



eHealth Network

EHEALTH DIGITAL SERVICE INFRASTRUCTURE

PROCEDURE 4:

**THE PROCEDURE TO OBTAIN THE EHN DECISION TO START THE
NCPEH NEW SERVICE ROUTINE OPERATIONS**

Adopted by the eHealth Network on 03.06.2020

PROCEDURE 4
THE PROCEDURE TO OBTAIN THE eHN DECISION TO START THE NCPeH NEW SERVICE
ROUTINE OPERATIONS

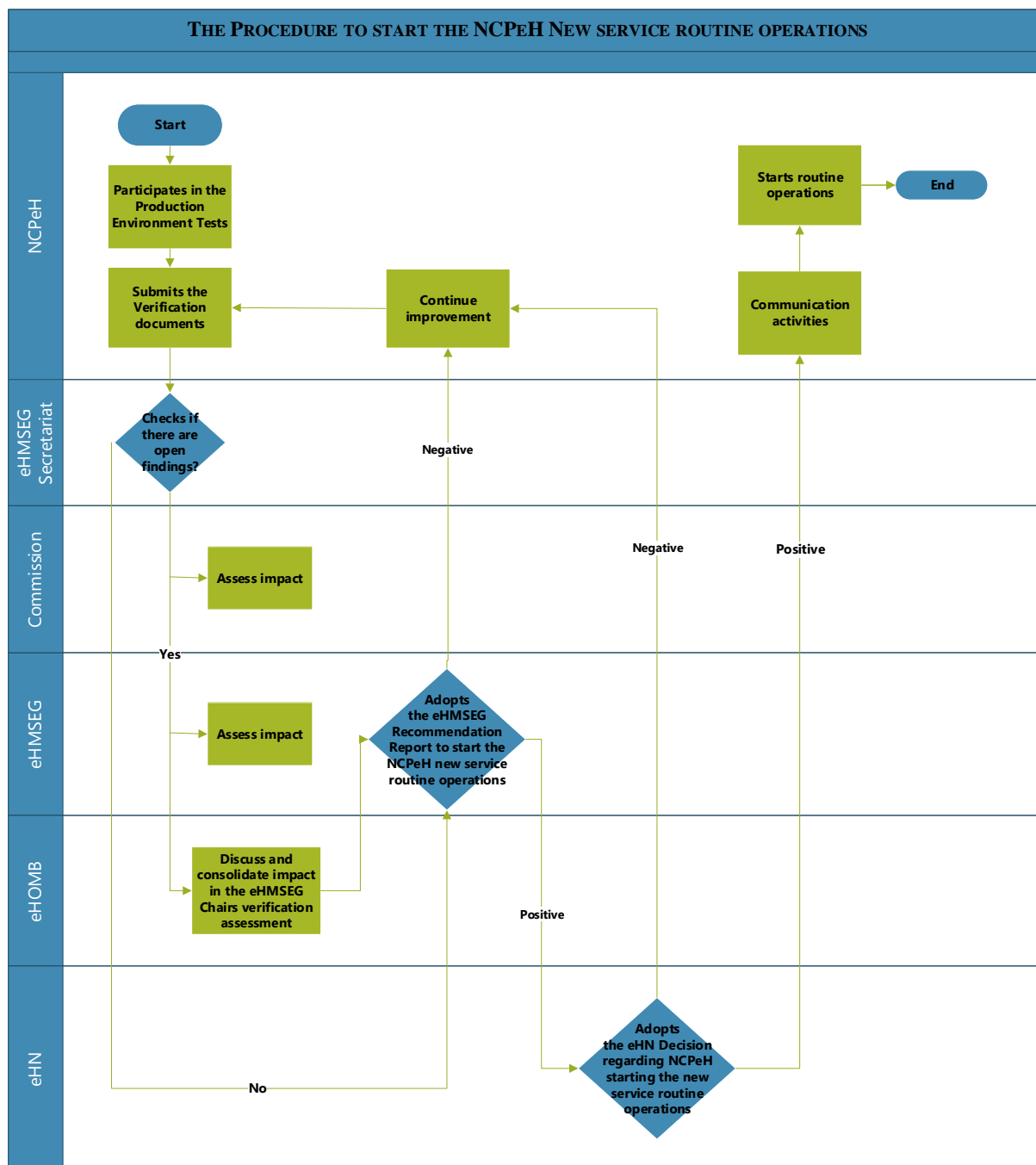
Applicable to Member States, which want to start the new service routine operations.

