



OPAC EN10138-00

Operating Procedure for the Attestation of Conformity according to EN10138 Revision 0

Approved by BT1 on 20060000, by the Board of Directors on 20060000

Operating Procedure for the Attestation of Conformity of Prestressing Steel in compliance with Annex ZA of EN 10138

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1 Scope of the document

This document specifies the procedure to be applied for the attestation of conformity of Prestressing Steel in compliance with Annex ZA of EN 10138.

It applies to all products covered by EN 10138 and to other similar products related in other standards whose application is made in accordance with the Construction products Directive (CPD - 89/106/EEC).

The rules underlying the present operating procedure comply with different official papers issued by the European Commission whose reference is quoted.

The present operating procedure may be completed by further documents not subjected to publication and intended for internal use by the notified body in charge of the certification process.

2 The Attestation of Conformity Systems in the field of the CPD

Guidance Paper K goes into detail on the various attestation of conformity (AoC) systems within the context of the implementation of the CPD. It also addresses the relation between the AoC systems and the notified bodies (NB). It clarifies the role of the relevant notified bodies under the different AoC systems.

2.1 Underlying principles

The CPD identifies a complete set of attestation of conformity systems including all the actors with their respective roles and tasks. Voluntary European or international standards [ISO 9000 series, ISO 17025, EN 45000 series] can be used as a starting point where appropriate but are not obligatory.

The producer is fully responsible for the attestation that products are in conformity with the requirements of a technical specification. The involvement of a third party, even to provide an EC certificate of conformity, does not relieve the producer of any of his obligations. However, under the CPD, responsibility for specific actions is given to a third party for all systems of attestation of conformity (AoC) except system 4.

Whether or not there is third party intervention in attestation of conformity, all of the tests and procedures required by the CPD and the technical specifications must be performed and documented correctly. The documentation shall be available for notifying authorities and surveillance authorities where relevant.

2.2 Methods of control of conformity

2.2.1 Initial Type-Testing (ITT)

Initial type-testing of the product by the manufacturer or a notified body is applicable to all AoC systems. An initial type-test is the complete set of tests or other procedures described in the harmonised technical specification, determining the performance of samples of products representative of the product type. An ITT verifies that a product complies with the harmonised technical specification. It defines the performance of all harmonised characteristics to be declared. Depending on the limitations of intended uses chosen by, and the specific markets envisaged by the manufacturer, the scope of the ITT could be limited to those applicable to the uses foreseen. A product range may cover several versions of the product, provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product. An initial type-test is not an assessment of the fitness for use of a product. The ITT is rather a determination of the performance of a product, on the basis of tests or other procedures described in the technical specifications. The ITT is only one element which determines whether or not a product can be attested to be in conformity with a technical specification. However, the ITT does play a fundamental role under the CPD as it provides the reference for the declared performance of the product.

2.2.2 Audit-testing (AT)

Audit-testing of samples taken at the factory, on the open market or on a construction site is made by the manufacturer or a notified body. Commission Decisions generally limit audit testing by Notified Bodies, under the attestation of conformity procedures, to the premises of the manufacturer or his authorised representative. A proper "audit-test" assumes that:

- The construction products is tested in accordance with the test methods specified in the technical specification and the initial type-test.
- The test results are compared with the declared performances of the product derived from the initial type-test.
- A test report is delivered, confirming that the findings are in conformity with the technical specifications, the ITT and FPC provisions.

2.2.3 Factory Production Control (FPC)

In the CPD, factory production control means the permanent internal control of production exercised by the manufacturer. Normally this includes testing by the manufacturer, to assure compliance of the manufactured products with the declared performances of the initial type-test.

2.3 Systems of conformity attestation

The systems of conformity attestation include:

- Certification of the conformity of the product by a notified certification body on the basis of different tasks for the manufacturer and notified bodies (Systems 1 and 1+).
- Declaration of conformity of the product by the manufacturer (Systems 2, 2+,3 and 4)

2.4 System 1+

2.4.1 Tasks and basis for CE marking

According to system 1+, in force according to EN 10138 for prestressing Steel, the different tasks are defined as follows:

- Task for manufacturer
 - Factory production control
 - Further testing of samples taken at factory
- Task for notified body
 - Initial type-testing of product
 - Initial inspection of factory and factory production control
 - Continuous surveillance, assessment and approval of factory production control
 - Audit testing of samples taken at factory
- Basis for CE marking
 - Manufacturer's conformity Declaration,
 - Certificate of product conformity.

