



eHealth Network

EHEALTH DIGITAL SERVICE INFRASTRUCTURE

PROCEDURE 2:

THE PROCEDURE TO START THE NCPEH ROUTINE OPERATIONS

Adopted by the eHealth Network on 03.06.2020

PROCEDURE 2

THE PROCEDURE TO START THE NCPeH ROUTINE OPERATIONS

Applicable to Member States, which received the eHN decision on go-live by the end of 2019.

GENERAL REMARKS

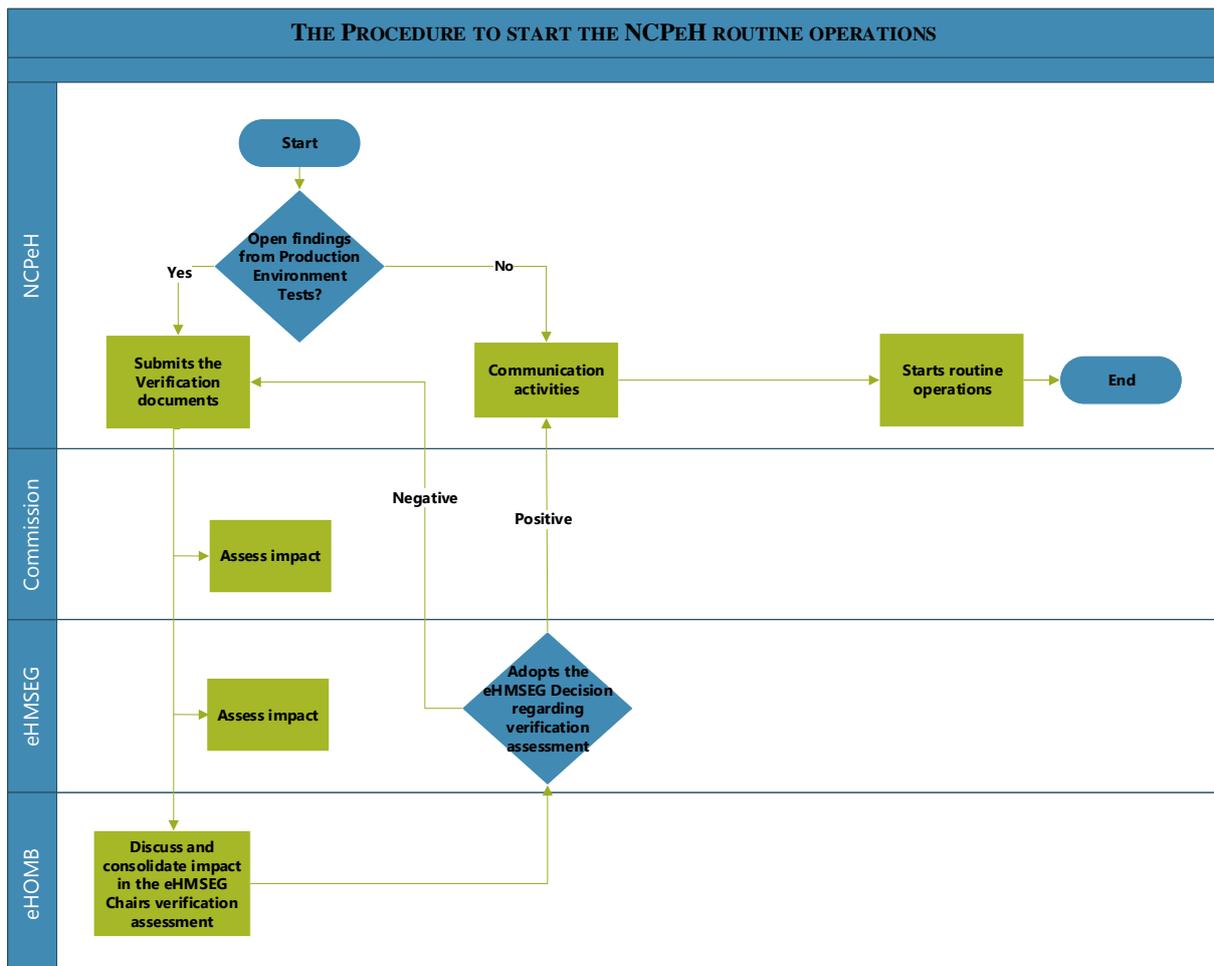
- (1) The eHealth Digital Service Infrastructure Governance bodies work through their Secretariats provided by the Commission, as follows:
 - eHealth Operational Management Board – via eHOMB Secretariat (SANTE-EHEALTH-DSI@ec.europa.eu)
 - eHealth DSI Member States Expert Group – via eHMSEG Secretariat (SANTE-EHDSI-SECRETARIAT@ec.europa.eu)
 - eHealth Network – via eHN Secretariat (eHEALTH-NETWORK@ec.europa.eu)
- (2) For every specific service role with every specific partner MS, the NCPeH may start the routine operations only after:
 - Receiving the eHN Positive Decision regarding go-live for the NCPeH (I) or the eHN Conditional Positive Decision regarding go-live for the NCPeH (II)
 - Completing the Production Environment Testing. The Production Environment Testing may result in (a) no findings; (b) new open test findings. The status of the conformance and functional findings is recorded in the Updated Outcome Summary Test Report.
- (3) In the case of any open findings, the eHDSI relevant governance bodies need to assess their impact on the eHDSI.
- (4) As support materials for the impact assessment, the following verification documents have to be provided by the NCPeH:
 - Updated Outcome Summary Test Report (issued by the eHDSI Solution Provider, DG SANTE A4) – this report describes the status of the conformance and functional findings.
 - Follow up Audit Report or Verification of implementation of corrective actions (issued by the eHDSI Audit team, DG SANTE F5) – this report describes the status of the audit findings.

