ECS European Certification System	**PERMANENT DOCUMENT**	**CIG 021**

Factory Inspection Procedures
Harmonised Requirements

WARNING:
THIS DOCUMENT IS ONLY VALID IF USED BY ECS MEMBERS
AND THEIR AUTHORISED AGENTS

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FACTORY INSPECTION PROCEDURES
HARMONISED REQUIREMENTS

1 INTRODUCTION

This document deals with the factory inspection procedures and tests which Manufacturers are expected to provide and operate to ensure that all certified products are identical, within accepted manufacturing tolerances, to the sample against which the product certification was granted. This document should be taken to represent the minimum acceptable standard.

Compliance with these requirements will be checked during factory inspections.

Pre-Licence inspections shall be announced and arranged with the Manufacturer in order to assure that all persons involved can be available.

Routine inspections are normally un-announced. However in certain cases, it might be necessary to meet the right contact person. In such circumstances, an inspection visit may need to be pre-announced. On the other hand, due to a specific situation with a Manufacturer, an inspection may need to be imperatively carried out un-announced.

It is the Certification Body who shall decide in this respect.

To verify that the conditions for the production of certified products are given to ensure that a uniform manufacturing can be expected the inspection shall be always conducted and a complete inspection report (CIG 023) shall be issued even if there is no production of certified products at the time of inspection.

All details about the testing, test equipment and calibration are equally important even if there is no production or there are other products in production.

***NOTES**:*

1. *The following abbreviations are used throughout this document:*
   CIG 021: stands for PD ECS CIG 021
   CIG 022: stands for PD ECS CIG 022
   CIG 023: stands for PD ECS CIG 023
   CIG 024: stands for PD ECS CIG 024
2. *Current editions of the OSM-FIP Documents can be found under the following path: www.eepca.eu → Document Server → OSM-FIP Public Documents → Permanent and Operational Documents.*

2 DEFINITIONS

2.1 Licence Holder

Any organisation or person who has entered into an agreement with the Certification Body for the certification of the product.

The Licence Holder has the full responsibility for the certified product and it's compliance with the certification requirements.

2.2 Manufacturer

Any manufacturing organisation or person (including subcontractors and outworkers) responsible for the final assembly, testing and/or marking of products certified by an Certification Body in accordance with the specific requirements of the Licence Holder of a certified product.

2.3 Subcontractor

Any manufacturing organisation undertaking the production of any sub-assembly in accordance with the specific requirements of the Manufacturer of a certified product.

2.4 Out-Worker

Any person who undertakes work at a place other than the factory location on component parts supplied by the Manufacturer of the certified product and in accordance with the specific requirements of the Manufacturer.

2.5 Factory Location / Manufacturer's Premises

The location where the final assembly and/or testing of certified products normally takes place and the Certification Mark is applied.

2.6 Procedure

Specified way to carry out an activity or a process. Procedures can be documented or not. When a procedure is documented, the term "documented procedure" is frequently used.

2.7 Calibration

Calibration is the process of establishing the relationship between the test and measuring equipment and reference equipment according to the requirements as given in EN ISO/IEC 17025.

The reference equipment shall have a calibration traceable to (inter)national standards and documented by a calibration certificate.

***NOTE**:*
In general calibration is done by accredited laboratories.

2.8 Verification

Verification is the process of establishing the relationship between the test and measuring equipment and reference equipment where the requirements as given in EN ISO/IEC 17025 are met only partially.

The reference equipment shall have a calibration traceable to (inter)national standards and documented by a calibration certificate.

***NOTE**:*
In general verification is done "In-House".

3 GENERAL ARRANGEMENTS

Factory locations of certified products shall be inspected at least once per year unless otherwise required by individual certification bodies or certification schemes. Should inspection prove to be unsatisfactory, the certification of products may be suspended until such time as the complete production process has again been found to be satisfactory. However, production under the certification scheme may, in some cases, be allowed to continue whilst corrective action is taken, provided adequate written assurances are given by the Licence Holder.

