ETICS	**OPERATIONAL DOCUMENT**	**CIG 024**

Factory Inspection Procedures
Guidance to Certification Bodies, Inspectors, Factories and Licence Holders

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

Draft rev1

Change:

Part IV clause 1.2
"Enter the actual name and factory address. Give enough information to identify the ~~Factory~~ License Holder."

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THE CONDUCT OF FACTORY INSPECTIONS

INTRODUCTION

This document has been produced to provide help and guidance to Certification Bodies, Inspectors, Factories and Licence Holders on how Factory Inspections are conducted. Under the CCA procedures, irrespective of which Certification Body undertakes the inspection, the procedures whereby Certification Bodies have factories inspected and Inspectors undertake this inspection are the same throughout CCA.

The following documents are currently used within the Harmonized Inspection Scheme:

- **OD CIG 021 –** Factory Inspection Procedures Harmonised Requirements
- **OD CIG 022 – Section A** Request of Inspection to be Completed by The Certification Body Requesting Visit
- **OD CIG 022 – Section B1** Pre-Licence Factory Inspection Questionnaire to be Completed by The Licence Holder
- **OD CIG 022 – Section B2** Pre-Licence Factory Inspection Questionnaire to be Completed by The Factory
- **OD CIG 023 –** Factory Inspection Report
- **OD CIG 023 – Appendix 1** Factory Inspection Report Appendix 1 - Signature Page (Part 1) - Inspection Summary Page (Part 2)
- **OD CIG 023 – Appendix 2** Additional Quality System Requirements for ENEC Agreement
- **OD CIG 023 – Appendix 3** Additional Requirements for ENEC+ Agreement
- **OD CIG 023 – Appendix 4** Inspectors Finding/Observation Sheet - Part 2 and Part 3
- **OD CIG 024 –** Factory Inspection Procedures Guidance to Certification Bodies, Inspectors, Factories and Licence Holders

Current editions of the OSM-FIP Documents can be found under the following path:

https://www.etics.org/doc/ Document Server/ ECS Public Documents/ Permanent and Operational Documents.

The document has been divided into four parts:

Part I: Advice to the Licence Holders and Factories

Part II: Part II-1: Guidance to Licence Holders on completing Form **OD CIG 022 – Section B.1** Pre-Licence Factory Inspection Questionnaire to be Completed by The Licence Holder

Part II-2: Guidance to Factories on completing Form **OD CIG 022 – Section B.2** Pre-Licence Factory Inspection Questionnaire to be Completed by the Factory

Part III: Guidance to Certification Bodies on completing Form **OD CIG 022 – Section A** Request of Inspection to be Completed by The Certification Body Requesting Visit

Part IV: Guidance for Inspectors undertaking Factory Inspections and completing form **OD CIG 023 –** Factory Inspection Report

Parts I and II are of immediate concern to Factories and Licence Holders, since they offer advice and guidance on actions which the Factories/Licence Holders shall take.

Parts III and IV are for Certification Bodies. However, they may be sent to the Licence Holder and/or the Factory on request to inform them of the instructions given to Factory Inspectors so that the Licence Holder and/or the Factory understands what the Inspector is looking for during the inspection.

Clarification:

Part I This gives general advice and information to the Licence Holder and the Factory on the overall procedures for Factory Inspections.

Part II This gives information to the Licence Holder and the Factory on how to complete OD CIG 022 Section B.

When a Licence Holder advises a Certification Body that he intends to have a certified product manufactured in a factory that has not previously been inspected, the document OD CIG 022 Section B.1: Questionnaire needs to be completed.

The Certification Body processing the approval application is responsible for ensuring that it attaches a copy of the OD CIG 024 (at least Part II-1 and Part II-2) to each OD CIG 022 Section B: Questionnaire sent.

The Licence Holder needs to answer the questions in Section B.1 and forward the Section B.2 to his Factory for completion.

For each individual Factory a separate questionnaire shall be filled.

As the whole of the factory inspection system depends upon this initial questionnaire being completed fully and accurately, much time can be saved by the Licence Holder, the Factory and the Certification Body, if this form is filled in correctly the first time and returned promptly to the requesting Certification Body.

Part III It is the common policy that the Factory Inspection is conducted by the inspection body in the country in which the Factory is located. Part III describes the document used by the Certification Body to request the inspection body in another country to perform an inspection of a factory location on its behalf. This part is primarily the concern of Certification Bodies.

Part IV This part gives instruction to Inspectors. It gives detailed information on what the Inspector should be looking for and how he is to make the assessment. The aim of Part IV is to ensure that, irrespective of which inspection body conducts the Inspection, the same criteria are used to assess whether the factory meets the Minimum Harmonised Requirements set down by the OD CIG 021.

In the context of the CIG-Inspection Scheme the factory surveillance is an assessment of a production line within the process of a product certification. It is not an audit of a management system. Furthermore, a factory surveillance can take place announced and unannounced. From the view point of quality assurance, a factory shall be always able to produce in a requested, stable quality, regardless of present contact persons and/or pre-announced audit plan. The focus of a factory surveillance is to ensure that all certified products are identical, within accepted manufacturing tolerances, to the sample against which the product certification was granted (certified version).

FACTORY INSPECTIONS

Part I: Advice to Licence Holders and Factories

INTRODUCTION

The following instructions have been established to help Licence Holders and Factories understand and correctly interpret the basic requirements of Certification Bodies when preparing for inspection.

CONDUCT OF THE INSPECTION

The inspection will be conducted during normal working hours.

The Factory's representative or his deputy should be available within a reasonable time after being contacted from reception.

The Certification Body, and hence the Inspector, is to be given full access to the Factory's premises so that compliance with the requirements of the OD CIG 021 can be verified.

Also, the Factory shall give full co-operation throughout the inspection.

Any unwarranted or personal criticism or lack of co-operation by the Factory may be reported to the requesting Certification Body(ies).

Inspectors will be aware that they are at all times acting as representative of the requesting Certification Body(ies) and they, in their turn, are expected to behave accordingly.

At the end of the inspection, it will be helpful that the Inspector be given an appropriate place where he can complete his inspection report, since he is requested to complete the report and hand a copy thereof to the Factory's representative before he leaves the factory.

INSPECTOR'S RESPONSIBILITIES

The Inspector shall establish that the Factory keeps and has in operation a quality system, which guarantees that products leaving the factory are at all times complying with the relevant requirements.

To be able to verify the Factory's ability to comply, it is essential that the Inspector visits all areas necessary (such as receiving, in-process and final inspection, and laboratories etc.). When planning and conducting such an inspection, the Inspector has to have allocated enough time so as to be able to conduct a thorough job.

Special care as to testing and record keeping will be taken where product or parts thereof have been manufactured or assembled at Subcontractors or Out-Workers.

It is emphasised that confidentiality of all information gathered at a Factory shall be maintained.

If a Factory is producing products for more than one Licence Holder and an inspector's finding does not apply to all Licence Holders a separate OD CIG 023 Inspection Report might be completed for each Licence Holder individually as per request of the contact person (see OD CIG 023 Cl. 17.3).

SCHEDULING INSPECTIONS

The frequency and period of inspection visits are, as far as possible, scheduled in accordance with the wishes of the requesting Certification Body(ies).

Pre-Licence inspections shall be announced and arranged with the Factory to assure that all persons involved are 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 Factory, an inspection may need to be imperatively carried out un-announced.

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

FACTORY INSPECTIONS

Part II-1: Guidance to Licence Holder on completing Form OD CIG 022: Questionnaire Section B.1

> ***NOTE**:*
> *The "Factory Inspection Procedures – Harmonized Requirements" are referred to as OD CIG 021 in this document.*

Section B.1 shall be filled out by the Licence Holder.

The completed questionnaire has to be returned to the requesting Certification Body before the Pre-Licence inspection may be scheduled.

Complete and accurate information will enable a proper evaluation to be carried out and thus avoid a possible repetition of the Pre-Licence inspection, additional costs and a delay in granting the Certification Mark.

B.1.1 The Licence Holder is the company who signs the certification agreement with the Certification Body. The Licence Holder may be different from the Factory.

The Licence Holder's representative is the key-person having the contacts with the Certification Body.

B.1.2 List the kind of product (family name, e.g. vacuum cleaner), all brand and/or trade names and type references/model designations of the product(s) intended to be marked with the Certification Mark.

B.1.3 Enter all the Certification Mark(s) intended to be applied on the product(s) and other requested information if available.

B.1.4 The purpose of this item is to demonstrate in which way it is assured that constructional changes of the certified product will be made only after approval by the Certification Body.

1) Self-explanatory
2) Self-explanatory
3) 'YES', if the Licence Holder is responsible for the production quality system at the factory.

   'NO', if the factory is producing according its own quality system, even when the Licence Holder verifies the functioning of this quality system.
4) 'YES', if the Licence Holder has a contract with the factory that (at least) covers the items 1), 2) and 3) above.

   'NO', if there is no contract covering the items 1), 2) and 3) above.

   Also 'NO', if the factory belongs to the same company as the Licence Holder. In this case it should be stated that the factory and the Licence Holder belong to the same company.

> ***NOTE**:*
> *Where this paragraph refers to a quality system, this quality system might be but does not need to be a certified quality system.*

B.1.5 Section B.1 of this document shall be verified and signed by an authorised management representative of the Licence Holder.

FACTORY INSPECTIONS

Part II-2: Guidance to Factory on completing form OD CIG 022: Questionnaire Section B.2

***NOTE**:*
The "Factory Inspection Procedures – Harmonized Requirements" are referred to as OD CIG 021 in this document.

Section B.2 shall be answered by the Factory.

The completed questionnaire has to be returned to the requesting Certification Body before the Pre-Licence inspection may be scheduled.

Complete and accurate information will enable a proper evaluation to be carried out and thus avoid a possible repetition of the Pre-Licence inspection, additional costs and a delay in granting the Certification Mark.

B.2.1 Actual factory location and geographical (street) address.

Please also provide local street map or sketch, best mode of transportation, parking facilities etc.

B.2.2 The contact person is the key-person to guide the Inspector through the factory. The contact person shall be familiar of the quality system and product certification requirements and have full access to all relevant information and facilities.