2.4.2 Specificities

Under system 1+, responsibility for the certification of the conformity of the product (on the basis of tasks by the producer and the notified body) is given to a third party. It is normal practice that the individual tasks required to enable product certification to take place are carried out by various parties - e.g. producer, certification body, inspection body, laboratory. The certification body is responsible for assembling all of the relevant information, verifying that tasks have been carried out according to the technical specification and assessing and certifying the conformity of the product. Product certification can therefore be considered to be an umbrella activity, making use of information from various sources. Within this overall scheme, the producer has a significant role to play, including the testing of certain product characteristics as part of an initial type-test. The allocation of such tests to the producer shall be indicated in the technical specifications, elaborated on the basis of the mandates from the Commission.

Under system 1+, responsibility for product sampling for the ITT, in accordance with the rules laid down in the technical specification ¹ lies with the certification body (often delegated to an inspection body), rather than the producer.

The result of the actions of the notified body under CPD Annex III.2(i) (Systems 1 and 1+) is in all cases a product conformity certificate. The only difference between the commonly used terms “system 1” and “system 1+” are the methods used by the notified body to assess the product (ie. 1+ includes audit testing).

3 Main Issues in Annex ZA of EN 10138

3.1 Clauses of this European Standard addressing the provisions of EU Construction Products Directive

The European Standard has been prepared under a mandate M/115 [Reinforcing and prestressing steel (for concrete)] given to CEN by the European Commission and the European Free Trade Association. The clauses of the EN 10138 shown in this annex meet the requirements of the mandate given under the EU Construction Products Directive (89/106/EEC). Compliance with these clauses confers a presumption of fitness of the prestressing Steel covered by this annex for the intended uses indicated herein; reference shall be made to the information accompanying the CE marking.

¹ In the absence of sampling rules (and other initial type-testing or factory production control details) in the technical specification, the Group of Notified Bodies shall provide appropriate common instructions to producers. These common instructions will be communicated to the Standing Construction Committee for endorsement. Specification writers could use these as basis for future amendments of the specifications.

3.1.1 Essential characteristics for prestressing steel in wire

| Essential characteristics | Requirement clauses in this and other European Standard(s) | Levels and/or classes | Notes |
|-----------------------------------------------------------------|-------------------------------------------------------------------|------------------------------|---------------------------------|
| Stress ratio (ultimate tensile strength/tensile yield strength) | 7.2.2.1 | - | Maximum force/0,1 % proof force |
| Tensile yield strength | 7.2.2.3, prEN 10138-2 Table 4 | - | 0,1% proof force |
| Elongation at maximum force | 7.2.2.4, prEN 10138-2 Table 5 | - | Minimum value % |
| Relaxation | 7.3.2, prEN 10138-2 Table 5 | - | Maximum value % |
| Sections and tolerances on sizes | 7.2.1, 7.2.2, prEN 10138-2, Table 4 | - | Declared value |
| Surface geometry | 7.2.1, prEN 10138-2 Table 4 | - | Declared value |
| Fatigue | 7.3.3, prEN 10138-2 Table 5 | - | Threshold value |
| Modulus of elasticity | prEN 10138-2 Table 4 note a) | - | Declared value |
| Deflected tensile strength | not relevant | - | - |
| Durability | 7.3.5, prEN 10138-2 Table 5 | - | Pass/fail |

3.1.2 Relevant clauses for prestressing steel in strand

| Essential characteristics | Requirement clauses in this and other European Standard(s) | Levels and/or classes | Notes |
|-----------------------------------------------------------------|-------------------------------------------------------------------|------------------------------|---------------------------------|
| Stress ratio (ultimate tensile strength/tensile yield strength) | 7.2.2.1 | - | Maximum force/0,1 % proof force |
| Tensile yield strength | 7.2.2.3, prEN 10138-3 Tables 3, 4 | - | 0,1% proof force |
| Elongation at maximum force | 7.2.2.4, prEN 10138-3 Table 5 | - | Minimum value % |
| Relaxation | 7.3.2, prEN 10138-3 Table 5 | - | Maximum value % |
| Sections and tolerances on sizes | 7.2.1, prEN 10138-3 Table 3 | - | Declared value |
| Surface geometry | 7.2.1, prEN 10138-3 Tables 3, 4 | - | Declared value |
| Fatigue | 7.3.3, prEN 10138-3 Table 5 | - | Threshold value |
| Modulus of elasticity | prEN 10138-3 Tables 3, 4 note a) | - | Declared value |
| Deflected tensile strength | 7.3.4, prEN 10138-3 Table 5 | - | - |
| Durability | 7.3.5, prEN 10138-3 Table 5 | - | Pass/fail |