I. PROCEDURE SCOPE

The procedure describes scenarios and dependencies between the eHN Decision regarding go-live and the Production Environment Test results. The objective of this process is to assess if the NCPeH can start the routine operations.

There are four possible scenarios:

1. (I) The eHN Positive Decision regarding go-live for the NCPeH
 - (a) No findings from the Production Environment Testing
2. (I) The eHN Positive Decision regarding go-live for the NCPeH
 - (b) New open test findings from the Production Environment Testing
3. (II) The eHN Conditional Positive Decision regarding go-live for the NCPeH
 - (a) No findings from the Production Environment Testing
4. (II) The eHN Conditional Positive Decision regarding go-live for the NCPeH
 - (b) New open test findings from the Production Environment Testing



SCENARIO 1

I. PROCEDURE DESCRIPTION

1. An NCPeH submits the Updated Outcome Summary Test Report to the eHMSEG.
2. The NCPeH informs the eHMSEG and the Commission's eHDSI Communication Unit (DG SANTE B3) about the exact date when they will start routine operations and prepare the communication related actions. When the communication related actions are in place, the NCPeH can officially enter routine operations.

II. FINAL STEPS

3. The eHMSEG informs the eHN that the NCPeH have started routine operations.

SCENARIO 2, 3, 4

I. ASSESSMENT PROCESS

1. The NCPeH submits the verification documents to the eHMSEG.
2. The eHMSEG submits the verification documents to the eHOMB, requesting the eHOMB discussion.
3. The Commission¹ submits to the eHOMB the assessment of the open findings impact on the eHDSI.
4. The Commission and the eHMSEG Chairs discuss the open findings impact during the eHOMB meeting.
5. The eHMSEG Chairs representing the eHMSEG decide on the verification assessment.
6. The eHMSEG Chairs submit their verification assessment to the eHMSEG Secretariat.

II. DECISION MAKING PROCESS

7. The eHMSEG decides during the meeting or in a written procedure (according to the eHMSEG Rules of Procedure), based on the eHMSEG Chairs verification assessment if the NCPeH is technically ready to start routine operations.
8. The eHMSEG informs the NCPeH, the eHN and the eHOMB about their decision.

III. FINAL STEPS

9. If the eHMSEG Decision regarding verification assessment is negative, the NCPeH continues the verification of the open Test and/or Audit findings.
10. If the eHMSEG Decision regarding verification assessment is positive, the NCPeH has to inform the eHMSEG and the Commission's eHDSI Communication Unit (DG SANTE B3) about the exact date when they will start routine operations and prepare the communication related actions. Then the NCPeH can officially start routine operations.

¹ Commission is regarded as data processor for patients' personal data processed through the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services. In its capacity as processor, the Commission shall manage the core services of the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services (Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU).