ETICS	**OPERATIONAL DOCUMENT**	**OD CIG ~~021~~421**

Factory Inspection Procedures Harmonised Requirements

~~WARNING:~~

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

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Rue des Deux Églises, 29 - 1000 BRUSSELS – E-mail : secretariat@etics.org
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FACTORY INSPECTION PROCEDURES
HARMONISED REQUIREMENTS

1 INTRODUCTION

This document deals with the factory inspection procedures and tests which Licence Holders 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 Factory 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 Licence Holder or Factory, 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 and to ensure that a uniform production can be expected, the inspection shall always be conducted, and a complete inspection report (CIG ~~023~~423) 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 421: stands for OD CIG 421
   CIG 422: stands for OD CIG 422
   CIG 423: stands for OD CIG 423
   CIG 424: stands for OD CIG 424
2. *Current editions of the OSM-FIP Documents can be found in* "OSM FIP Documents" on "https://www.etics.org/."

~~***NOTES***:~~
1. ~~*The following abbreviations are used throughout this document:*~~
   ~~*CIG 021: stands for OD CIG 021*~~
   ~~*CIG 022: stands for OD CIG 022*~~
   ~~*CIG 023: stands for OD CIG 023*~~
   ~~*CIG 024: stands for OD CIG 024*~~
2. ~~*Current editions of the OSM-FIP Documents can be found under the following path: https://www.etics.org/doc/*~~

~~→ *Document Server* → *OSM-FIP Public Documents* → *Permanent and Operational Documents.*~~

2 DEFINITIONS

2.1 Inspection

An inspection is an activity performed by the Certification Body to observe that the production of certified product is maintained by the Licence Holder. The inspection is normally performed at the Factory. If needed to observe the maintenance of the production, the Certification Body may decide to perform the activity even at the location of Licence Holder, Subcontractor or Out-Worker.

2.2 Licence Holder

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

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The Licence Holder has the full responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.

The Licence Holder is responsible for the production capacity, situated at a stated location or stated locations, that carries out or controls stages in the production, such as: the assessment, handling and storage of a product.

2.3 Subcontractor

Any manufacturing organisation undertaking the production of any sub-assembly in accordance with the specific requirements of the Licence Holder of a certified product. The subcontractor is under the control of the factory.

2.4 Out-Worker

Any person who undertakes work at a place other than the factory location on component parts supplied by the Licence Holder of the certified product and in accordance with the specific requirements of the Licence Holder. The out-worker is under the control of the factory.

2.5 Factory

The location where the final assembly and/or testing of certified products 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. When a procedure is not documented, the process must be automated or secured to be done according to the process implemented/decided.

2.7 Calibration

Calibration is the process of establishing the relationship between the test and measuring equipment and ~~reference~~ equipment ~~according~~traceable to ~~the requirements~~National or International Standards and documented by a calibration certificate (Requirements as given in EN ISO/IEC 17025~~.~~).

***NOTE**:*
In general, accredited laboratories fullfill these requirements.

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

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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.

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

The reference equipment shall be traceable to National or International Standards and documented by a calibration certificate (In general, calibration laboratory accredited according to EN ISO/IEC 17025)

***NOTE**:*
In general, verification is done "In-House" or at the test equipment Producer/ Supplier.

2.9 Finding

A finding is a nonconformity found during a factory inspection, thus a non-~~fulfillment~~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.

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2.10 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 CIG ~~023~~423 “Inspectors Finding/Observation Sheet” 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.

2.11 Routine tests

These tests are carried out by the factory on 100% of all manufactured products that bear a certification mark. For ENEC and ENEC+ these requirements are given in the PD ENEC 303 annexes. The factory may add other checks or tests, if considered necessary for this particular product. If a standard defines routine tests mandatorily, these requirements must be followed prior to the PD ENEC 303 Annexes.

***NOTE**:*
If the standard describes the routine test requirements as “informative”, the ENEC Certification Scheme may decide to make it mandatory in the scheme or define other options. Test results shall be kept at disposal of the inspectors of the Certification Body(ies).

