



Appendix 19

Quality Assurance Protocol

REFERENCE NUMBER: TN 591875

Notwithstanding exceptions provided for by law, no part of this invitation to tender may be duplicated and/or disclosed without the written consent of Enexis.

Version 2025

Tenderer must substance to Enexis' ambition in the framework of quality, by fulfilling the requirements and submitting the requested documents at the time of submitting the tender according to Appendix 19 – Quality Assurance Protocol. During the verification audit of the production facilities after the preliminary awarding of the Framework Agreement, these documents and processes will be audited. Findings and points for improvement by Enexis will become part of the audit report and be included as an appendix to the framework agreement. This will serve as the starting point. The implementation of these points for improvement will be monitored during the utilization phase of the framework agreement.

1. Control Plan

Products are produced on a production line in a production environment for which Tenderer shall demonstrate that this production process is monitored and executed in accordance with a Control Plan. The Tenderer shall submit a recent (< 3 years) Control Plan for the transformers offered. This plan should cover all steps from incoming goods up to and including the shipping of a finished product.

Tenderer will be audited on a control plan which contains at least the segments as below described.

- a. General data
 - a. Document number
 - b. Issue date and revision date, if any
 - c. Engineering change level (product revision)
 - d. Part number(s)
 - e. Part name/description
 - f. Process step/operation description
 - g. Customer information (customer requirements)
- b. Product control
 - a. Product-related special characteristics
 - b. Other characteristics for control (number, product, or process)
 - c. Specification/tolerance
- c. Process control
 - a. Process parameters
 - b. Process-related special characteristics
 - c. Machines, jigs, fixtures, tools for manufacturing
- d. Methods
 - a. Sample size and frequency
 - b. Control method
- e. Reaction plan and corrective actions
 - a. Reaction plan in case of off-spec measurements (include or reference)

2. DFMEA

Enexis is specially referring to a complete **DFMEA** that covers the ranking criteria, customer usage/functionalities, and recommended actions for potential failure modes with high risks. Ideally, the FMEA's are in the format of a standard FMEA as outlined in NEN-EN-IEC-60812:2018, annex F Table F.14

3. PFMEA

Enexis is specially referring to a complete **PFMEA** that covers the ranking criteria and recommended actions for potential failure modes with high risks (covering the process starting with incoming goods up to shipping). Ideally, the FMEA's are in the format of a standard FMEA as outlined in NEN-EN-IEC-60812:2018, annex F Table F.14

4. Complaint process according to 8D methodology

Enexis placed high importance on effective, transparent, and timely complaint management. Tenderers are required to demonstrate that they have a structured, traceable, and customer-oriented complaint-handling process in place. This includes the ability to receive, register, investigate, and resolve complaints within agreed timelines and according to contractually defined quality standards, reporting with a full 8D report (D1-D8).

1. Objective

The Tenderer shall demonstrate a robust, auditable complaint handling process based on the 8D (Eight Disciplines) problem-solving methodology. The process shall be aligned with ISO 9001 principles and ensure timely containment, effective root-cause elimination, and sustainable prevention of recurrence.

2. Scope

The requirements apply to all complaints related to product quality, performance, compliance traceability, documentation, testing evidence, and collaboration throughout the corrective and preventive action lifecycle.

3. Complaint Handling & 8D (“*-D”) Reporting Requirements

The Tenderer shall apply the 8D methodology (or equivalent (“*-D”) structure) as the standard approach for complaint handling.

3.1 Timeliness & Completeness (D1-D3)

Each complaint shall be handled with a clear problem definition, immediate containment actions to protect the customer, and full delivery of initial and interim 8D information with the agreed Service Level Agreement (SLA), which is to be determined during the contracting stage.

Minimum evidence includes complain registration, containment action records, verification results, and interim progress reporting.

3.2 Root Cause Analysis (D4)

A systematic root cause analysis shall be performed using recognized methods such as 5-Why and/or Ishikawa (fishbone). The Tenderer shall demonstrate full supply chain and process traceability to identify where and how the nonconformity originated.

Minimum evidence includes documented RCA results, supporting data, and traceability records (e.g. batch, process, or supplier chain information).

3.3 Corrective Actions (D5-D6)

Corrective actions shall eliminate the identified root cause and be embedded in production and quality processes. Administrative corrections alone are insufficient. Where applicable, PFMEAs and Control plans shall be reviewed and updated.

Minimum evidence includes a corrective action plan with responsible owners and deadlines, implementation proof, and updated PFMEA and/or Control Plan extracts.

3.4 Preventive Assurance (D7)

The Tenderer shall ensure long-term prevention through procedure updates, training, tooling improvements, and/or supply chain adjustments. QA documentation shall be maintained to reflect these preventive controls.

Minimum evidence includes updated procedures, training records, and revised quality documentation.

3.5 Communication & Collaboration

Throughout the complaint lifecycle, the Tenderer shall ensure transparent communication, timely status updates, and responsiveness to information requests. Supporting technical documentation such as datasheets and test results shall be provided where relevant.

3.6 Sustainability & Closure

Complaint closure shall demonstrate verified effectiveness of actions, prevention of recurrence, and integration of lessons learned into continuous improvement systems.

Minimum evidence includes effectiveness verification results, formal closure approval, and documentation updates.

4. Verification Audit Deliverables

Enexis will audit Tenderer during the verification audit on: (1) a description of their complain handling workflow based on 8D or equivalent, (2) a sample 8D report template, (3) an explanation of root cause and traceability methods, (4) an explanation of how corrective actions are embedded into quality and production systems, and (5) an overview of communication and reporting practices.