During routine inspections of a Manufacturer's premises/factory location, sample(s) of certified products and/or assemblies and components may be selected for re-examination testing to verify compliance with the relevant standard.

Special inspections may be deemed necessary when a large number of unsatisfactory or critical findings are found to the extent that conformity of the product with the standard may be endangered.

4 LICENCE HOLDER RESPONSIBILITY

The Licence Holder has the full responsibility for the certified product. That includes but is not limited to the construction, the production and the compliance with the certification and factory inspection requirements.

The Licence Holder shall inform any Manufacturer of certified products regarding the details of the certified construction. Documents in which the certified construction is specified (such as a parts list, drawings, etc.) shall be available at the Manufacturer's premises.

Furthermore the Licence Holder shall inform any Manufacturer about the certification requirements including the requirements of the Harmonized Inspection Scheme (CIG 021).

The Licence Holder is responsible to ensure that they are implemented.

The Licence Holder shall inform the certification body about changes to the certified product and get approval. Changes to certified products are only allowed after approval by the certification body.

The Licence Holder shall inform any Manufacturer about those changes approved. It shall be ensured that the Manufacturer does not make changes to the certified construction (including the application of alternative components) prior to permission of the Licence Holder.

The process by which the Licence Holder handles changes to certified products shall be described in a procedure and/or all personnel involved in the acceptance of changes shall be aware how changes to certified products are communicated with the Certification Body.

5 MANUFACTURER'S RESPONSIBILITY

5.1 General Information

The Manufacturer has the full responsibility to ensure that the complete production process of the certified products continuously complies with the ECS requirements as stated in this document.

That includes also the sub-contracting to Subcontractors and Out-Workers.

The Manufacturer shall exercise adequate control over all Subcontractors and Out-Workers preparing assemblies or parts which have a safety implication.

At all stages in the production and control process non-conforming materials, parts and/or products shall be clearly identified and/or segregated to prevent unauthorised use. The process by which non-conforming products are to be handled shall be described in a procedure.

The Manufacturer shall maintain appropriate records to demonstrate conformance with the ECS requirements. These records shall be made available to the Inspector. Records shall be legible and identifiable to the product and/or test equipment involved and shall be kept for a time which should be not less than the period between two inspection visits (e.g. one year).

At least the following records/documents shall be maintained as far as applicable:
– Incoming inspection of components (including Certificates of Conformity)
– Routine Tests
– Product Verification Tests
– Functional checks of test and measuring equipment
– Calibration of test and measuring equipment
– Results of self-assessment
– Customer complaints and corrective action
– Inspection Report from previous inspection

***NOTE**:*
Records can be stored in any format as long as they can be made available to the Inspector during the inspection.

5.2 Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)

The intention of this clause is to ensure that the components used remains identical to the components as accepted for the certified version.

Manufacturers shall ensure that all purchased materials, components and subassemblies comply with specified requirements. There shall be instructions as to which Certification Marks may have to appear on the components/products in order to accept them.

This shall be taken into account when selecting sources of supply and may involve close liaison on a regular basis with suppliers to such an extent that the Manufacturer relies on the suppliers' control procedures. It is the responsibility of the Manufacturer who undertakes final assembly to ensure that subassemblies completed by Subcontractors or Out-Workers meet the relevant safety requirements.

Materials, components and subassemblies which have a safety implication on the finished product and which are purchased from or prepared by an outside supplier, shall be verified as complying with the appropriate specification.

***NOTE**:*
Other materials and components may also need to be checked at Incoming Inspection. The extent of these further checks will vary according to the nature of the item. The method by which the Manufacturer achieves these objectives is not prescribed. Procedures may be required to ensure compliance with the specifications of components.