It is necessary that at least one deputy contact person is nominated. A deputy contact person shall be available in case of absence of the contact person.

The management representative is the person at the Factory responsible for the certified product. This may or may not be the contact person.

B.2.3 Self-explanatory

B.2.4 Give the total number of employees including temporary workers in the company.

Provide also the number of employees engaged in the production of certified products. Approximate numbers will do.

***NOTE**:*
This information is useful in order to enable the Inspection Body to estimate the time necessary for carrying out the inspection.

B.2.5 Specify the materials, components and sub-assemblies which are critical/have a safety implication on the finished product:
– specify the supplier(s) of these materials and/or components,
– indicate which components are certified and bear which Certification Mark(s),
– specify which sub-assemblies are received from which sub-contractor(s).

B.2.6 Complete and accurate information is needed for all products intended to be certified.

This is to allow the Inspector to satisfy himself with the Factory's quality system, as:
a) if written or documented procedures exists, it may prove helpful to attach copies of the relevant procedures.
b) if no written or documented procedures exists or cannot be made available to the requesting Certification Body, then the various stages of control, inspection and testing shall be described in chronological order.

Information should be detailed under the following headings:
- Incoming Inspection and Testing
  describe visual checks, tests, sampling procedures, acceptance criteria and/or all other verification methods (e.g. Certificate of Conformity).
- In Process Inspection and Testing:
  same as above, indicate whether the inspections and tests are 100 % production

line tests and/or random inspections and tests.

- Routine Tests (Cl. 5.3 of OD CIG 021):
  Specify the type of test, the test frequency, the applied test values, the tripping limit (= the max. and/or min. value) and testing time.

  A typical example for routine tests for a microwave oven might be:

Earth continuity	100 %	25 A a.c.	R<0,1 Ohm	3 s
Insulation resistance	100 %	500 V d.c.	R>2 MOhm	3 s
Dielectric strength	2 %	1375 V a.c.	0,3 < I < 5 mA	2 s
Input power	1/batch	230 V a.c.	1375 W <P<1450 W	N/A
Microwave leakage	100 %	mains supply	< = 3 mW/cm^2	5 s

- Product Verification Tests/Periodic Tests (PVT) (Cl. 5.8 of OD CIG 021):
  State which additional tests are performed on samples randomly selected from the production and/or stock, to verify the quality of the product and compliance with the certification standard.

  Specify the sampling rate, the type of test(s) performed (including the applied test values, tripping limit and test time) and the location where these tests are performed.

B.2.7 As far as applicable, specify by which other Certification Body(ies) the product has already been certified/which other certification marks are already applied to the product. State 'None' if no other product certifications for the product(s) to be certified exist.

> ***NOTE**:*
> *This questionnaire is used for preparation/organisation of a Pre-Licence Inspection. It might be that this Pre-Licence Inspection can be waived, based on already existing certification of the product.*

B.2.8 Details shall include type of standard, scope, name of certifier and expiry date of certificate or provide a copy of appropriate certificate.

B.2.9 Self-explanatory

B.2.10 Section B.2 of this document shall be verified and signed by an authorised management representative at the factory where the product is or will be produced.

FACTORY INSPECTIONS

Part III: Guidance to Certification Bodies on completing form OD CIG 022: Questionnaire Section A

Completion of Section A is the responsibility of the requesting Certification Body.

A.1 Name of Certification Body requesting the inspection and its file reference number.

A.2 Name of Certification Body, Inspection Body or Authorised Agent requested to perform the inspection.

A.3 Actual factory location and geographical (street) address. Include name and function of contact person as given in OD CIG 022, Section B.2, items B.2.1 and B.2.2

A.4 Licence Holder name and address

A.5 Use the product category abbreviation as commonly used within CCA.

> ***NOTE**:*
> *Current list of abbreviations of Product Categories can be found under the following path:* www.etics.org → *Document Server* → *OSM-FIP Public Documents* → *Decisions.*

Also give the product type, name and indicate type number or family series as practical.

A.6 Make reference to applicable standards: EN, HD, IEC or national standards.

A.7 Define clearly which Certification Mark or attach reference copy of mark. Refer to OD CIG 022, Section B.1, item B.1.3.

A.8 Provide number of Routine Inspections per year after the certification has been granted.

For Routine Inspections separate orders are to be issued.

A.9 Make reference to applicable documents or document list.

Under “other information” details are to be given regarding:
- test requirements;
- test equipment;
- sample selection;
- shipping instructions;
- billing instructions.

A copy of the completed OD CIG 022 Section B.1 and B.2 is to be attached to this OD CIG 022, Section A. If for special reasons the requesting Certification Body cannot provide the questionnaire OD CIG 022 Section B.1 and/or B.2, specify reason and give special instructions.

Enter date of issue of request.

The authorised representative of the requesting Certification Body shall sign this document.

FACTORY INSPECTIONS

Part IV: Guidance to Inspectors undertaking Factory Inspections on completing form OD CIG 023: Factory Inspection Report

PRE-LICENCE INSPECTION

Completion of the report serves as a proof that the information given in OD CIG 022 Section B.1 and B.2 is correct and that the quality system and the testing procedures as applied by the Factory will ensure the compliance with the requirements of the requesting Certification Body(ies).