2.12 Product Verification Tests (PVT)

The tests are carried out by the factory 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(ies). In selecting samples for periodic tests preference should be given to products whose characteristics are close to the limiting values.

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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 or Factory.

During routine inspections of a Factory, 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.

~~***GENERAL GUIDANCE***~~

- ~~*The questions of this Factory Inspection Report are based on the requirements given in Operational Document CIG 021.*~~
- ~~*Guidance for the Inspector is given in Operational Document CIG 024.*~~
- ~~*Both documents, CIG 021 and CIG 024 shall be taken into account during inspection.*~~
- ~~*Instructions to the Inspector are shown in italics.*~~
- ~~*The report shall be completed even if there is no production at the time of the visit.*~~
- ~~*For all 'NO' answers details shall be provided on the Inspectors Finding/Observation Sheet (part 1).*~~
- ~~*For 'N/A' answers rationale shall be provided as to why the item is not applicable, unless it is obvious to be not relevant.*~~
- ~~*If functional safety aspects need to be considered details should be given on Inspector's Information page.*~~
- ~~*Details should be given on Inspector's Information page.*~~
- ~~*This report as well as objective evidences attached to this report shall be written at least in English.*~~

IMPORTANT INFORMATION

- *This report is based on the PDF reference version of OD CIG 423 as provided under ETICS - CIG Public Documents (CIG Public Documents GROUP PERMANENT AND OPERATIONAL DOCUMENTS (etics.org))*
- *If any modification on the fixed wording, compared to the reverence version, is made, the reference to OD CIG 423 in footer of this document shall be removed!*
- *ETICS reserve the right to take appropriate action against violations accordingly.*
- *This document is only valid if used by CIG Members and their authorised agents!*

GENERAL GUIDANCE

- *The questions of this Factory Inspection Report are based on the requirements given in Operational Document OD CIG 421.*
- *Guidance for the Inspector is given in Operational Document OD CIG 424.*
- *Both documents, OD CIG 421 and OD CIG 424 shall be taken into account during inspection.*
- *Instructions to the Inspector are shown in italics.*
- *The report shall be completed even if there is no production at the time of the visit.*
- *For all 'NO' answers details shall be provided on the Inspectors Finding/Observation Sheet (part 1).*
- *For 'N/A' answers rationale shall be provided as to why the item is not applicable, unless it is obvious to be not relevant.*
- *If functional safety aspects need to be considered details should be given on Inspector's Information page.*
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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 Factory 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 Factory.

Furthermore, the Licence Holder shall inform any Factory about the certification requirements including the requirements of the ~~Harmonized~~CIG Inspection Scheme (CIG ~~021~~421).

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

The Licence Holder shall inform any Factory about those changes approved. It shall be ensured that the Factory 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 or in the agreement with the factory and/or all personnel involved in the acceptance of changes shall be aware how changes to certified products are communicated with the Certification Body.

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5 FACTORY'S RESPONSIBILITY

5.1 General Information

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

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

The Factory 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 Factory shall maintain appropriate records to demonstrate conformance with the ~~ECS~~CIG 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.*~~

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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.

Factories shall ensure that all purchased materials, components and subassemblies **which have a safety implication on the certified product** 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 Factory relies on the suppliers' control procedures. It is the responsibility of the Factory 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 Factory achieves these objectives is not prescribed. Procedures may be required to ensure compliance with the specifications of components.*~~

***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 Factory achieves these objectives is not prescribed. Procedures may be required to ensure compliance with the specifications of components.

If a Factory relies on Certificates / Declaration of Conformity to underwrite the compliance of components with their specifications, certificates / declarations shall clearly identify the materials, components and subassemblies, 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, component or material found during incoming inspection shall be clearly identified and/or segregated in a controlled way to prevent unauthorised use.

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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 Factory 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 production. 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.etics.org/doc/ → 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.*~~

***NOTE**:*
1. All ENEC required routine tests can be found in "ENEC 303 Annexes" on "www.etics.org."

2. In the absence of relevant standard 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 products ~~complies~~comply 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 Factory during testing of the certified product (Not applicable for spark testers in the production of cables and cords. For that test equipment the short circuit test is allowed as functional check).

