ETICS	**OPERATIONAL DOCUMENT**	**CIG ~~023~~423 Appendix 2**

Factory Inspection Report
Appendix 2
Additional Quality System Requirements
~~for the ENEC Agreement~~
(~~ENEC~~(QMS Appendix)

~~WARNING:~~

~~APPENDIX 2 TO PD CIG 023 SHALL NOT CONTAIN ANY UNAUTHORISED MODIFICATIONS CHANGING THE ORIGINAL MEANING OR THE REQUIREMENTS~~

~~THIS DOCUMENT IS ONLY VALID IF USED BY ENEC MEMBERS AND THEIR AUTHORISED AGENTS~~

Approved by:	~~Approved by ENEC members by correspondence~~	No. of pages: ~~1+3~~5
Date of issue:	~~December 2020~~	
Supersedes:	~~PD~~OD CIG 023 Appendix 2 – ~~September~~	~~Page 1 of 4~~

	~~2014~~December 2020	

Reference number of the body carrying out the inspection:

APPENDIX 2 TO ~~PD~~OD CIG ~~023~~423 FACTORY INSPECTION REPORT

Additional Quality System Requirements ~~for the ENEC Agreement~~

(~~ENEC~~QMS Appendix)

GENERAL GUIDANCE

This Appendix is to be used ~~only~~ if ~~all of the following conditions apply to the Manufacturer:~~

~~– ENEC certified products are manufactured, and~~

– Compliance with EN ISO 9001~~:2015 (EN ISO 9001)~~ is required, and

– There is no certificate, issued by an accredited Body, to demonstrate that the Quality Management System complies with the requirements of EN ISO 9001 ~~or the certificate issued does not cover the production of the ENEC certified products~~.

***NOTE**:*

– *Instructions to the Inspector are shown in italics.*

– *The questions of this factory inspection report are based on the requirements given by the* EN~~/~~ ISO 9001*.*

– *This document is to be completed by Inspectors who are familiar with the requirements of* EN~~/~~ ISO 9001*.*

– *These requirements apply to quality management systems (QMS) for processes (including resources) related to certified product(s) only.*

– *QMS processes to be considered are: training, design changes, purchasing, incoming controls, storage, production, testing and management (policy and objective definition, internal audits, review and corrective action definition).*

– *For guidance, references to* EN ISO 9001 *paragraphs are provided.*

– *The report shall be completed even if there is no production at the time of the visit.*

– *For all 'NO' answers details shall be provided on the Inspector's Findings page.*

– *For all 'N/A' answers rationale shall be provided as to why the item is not applicable*

– *Details should be given on Inspector's Information page.*

Compliance with these requirements does not imply full compliance to EN~~/~~ ISO 9001.

1 ~~Manufacturer's~~Factory registered name and factory location	
~~Manufacturer's~~Factory registered name:	
Street and No.:	
Postal Code:	
City:	
Province:	
Country:	
GPS-coordinates *(optional)*:	☐ N: ☐ S: ☐ E: ☐ W:

Name of Inspector:	**Date of inspection:** *(YYYY-MM-*

Inserted Cells

Reference number of the body carrying out the inspection:

2.1	**General Requirements** (in reference to **4.4.** as per EN ISO 9001): Has the ~~organisation~~organization established a QMS?	YES ☐	N/A ☐	NO ☐
~~**2.2**~~	~~**Quality Manual** (**4.4.1.- 4.4.2.** as per ISO 9001):~~ ~~Does the organisation have a quality manual (QM) with a description of the interaction of the QMS-processes?~~	~~YES~~ ☐	~~N/A~~ ☐	~~NO~~ ☐
2.2	**Quality Management system and processes** (in reference to **4.4.1.- 4.4.2.** ~~Does the QM include (references to) procedures and instructions for QMS-processes?~~as per EN ISO 9001): Does the organization determine the sequence and interaction of processes needed, maintain and retain documented information to support the operation and interaction of its processes.	YES ☐	N/A ☐	NO ☐
	Does the QMS include (references to) procedures and instructions, documented information for processes?	YES ☐	N/A ☐	NO ☐
	Is the ~~QM~~documented information up-to-date?	YES ☐	N/A ☐	NO ☐
2.3	**Document Control** (in reference to **7.5.** as per EN ISO 9001): Are all documents required by the QMS controlled?	YES ☐	N/A ☐	NO ☐
~~**2.3**~~	~~**Document Control** (**7.5.** as per ISO 9001):~~ ~~Are all documents required by the QMS controlled?~~	~~YES~~ ☐	~~N/A~~ ☐	~~NO~~ ☐
2.4	**Record control** (in reference to **7.5.** as per EN ISO 9001): Are records defined and kept for:	YES	N/A	NO
	- management review (2.9 as per OD CIG ~~023~~423 Appendix 2) including action definitions	☐	☐	☐
	- supplier selection and evaluation (2.13 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- incoming controls, in process controls, end tests (2.13 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- customer complaints (2.12 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- internal audits (2.15 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- training (2.10 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- maintenance (2.11 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
	- calibration (2.11 as per OD CIG ~~023~~423 Appendix 2)	☐	☐	☐
2.5	**Management commitment** (in reference to **5.1**. as per EN ISO 9001): Does management provide resources for the development of the QMS and QMS-processes?	YES ☐	N/A ☐	NO ☐
~~**2.6**~~	~~**Quality Policy** (**5.2.** as per ISO 9001):~~ ~~Has management defined and documented a quality policy?~~	~~YES~~ ☐	~~N/A~~ ☐	~~NO~~ ☐

