Standard Operating Procedure

Number: **026**

Name: **Data security audit**

Title: Procedure for carrying out an audit for data security

Category: Data management

Status: Approved

Version: 1.0

Date: 2024-02-07

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1 Document history

1.1 Current Release

1.1.1 Drafted

Submitted on 2023-06-05 by Michael Rubinigg, quality manager.

1.1.2 Reviewed

Reviewed on 2023-06-30 by Noa Simòn Delso, general manager.

1.1.3 Approved

Approved on 2024-02-07 by Michael Rubinigg, quality manager.

1.2 Change history

n.a.

2 Abbreviations

EU	European Union
EUPH	EU Pollinator Hub
n.a.	not available
SOP	Standard Operating Procedure

3 Introduction

This SOP describes the procedure for testing the compliance of the process set up to assure data security with the quality management system and to present the results thereof in a useful and consistent manner. It assesses the following components of the quality management system:

- SOP-004 Organisation chart
- SOP-011 Data protection
- SOP-016 Release management
- SOP-020 Issue management
- SOP-023 Method validation
- SOP-024 Instrument qualification
- SOP-027 System maintenance
- SOP-028 User management

4 Validity

4.1 Area

The validity of this document is limited to testing the compliance of the process set up to assure data security with the quality management system and to present the results thereof in a useful and consistent manner.

4.2 Time

The period of validity of this SOP begins on 2024-02-07 and ends with its revocation.

4.3 Related Documents

Document type	Number	Name
SOP	004	Organisation chart
SOP	011	Data protection
SOP	016	Release management
SOP	020	Issue management
SOP	023	Method validation
SOP	024	Instrument qualification
SOP	027	System maintenance
SOP	028	User management

4.4 Related Tasks

Persons who have been assigned one of the following tasks, as defined in SOP-004, assume a responsibility within this SOP:

- Performance of internal audits

5 Procedure

5.1 Drafting of the Audit Report

5.1.1 General rules

5.1.1.1 Editing

- The template provided by the quality manager, should be used for drafting an Audit Report.

5.1.1.2 Text

- In the present SOP, text to be included as such in the Data Security Audit Report to be drafted is written in ***bold italic***, information intended as placeholder is written between [square brackets].
- Text in the Data Security Audit Report shall appear as follows:
  - General: Font type Calibri, full justified; line spacing 1,5 lines; alignment justified
  - Body text: Font weight normal; font size 11 pt
  - Headings: Font weight normal; font size 14 pt (first level), 13 pt (second level), 12 pt (third level), 11 pt (fourth level). First level headings start after a page break.
  - The name of databases, tables of databases, columns of tables, directories, files shall be written in *italic*.
  - The symbol to be used as decimal separator is the baseline dot.

5.1.1.3 Dates

- Dates are given in the following format, including a leading zero: [YYYY-MM-DD] where Y stands fore Year, M for month and D for day.

5.1.1.4 Document header

The document header contains information on the institution by which the dataset has been issued.

- Even page numbers: Name of the institution (***EU Pollinator Hub***), left aligned.
- Odd page numbers, except for cover page, left aligned: ***DSAR*** [number of the data security audit report] [YYMMDD]***, Version*** [version number]
- Odd page numbers, including cover page, right aligned: logo of the institution.

5.1.2 Cover page

- The cover page contains a summary of the most important control information of the dataset required to configure management and compliance standards:
  - ***Data Security Audit Report***, font weight normal; font size 20 pt; center alignment

- ***Number:*** A consecutively numbered identifier of the Data Security Audit Report, starting at 1 written in **bold letters**.
- ***Process:*** Description of the inspected process
- ***Status:*** One of the following status information: ***Draft*** | ***Approved***.
- ***Version****:* Version number.
- ***Date****:* Date of release of the current version.
- ***Author****:* Name of the author(s) of the current release of the Data Security Audit Report.
- Disclosure rules: Text containing the explicit statement by whom the document is intended to be used as well as to whom, by whom and for which purpose the document may be disclosed.