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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 Factory'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 ~~depending on usage and the results of previous calibration/verification. Equipment to perform routine testing and periodic tests (PVT's) shall be calibrated/verified with an interval of maximum 12 month. The extension of the calibration interval to more than one year shall be limited to seldomly used test equipment (other than used for routine/periodic tests, e.g., mechanical equipment).~~.

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 used, 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 and documented by a calibration certificate. The test and measuring~~The equipment shall be provided with a label or similar indicating the next 'calibration ~~-~~/verification due' date ~~or another method ensuring the valid calibration/verification status.~~.

In any case, the equipment ~~to perform routine testing~~ shall have a valid calibration/verification status at the time ~~when the production~~of use.

In case of ~~certified products runs.~~verification/calibration the reference equipment shall be traceable to National or International Standards and documented by a calibration certificate (In general, calibration laboratory accredited according to EN ISO/IEC 17025)

5.6.1 For Routine Test Equipment and test equipment used for function checks (dummy test):

- Calibration or verification accepted.
- Calibration/verification interval 12 months!
- No extension of calibration/verification interval.

5.6.2 For PVT equipment

- Calibration or verification accepted.
- Calibration/verification interval 12 months, for electrical test equipment!
- Calibration/verification interval 36 months, for mechanical test equipment!
    - Example of mechanical test equipment: Gauges, non-electrical callipers, rulers, …
    - Example of non-mechanical test equipment: Multi meter, scales, temperature meters, …
- No extension of calibration/verification interval.
- If a laboratory accredited according to EN ISO/IEC 17025 are used for PVT testing this is acceptable.

5.6.3 For reference Equipement of the factory:

- Only calibration accepted.

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- Calibration interval 12 months, for electrical test equipment!
- Calibration interval 36 months, for mechanical test equipment!
    - Example of mechanical test equipment: Gauges, non-electrical callipers, rulers, …
    - Example of non-mechanical test equipment: Multi meter, scales, temperature meters, …
- No extension of calibration interval.

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~~5.6~~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.

~~5.7~~5.8 Product Verification Tests / Periodic Tests (PVT)

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

~~***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 Factory 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 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 Factory's premises, but records with the results shall be available with the Factory 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. *All ENEC required periodic tests can be found in* "ENEC 303 Annexes" on "www.etics.org."
2. *In the absence of relevant standards by the Technical Committees covering the subject, National Certification Bodies' specifications apply.*

~~***NOTES**:*~~
~~1. *See the OSM-FIP Decision "Product Verification Tests" for guidance under the following path: www.etics.org/doc/ → 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 Licence Holder's or Factory'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.

~~5.8~~5.9 Void

~~5.7 Corrective actions in response to Inspector's evaluation~~

5.10 Unsatisfactory Findings from Previous Inspection - Follow-Up

It is the Licence Holder's or Factory'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.

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~~5.9~~5.11 Quality Management System

The Factory is not required to have a certified Quality system. If the Factory 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 Factory is audited by the same organisation as the Body carrying out the subjected factory inspection.*~~

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

~~5.10~~5.12 Factory's self-assessment of the manufacturing and control process of certified products

The Factory shall monitor the procedures used in the manufacturing and control process of certified products, on a yearly basis, on a way that every element of CIG 423 is covered within a 3-year period. This monitoring shall at least include verification that the procedures, instructions, guidelines and records are up-to-date and properly applied by personnel. Factory's procedures shall at least cover the requirements as given in this document (CIG ~~021~~421). 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 Factory's self-assessment by use of CIG 023 is acceptable.*~~

~~5.11~~5.13 Void

~~5.12~~5.14 ~~Technical~~ Complaints

The Factory shall record complaints, at least 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 Factory 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.

~~5.13~~5.15 Certified Products and Changes to Certified Products

The Factory 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, Product certificate including annexes, Reference for certification mark, Test report from certification body or 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 Factory about those changes approved.

The Factory 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.

