>Name</i>		<i>dd-mm-yyyy</i>	First draft Second draft Final version Minor changes Major changes No change (routine review)
<i>Name</i>		<i>dd-mm-yyyy</i>	
<i>Name</i>		<i>dd-mm-yyyy</i>	
<i>Name</i>		<i>dd-mm-yyyy</i>	
<i>Name</i>		<i>dd-mm-yyyy</i>	