3.1.3 Relevant clauses for prestressing steel in bar

| Essential characteristics | Requirement clauses in this and other European Standard(s) | Levels and/or classes | Notes |
|-----------------------------------------------------------------|------------------------------------------------------------|-----------------------|---------------------------------|
| Stress ratio (ultimate tensile strength/tensile yield strength) | 7.2.2.1 | - | Maximum force/0,1 % proof force |
| Tensile yield strength | 7.2.2.3, prEN 10138-4 Table 2 | - | 0,1% proof force |
| Elongation at maximum force | 7.2.2.4, prEN 10138-4 Table 3 | - | Minimum value % |
| Relaxation | 7.3.2 | - | Maximum value % |
| Sections and tolerances on sizes | 7.2.1, prEN 10138-4 Table 2 | - | Declared value |
| Surface geometry | 7.2.1, prEN 10138-4 Table 2 | - | Declared value |
| Fatigue | 7.3.3, prEN 10138-4 Table 3 | - | Threshold value |
| Modulus of elasticity | prEN 10138-4 Table 2 note a) | - | Declared value |
| Deflected tensile strength | not relevant | - | - |
| Durability | 7.3.5, prEN 10138-4 Table 3 | - | Pass/fail |

3.1.4 No Performance Determined Option

The requirement on a certain characteristic is not applicable in those Member States (MSs) where there are no regulatory requirements on that characteristic for the intended use of the product. In this case, manufacturers placing their products on the market of these MSs are not obliged to determine nor declare the performance of their products with regard to this characteristic and the option "No performance determined" (NPD) in the information accompanying the CE marking may be used. The NPD option may not be used, however, where the characteristic is subject to a threshold level.

3.2 Systems for the attestation of conformity of products

3.2.1 General

For products and intended uses listed below, the system of attestation of conformity of prestressing Steel shall be as follows:

3.2.1.1 Products

- prestressing steel products
 - wires (stress relieved cold drawn wires, smooth wires, indented wires)
 - strands (multi-wire strands, multi wire compacted strands, indented and high bond strand)
 - bars (hot rolled and processed bar, threaded bars, ribbed or plain or smooth bars)

3.2.1.2 Intended uses

Use for the prestressing of concrete.

3.2.1.3 Attestation of conformity system

System 1+: according to CPD Annex III.2.(i) **with** audit testing of samples.

3.2.2 Steps of conformity control

The steps of control of conformity are set out hereunder.

| |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Certificate of conformity of the product by the notified body Declaration of conformity of the product by the manufacturer |
| Initial type-testing of the product by the notified body |
| Factory production control by the manufacturer |
| Further testing of samples taken at the factory by the manufacturer |
| Initial inspection of factory and factory production control by the notified body |
| Continuous surveillance, assessment and approval of the factory production control by the notified body |
| Audit testing of samples taken at the factory by the notified body |
| Note: the notified body is the certification body or the inspection body acting on behalf of the certification body who both are granted by their Member State with the notification for concerned activities |

The assignation of evaluation of the conformity tasks is defined in the following Table.

| Tasks | | Content of the task | Evaluation of conformity clauses to apply |
|------------------------------------------------------------------|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Tasks under the responsibility of the manufacturer | Factory production control (FPC) | Parameters related to all relevant characteristics of Tables ZA.1.1 to ZA.1.3 | 8.3 |
| | Further testing of samples taken at factory | All relevant characteristics of Tables ZA.1.1 to ZA.1.3 | 8.4.2 |
| | Initial type testing by a notified test laboratory | Those relevant characteristics of Tables ZA.1.1 to ZA.1.3 tested by a notified test laboratory | 8.2 |
| | Initial type testing by the manufacturer | Those relevant characteristics of Tables ZA.1.1 to ZA.1.3 not tested by the notified test laboratory | 8.2 |
| Tasks under the responsibility of the product certification body | Initial type testing | All relevant characteristics of Tables ZA.1.1 to ZA.1.3 | 8.2 |
| | Initial inspection of factory and of FPC | Parameters related to all relevant characteristics of Tables ZA.1.1 to ZA.1.3 | 8.3 |
| | Continuous surveillance, assessment and approval of FPC | Parameters related to all relevant characteristics of Tables ZA.1.1 to ZA.1.3, in particular: sections and Tolerances on sizes and surface geometry | 8.3 and 8.4 |
| | Audit testing of samples taken at factory | All relevant characteristics of Tables ZA.1.1 to ZA.1.3 | 8.4.2 |

3.2.2.1 Initial type-testing by the notified body

An initial type-testing program shall be carried out under both the approval of the notified body and the responsibility of the manufacturer of the products before these products are first placed on the market. Such a program shall be carried out for each type of prestressing Steel which a manufacturer places on the market in accordance with EN 10138 or other related standards.