5.1.3 Table of contents

- A Data Security Audit Report may include a section ***Table of Contents*** at two levels with the page number.

5.1.4 Document history

- Section ***1 Document history*** contains a complete list with the following information on previous versions and/or releases of the Data Security Audit Report in decreasing chronological order.
  - ***Version****:* Version number.
  - ***Date****:* Date of release of the current version.

5.1.4.1 Release

- Section ***1.1 Release*** contains the following technical information in the current release:
  - ***Version*** [version number].
  - ***released on*** [date of release].
  - ***Written by*** [full name of all authors separated by comma]**.**
  - ***Reviewed by*** [full name of all reviewers separated by comma].
  - ***Approved by*** [name of person responsible for the release of reports].

5.1.4.2 Revision

- Section ***1.2 Revision*** contains a tabular summary of the revisions made within each release:
  - ***Id***: Identifier of the row.
  - ***Date***: Date of the finalisation of a revision.
  - ***Description***: Short description of the reviewed item before and after the revision.
  - ***Reason***: Reason for revision.

5.1.5 Abbreviations

- Section ***2 Abbreviations*** contains a list of abbreviations used in the document in increasing alphabetical order and the description.
  - Abbreviation
  - Description

5.1.6 Summary

Section ***3 Executive Summary*** should provide background information on the inspected process, the type of inspection that was conducted (scheduled, exceptional), a summary of the deviations that were noted, and the responses of the responsible person to the presented deviations.

5.1.7 Introduction

Section ***4 Introduction*** should include some or all following elements:

- The purpose and general description of the inspection, including the role of the person responsible for the performance of internal audits, as defined by SOP-004, and the security standards serving as the basis for the inspection.
- An identification of the person responsible for the performance of internal audits, as defined by SOP-004, and the dates of inspection.
- A description of the inspected process.
- The type of inspection that was conducted (scheduled, exceptional).
- Date and time of the beginning and the end of an inspection.
- The date of the previous inspection, resulting compliance status, and relevant changes made since that inspection.

5.1.8 Narrative

For section ***5 Narrative*** the inspection protocols available in section 7 should be used.

The Narrative portion of the report should contain a complete and factual description of the observations made and activities undertaken during the course of the inspection. Where possible, deviations should be supported by documentation (*e.g.* screenshots). All such documentation should be referenced and discussed in the narrative and attached in the Annexes.

When a process has been selected for audit, the report should describe the procedure for conducting the audit, including a description of the portion of the process that was actually examined. Any findings during the audit should be described in the Narrative in column **comments**. In column **compliance** one of the following terms may be entered: ***compliant*** | ***not compliant*** | ***not investigated***.

5.1.9 Exit conference

At the end of an inspection, an Exit Conference should be held between the person responsible for the performance of internal audits, according to SOP-004, and the person responsible for the inspected process, as defined by SOP-004, at which deviations found during the inspection may be discussed. During this Exit Conference a written list of observations should be presented describing the deviations if any have been observed. The exit discussion should be summarized in this section.

Section ***6 Exit Conference*** should note the date and time of the Exit Conference; the names of attendees with their roles. It should also give a brief summary of deviations noted by the inspection team during the inspection. Responses of the person responsible for the inspected process, as defined by SOP-004, to the remarks of the person responsible for the performance of internal audits, as defined by to SOP-004, should also be described.

5.1.10 Annexes

- If applicable, section ***7 Annexes*** contains annexes.
- If no annexes are contained write: **There are no annexes in the current document.**

5.2 Specific rules

5.2.1 Respoonsibilities

- The person responsible for the performance of internal audits, as deifned by SOP-004, performs internal audits.

5.2.2 Frequency of audits

- Scheduled audits are performed once per year.

6 References

There are no sources in the current document.

7 Annexes

There are no annexes in the current document.