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) The new service is an eHDSI service (ePrescription or Patient Summary) in a specific role (country A or country B), for which routine operations are to be commenced by the deploying Member State.
- (3) The NCPeH may apply to start the new service routine operations only after:
 - Receiving the eHMSEG Positive Decision regarding the NCPeH authorisation to start the Production Environment Testing for this service.
 - Completing at least one Production Environment Testing for this service. This 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.
- (4) In the case of any open findings for this service, the eHDSI relevant governance bodies need to assess their impact on the eHDSI.
- (5) 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.
- (6) The eHN decision regarding NCPeH starting new service routine operations refers to specific service. The NCPeH can choose to obtain the eHN Decision to start the NCPeH new service routine operations for one or more services at the same time (for each new service there must be at least one successfully performed Production Testing).
- (7) Separately from obtaining the eHN decision to start the NCPeH new service routine operations, the NCPeH can effectively start the new service routine operations only with a partner who also fulfils all the above-mentioned criteria.

I. PROCEDURE SCOPE

The objective of this process is to obtain the eHN Decision to start the NCPeH new service routine operations.



II. ASSESSMENT PROCESS

1. The NCPeH submits the verification documents to the eHMSEG Secretariat.
2. The eHMSEG Secretariat checks if there are open findings for this new service.
3. In case of open findings:
 - a. The Commission¹ submits to the eHOMB the assessment of the open findings impact on the eHDSI.
 - b. The Commission and the eHMSEG Chairs discuss the open findings impact during the eHOMB meeting.
4. The eHMSEG Chairs representing the eHMSEG propose the eHMSEG Recommendation Report to start the NCPeH new service routine operations and submit it to the eHMSEG Secretariat. .
5. The eHMSEG, after having assessed the submitted documentation, adopts the eHMSEG Recommendation Report to start the NCPeH new service routine operations. The adoption takes place during the meeting or in a written procedure, according to the eHMSEG Rules of Procedure.
6. If there is a negative eHMSEG Recommendation Report to start the NCPeH new service routine operations, the NCPeH will continue the test and audit verification processes, according to the eHDSI Audit and Test Frameworks. The NCPeH can apply again to start new service routine operations by submitting the verification documents to the eHMSEG Secretariat.
7. If there is a positive eHMSEG Recommendation Report to start the NCPeH new service routine operations, the eHMSEG Secretariat submits the eHMSEG Recommendation Report to start the NCPeH new service routine operations to the eHN.

III. DECISION MAKING PROCESS

8. The eHN, after having examined the eHMSEG Recommendation Report to start the NCPeH new service routine operations and any supporting documentation, adopts the eHN Decision regarding NCPeH starting the routine operations. The adoption takes place during the eHN meeting or in a written procedure, according to the eHN Rules of Procedure.

The eHN may decide one of the following:

- I. Go-live with new service (the eHN Positive Decision regarding NCPeH starting the new service routine operations).
- II. Not to go-live with new service (the eHN Negative Decision regarding NCPeH starting the new service 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).

IV. FINAL STEPS

9. If the eHN decision is negative, the NCPeH continues the verification of the open Test and Audit findings. The NCPeH can apply again to start routine operations after they meet the remaining go-live requirements indicated by the eHN.
If the eHN decision 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 enter new service routine operations.
10. The eHMSEG Secretariat informs the NCPeH, the eHOMB, the eHMSEG, and the eHN about the date when the NCPeH started the NCPeH new service routine operations and with which partner NCPeH.