If a Manufacturer relies on Certificates of Conformity to underwrite the compliance of components with their specifications, certificates shall clearly identify the products to which they refer, the quantity of items covered, the specification to which the products conform, the production date and be signed or otherwise systematically issued and dated by the supplier's authorised person.

Any non-conforming product, found during incoming inspection shall be clearly identified and/or segregated in a controlled way to prevent unauthorised use.

5.3 Production Control, Monitoring and Routine Tests

Production shall be controlled and monitored at appropriate stages of manufacture to ensure that parts, components, subassemblies, wiring runs, workmanship, etc. are in accordance with the sample for which certification was granted (the Certified Version). Quality Assurance and assembly personnel shall be adequately briefed on their duties and have readily available up-to-date instructions, photographs, drawings or samples on all those parts which have an impact on the safety of the finished product.

The method of monitoring adopted by a Manufacturer will obviously depend on local circumstances and the type of product being manufactured. Particular attention shall be paid to those operations which, in themselves, have a critical impact on the safety of the product, for example: the dressing and routing of wiring, the correct location of a safety controls, that connections are correctly made, clearances are adequate, nuts, screws and connections are tight, there are no sharps edges that can damage wiring or harm the user and that any earth bonding is satisfactory.

In addition to the above mentioned monitoring, routine tests may be required. These are line tests performed on 100 % of the production and are normally carried out at the final stage of manufacture. These tests shall include such functional tests as are deemed necessary to ensure that the final product is operating safely.

Normally no further operations, except for marking and packing, may be carried out after these tests.

***NOTES**:*

1. *See the OSM-FIP Decision "Routine Tests" for guidance under the following path: www.eepca.eu → Document Server → OSM-FIP Public Documents → Decisions.*
2. *In the absence of relevant standards by the Technical Committees covering the subject, National Certification Bodies' specifications apply.*

It is required that there is evidence that the system of monitoring and routine tests is planned and ensures that the finished product complies with the standard to which it was originally certified. Records of tests and monitoring undertaken shall be maintained.

Any non-conforming product shall be clearly identified and segregated to prevent unauthorised use, delivery or mixing with conforming products. There shall be a method or procedure that ensures that repaired and reworked product are re-examined to the same requirements as applicable to new produced products.

5.4 Functional Check of Test and Measuring Equipment used for Safety Tests

An operational or functional check shall be conducted at intervals which will allow previous production to be re-tested if incorrect functioning of the test and measuring equipment used for safety (routine) tests is detected.

Options for functional checks are e.g.: Simulated failure (dummy), test procedure according to the equipment manual, internal self-test of the equipment; test program included in equipment certification

As a minimum daily checks are recommended at the end of the production but in any case before shipment. For lot production taking less than a day a check before and after the lot has been produced is recommended. The operational or functional check can be satisfied by subjecting the test equipment to pre-determined fault conditions by a simulated failure (dummy). The simulated failure shall represent the tripping limits used by the Manufacturer during testing of the certified product (Not applicable for spark testers in the production of cables and cords. For those test equipment the short circuit test is allowed as functional check).

The results of all these checks shall be recorded. Operators shall be instructed on what action is to be taken if a functional test is found to be unsatisfactory. In all cases subsequent corrective action taken shall be recorded.

5.5 Products seen in Production during visit – Marking of Products

The Certification Mark shall be applied according to the requirements of the Certification Body. It is the Manufacturer's responsibility to ensure that the Certification Mark is applied only to products that comply with the requirements.

5.6 Calibration/Verification of Safety Test and Measuring Equipment

Test and measuring equipment used for determining the safety of the products being manufactured shall be calibrated or verified on a regular basis, preferably once per year, depending on usage and the results of previous calibration/verification. Records of calibration/verification undertaken on the safety test and measuring equipment shall be kept. The records shall include equipment identification, location, calibration frequency, reference equipment, measured values, deviation, results, signature and date. The calibration of the reference equipment used for calibration/verification shall be traceable to National or International Standards. The test and measuring equipment shall be provided with a label indicating the next 'calibration due' date or another method ensuring the valid calibration/verification status.