By **type** of prestressing Steel, it is understood the following:

- At each type corresponds a given exclusive reference code given by the manufacturer;
- ...

3.2.2.1.1 Responsibility

The definition of the Product types is under the responsibility of the Manufacturer who must lists these and the products referred to in a written document.

The definition of the Product types proposed by the Manufacturer must be validated by the Certification and Inspection Bodies.

3.2.2.1.2 Extension of Products types

A manufacturer may extend a given Product type with new products. To this aim,

- the Manufacturer defines the requested extension,
 - and proposes to it to the certification body.
- The certification body appraises the extension and
 - decides to validate it or not and fixes the proper conditions to
 - update the Initial Type-testing for the new concerned products.

Each type of prestressing Steel must undergo the whole initial type-testing. Initial type-testing must address the characteristics listed in Annex ZA and must assess these according to the methods specified in the EN 10138 standard.

Initial type-testing shall be performed on first application of the standard. Tests previously performed in accordance with the provisions of this standard (same product, same characteristic(s), test method, sampling procedure, system of attestation of conformity, etc.) may be taken into account. In addition, initial type-testing shall be performed at the beginning of a new method of production (where this may affect the stated properties).

3.2.2.1.3 Initial type-testing program

The initial type-testing program comprises:

- Identification of the different types of products by the manufacturer,
- Documentation by the manufacturer of existing or to be performed tests relating to each type and assessing the conformity to the characteristics,
- Submission of the documentation to the notified body,
- Examination and assessment of the documentation by the notified body,
- Definition of the final initial type-testing program by the notified body,
- Approval by the manufacturer,

- Performance of tests by the manufacturer under the supervision of the notified body (this may include traceable tests contracted to third part laboratories provided they are previously proposed to the notified body and approved by the latter);
- Assessment of initial type-testing by the notified body;
- Decision regarding initial type-testing by the notified body and notification to the manufacturer.

3.2.2.1.4 Documentation

The results of the initial type-testing program shall be recorded and such records shall be maintained and be made available for inspection for a period of at least 10 years after the date when the last product to which the test program refers to was delivered.

3.2.2.2 Factory production control

The manufacturer shall operate a factory production control system. In the Construction Products Directive, factory production control means the permanent internal control of production exercised by the manufacturer. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures. This production control system documentation shall ensure a common understanding of quality assurance and enable the achievement of the required product characteristics and the effective operation of the production control system to be checked. A quality system in accordance with EN ISO 9001 which includes the requirements of this European Standard meets the requirements for a factory production control in the sense of the Construction Products Directive.

The factory production control system shall be approved by the notified body.

3.3 Continuous surveillance

Continuous surveillance inspections shall be performed at a frequency considered necessary by the notified body but not less than twice a year.

3.4 Re-assessment and renewal of certification

The duration of certification, based on satisfactory maintenance of approval shall be for a period of 5 years from the date of issue of the applicable certificate. After this period the manufacturer's system of factory production control shall be subject to a re-assessment which shall include all elements of the system at this stage. Sampling and testing of the product at this stage shall be at the continuous surveillance level.

Renewal of certification will be subject to compliance with the requirements applicable to system 1+.

3.5 EC certificate of conformity

When compliance with the conditions of Annex ZA in EN 10138 is achieved, the certification body shall draw up a certificate of conformity (EC certificate of conformity), with the information indicated below:

- name, address and identification of the certification body;
- name and address of the manufacturer, or the name of his authorised representative established in the EEA, and the place of production;
- description of the product (type, identification, use, copy of information accompanying the CE marking giving indications to identify the characteristics of the product);
- provisions to which the product conforms (e.g. Annex ZA of EN 10138);
- particular conditions applicable to the use of the product [e. g. provisions for the use of a prestressing Steel under certain conditions, ...];
- the number of the certificate;
- conditions and period of validity of the certificate, where applicable;
- name of, and position held by, the person empowered to sign the certificate.

3.6 Declaration of conformity

In addition the manufacturer shall draw up a declaration of conformity (EC Declaration of conformity) including the following:

- name and address of the manufacturer, or his authorised representative established in the EEA;
- name and address of the certification body;
- description of the product (type, identification, use ...) and a copy of the information accompanying the CE marking;
- provisions to which the product conforms (e.g. Annex ZA of EN 10138);
- particular conditions applicable to the use of the product [e. g. provisions for the use under certain conditions, ...];
- the number of the accompanying EC certificate of conformity;
- name of, and position held by, the person empowered to sign the declaration on behalf of the manufacturer or his authorised representative.

The above mentioned declaration and certificate shall be made available in the official language(s) of the member state of use of the product.

