Procedure for the exchange of reports of supervision of safety features repositories system

Purpose

This procedure describes the process for the exchange of reports of supervisory activities prepared by National Competent Authorities as required by Article 44 of Commission Delegated Regulation (EU) 2016/161.

The objective is to have a harmonised process for the exchange of reports within the EU network.

Scope

This SOP applies to EU/EEA national competent authorities responsible for human medicinal products, the European Commission and the European Medicines Agency.

It covers the reports of national medicine verification systems (NMVS) as well as of the EU medicine verification system (EMVS).

Responsibilities

The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of the section entitled "Procedure".

Documents needed for this SOP

- Inspection report template (Annex 1)
- MMD - Client requirements and configuration quick guide: http://docs.eudra.org/docs/Doc_10_Client_Req_Quick.pdf

Related documents

- Commission Delegated Regulation (EU) 2016/161 https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

Definitions

EC: European Commission

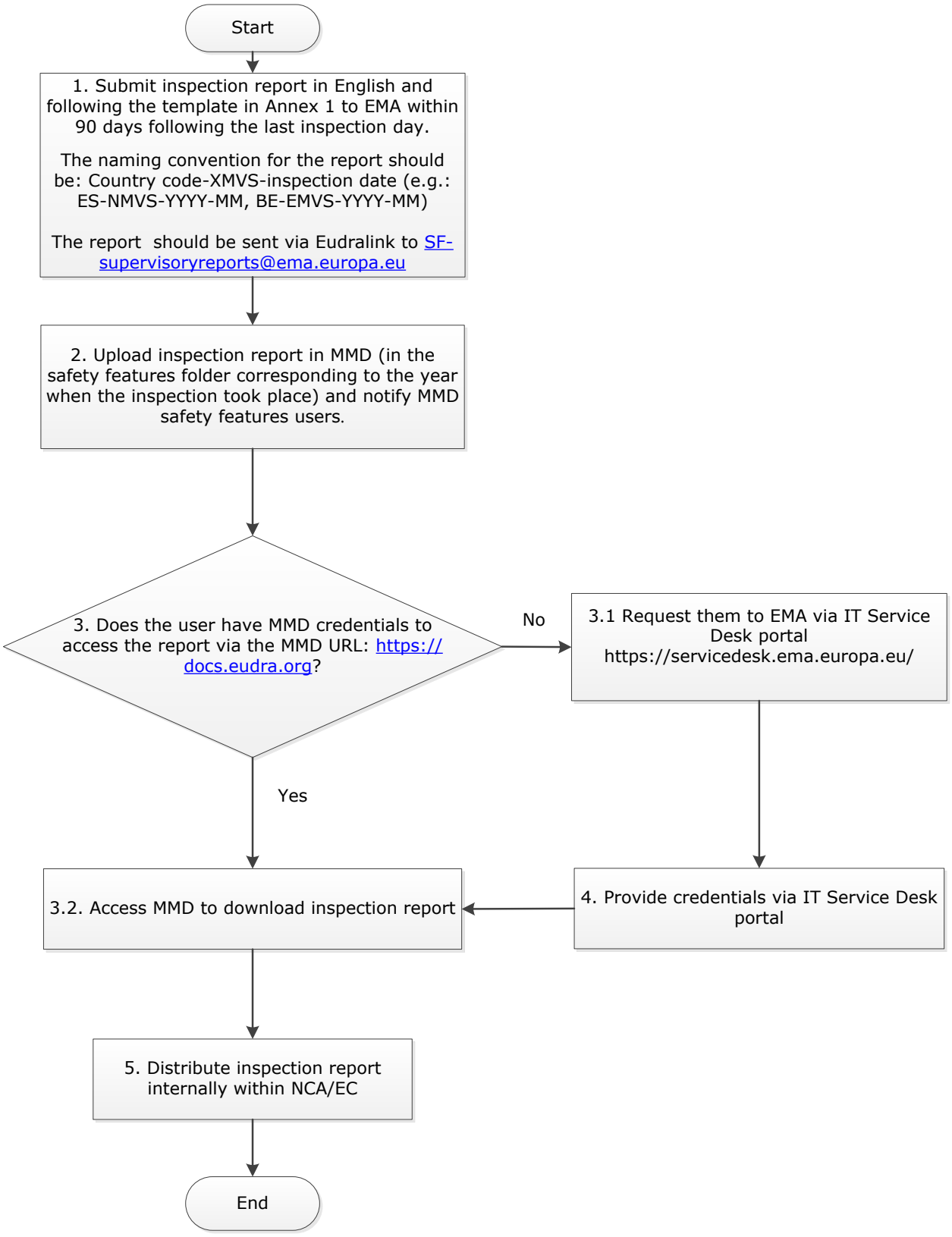
EMVS: EU medicine verification system

MMD: Managing Meeting Documents system

NCA: National Competent Authority

NMVS: National medicine verification system

Process map/ flow chart



Procedure

Step	Action	Responsibility
1.	Submit inspection report in English and following the template in Annex 1 to EMA within 90 days following the last inspection day. The naming convention for the report should be: Country code-XMVS-inspection date (e.g.: ES-NMVS-YYYY-MM, BE-EMVS-YYYY-MM). The report should be sent via Eudralink to SF-supervisoryreports@ema.europa.eu	NCA
2.	Upload inspection report in MMD (in the safety features folder corresponding to the year when the inspection took place) and notify MMD safety features users.	EMA
3.	Does the user have MMD credentials to access the report via the MMD URL: https://docs.eudra.org ? 3.1. If no, request credentials to EMA via IT Service Desk portal: https://servicedesk.ema.europa.eu/ and continue with step 4. 3.2. If yes, access MMD to download inspection report and continue with step 5.	NCA/EC
4.	Provide credentials to NCA/EC user via IT Service Desk portal	EMA
5.	Distribute inspection report internally within NCA/EC.	NCA/EC

Annex 1: Inspection report template

Inspection/Report Reference no.:		
Inspected NMVO:		
Name and full address of the inspected organisation		
Inspection Type	On-site: ☐	Remote (Desktop): ☐
Purpose of the Inspection	Routine: ☐	Other: ☐ *Indicate reasons*
Inspection Date(s):	*Date(s), month, year*	
Inspector(s) and Expert(s):		
Name(s) of the inspector(s). *Name(s) of expert(s) (if applicable).* *Name(s) of Competent Authority(ies).*		
Introduction:		