5.7 Handling and Storage

Components, materials and sub-assemblies that have been accepted during incoming inspection shall be properly identified and shall be stored in such a way (e.g.

environmental conditions; Electrostatic Discharge (ESD) safe; First In First Out (FIFO) principle) that no damage and/or reduction of properties can occur.

Finished products shall be stored and handled in such a way as to ensure that they will continue to comply with the applicable standards.

5.8 Product Verification Tests / Periodic Tests (PVT)

***NOTE**:*
Under the ENEC certification scheme these tests are described as periodic tests.

Product Verification Tests shall be conducted under the responsibility of the Licence Holder and carried out by the Manufacturer or other sub-contracted organisations with at least the frequency required. Test Records shall be made available to the Inspector.

Product Verification Tests are in addition to the production line inspection and routine tests and are performed on samples taken randomly from the production line. For sample selection the most critical construction shall be considered.

These tests are performed according the paragraphs of the certification standard to demonstrate continuous compliance with the certification standard. The tests may be carried out at a location other than the Manufacturer's premises, but records with the results shall be available with the Manufacturer and shall also include information about test and measuring equipment used, including calibration. Product Verification Tests may be standardized or may not be required for certain product categories, if the relevant Technical Committee so decides.

***NOTES**:*
1. *See the OSM-FIP Decision "Product Verification Tests" for guidance under the following path: www.eepca.eu → Document Server → OSM-FIP Public Documents → Decisions.*
2. *In the absence of relevant standards by the Technical Committees covering the subject, National Certification Bodies' specifications apply.*

For the Product Verification Tests a procedure shall be available. It is the Manufacturer's responsibility to ensure that appropriate corrective actions are taken in the case that the results of the Product Verification Tests are found to be unsatisfactory. The actions to be taken shall also be part of a procedure.

The Inspector or Certification Body's representative will check that this obligation is adequately fulfilled.

5.9 Void

5.10 Corrective actions in response to Inspector's evaluation

It is the Manufacturer's responsibility to take corrective action to any unsatisfactory finding found during the factory inspection. The Certification Body shall be informed about the corrective actions taken. Depending on the number and the seriousness of the findings the Certification Body may decide to verify the implementation of the corrective actions during a special inspection or during the next routine inspection.

5.11 Quality Management System

The Manufacturer is not required to have a certified Quality system. If the Manufacturer has a Quality System certified by an accredited body according to EN ISO 9001 the inspector shall verify if the production of the certified products is covered by the scope of the certificate and if the relevant procedures cover the requirements of this document.

***NOTE**:*
Combined inspections/audits are permitted if the Quality System of the Manufacturer is audited by the same organisation as the Body carrying out the subjected factory inspection.

5.12 Manufacturer's self-assessment of the manufacturing and control process of certified products (formerly: Audits of the Quality System)

The Manufacturer shall regularly monitor all procedures used in the manufacturing and

control process of certified products. This monitoring shall at least include verification that the procedures, instructions and guidelines are up-to-date and properly applied by personnel (including the keeping of records). Manufacturer's procedures shall at least cover the requirements as given in this document (CIG 021). The results of the monitoring shall be recorded, including corrective actions taken. Persons carrying out the monitoring shall preferably be independent from the production process they are monitoring.

***NOTE**:*
Documentation of the results of the Manufacturer's self-assessment by use of CIG 023 is acceptable.

5.13 Void

5.14 Technical Complaints

The Manufacturer shall record any technical complaint regarding the certified product (independent if the complaints are coming from the Licence Holder or the field). On a regular basis the Manufacturer shall review whether the complaints received are related to single errors or system errors. All decisions and corrective actions taken shall be recorded. The originator of the complaint shall be informed about the handling and the result of the complaint.