Reference number of the body carrying out the inspection:

2.6	~~Is the defined policy known by relevant employees? (~~**Quality Policy** (in reference to **5.2.**~~2.~~ as per EN ISO 9001): Has management defined and documented a quality policy?	YES ☐	N/A ☐	NO ☐
~~**2.7**~~	~~**Quality Objectives (6**~~Is the defined policy known by relevant employees? **(**in reference to **5.2.2. as per EN ISO 9001):** ~~Has management established measurable objectives?~~	YES ☐	N/A ☐	NO ☐
2.~~8~~**7**	~~**Management representative (5.3.**~~**Quality Objectives** (in reference to **6.2.** as per EN ISO 9001): ~~Is a management representative assigned with defined responsibilities and authorities for the processes, reporting on performance of QMS and promoting awareness of customer requirements and QMS-requirements?~~Has management established measurable objectives?	YES ☐	N/A ☐	NO ☐
2.8	**Management representative** (in reference to **5.3.** as per EN ISO 9001): Is a management representative assigned with defined responsibilities and authorities for the processes, reporting on performance of QMS and promoting awareness of customer requirements and QMS-requirements?	YES ☐	N/A ☐	NO ☐
2.9	**Management review** (in reference to **9.3.** as per EN ISO 9001): Has management reviewed the QMS in accordance with planned arrangements, including:	YES	N/A	NO
	- process performance	☐	☐	☐
	- product quality	☐	☐	☐
	- customer complaints	☐	☐	☐
	- internal audit results	☐	☐	☐
	- corrective action results	☐	☐	☐
	- policy and objectives	☐	☐	☐
2.10	**Human resources** (in reference to **7.2.-7.3.** as per EN ISO 9001): Is the necessary competence of personnel including temporary personal determined and the necessary training identified and provided?	YES ☐	N/A ☐	NO ☐
~~**2.11**~~	~~**Infrastructure** (7.1.3. as per ISO 9001):~~ ~~Are installations, machines and instruments required for production and tests maintained in accordance with planned arrangements?~~	~~YES~~ ☐	~~N/A~~ ☐	~~NO~~ ☐
2.~~12~~**11**	~~**Customer related processes (8.2**~~**Infrastructure** (in reference to **7.1.3**. as per EN ISO 9001): ~~Have arrangements to communicate with customers with regard to product information, enquiries and complaints been established?~~Are installations, machines and instruments required for production and tests maintained in accordance with planned arrangements?	YES ☐	N/A ☐	NO ☐
2.12	~~Are customer requirements reviewed? (~~**4Customer related processes** (in reference to **8.2.1.** as per EN ISO 9001): Have arrangements to communicate with customers with regard to product information, enquiries and complaints been established?	YES ☐	N/A ☐	NO ☐

Reference number of the body carrying out the inspection:

~~2.13~~	~~**Purchasing process** (8.~~Are customer requirements reviewed? **(**in reference to **4.2. as per** EN ISO 9001**):** ~~Are suppliers selected and evaluated?~~	YES ☐	N/A ☐	NO ☐
2.~~14~~ 13	~~**Control of production** (~~**Purchasing process** (in reference to **8.~~5. – 7.1.5~~4.** as per EN ISO 9001): ~~Is the production carried out under controlled conditions, including the availability of work instructions, equipment and measuring devices, as applicable?~~Are suppliers selected and evaluated?	YES ☐	N/A ☐	NO ☐
2.14	~~Is the product identified at all stages? (~~**Control of production** (in reference to **8.5.~~2.~~** as per EN ISO 9001): Is the production carried out under controlled conditions, including the availability of work instructions, equipment and measuring devices, as applicable?	YES ☐	N/A ☐	NO ☐
~~2.15~~	~~**Monitoring and measurement** (9.1. Is the product identified at all stages?~~ **(**in reference to **8.5.2. as per** EN ISO 9001**):** ~~Are internal audits planned and executed? **(9.2. as per ISO 9001):**~~	YES ☐	N/A ☐	NO ☐
2.15	**Monitoring and measurement** (in reference to **9.1.** as per EN ISO 9001): Are internal audits planned and executed? **(**in reference to **9.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐
	Is it ensured that nonconforming products cannot be released? **(**in reference to **10.2. as per** EN ISO 9001**):**	YES ☐	N/A ☐	NO ☐