3.7 CE marking and labelling

The manufacturer or his authorised representative established within the EU or EFTA is responsible for the affixing of the CE marking.

3.7.1 Information

The CE marking symbol to affix shall be in accordance with Directive 93/68/EC. The following information shall accompany the CE marking symbol:

- identification number of the certification body;
- name or identifying mark and registered address of the producer;
- the last two digits of the year in which the marking is affixed;
- number of the EC Certificate of conformity or factory production control certificate (if relevant);
- reference to this European Standard;
- description of the product: generic name, material, dimensions, and intended use;
- information on those relevant essential characteristics listed in Table ZA.1 which are to be declared presented as:
 - the specified values of the technical class and a declaration for each essential characteristic as indicated in Table ZA.1 (including "pass" for pass/fail requirements, where necessary);
 - an alternative, the product number alone;
 - "No performance determined" for characteristics where this is relevant.

The "No performance determined" (NPD) option may not be used where the characteristic is subject to a threshold level. Otherwise, the NPD option may be used when and where the characteristic, for a given intended use, is not subject to regulatory requirements in the Member State of destination.

The CE marking and the accompanying information shall be placed in one of the following locations:

- on the prestressing Steel,
- or when not possible it may be
 - on the accompanying label,
 - on the packaging or
 - on the accompanying commercial documents, e.g. a delivery note

3.7.2 Example for CE marking ²

Figure 1 gives an example of the information to be given on the product, label, packaging and/or commercial documents.

Figure 2 gives a simplified example for alternative CE marking.

In addition to any specific information relating to dangerous substances shown above, the product shall also be accompanied, when and where required and in the appropriate form, by documentation

² 1148 affixed after the CE-logo is the notification index of OCAB-OCBS

listing any other legislation on dangerous substances for which compliance is claimed, together with any information required by that legislation.

CE 1148

Any Co Ltd. PO Box 21, B1050

03

Certificate number:...

EN 10138-1

Prestressing Steel intended to be used for prestressing Steel of concrete

Stress ratio - 1,1 %

Tensile yield strength -1 770 MPa

Elongation at maximum force - 3,5%

Relaxation - $\leq 2,5\%$

Sections and tolerances on sizes - $19,3 \text{ mm}^2 \pm 2\%$

Surface geometry -Indented type 1

Modulus of elasticity - 205 GPa

Durability - Pass

Figure 1.


| |
|------------------------------------------------------------------------------------|
|  |
| Any Co Ltd. PO Box 21, B1050 03 Certificate number:... |
| EN 10138-1 Strand – EN 10138-3 – Y1860S7 – 15,7 |
| Coil number |

Figure 2.

3.7.3 Information affixed on the product itself or on a label attached to it

In any case, the following information regarding the CE marking must be directly placed on the product itself or on a label firmly attached to it:

CE-logo followed by “1148”, EN 10138/., Year of manufacture, Name of certificate holder (fabricant), Code of the product.

4 Basic rules for FPC edited by Guidance Paper B

4.1 General comments

The manufacturer is responsible for organising the effective implementation of the factory production control system. Tasks and responsibilities in the production control organisation shall be documented and this documentation shall be kept up-to-date. In each factory the manufacturer may delegate the action to a person having the necessary authority to:

- identify procedures to demonstrate conformity of the product at appropriate stages;
- identify and record any instance of non-conformity;
- identify procedures to correct instances of non-conformity.

The manufacturer shall draw up and keep up-to-date documents defining the factory production control which he applies. The manufacturer's documentation and procedures shall be appropriate to the product and manufacturing process. All FPC systems shall achieve an appropriate level of confidence in the conformity of the product. This involves:

- the preparation of documented procedures and instructions relating to factory production control operations, in accordance with the requirements of the reference technical specification;
- the effective implementation of these procedures and instructions;
- the recording of these operations and their results;
- the use of these results to correct any deviations, repair the effects of such deviations, treat any resulting instances of non-conformity and, if necessary, revise the FPC to rectify the cause of non-conformity.

Production control operations include some or all of the following operations:

- the specification and verification of raw materials and constituents;
- the controls and tests to be carried out during manufacture according to a frequency laid down;
- the verifications and tests to be carried out on finished products according to a frequency which may be laid down in the technical specifications and adapted to the product and its conditions of manufacture.

4.2 Verifications and tests

The manufacturer must have or have available the installations, equipment and personnel which enable him to carry out the necessary verifications and tests. He may, as may his agent, meet this requirement by concluding a subcontracting agreement with one or more organisations or persons having the necessary skills and equipment.

