



eHealth Network

EHEALTH DIGITAL SERVICE INFRASTRUCTURE

PROCEDURE 3:

**THE PROCEDURE TO OBTAIN THE EHMSEG DECISION
TO BE AUTHORISED TO START PRODUCTION ENVIRONMENT TESTS**

Adopted by the eHealth Network on 03.06.2020

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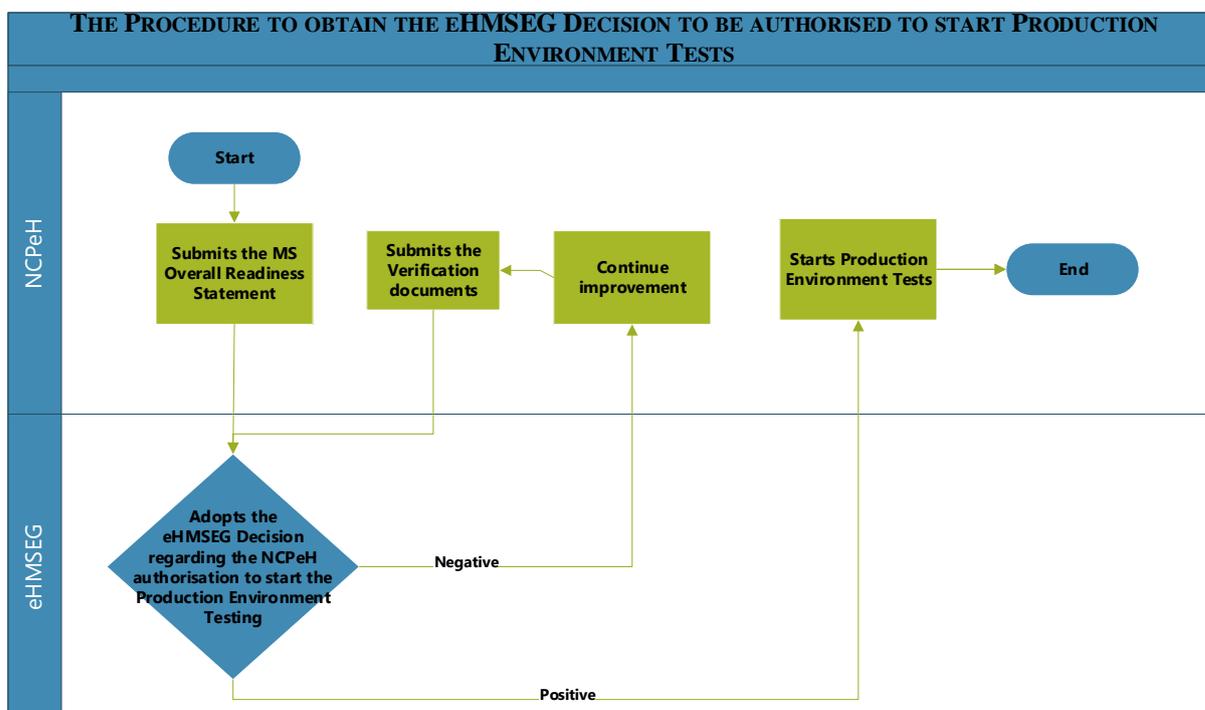
Applicable to Member States, which have applied to eHMSEG for Decision regarding the NCPeH authorisation to start the Production Environment Testing (from 2020 onwards).

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) To request the eHMSEG decision to be authorised to start Production Environment Tests an NCPeH needs to go through the testing and auditing procedures (according to Test and Audit Frameworks). An NCPeH has to summarise its testing and audit results in the MS Overall Readiness Statement, which contains below annexes:
 - Outcome Summary Test Report after the eHDSI Formal Pre-Production Test event (depending on the NCPeH situation, one of the following documents could be applicable: Initial Outcome Summary Test Report or Updated Summary Test Report – after the Solution Provider verification process).
 - Audit Reports (depending on the NCPeH situation, one or several following documents could be applicable: the Initial Audit Report or Auditors assessment of Action Plan + Initial Audit Report or Follow-up Audit Report + proposed actions for addressing recommendations of the Follow-up Audit Report or Verification letter).
 - Signed Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services (the signed Agreement could be provided in the later stage, in due time for the eHealth Network decision to start the routine operations).
- (3) To reapply to start Production Environment Testing, 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 objective of this process is to obtain the eHMSEG Decision to be authorised to start the Production Environment Testing. The successful Production Environment Testing will allow the NCPeH to apply for the eHN decision to start the routine operations.



II. PROCEDURE DESCRIPTION

1. An NCPeH submits the MS Overall Readiness Statement to the eHMSEG via the eHMSEG Secretariat.

III. DECISION MAKING PROCESS

2. The eHMSEG, after having assessed the submitted documentation, proposes and adopts the eHMSEG Decision regarding the NCPeH authorisation to start the Production Environment Testing. The adoption takes place during the meeting or in a written procedure, according to the eHMSEG Rules of Procedure.
3. The eHMSEG may decide one of the following:
 - A. Start Production Environment Testing (the eHMSEG Positive Decision regarding the NCPeH authorisation to start the Production Environment Testing).
 - B. Not to start Production Environment Testing (the eHMSEG Negative Decision regarding the NCPeH authorisation to start the Production Environment Testing).

IV. FINAL STEPS

4. If the eHMSEG took a positive decision regarding the NCPeH authorisation to start the Production Environment Testing, the NCPeH can start the Production Environment Testing, according to the eHDSI Test Framework.

If the eHMSEG took a negative decision regarding the NCPeH authorisation to start the Production Environment Testing, 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 Production Environment Testing by submitting the verification documents to the eHMSEG.