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~~5.14~~5.16 Selection and Shipping of ~~Re-Examined~~ Sample(s)

If required by the Certification Body or Certification Scheme the Factory 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~~inspector, the Factory 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 or certification schemes. Therefore, the individual requirements have to be followed.*~~

It is within the factories responsibility to take the necessary steps to dispatch the units, clear them through customs and pay carriage, in order that the addressee-organisation should not handle any possible custom clearance.

> ***IMPORTANT NOTICE:***
> *The selection of samples for Product Surveillance is an essential aspect to maintain the validity of the Product Licence. Not providing samples might result in suspension or withdrawal of the Product Licence!*

6 FACTORY INSPECTION DOCUMENTS

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

> ***NOTE:***
> *Current editions of the OSM-FIP Documents can be found in* "OSM FIP Documents" on "https://www.etics.org/"

> ~~***NOTE:***~~
> ~~*Current editions of the OSM-FIP Documents can be found under the following path: www.etics.org/doc/ → Document Server → OSM-FIP Public Documents → Permanent and Operational Documents.*~~

6.1 CIG ~~021~~421: Factory Inspection Procedures – Harmonised Requirements

This document defines the responsibilities of the Licence Holder and the Factory within the ~~Harmonized~~CIG Inspection Scheme.

6.2 CIG ~~022~~422: Pre-Licence Factory Inspection Questionnaires

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

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 Factory are not the same).

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

Before making the Pre-licence Inspection in the factory this Part is to be completed by the Factory. 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~~423: Factory Inspection Report

This report is completed by the Inspector either during Pre-licence inspections or during Routine inspections or other inspections. Completion of this report during the Pre-licence inspection will take into account the information given in CIG ~~022~~422 Section B.1 and B.2.

Member bodies may use an alternative format/layout of the CIG ~~023~~423 Factory Inspection

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Report; However, the issuing body must assure and declare that the content of the inspection report is identical to the official approved version.

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6.4 CIG ~~023~~423 – Appendix 1: Signature Page (Part 1); Inspection Summary Page (Part 2)

This Appendix is to be used if the CIG ~~023~~423 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~~423.

6.5 CIG ~~023~~423 – Appendix 2: Additional Quality System Requirements ~~for ENEC Agreement~~(QMS Appendix)

This Appendix is to be used if all of the following conditions apply to the Factory:

- Calibration or verification accepted.

Calibration

- 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 ~~023~~423 – Appendix 3: Additional Requirements for ENEC+ Agreement

This appendix is to be used only if the factory is manufacturing ENEC+ certified products.

6.7 CIG ~~023~~423 – Appendix 4: Inspectors Findings/Observation Sheet Part 2 and Part 3

This Appendix is to be used if requested by the Certification Bodies. Document for optional use! (both Part 2 and Part 3)

Certification Body decides whether to use this form or not for their internal processes.

Part 2 shall be filled by the Factory/Licence holder ONLY if requested by the Certification Body. (This sheet shall not be filled by the Inspector)

Part 3 shall be filled by the Certification Body as needed.

***NOTE**:*
CIG 423 contains Inspectors Finding/Observation Sheet (part 1). This sheet has to be filled by the Inspector in case findings have been detected in the course of the inspection. One sheet per finding has to be issued. CIG 423 is a mandatory document!

~~Note: CIG 023 contains Inspectors Finding/Observation Sheet (part 1). This sheet has to be filled by the Inspector in case findings have been detected in the course of the inspection. One sheet per finding has to be issued. CIG 023 is a mandatory document!~~

6.8 ~~CIG 024~~CIG 424: Factory Inspection Procedures Guidance to Certification Bodies, Inspectors, Factories and Licence Holders

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

6.9 Current OSM-FIP Decisions

These documents contain the decisions of the committee in charge with the development of the requirements for the ~~Harmonized~~CIG Inspection Scheme (~~ECS~~ETICS-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 in "OSM-FIP Decision Sheets" on "https://www.etics.org/".

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~~*NOTE:*~~
~~*Current editions of the OSM-FIP Decisions can be found under the following path: www.etics.org/doc/ → Document Server → OSM-FIP Public Documents → Decisions.*~~

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