

**Factory Inspection Procedures  
Harmonised Requirements**

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

Approved by:	ECS General Meeting, 22/23-04-2009	Nr of pages: 11
Date of issue:	May 2009	Incl. Annexes A and B
Supersedes:	PD CIG 021 - June 2004	Page 1 of 11

# 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 has to 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 (PD CIG 023) has to 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.

To verify that the conditions for the production of certified products are given to the effect that a uniform manufacture can be expected, inspections are to be conducted even in cases where certified products are not presently in production.

### **2. Definitions**

The terms used in this document have the meanings defined in ISO 9001:2000 except for:

#### **2.1 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.

#### **2.2 Manufacturer**

Any manufacturing organisation or person (including subcontractors and outworkers) responsible for the final assembly, testing and/or marking of products certified by an ECS member Certification Body.

#### **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.

## **2.5 Licence Holder**

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

## **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 once per year unless otherwise indicated in document OD ECS 026 or similar document of individual ECS members' certification schemes to ensure that the necessary routines and procedures are being maintained at an acceptable standard. 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.

It is the responsibility of the Licence Holder to notify the Certification Body of any change of factory location of the certified product.

## **4. Manufacturer's Responsibility**

### **4.1 General Information**

It is the Manufacturer's responsibility to ensure that the complete production process of the certified products continuously complies with the ECS requirements as stated in this document.

The manufacturer shall exercise adequate control (e.g. by inspection or otherwise) 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.

At least the following records 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

*Note: Records stored on computer or microfilm are acceptable*

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

Manufacturers shall ensure that all purchased materials, components and subassemblies comply with specified requirements. 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 Quality Plans and/ or 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 inspector or 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.

### **4.3 Production Control, Inspection and Routine Tests**

Production shall be inspected at appropriate stages of manufacture to ensure that piece-parts, components, subassemblies, wiring runs, workmanship, etc. are in accordance with the sample for which certification was granted. 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 a bearing on the safety of the finished product. The method of inspection 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 bearing 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 inspections, 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. See Annex A for guidance. Normally no further operations, except for marking and packing, may be carried out after these tests.

*Note: 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 inspection 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 inspections 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-inspected to the same requirements as applicable to new produced products.

### **4.4 Functional Check on Test and Measuring Equipment used for Safety Tests (Dummy Test)**

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.

As a minimum daily checks are recommended at the end of the daily production, 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. 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.

### **4.5 Products seen in Production during visit - Marking of products**

The Certification Mark shall be applied according to the regulations 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.

### **4.6 Calibration 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 measurements. Records of calibration/verification undertaken on the safety test- and measuring equipment and on reference equipment owned by the manufacturer shall be kept. The records should 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 a similar method providing the same level of information.

#### **4.7 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 (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.

#### **4.8 Product Verification Tests / Periodic Tests (PVT)**

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

The tests are carried out by the manufacturer or on its behalf with at least the frequency indicated and the test results shall be kept at disposal of the inspectors of the Certification Body.

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.

In selecting samples for periodic tests preference should be given to products whose characteristics are close to the limiting values and to tests relevant for safety considerations according to the relevant standard.

These tests are performed according to 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 standardised or may not be required for certain product categories, if the relevant Technical Committee so decides. See Annex B for guidance.

*Note: Unless decided otherwise by the relevant Technical Committee, National Certification Bodies' specifications apply.*

In cases where there are no certification body and/or certification scheme requirements it is up to the Manufacturer to determine the need, nature and frequency of these tests and the sampling rate, taking into account the construction of the product, the nature of the standard, the results of the original type tests, inspections and routine tests, the quality control and the quantity of products manufactured. It is the responsibility of the Manufacturer to choose the appropriate methods. Product verification tests need not to be identical to the type tests specified in the relevant standard.

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 the Manufacturer's obligation is adequately fulfilled.

#### **4.9 Void**

#### **4.10 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.

#### **4.11 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.*

#### **4.12 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 comply with the requirements as given in this document. 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.

#### **4.13 Void**

#### **4.14 Customer complaints**

The Manufacturer shall record any technical complaint regarding the certified product. 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.

#### **4.15 Changes to Certified Products**

Constructional changes which may affect compliance with the relevant standard shall be notified, prior to its implementation on certified products, to the issuing Certification Body for their (prior) approval. 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.

The Licence Holder is also responsible to 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) shall be available at the Manufacturer's premises. It is to be assured that the Manufacturer shall not make changes to the certified

construction (including the application of alternative components) prior to permission of the Licence Holder.