The manufacturer must calibrate or verify and maintain the control, measuring or test equipment in good operating condition, whether or not it belongs to him, with a view to demonstrating conformity of the product with its technical specification. The equipment must be used in conformity with the specification or the test reference system to which the specification refers.

4.2.1 Monitoring of conformity

If necessary, monitoring is carried out of the conformity of intermediate states of the product and at the main stages of its production. This monitoring of conformity focuses where necessary on the product throughout the process of manufacture, so that only products having passed the scheduled intermediate controls and tests are dispatched.

4.2.1.1 Tests

Tests shall be in accordance with the test plan and be carried out in accordance with the methods indicated in the technical specification. These methods shall generally be direct methods. It is however

possible, in the case of certain characteristics, that the prescribed specification gives the possibility of using indirect test methods if a definite correlation or relationship can be established and if possible verified between specified characteristic X - the characteristic to be verified - and another characteristic Y which is easier or safer to measure than characteristic X. Indirect test methods may be retained when available and appropriate.

4.2.1.2 Test Records

The manufacturer shall establish and maintain records which provide evidence that the product has been tested. These records shall show clearly whether the product has satisfied the defined acceptance criteria. Where the product fails to satisfy the acceptance measures, the provisions for non-conforming products shall apply.

4.2.1.3 Treatment of products which do not conform

If control or test results show that the product does not meet the requirements, for example if the statistical variation of test results exceeds the limits allowed by the technical specification, the necessary corrective action must immediately be taken. Products or batches not conforming must be isolated and properly identified. Once the fault has been corrected, the test or verification in question must be repeated. If products have been delivered before the results are available, a procedure and record shall be maintained for notifying customers.

4.2.1.4 Recording of verifications and tests (manufacturer's register)

The results of factory production controls must be properly recorded in the manufacturer's register. The product description, date of manufacture and of sampling, test method adopted, test results and acceptance criteria must be entered in the register under the signature of the person responsible for control who carried out the verification. With regard to any control result not meeting the requirements of the technical specification, the corrective measures taken to rectify the situation (e.g. a further test carried out, modification of manufacturing process, throwing away or putting right of product) must be indicated in the register.

4.2.2 Traceability

It is the manufacturer's, or his agent's, responsibility to keep full records of individual products or product batches, including their related manufacturing details and characteristics, and to keep records of to whom these products or batches were first sold. Individual products or batches of products and the related manufacturing details must be completely identifiable and retraceable. The expression of the requirement in the relevant technical specifications shall be realistically adapted keeping in view a traceability as complete as possible.

4.3 Contents of the technical specifications on products

Technical specifications specify in the appropriate chapters the elements and requirements either mandatory or informative referred to above. Everything comprising the necessary provisions of factory production control and the attestation of conformity adopted for the product to which the specification relates has a mandatory character. Where possible, the elements mentioned and the requirements set out must be adapted or adaptable:

- to the particular features of the manufacturing processes. In particular, production control must be able to be adapted depending on the degree of automation of the manufacturing chain, adjustment devices, self adjustment, which manufacture may comprise.
- to the performance level the product is intended to have where the technical specification of the product provides for a range of performance levels and where the risk resulting from not achieving the intended performance varies with the level.

The adaptation procedures must be chosen in the interests of ensuring that the level of confidence obtained by the production control is effectively the same for all conceivable situations of manufacture.

4.4 Compliance with ISO 9000

The ISO 9000 series of standards is not a mandatory requirement in the framework of the Construction Products Directive and shall not be included as such in harmonised technical specifications.

Manufacturers having an FPC system which complies with ISO 9000 and which addresses the requirements of the appropriate harmonised standard are recognised as satisfying the FPC requirements of the Directive.

5 Factory production control by the manufacturer

5.1 General requirements

The purpose of factory production control is to ensure that the prestressing Steel is manufactured in a controlled way to meet all of the requirements of the relevant product specification standard. In order that a notified body can verify such a system it has to be documented in a structured way. This is carried out in a Works' quality manual supported and cross-referenced by a series of procedures, work instructions and other associated and relevant documents. These need to be clear, concise and adopt recommended good practices where applicable. The factory production control system may form part of a wider, integrated management system provided it can be demonstrated that all applicable EN 10138 requirements are addressed.

5.1.1 Factory production control for decoilers

SG14 has edited a Position Paper dealing with the factory production control requirement applicable by decoilers. This document is of application.

5.2 Works' quality manual

The manufacturer's documentation and procedures for factory production control shall be described in a Works' quality manual, which shall adequately describe, among other things:

- the quality aims and the organisational structure, responsibilities and powers of the management with regard to product quality and the means to monitor the achievement of the required product quality and the effective operation of the internal quality control;
- the manufacturing and quality control techniques, processes and systematic actions that will be used;
- the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out.

The Works' quality manual prepared by the manufacturer for each factory shall include an adequate system of documentation. The Works' quality manual shall address and document the procedures operated to ensure that the manufactured prestressing Steel conform to the technical specifications. The manual may reference associated documents which provide further details of the autocontrol testing of samples and the internal quality control. For the purpose of this scheme, the term Works' quality manual shall be considered to include these associated documents.

In the case of an existing quality management system according to EN ISO 9000, the notified body may examine if the corresponding quality manual meets all the requirements of EN 10138 which are relevant to the factory production control of prestressing Steel. Provided all the requirements are included, this quality manual may also be applied for product certification.

Guidelines

- The Works' quality manual is the fundamental document that describes the factory production control system operated by the prestressing Steel factory. It shall clearly state the scope of the factory production control system and must describe how each of the elements of the system are controlled and maintained.
- The Works' quality manual normally comprises a main document together with associated documents and technical procedures. All these documents are written in the current language of the factory's country.
- To ensure an effective factory production control system, there needs to be a well defined organisational structure within the factory, showing very clearly the lines of reporting and this is best achieved by one or more simple diagrams. The manual shall list all personnel who can affect quality within the manufacturing process together with their job titles and refer to a description of

their tasks and responsibilities within the quality function. These shall pay particular attention to the level of authority to check, assess, verify and pass conforming product.

- There needs to be a quality plan for the production of conforming prestressing Steel and whilst it must be recognised that the plan can take on one of many forms and include such things as process flow charts and control tables, it must show how each of the parts of the process are connected. There must be a clear indication of where samples are taken and at what frequency, together with the tests to be applied. Targets and acceptability criteria shall also be documented.
- In the case of an existing quality management system in accordance with ISO 9000 it shall be clearly stated in the Works' quality manual that the system is also used for factory production control according to EN 10138 and the other relevant product specification standards.

5.3 Management systems

5.3.1 Quality policy statement

The Works' quality manual shall include a statement by management defining its quality policy, objectives and commitments to the attainment of product quality.

Guidelines

- The quality policy statement is a document signed normally by the managing director of the company or by the manager of the factory, depending on the organisation of the company, or by both. It shall include the quality aims and its commitment to meeting the requirements of standards and/or of its customers and to ongoing improvement, both internally and externally. It shall indicate approval of the factory production control system as outlined in the Works' quality manual and that it is mandatory.
- The system by which all personnel are informed of the quality policy shall be documented. A route for feedback shall be established to aid understanding of the policy.
- In the case of an existing quality management system in accordance with EN ISO 9000, the quality policy statement shall include a commitment to the attainment of prestressing Steel quality in relation to the relevant product specification standard.
- The Quality Policy shall be reviewed periodically to ensure changes in aims are incorporated.

5.3.2 Management representative

The manufacturer shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of EN 10138 for the evaluation of conformity are implemented and maintained.

Guidelines

- The Management Representative shall be clearly shown to have the necessary dedication, time and authority to ensure that prestressing Steel continues to conform to the relevant product specification standard by the adoption of the requirements of the documented factory production control system. As he has the ultimate responsibility for the effective operation of factory

production control his responsibilities shall at least include maintenance of the Works' quality manual, the operation of process and autocontrol and the evaluation of the prestressing Steel data to the relevant product specification standard requirements. Effective and unrestricted communication channels to other affected departments must be open to the management representative to discuss possible problems.

- The authority and responsibility for the factory production control system and the quality assurance of prestressing Steel are not necessarily held by the same person.
- The Works' quality manual shall state to whom the responsibility is transferred in the absence of the management representative.

5.3.3 Internal audits and management review

In order to ensure the continuing suitability and effectiveness of the Work's quality manual to meet the requirements of EN 10138, the manufacturer shall perform at least once per year:

- internal audits;
- a management review of the factory production control, taking into account records of the internal audits.

Guidelines

- For audits to be of value there needs to be evidence that non-conformities raised are progressed to a satisfactory conclusion and this must be assessed by management during the review. Reviews shall be conducted to an established formal agenda by a management team and a record made of the findings, showing actions to be taken and relevant responsibilities. Reviews will need to take account of not only the internal audits but also of customer complaints.
- Audits need to be carried out at an established frequency, procedures and plan, by trained personnel independent of the area to be audited. It is essential that internal audits cover all aspects dealt with in the Works' quality manual, not forgetting compliance of prestressing Steel constituents with standard requirements and in-process specifications.

5.3.4 Training

The Works' quality manual shall describe the measures taken to ensure that all the personnel involved in operations that can affect internal quality control and product quality have appropriate experience or training. Appropriate records shall be retained.

