Title: Preparation and approval of new Standard Operating Procedures		
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Lead Author	Approver	Effective Date: 16-JAN-06
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Signature: On file	Signature: On file	Supersedes: SOP/EMEA/001 (28-JUL-04)
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1. Purpose

To enable the development and presentation of Standard Operating Procedures (SOPs) at the EMEA in a consistent way by the use of process maps and the EMEA SOP template. An existing SOP should be revised according to the SOP on Review and Revision of Effective SOPs (SOP/EMEA/0013).

2. Scope

This SOP applies to all members of staff in EMEA Directorate, Units and Sectors.

3. Responsibilities

Each Unit and Sector Head under the responsibility of the Executive Director must ensure that this procedure is adhered to within their own unit or sector. The responsibility for the execution of each step of this procedure is identified under **9. Procedure**.

4. Changes since last revision

Extensive revision to re-write SOP in the revised template format, to take into account the increasing role of IQM Co-ordinators in the procedure, the introduction of Work Instructions, the removal of internal/external categorisation of SOPs and the introduction of a new web-based IQM Manual.

5. Documents needed for this SOP

SOP Template in MS Word (provided by the IQMCo).

Process Map Template in MS PowerPoint (provided by the IQMCo).

Transmission Slip – SOPs/WINs (located at WORD/File/New/Transmission Slips/SOP&WIN transmission slip).

6. Related documents

SOP/EMEA/0037: Publication or withdrawal of SOPs/WINs

WIN/EMEA/0022: Use of SOP/WIN Tracking Database

WIN/EMEA/0035: Creating and maintaining SOP/WIN folders in EDMS

WIN/EMEA/0036: Creating flow charts

7. Definitions

EMEA Bodies: Management Board, Scientific Committees, Working Parties, Scientific Advisory Groups, etc.

ManualCo: IQM Manual Co-ordinator or delegate

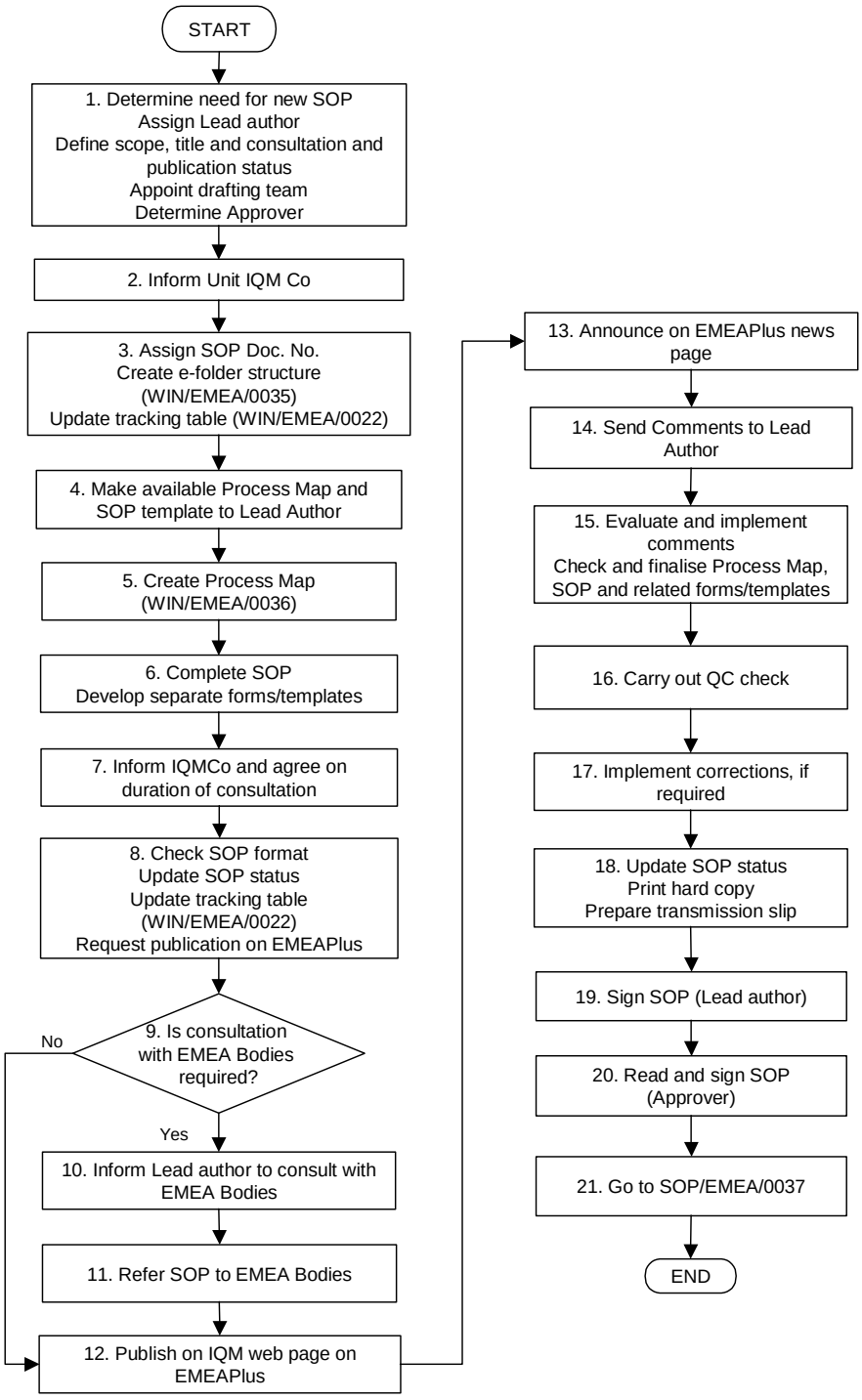
HoU/HoS: Head of Unit/Head of Sector

IQMCo: IQM Co-ordinator or delegate

SOP: Standard Operating Procedure - Detailed, written instructions to achieve uniformity of the performance of a specific process; the instructions usually cover more than one task or area within the Agency, Unit, or Sector.

WIN: Work Instructions – Detailed descriptions of how to perform and record tasks; they may be, for example, detailed written descriptions, flow charts, checklists, pictures, or combinations thereof (definition adapted from ISO/TR 10013:2001 – Guidelines for quality management system documentation)

8. Process Map(s)/ Flow Chart(s)



9. Procedure

Step	Action	Responsibility
1	Determine need for a new SOP. Assign Lead author of SOP. Define scope and purpose of SOP with Lead author. Appoint drafting team having a good knowledge of the process. If cross-Sector/Unit representation is necessary, consult with other HoS to appoint team members. Determine who will be the Approver of the SOP. Determine whether the SOP will be made available only for internal EMEA staff consultation or will be extended to other EMEA Bodies. Determine publication status of final SOP, i.e. PUBLIC (for publication on intranet and external web site) or CONFIDENTIAL (for publication on intranet and title only published on external web site).	HoU/HoS
2	Inform Unit IQMCo of SOP title, consultation status and publication status.	Lead author
3	Verify if any other SOP or WIN for similar processes at the EMEA exists or is under development to avoid duplication or divergence. If not, assign SOP document number, create SOP-specific folder and templates in EDMS (refer to WIN/EMEA/0035) and update tracking database (refer to WIN/EMEA/0022).	IQMCo
4	Inform Lead author of location of SOP-specific folder and templates.	IQMCo
5	Prepare process map in PowerPoint for the process to be documented (refer to WIN/EMEA/0036) using the blank template provided by the IQMCo. Save the document in the SOP-specific folder provided.	Lead author/drafting team
6	Complete SOP template provided by the IQMCo. Describe the process in clear and concise steps, based on the process map. Refer to documents required for the process, using the document title/number without version number. Insert a **black and white** copy of the updated process map in the SOP (refer to WIN/EMEA/0036). Save the SOP in the SOP-specific folder provided. If the process described in the SOP requires the use of templates/forms, develop them in parallel to the SOP, NOT as appendices to the SOP. Refer to them in the SOP, and save the templates/forms in the SOP-specific folder. In case of difficulty with any part of this Step, seek assistance of the Unit IQMCo.	Lead author/drafting team
7	When drafting is complete, inform the IQMCo and discuss the required length of consultation, i.e. 2 or 4 weeks of internal EMEA staff consultation (the length of consultation depends on the urgency to publish and the degree of cross-Agency consultation required). When other EMEA bodies need to be consulted, the length of consultation may be longer than 4 weeks.	Lead author
8	Check that SOP has been completed according to the instructions in the template. Update status of SOP to CONSULTATION (CONFIDENTIAL). Update the tracking database (refer to WIN/EMEA/0022) with the agreed consultation dates.	IQMCo

Step	Action	Responsibility
	Inform ManualCo by email to publish for consultation on EMEAPlus IQM web page and to request announcement of publication. Provide a contact name for feedback comments and inform of the length of consultation. Attach electronic files (NOT EDMS locators) of the SOP and forms/templates, if applicable, to the email.	
9	If the SOP does not require consultation with EMEA Bodies, go to Step 12. If the SOP requires consultation with EMEA Bodies, go to Step 10.	IQMCo
10	Inform Lead author that SOP is ready for consultation with EMEA Bodies.	IQMCo
11	Refer SOP and forms/templates, if applicable, to EMEA Bodies for the period of consultation as agreed with the IQMCo in Step 7.	Lead author
12	Create a link to the copies of the SOP and forms/templates, if applicable, on EMEAPlus IQM web page. Inform the News Editors to advertise the SOP consultation on EMEAPlus news page and provide a contact name and the deadline for consultation.	ManualCo
13	Announce SOP consultation on EMEAPlus news page.	EMEAPlus web editors
14	Review draft SOP and provide Lead author with comments by email.	EMEA staff
15	Evaluate comments from internal staff and, if applicable, EMEA bodies. Implement appropriate suggested improvements in the SOP. Check and finalise Process Map, SOP and forms/templates, if applicable. Inform IQMCo when ready.	Lead author/drafting team
16	Carry out quality check and request Lead author to make corrections, if required.	IQMCo
17	Make necessary corrections to SOP and forms/templates, if required.	Lead author
18	Update status of SOP as agreed in Step 1. Print hard copy of SOP and prepare transmission slip. Forward SOP and transmission slip to Lead author.	IQMCo
19	Sign SOP and transmission slip. Forward to Approver.	Lead author
20	Read SOP. Sign SOP and transmission slip. Forward to IQMCo.	Approver
21	Refer to SOP/EMEA/0037.	IQMCo

10. Records

When completed and approved, the original, signed hard copy will be retained by the IQM Manual Co-ordinator in the controlled documents Master File (refer to WIN/EMEA/0037).