#### **4.16 Selection and Shipping of Re-Examination 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.

### **5. Factory Inspection Documents**

Manufacturers should be made aware of the report forms and guidance documents used during ECS Factory Inspections.

#### **5.1 CIG 021: Factory Inspection Procedures - Harmonised Requirements**

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.

Annexes:

Annex A: Routine Tests

Annex B: Product Verification Tests / Periodic Tests (PVT)

#### **5.2 CIG 022: Pre-licence Factory Inspection Questionnaire**

Section A: To be completed by the Certification Body requesting the visit.

Section B: Before making the Pre-licence Inspection in the factory this section is to be completed. Part B.1 is to be completed by the Licence Holder; part B.2 is to be completed by the Manufacturer. The completion should be made in considerable detail, particularly with reference to paragraphs B.1.4 (if the Licence Holder and the Manufacturer are not the same) and B.2.5 and B.2.6 (where inspection and test sampling rates and limits for test parameters are to be given in detail).

#### **5.3 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 previous information given in PD CIG 022 Section B and this will be compared with the situation observed in the factory. The intention of completing this report during the routine inspection is to verify that compliance with the test and quality assurance procedures continues throughout the period for which the CCA Bodies' Certification is in force.

#### **5.4 CIG 023 Appendix 1: Signature Page**

This Appendix shall be used if the PD CIG 023 factory inspection report is completed electronically and a hand written signature of the inspector and the contact person is required.

## **5.5 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

## **5.6 CIG 024: The Conduct of Factory Inspections**

This document has been established in order to provide information and guidance to Certification Bodies, Inspectors, Manufacturers and Licence Holders on how factory inspections are conducted.

## **5.7 Current OSM/FIP Decisions**

The inspector shall make reference to current OSM/FIP decisions, if relevant.

## Annex A

### ROUTINE TESTS

<b>Product Category</b>	<b>Product examples</b>	<b>Requirements for common Certification Marks</b> <i>The routine test requirements are contained in the standards listed below. Note also that there may be additional requirements from individual certification bodies.</i>
Components	Controls (EN 60730)	EN 50344-1:2002
	Switches	EN 61058:2008 Annex R
	Low voltage switchgear (EN 60439)	EN 60439:1999, Cl. 8.3
	Plugs/ port. socket outlets	IEC 60439-1:2008 incl. Annex A1
	Low voltage switchgear (EN 60947)	EN 60947:2004, Cl. 8 (EN 60947:2007 Cl. 8.1.3)
	Other components	CB requirements
Household Appliances	All types	EN 50106:1997+A1:1998 +A2:2001
Hand Held Motor Operated Electric Tools	Hand held electrical tools Transportable electrical tools	EN 60144-1:1998 Annex E EN 60745:2006 Annex N
Battery Powered Tools	All types	EN 61029-1:2000 Annex ZA EN 50260:2002 (Annex E)
Insulating and Safety-Insulating Transformers	All types	EN 61558-1:2005 (Annex L)
Luminaries	All types	EN 60598-1:2004 (Annex Q)
Electronic Equipment	Audio and video equipment	EN 60065: 2002 (Annex N)
	Laboratory equipment	EN 61010-1:2001 Annex F
	Other equipment	CB requirements
Information Technology Equipment incl. Electrical Business Equipment	All types	EN 50116:2006
UPS (EN 62040-1-1: 2003)	Operator access	CB requirements
	Restricted access	CB requirements
Medical Equipment	All types	EN 60601:1990 incl. Am. 1,2,12 and 13 Cl. 4.1 (recommendations)
All within ENEC scheme	All types	For ENEC mark - PD ENEC 303

## Annex B

### PRODUCT VERIFICATION TESTS / PERIODIC TESTS (PVT)

<b>Product Category</b>	<b>Product examples</b>	<b>Requirements for common Certification Marks</b> <i>Note that there may be additional requirements from individual certification bodies.</i>
Components	All types	Under consideration by the relevant Technical Committee
Household Appliances	All types	None required As determined by CLC/TC61
Handheld Motor Operated Tools	All types	Under consideration by the relevant Technical Committee
Insulating and Safety-Insulating Transformers	All types	Under consideration by the relevant Technical Committee
Luminaries	All types	Under consideration by the relevant Technical Committee
Electronic Equipment	All types	Under consideration by the relevant Technical Committee
Information Technology Equipment including Electrical Business Equipment	All types	None required As determined by CLC/TC74
Medical Equipment	All types	Under consideration by the relevant Technical Committee
<b>Product category</b>	<b>Product examples</b>	<b>Requirements for other marks</b>
All within ENEC scheme	All types	For ENEC mark - PD ENEC 303