The visit has to be pre-announced to ensure that the contact person, knowledgeable of the quality system is available.

The Factory shall be made aware that at the time of the visit all relevant documentation and test equipment shall be available and ready for inspection.

ROUTINE INSPECTION

Completion of the report serves as a proof that the quality system and test procedures, as found during the Pre-Licence Inspection, are still maintained and are in compliance with the current requirements of the requesting Certification Body(ies).

GUIDANCE TO INSPECTOR ON COMPLETING FORM OD CIG 023:

***NOTE**:*
The Inspectors are requested to write the report in a legible manner.

"Inspection carried out by (Inspection Body) ....." : Enter name of your inspection organisation.

Reference number of the body carrying out the inspection: Enter the reference number used by your organisation. This reference number shall be a unique reference number. In the case the reference number is based on the file number of the Factory e.g. a year/date code of the inspection visit is to be added.

The reference number has to be indicated at each single page.

Be sure to:

a) tick the boxes as appropriate;
b) explain clearly, and in each case, why you consider a question as 'N/A';
c) explain all 'NO' answers on the Inspectors Finding/Observation Sheet (Part 1) .

Records

The records need to be carefully reviewed.

The minimum period the Factory has to keep records shall not be less than the period between two inspections. The Factory shall state the retention period.

1 GENERAL INFORMATION

1.1 The address the Inspector should visit is given in OD CIG 022 Section B.2 under B.2.1.

Enter the actual name and factory address. Give enough information to identify the ~~Factory~~ License Holder.

1.2 Enter name and function of the Factory's representative; also, when the Factory's representative was not present during the inspection.

The Factory's representative is the person to whom correspondence on items related to factory inspections is to be send.

1.3 Enter name(s) and function(s) of the **main** people involved in this inspection

1.4 Tick box ☒ to indicate type of inspection(s). The inspection is considered basic if "Others" is not crossed.

Cross "Others" only for a re-inspection or, for example, for a special sample selection visit, etc. The type of special inspection is to be registered, including the reference to the request of the Certification Body.

1.5 This question is only applicable for Pre-Licence Inspections and needs not to be answered during Routine Inspections (Tick the N/A box).

In the case of a Pre-Licence Inspection check if the information given in OD CIG 022 Sections B.1 and B.2 is accurate and complete. If not, include the corrections in OD CIG 022 Sections B.1 and/or B.2 and attach a copy of this document to the inspection report.

1.6 Enter information as received from the requesting Certification Body(ies).

Example of how to fill out the table:

Certification Body requesting inspection	Inspection X of Y	File Reference No.	Category	Product
DEKRA	1 of 1	54818	HOUS	Hair Dryer
VDE	1 of 1	30004711/5158297	TOOL	Hand Held Drilling Machine

***NOTE**:*
Current list of abbreviations of Product Categories to be used to complete this table (and other locations within the OD CIG 023 Factory Inspection Report) can be found under the following path: www.etics.org→ *Document Server → OSM-FIP Public Documents → Decisions.*

1.7 Enter name of Inspector and date of inspection.

Remember to always complete the report in full, even if there is no production of certified products. All details about the testing, test equipment and calibration are equally important even if other products are in production.

1.8 Determine if relevant changes have been made to production since last factory inspection. Give details on Inspector's Information Page. Please, number the copies of factory documents and note attachment number in provided space.

If the inspection is a pre-license inspection, tick "N/A".

1.9 Determine if relevant changes have been made to company's organisation with impact to inspection since last factory visit.

If the inspection is a pre-license inspection, tick "N/A".

Give details on Inspector's Information Page. Please, number the copies of factory documents and note attachment number in provided space.

2 VERIFICATION OF PURCHASED COMPONENTS AND MATERIALS WHICH HAVE A SAFETY IMPLICATION ON THE CERTIFIED PRODUCT (INCOMING INSPECTION)

2.1 The Inspector has to look for procedures used by the Factory to ensure

compliance of materials, components and sub-assemblies. The personnel shall have clear instructions on what and how to perform checks. There shall be instructions as to which Certification Marks may have to appear on the components/products in order to accept them as to comply with the standards. (PD CCA 210 shows the various Certification Marks which may appear on a product or component).

2.2 Tick the box(es) that are applicable; ALSO, when question 2.2 is answered with 'NO'.

When the Factory performs an identification check, specify what is being checked.

When you tick the box "Others", specify what other method of verification is performed.

2.3 Self-explanatory

2.4 If a documented procedure exists please give reference.

If no documented procedure exists, the procedure in place shall be observed and described as found.

The Inspector's description of the procedure shall cover at least the following items:

- What action is taken by the Factory, if the components/materials fail the control requirements?
- Are the non-conforming components/materials clearly identified and/or segregated?
- What are the instructions as to the disposition of non-conforming components/materials?
- Does the system ensure that reworked components/materials are subjected to the control requirements again, before being released?
- Are non-conforming components/materials recorded?

2.5 Regarding this question the Inspector has to evaluate the procedure and to verify whether the procedure is sufficient.