Short description of the organisation. *Indicate whether the repository is national or supranational.* *Include details of the NMVS Service Provider.* *Indicate whether the NMVS is a Blueprint, Customised Blueprint or Bespoke System.* *Include the following details, as applicable:* ➢ *Date of previous inspection.* ➢ *Name(s) of inspector(s)/expert(s) involved in previous inspection.* ➢ *Significant changes since the previous inspection.*		
Brief report of the inspection activities undertaken:		
Scope of Inspection: *Short description of the inspection.* Inspected area(s): *Each inspected area should be specified.*		
Activities not inspected:		
Where applicable attention should be drawn to areas or activities not subject to inspection on this occasion.		
Personnel met during the inspection:		
The names and job titles of key personnel met should be specified.		
Findings and observations relevant to the inspection and non-compliances:		
Relevant headings from the Commission Delegated Regulation (EU) 2016/161, as applicable. *This section can link the findings to the non-compliances.* *Headings which may be used (other headings may be introduced when relevant):* *Establishment of the repositories system* *Structure of the repositories system* *Uploading of information in the repositories system* *Functioning of the hub* *Characteristics of the repositories system* *Operations of the repositories system* *Obligations of legal entities establishing and managing a repository which is part of the repositories system* *Data protection and data ownership* *Qualification/Validation of the Systems*		

Quality Management System

- *Overview of inspection findings from the last inspection and corrective action taken*
- *System Access Management*
- *Information Security Management*
- *Connection of End-users*
- *Management of Incidents/Potential Incidents of Falsification*
- *Change Management*
- *Complaint Management*
- *Risk Management*
- *CAPA Management*
- *Training*
- *Business Continuity*
- *Audit Management*

Annexes attached:

List of any annexes attached

List of non-compliances:

Non-compliances should be listed and the relevant reference to the Delegated Regulation should be mentioned.

The organisation should be asked to respond to the findings including proposed time schedule for corrections.

Compliance rating:

Indicate the compliance rating

☐ Compliant

☐ Compliant with observations

☐ Non-Compliant

☐ Not Operational

Competent Authority comments on the organisation's response to the inspection findings:

i.e. are the responses acceptable?

Summary and conclusions:

The Competent Authority should state whether the organisation operates in general compliance with the requirements of the Commission Delegated Regulation (EU) 2016/161.

Name(s):

The inspection report should be signed and dated by all personnel having participated in the inspection.

Signature(s):

Competent Authority Name:

Date: