



**FACTORY INSPECTION PROCEDURES
AND TESTS**

– Requirements for Manufacturers –

CONTENTS**Page No.**

FOREWORD	2
1 INTRODUCTION	2
2 DEFINITIONS	2
2.1 Factory Location/Manufacturer's Premises	2
2.2 Manufacturer	2
2.3 Subcontractor	2
2.4 Out-Worker	2
2.5 Licence Holder	2
2.6 Procedure	2
2.7 Calibration	2
2.8 Measuring and Testing Equipment Verification	2
3 GENERAL ARRANGEMENTS	3
4 MANUFACTURER'S RESPONSIBILITY	3
4.1 General Information	3
4.2 Verification of Purchased Components and Materials which have a safety implication on the Certified Product (Incoming Inspection)	3
4.3 Production Control, Internal Inspection and Routine Tests	4
4.4 Functional Check on Test and Measuring Equipment used for Safety Tests (Dummy Test)	4
4.5 Marking of products	4
4.6 Calibration of Safety Test and Measuring Equipment	4
4.7 Handling and Storage	4
4.8 Product Verification Tests/Periodic Tests (PVT)	5
4.9 Manufacturer's Self Assessment of the Manufacturing and Control Process of Certified Products	5
4.10 Customer Complaints	5
4.11 Changes to Certified Products	5
5 FACTORY INSPECTIONS CONDUCTED BY BBJ	6
5.1 Guidance in Completing Form PD CIG 022 Section B	6
5.2 Inspection Procedure	7
5.3 Selection and Shipping of Re-Examination Sample(s)	7
5.4 Corrective Actions in Response to Inspector's Evaluation	7

FOREWORD

This document has been produced based on PD CIG 021 and PD CIG 024¹.

It covers requirements on factory inspection and tests that should be fulfilled by the Manufacturer of the products certified by Quality Testing Office (**BBJ**) according to system 5. of PN-EN ISO/IEC Guide 67.

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 conducted on behalf of **BBJ**.

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 of **BBJ** 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.

2 DEFINITIONS

The terms used in this document have the meanings defined in PN-EN ISO 9001:2009 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 **BBJ**.

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 **BBJ** for the certification of the product according to the programme on marking legally registered by **BBJ** certification mark.

*Note: In case of system 5. certification according to ISO/IEC Guide 67 conduct by **BBJ** the Licence Holder may be a Manufacturer or his legal representative only.*

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 PN-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 Measuring and Testing Equipment Verification

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

¹ PD CIGs are the documents developed by EEPCA within European Certification System (ECS).

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 by **BBJ** once per year² to ensure that the necessary routines and procedures are being maintained at an acceptable level. 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 in **BBJ** laboratory to verify compliance with the relevant standards.

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 **BBJ** 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 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 **BBJ** requirements. These records shall be made availa-

ble 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);
- Product Verification Tests;
- Routine 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.

² Unless otherwise indicated in specific certification scheme.

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

Note: In the absence of relevant standards covering the scope of Routine Tests, relevant specifications developed by BBJ apply³.

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 Marking of Products

The Certification Mark shall be applied according to the regulations of **BBJ**.

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

³ These documents may be updated periodically by **BBJ**. They are listed in document DC 102-1.

(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 **BBJ** inspectors.

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 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 by **BBJ** for certain product categories.

In cases where there are no **BBJ** 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 **BBJ** representative will check that the Manufacturer's obligation is adequately fulfilled.

4.9 Manufacturer's Self Assessment of the Manufacturing and Control Process of Certified Products

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.

4.10 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.

4.11 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 **BBJ** 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 **BBJ**.

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.

5 FACTORY INSPECTIONS CONDUCTED BY BBJ

5.1 Guidance in completing Form PD CIG 022 Section B⁴

The completed questionnaire PD CIG 022 Section B has to be returned to **BBJ** before the Pre-licence inspection may be scheduled.

Section B1 shall be filled out by the Licence Holder first and thereafter the document is to be sent to the Manufacturer where the product is produced.

Section B2 shall be answered by the Manufacturer.

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 See cl. 2.5 of this document.

B.1.2 List the product category (family name), all brand/trade names and type references of products intended to be marked with the Certification Mark.

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

B.1.4 Self-explanatory. 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 **BBJ**.

B.1.5 Section B1 of this document shall be verified and signed by an authorised management representative of the Licence Holder.

B.2.1 Actual factory location and geographical (street) address. Provide local street map or sketch, best mode of transportation, parking facilities etc.

B.2.2 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 be nominated. A deputy contact person shall be available in case of absence of the contact person.

The management representative is the person at the Manufacturer 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 List Materials, components and sub-assemblies which have a safety implication on the finished product, and which are purchased from, or produced by an outside supplier. Please indicate which components are certified and bear which Certification Marks.

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 Manufacturer'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 are made available to the requesting Certification Body, then the various stages and limitations of inspection and testing shall be described in chronological order.

Information should be detailed under the following headings:

- Receiving 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

(See cl. 4.3 of this document)

- Product Verification Tests/Periodic Tests (PVT)

(See cl. 4.8 of this document)

State how you intend to meet the requirements. If additional tests to those stated above are performed, please describe.

B.2.7 What Certification Marks, if any, have already been granted for this product category by other Certification Bodies?

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.

⁴ See document DC 102-2.

B.2.9 Section B2 of this document shall be verified and signed by an authorised management representative at the factory where the product is or will be produced.

5.2 Inspection Procedure

The inspection will be conducted during normal working hours. The Manufacturer's representative or his deputy should be available within a reasonable time after being contacted from reception. **BBJ**, and hence the Inspector acting on its behalf, will be expected to be given full access to the Manufacturer's premises and be accorded his full co-operation throughout the inspection. Any unwarranted or personal criticism or lack of co-operation by the Manufacturer may be reported by the Inspector to **BBJ**.

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 Manufacturer's representative before he leaves the factory.

5.3 Selection and Shipping of Re-Examination Sample(s)

If required by **BBJ** 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 **BBJ** in accordance with **BBJ**'s requirements.

5.4 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. **BBJ** shall be informed about the corrective actions taken. Depending on the number and the seriousness of the findings **BBJ** may decide to verify the implementation of the corrective actions during a special inspection or during the next routine inspection.

TRUST US
...OTHERS WILL TRUST YOU