The Inspector has to confirm that the applied procedure is satisfactory and will continue to be so. If the procedure applied is not satisfactory, please report details.

2.6 Self-explanatory
If the procedure applied is not satisfactory, please report details.

2.7 Self-explanatory
If the procedure applied is not satisfactory, please report details.

3 PRODUCTION CONTROL, MONITORING AND ROUTINE TESTS

3.1 Look for instructions and check if they are understood and followed by all personnel involved.

3.2 Is there sufficient information available to ensure that parts having an impact on the safety of the finished products are properly manufactured/assembled (mounted) and tested?

3.3 There shall be evidence that the production/assembly process is controlled in such a way that the finished products are identical to the certified version.

3.4 Make sure that no product can pass the 100 % Routine Test without being tested.

3.5 Self-explanatory

3.6 The completion of the routine test table is to be based on the tests witnessed or the test results recorded by the Factory.

Enter on the TEST DATA SHEET the routine tests witnessed (indicate 'W').

For tests not witnessed, the routine test records shall be reviewed, and data entered in the table (indicate ‘R’).

Use the free space to describe other tests applied.

If more than one product category or insulation class is inspected use separate test data sheets for each product category and/or insulation class.

For tests that could not be witnessed, the function of the test equipment is still to be verified (indicate in 4.1).

Example of how to fill out the table on TEST DATA SHEET – Routine Tests

TEST DATA SHEET – Routine Tests

☐ Production seen	☐ No production seen	Certification mark:	
Product Category:	Kind of product:	Rated voltage:	Electrical Insulation Class:
Type reference:		Certification Bodies Routine Test Requirement:	

TESTS		% check	Test value applied	Time	Factory limits applied:	Failure indicated by	Remarks	W / R
a	Earth continuity	100 %	12 V d.c. 10 A	2 s	0,2 Ohm Ohm (max.)	Instrument Lamp	Including resistance of the supply cord & plug	W
b	Insulation resistance	100 %	500 V d.c.	4 s	2 MOhm (min.)	Instrument		W
c	Leakage current	5 %	230 V a.c.		5 mA (max.)	Instrument		R
Dielectric strength	Basic insulation	100 %	1 000 V a.c.	2 s	30 mA (max.)	Instrument, Lamp Buzzer	Manual reset needed	W
Dielectric strength	Supplementary insulation	n/a	V	s	mA (max.)			
Dielectric strength	Reinforced insulation	n/a	V	s	mA (max.)			
e	Load deviation	100 %	230 V a.c.	5 s	+ 5 – 10 %	Instrument	(e) cold	R
f	Functional test	100 %	230 V a.c.			No Function	(f) yes	W
	Microwave leakage	100 %	230 V a.c.		50 W/m^2			W

e Indicate method used (hot/cold, at mains voltage, low voltage resistance check, etc.).
f Are all controls and components checked during the test?
W = Test witnessed by the Inspector; R = according to records

3.7 Check if the routine test procedure, performed by the Factory, complies with the routine test requirements received from the requesting Certification Body(ies).

Different certification bodies and/or different certification schemes may have different requirements.

3.8 If a documented procedure exists please give reference.

If no documented procedure exists, the procedure in place shall be observed and described as found.

The Inspector's description of the procedure shall cover at least the following items:

– What action is taken by the Factory, if the product fails a required test?
– Is the non-conforming product clearly identified and/or segregated?
– What are the instructions as to the disposition of non-conforming products?
– Does the system ensure that re-worked items are again subjected to appropriate tests/inspections?
– Are non-conforming products recorded?

Tick the box(es) that is (are) applicable, also when question 3.8 is answered with 'NO'.

3.9 Regarding this question the Inspector has to evaluate the procedure and to verify whether the procedure is sufficient.

The Inspector must confirm that the applied procedure is satisfactory and will continue to be so. If the procedure applied is not satisfactory, please report details.

The Factory shall provide visual identification of any non-conforming product. If special segregation areas are used, make sure that they are clearly marked as such.

3.10 In case of failures detected, verify that the Factory has a procedure which ensures that corrected items are again subjected to appropriate tests/examinations.

3.11 Record shall be legible and identifiable to the products and shall specify tests conducted.

3.12 Self-explanatory

4 FUNCTIONAL CHECK OF TEST AND MEASURING EQUIPMENT USED FOR SAFETY TESTS

4.1 The Factory must assure that the test equipment is functioning properly. The test equipment must give a failure indication when the test result is outside tolerances.

This verification is also to be performed in the case that there is no running production of the certified product(s).

The Inspector shall look for evidence that this verification is done properly; preferably by witnessing the verification.

4.2 Describe, by ticking a box, in which way the proper functioning of the test equipment is checked.

Verify that the procedure how to perform the functional test is available and understood by the operator(s).

If no written instruction is available, describe on Inspector's Information page how instructions are given and how understanding is verified.

4.3 Check if means are available to verify correct function of test equipment.

Ensure that also all wiring is included in the verification of the proper functioning of the test equipment.

4.4 The Inspector shall verify that the Factory has a system that ensures that no products are shipped to a client before the correct functioning of the test equipment has been checked.

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.

4.5 The simulated failure (dummy, if used) shall represent the tripping limits used by the Factory during testing of the certified product. Directly short cut of the test pins is not acceptable.

> ***NOTE***:
> *This does not apply to spark testers. This exception is based on the requirements given in the standard(s) for certification of wiring, cables and cords.*

4.6 Operators shall be instructed on what action to take if a test proves to be unsatisfactory.

The Inspector shall check that the operator clearly understands these instructions.

4.7 The Inspector shall verify that the Factory will identify all products checked since the previous dummy test and will test these products again before shipment to the client.

4.8 Check that corrective action is or will be recorded and include information of re-tested products.

4.9 Record shall include test equipment identity number.

4.10 Self-explanatory

5 PRODUCTS SEEN IN PRODUCTION DURING VISIT

If there is production, tick the respective box and provide the requested information.

If Certification Marks are not applied but nevertheless referenced in sales information, installation instructions, manuals, etc. please state accordingly.

If there is no production of certified products, indicate if similar products were manufactured and whether or not similar testing is applied.

For each product category and /or electrical insulation class that can be produced by the Factory a separate **TEST DATA SHEET – Routine Tests** table shall be completed.

6 CALIBRATION/VERIFICATION OF SAFETY TEST AND MEASURING EQUIPMENT

6.1 The Inspector shall check that the Factory maintains an effective calibration/verification program.

Whereat calibration means the process of establishing the relationship between test and measuring as well as reference equipment to the requirements as given in EN ISO/IEC 17025, as also defined in OD CIG 021, in clause 2.7.

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

Verification is the process of establishing the relationship between test and measuring equipment to the calibrated reference equipment.

The calibration/verification of the safety test and measuring equipment should preferably be performed at least once a year depending on usage and the results of previous calibration/verification. Less frequent calibration/verification need to be explained by the Factory to be appropriate e.g. by reasons of previous calibration/verification results (no trend shift) or other engineering considerations. Inspector needs to evaluate if this is reasonable.

6.2 This paragraph is covering the calibration of the reference equipment that is used for the verification of the test and measuring equipment, as far as this reference equipment is available with the Factory. (Information of the calibration/verification of the test and measuring equipment on the production line is to be given in cl. 6.1)

6.3 Where the Factory is using a method different from calibration labels, describe the method used.

6.4 All calibration/verification undertaken shall be traceable to national/international standards of measurement.

Records shall clearly identify the equipment and shall include as a minimum:
– date of calibration/verification
– test results (it is desirable that actual values be recorded – acceptance criteria shall be defined.)
– next date of calibration/verification
– action taken, if found to be out of calibration/verification

***NOTE**:*
Some NCBs require that records are signed.

6.5 Self-explanatory

6.6 Self-explanatory

7 HANDLING AND STORAGE

7.1 It is to be verified that the handling and storage of components and materials to be used for production will ensure that no damage/reduction of properties will occur. Attention is to be paid to e.g. identification, environmental conditions, Electrostatic Discharge (ESD); First In First Out (FIFO) principle.

7.2 The handling and storage of finished products shall ensure that these products will remain electrical and mechanical safe and will continue to comply with the applicable certification standard(s).

8 PRODUCT VERIFICATION TESTS/PERIODIC TESTS (PVT)

***NOTE**:*
Details of any non-required PVT should also be entered by the Inspector on the TEST DATA SHEET – Product Verification Tests/Periodic Tests (PVT).

8.1 Describe on the TEST DATA SHEET (PVT) what tests the Factory is performing in order to verify continuous compliance of the certified products with the relevant standard(s). Copy of the Factory's PVT record is also sufficient

Example of how to fill out the table on TEST DATA SHEET – Product Verification Tests/Periodic Tests (PVT)

TEST DATA SHEET – Product Verification Tests/Periodic Tests (PVT)

CB	Product, Sampling rate, Standard's clause or Test-parameters, Results
LCIE	PVT not required but performed by the Factory.
	Hair dryer, type ER4, one unit per type per year from running production
	Tests acc. to EN 60335-1: Marking, protection against electric shock, mechanical strength, creepage distances, clearances.
	Verification of components with originally approved versions
	Dielectric strength test for class II – accessible metal parts against live parts 2 500 V a.c. 60 s
	Abnormal operation: blocking air outlet – functioning of thermostat
	Tests performed in Factory's own laboratory
	No ongoing testing during visit, however records show that tests were satisfactory.

8.2 Self-explanatory

8.3 Verify if specific equipment required by any Certification Body is available and tick the relevant box. If the equipment could not be seen, for example because it was located elsewhere than at the factory, then this shall be noted on the Inspector's Information page.

8.4 Self-explanatory

8.5 Verify that a procedure exists to take corrective actions if deviations are found.

Check if these corrective actions are sufficient.

In case no actions are taken or if you are in doubt about the actions taken, specify on Inspectors Finding/Observation Sheet (Part 1).

8.6 Self-explanatory

8.7 Self-explanatory

9 VOID

10 UNSATISFACTORY FINDINGS FROM PREVIOUS INSPECTION - FOLLOW-UP

10.1 Self-explanatory

10.2 The Inspector shall verify that any unsatisfactory findings found during the last inspection and entered in the last inspection report were corrected sufficiently. If no or insufficient corrections were introduced, then this shall be reported on the Inspectors Finding/Observation Sheet (Part 1).

The Inspector shall be convinced that any corrective action(s) taken by the Factory are acceptable to the Certification Body concerned.

11 QUALITY MANAGEMENT SYSTEM

Please, mention the name of the organisation which assessed or certified the Factory.

State type and issued date of the certification.

***NOTE**:*
Combined inspections/audits can be organized if the Quality System of the Factory is audited by the same organization as the Body carrying out the subjected factory inspection.

12 FACTORY'S SELF-ASSESSMENT OF THE PRODUCTION AND CONTROL PROCESS OF CERTIFIED PRODUCTS

12.1 The Inspector shall verify that the Factory has a system which will ensure that all tests/inspections/procedures are followed and are effective.

12.2 If records could not be examined, for example because they were located elsewhere than at the factory, this shall be noted on the Inspector's Information page. In that case tick "NO".

12.3 Self-explanatory

12.4 The Inspector shall verify the records of Factory's self-assessment on non-conformities and the way these non-conformities have been handled.

The Inspector shall also verify the actions taken on the non-conformities found.

13 VOID

14 TECHNICAL COMPLAINTS

14.1 Self-explanatory

14.2 Check if the management reviews technical complaints.

14.3 The records need to be carefully reviewed.

14.4 Self-explanatory

14.5 Self-explanatory

14.6 Self-explanatory

15 CERTIFIED PRODUCTS AND CHANGES TO CERTIFIED PRODUCTS

15.1.1 Specify in which way the Factory has information regarding the construction of the certified product(s) available.

15.1.2 Evidence that the reference is controlled by the Licence Holder shall be by signature or other methods that link the reference to the Licence Holder.

15.2.1 Verify if any changes have been made to the certified version since the previous inspection.

Tick the 'YES' or 'NO' box accordingly and note any statement of the Factory concerning this issue.

If the answer is 'YES', please answer 15.2.2.

If the answer is 'NO', tick 'N/A' for 15.2.2. This is not a non-conformity and need not to be handled as such.

15.2.2 If the answer to 15. 2.1 1 is 'YES' verify that these changes have been made with the written authorisation of the Certification Body and the Licence Holder.

If the answer to 15. 2.2 is 'YES' give details on the Inspectors Informative page and/or provide objective evidence.

If the answer to 15. 2.2 is 'NO' specify the changes made on the Inspectors Finding/Observation Sheet (Part 1). In this case the scoring of the Inspectors evaluation according to 17.2 cannot be better than 3 "Major unsatisfactory findings"!

15.3 The Inspector has to verify that the applied procedure is satisfactory and will continue so.

15.4 Self-explanatory

16 SELECTION AND SHIPPING OF RE-EXAMINATION SAMPLE(S)

Number of samples to be selected is normally specified on the OD CIG 022, Section A or on the Certification Bodies factory inspection specifications.

Be sure to verify this information carefully, since selection and testing of re-examination samples can be an essential aspect of the product certification of the requesting Certification Body.

If the factory surveillance is conducted for the ENEC Scheme, the mandatory process OD ENEC 324 Annex C shall also be applied.

Give information about where samples were selected and how they are transferred to the Certification Body by using code letter.

> ***NOTE**:*
> *Some NCBs do not require their Certification Marks to appear on the product – Samples still need to be selected if shown on their certification lists.*

All comments related to the selected sample(s) shall be stated in the table "Sample Selection Sheet" This may include information about changes made to the product, suspected misuse of the Certification Mark, etc.

16.1 If no sample selection is made explain the reason why by using the tick box.

16.2 When a sample not bearing the Certification Mark is selected, explain why the sample was selected by using the tick boxes. At least get Factory's confirmation that the selected sample is identical to the certified product.

Care is to be taken when products are not marked but references are given in sales pamphlets, installation instructions, manuals, etc. Follow the individual Certification Bodies guideline if in such cases samples without any Certification Mark applied need to be selected.

17 INSPECTOR'S EVALUATION

17.1 All unsatisfactory findings shall be recorded. The Factory may propose suggestions as to how it intends to correct the non-compliances identified. Please, note also such commitments. Where appropriate, the Licence Holder shall also confirm the proposed corrective actions he intends to take to the requesting Certification Body in writing.

Report the findings requiring corrective actions and observations on the **'Inspector's Finding/Observation Sheet (Part 1)'**.

Finding

A finding is a nonconformity found during a factory inspection, thus a non-fulfilment of a requirement. The findings are given as:

- Minor unsatisfactory finding
- Major unsatisfactory finding. Safety not directly affected

Special or early routine inspection may be recommended for checking corrective action.

- Critical unsatisfactory finding. Safety directly affected

Certification refused/suspended and repeated factory inspection recommended after the factory has confirmed implementation of corrective action.

Observation

An observation is an occurrence found during a factory inspection, not as severe as a finding. Hence, an observation identifies an opportunity for potential improvement, enough to be communicated on OD CIG 023 "Inspectors Finding/Observation Sheet" (Part 1) to the certification body requesting the factory surveillance.

An example for an observation is the following situation:

A certification body or certification scheme is requiring sampling during the factory inspection, but due to no production and no stock it is not possible to select samples. This is a violation of the requirement and shall result in a nonconformity for the certification body requirements or certification scheme but not for the factory. The factory cannot correct the lack of a missing client order. The "observation" adequately addresses the occurrence to the certification body.

Report general matters such as change of address, name change, etc. on the page entitled **'Inspector's Information page'**.

> ***NOTE**:*
> *Use separate Inspector's Finding/Observation Sheet (Part 1) and/or Information Pages for different Certification Bodies and/or Licence Holders if necessary; e.g. for reasons of confidentiality.*

17.2 Inspector's Recommendations:

Ticking of any box is based entirely on the Inspector's judgement.

Any resulting consequences shall be notified by the requesting Certification Body to the Licence Holder/Factory and the Inspection Body in writing.

If a limited number of major unsatisfactory findings, where safety not directly affected, is reported and where in the Inspector's judgement an early routine inspection is not necessary, then the Inspector may cross out "early routine inspection recommended".

17.3 Tick boxes for listed attachments that are included and number of the attachment pages.

General remarks:

The Factory shall be made aware of the contents of the report.

The Inspector is required to give a copy to the Factory's contact person who shall sign for the receipt.

Time in factory: state number of hours spent in factory.

Any matter which may be of an informative character shall be recorded on the Inspector's Information page.

This may include:

- technical matter discussed during the visit;
- matters to be checked in greater details during the next inspection visit;
- how and where the Certification Mark is applied;
- Factory's working hours, holidays or closing days.

OD CIG 023 - Appendix 1: Signature Page (Part 1); Inspection Summary Page (Part 2)

This Appendix, with its Part 1 and Part 2, is to be used if the CIG 023 Factory Inspection Report is electronically completed and no copy can be printed and/or if the Certification Body request an Inspection Summary Page to be completed.

Signature Page (Part 1) and Inspection Summary Page (Part 2) might be used individually (part 1 or part 2), combined (part 1 and part 2) or combined with CIG 023.

OD CIG 023 - Appendix 1: Signature Page (Part 1)

The OD CIG 023 – Appendix 1 Signature Page (Part 1) is actually an extract of section 17 of OD CIG 023. Hence, the instructions from section 17 do apply here accordingly.

The inspector and the factory's contact person shall sign the page 2 as well. Two copies might be prepared: one for the factory and one for documentation of the factory inspection.

OD CIG 023 - Appendix 1: Inspection Summary Page (Part 2)

The use of this appendix is optional. If the certification body asks for the inspector shall prepare the needed copies. This part 2 is like part 1 an extract of section 17 but supplemented with the general information and items 1.4, 1.6 and 16.1. Accordingly, the instructions to fill out are the same as the ones for OD CIG 023.

OD CIG 023 - Appendix 2: Additional Quality System Requirements for ENEC Agreement

This Appendix is to be used if all the following conditions apply to the factory:
– 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.

Under "NOTE" a guideline is given to the inspector to fill out this appendix. The inspector shall be familiar with EN/ISO 9001. In the clauses references to ISO 9001 are given to support the inspector.

The clauses of this appendix are self-explanatory regarding the required information.

OD CIG 023 – Appendix 3: Additional Requirements for ENEC+ Agreement

This appendix is only to be used if the factory produces luminaires equipped with LEDs which are ENEC certified products in conjunction with IEC performance standards.

The “NOTE” contains instructions for inspector how to complete this appendix.

The clauses of this appendix are self-explanatory.

OD CIG 023 – Appendix 4: Inspectors Findings/Observation Sheet Part 2 and Part 3

The Inspectors Findings/Observation Sheet (Part 1) is an integral part of OD CIG 023 “Factory Inspection Report”. The Findings/Observation Sheet Part 1 is filled in by the factory surveillance inspector in case of findings detected during the inspection. For each finding/observation one sheet shall be issued.

Findings and observations are defined in clause 17.1.

This appendix (Part 2 and Part 3) is intended for optional use. The involved certification body decides whether this form is used for their internal processes.

OD CIG 023 – Appendix 4: Inspectors Findings/Observation Sheet Part 2

The Part 2 shall only be completed by the Factory/Licence Holder if a certification body is requesting it. The inspector must not fill in that form.

After giving general information about the factory, the Factory/Licence Holder has to address the Finding/Observation followed by a deep “Root Cause Analysis” (RCA). The RCA shall deliver an effective “Corrective Action” (CA) that prevents a reoccurrence of the Finding/Observation. The Factory/Licence Holder attaches appropriate documents as evidence for the planned/implemented CA(s). The Factory/Licence Holder finalises the document with date and signature.

OD CIG 023 – Appendix 4: Inspectors Findings/Observation Sheet Part 3

Part 3 of Appendix 4 is completed by the certification body. In the information part the certification body gives general data related to the factory and Finding/Observation. Following the certification body judges the “Root Cause Analysis”, “Corrective Action”, “Objective Evidence” and if the implementation date is acceptable. The certification body closes the evaluation of addressed Finding/Observation with date and signature.