5.15 Certified Products and Changes to Certified Products

The Manufacturer shall have available all relevant information about the construction of the certified product. The information shall be provided and controlled by the Licence Holder.

The information could contain e.g. Drawings, Parts List, Product Description, Reference Sample, Photo-documentation, other specification as applicable.

Changes to certified products are only allowed after approval by the certification body.

The Licence Holder shall inform the certification body about changes to the certified product and get approval prior to implementation. The Licence Holder shall inform the Manufacturer about those changes approved.

The Manufacturer shall not make changes to the certified product without permission from the Licence Holder. This shall be described in a procedure and/or all personnel involved shall be aware on how changes to certified products are managed.

5.16 Selection and Shipping of Re-Examined Sample(s)

If required by the Certification Body the Manufacturer shall assure that re-examination samples can be selected by the Inspector from the production line or from stock. If the re-examination sample(s) are not transported by the Inspector the Manufacturer shall assure that no modifications are made to the sample(s) selected and shall send the samples to the Certification Body in accordance with the Certification Body's requirements.

***NOTE**:*
Sample selection for conformity control is an essential aspect for some certification bodies. Therefore the individual requirements have to be followed.

6 FACTORY INSPECTION DOCUMENTS

Manufacturers should be made aware by the Licence Holder of the report forms and guidance documents used within the Harmonized Inspection Scheme.

***NOTE**:*
Current editions of the OSM-FIP Documents can be found under the following path: www.eepca.eu → Document Server → OSM-FIP Public Documents → Permanent and Operational Documents.

6.1 CIG 021: Factory Inspection Procedures – Harmonised Requirements

This document defines the responsibilities of the Licence Holder and the Manufacturer within the Harmonized Inspection Scheme.

6.2 CIG 022: Pre-Licence Factory Inspection Questionnaires

Section A: This document is to be used by Certification Bodies to request factory inspection service from other ECS member bodies.

Section B.1: This document is to be used to obtain information about the Licence Holder.

Before making the Pre-licence Inspection in the factory this Part is to be completed by the Licence Holder. The completion should be made in considerable detail, particularly with reference to paragraphs 1.4 (if the Licence Holder and the Manufacturer are not the same).

Section B.2: This document is to be used to obtain information about the Manufacturer.

Before making the Pre-licence Inspection in the factory this Part is to be completed by the Manufacturer. The completion should be made in considerable detail, particularly with reference to paragraphs 2.5 and 2.6 (where inspection and test sampling rates and limits for test parameters are to be given in detail).

6.3 CIG 023: Factory Inspection Report

This report is completed by the Inspector either during Pre-licence inspections or during Routine inspections. Completion of this report during the Pre-licence inspection will take into account the information given in CIG 022 Section B.1 and B.2.

Member bodies may use an alternative format/layout of the CIG 023 Factory Inspection Report, however the issuing body must assure and declare that the content of the inspection report is identical to the official approved version.

6.4 CIG 023 – Appendix 1: Signature Page

This Appendix is to be used only if the CIG 023 Factory Inspection Report is electronically completed and no copy can be printed.

6.5 CIG 023 – Appendix 2: Additional Quality System Requirements for ENEC Agreement

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 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.

6.6 CIG 024: Factory Inspection Procedures Guidance to Certification Bodies, Inspectors, Manufacturers and Licence Holders

This document has been established in order to provide information and guidance to Certification Bodies, Inspectors, Manufacturers and Licence Holders about the requirements of the Harmonized Inspection Scheme.

6.7 Current OSM-FIP Decisions

These documents contain the decisions of the committee in charge with the development of the requirements for the Harmonized Inspection Scheme (ECS-OSM-FIP – Operational Staff Meeting for Factory Inspection Procedure). These decisions have the status of requirements within the scheme and shall be applied during its application.

***NOTE**:*
Current editions of the OSM-FIP Decisions can be found under the following path: www.eepca.eu → Document Server → OSM-FIP Public Documents → Decisions.