Standard Operating Procedure

Number	**021**
Name:	**Change management**
Title:	Procedure for the implementation, documentation and notification of software changes on the EU Pollinator Hub
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1 Document history

1.1 Current Release

1.1.1 Drafted

Submitted on 2023-06-17 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

CMR	Change Management Report
EU	European Union
EUPH	EU Pollinator Hub
n.a.	not available
SOP	Standard Operating Procedure

3 Introduction

This document regulates the procedure for the implementation, documentation and notification of software changes on the EU Pollinator Hub.

4 Validity

4.1 Area

The of validity of this document is limited to the procedure for the implementation, documentation and notification of software changes on the EU Pollinator Hub.

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	001	SOP instructions
SOP	004	Organisation chart
SOP	009	Methods
SOP	023	Method validation

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:

- Quality management
- Software development
- Acquisition and maintenance of hard- and software

5 Procedure

5.1 Updates in software related to the data module of the EU Pollinator Hub

5.1.1 Change tracking

5.1.1.1 Version control software

- The distributed version control system Git is used for development of the software.

5.2 Changes of software or hardware

5.2.1 Risk analysis

5.2.1.1 Changes in software

- The person responsible for software development, as defined by SOP-004, or a person appointed by him/her for this purpose, performs a risks analysis on the effects of a planned change in software or software configuration on data assets.

5.2.1.2 Changes in hardware

- The person responsible for acquisition and maintenance of hard- and software, as defined by SOP-004, or a person appointed by him/her for this purpose, performs a risks analysis on the effects of a planned change in hardware or hardware configuration on data assets.

5.2.2 Testing changes

5.2.2.1 Test Protocol

- If a risk analysis carried out according to section 5.2.1 concludes, that the integrity of data assets could be affected by the planned change, the person responsible for quality management, as defined by SOP-004, or a person appointed by him/her for this purpose, develops a test protocol for the measurement of the potential effect on data assets, with the exception of assets covered by SOP-023.
- The Test Protocol contains the following elements:
  - Description of the change.
  - For each method the following parameters and their values must be defined:
    - Parameters to be measured before the change;
    - Parameters to be measured after the change;
    - Expected result for each parameter after the change;
  - Method(s) to be used to measure and record parameters, according to SOP-009.
- The person performing the risks analysis either requests modifications in the test protocol or approves it.

5.2.2.2 Testing environment

- Tests that can be performed in a local test environment shall be performed in a local test environment.
- Only tests that must be performed in a production environment in order to give meaningful results shall performed in a production environment.

5.2.2.3 Testing before change

- The person responsible for quality management, as defined by SOP-004, or a person appointed by him/her for this purpose, performs the measurements before the change contained in the approved test protocol.

5.2.2.4 Change execution

- The person responsible for software development, as defined by SOP-004, or a person appointed by him/her for this purpose, die executes the change.

5.2.2.5 Testing after change

- The person responsible for quality management, as defined by SOP-004, or a person appointed by him/her for this purpose, performs the measurements after the change contained in the approved test protocol.

5.2.2.6 Reporting

- A template file provided by the person responsible for quality management, shall be used for drafting the Change Management Report (CMR).
- A CMR consists of risk analysis (section 5.2.1), test protocol (section 5.2.2), test results (sections 5.2.2.2 and 5.2.2.5) and final decision (section 5.2.2.7).
- An incrementing report number is assigned to the report.
- The file name of the CMR is composed as follows: ***CMR_*** [*report number*].

5.2.2.7 Final decision

- If, based on the results of the test, the person responsible for quality management, as defined by SOP-004, concludes that the test results after the change are consistent with the expected results, it approves the change.
- If, based on the results of the test, the person responsible for quality management, as defined by SOP-004, concludes that the test results after the change are not consistent with the expected results, it rejects the change.
- In case of approval, changes that were tested in a local test environment may be deployed to production environment.
- In case of a rejection, the person responsible for the change, as defined in section 5.2.1, or a person appointed by him/her for this purpose, reverts the executed change.

6 References

There are no sources in the current document.

7 Annexes

There are no annexes in the current document.