Guidelines

- The adequate training of all personnel engaged in quality related matters and forming part of the factory production control system is of prime importance. It ensures that the exact skills and level of understanding are achieved to allow tasks to be carried out correctly and efficiently.
- A training plan, covering all the relevant personnel shall be available, listing the essential skills and education required for each element of the task/responsibility to be covered. These need to

cover both technical skills and an understanding of the function and operation of quality systems. The training plan must be supported by management and be continuous. It shall indicate the minimum educational level required for each role. Training can be external, as well as internal - details of these shall be recorded.

- A separate training plan for new starters will be required to cover induction training.

5.4 System of documentation

5.4.1 Document control

The management representative shall be responsible for the control of all documents and data related to factory production control and to this scheme for the evaluation of conformity.

This control shall ensure that the appropriate issues of all documents are available at essential locations that obsolete documents are withdrawn and that changes or modifications to any document are effectively introduced.

A master list shall be established to identify the current version of documents in order to prevent the use of non-applicable documents.

Guidelines

- The effectiveness of the factory production control system relies on the availability and use of correctly updated documents and data which include the Works' quality manual, procedures, operating instructions, technical specifications, plans, flowcharts, test methods and data records; this list is not exhaustive. A procedure must be available covering the issuing of amendments and updated documents. All documents shall be listed, giving proper identification, issue status and approval, holders and locations and mode of disposal of previous issues. If previous issues are to be retained they must be suitably marked to indicate that they are obsolescent and withdrawn.
- The principles of the document control are the same as those of ISO 9000, which can therefore be used as guidelines.

5.4.2 Quality records

The manufacturer shall retain records of factory production control for at least the period required to comply with relevant legislation.

Guidelines

- All factory production control records shall be kept for a minimum period of seven years and the Works' quality manual will identify retention periods and location of all records. Factory production control records that relate directly to the finished prestressing Steel shall be retained for at least the period necessary to satisfy product liability legislation and for at least a period of ten years.

- All records must be legible, identifiable, retrievable and protected from damage, deterioration or loss. Where records have been transferred to electronic or optical storage media, suitable back up copies shall be taken.

5.5 Internal quality control

5.5.1 Process control

The Works' quality manual shall describe the parameters for process planning, process control and testing, inspection, corrective action, verification, dispatch and the associated records.

Guidelines

- Process control shall be designed to prevent non-conformities arising. This cannot be achieved by testing only. To ensure that prestressing Steel complies with the relevant product specification standard, planning of the production process is required and shall address the following:
 - A process flow description/diagram to illustrate the important production elements and show how each stage is interrelated.
 - Targets and control limits (and subsequent actions if these are not met for each process stage, including parameters that are not included in the product specification standard);
 - Method and frequency of data collecting and processing;
 - Adequate testing and control of intermediate products.

5.5.2 Constituents of prestressing Steel

The manufacturer shall establish documented procedures and appropriate test methods to ensure that the constituents meet the requirements of the relevant product specification standard and are suitable to enable prestressing Steel to be produced meeting the technical specification.

The Works' quality manual shall describe the methods used by the manufacturer to ensure that the constituents of the prestressing Steel conform to the relevant product specification standard, including appropriate test methods.

5.5.2.1 Nitrogen content

A Position paper has been prepared by SG14 regarding the allowable content of nitrogen in presence of binding elements. This document is of application.

Guidelines

- Incoming supply shall be assessed against a previously agreed specification and will generally involve sampling and testing.
- The target level values of all constituents shall be specified and recorded.

5.5.3 Measuring and testing

5.5.3.1 Inspection, measuring and test equipment

The equipment for in-process inspection and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the Works' quality manual.

Guidelines

- All equipment shall be uniquely identified and verified to a programme prescribed in the Works' quality manual. Equipment used to control and monitor standard properties shall be checked and calibrated. Verification and calibration records shall enable verification of the calibration status of the equipment and that out of specification or calibration shall be marked "not for use" and isolated. Verification and calibration procedures shall be documented.

5.5.3.2 Inspection and test status

Procedures for the inspection and test status through the stages of manufacture shall be detailed in the Works' quality manual.

Guidelines

- The quality system and procedures shall ensure that all required inspections and tests are carried out. The system needs to provide a way of showing these have been done and the particular status of materials at each stage of the process. This is probably best achieved by the signing-off of results in the operating logbooks by the quality manager or his appointee, supported by designated storage areas for the various materials.

5.5.4 Statistical methods

SG14 has edited a Position Paper on the statistical analysis of the results in the frame of EN10138. This document is of application.

5.5.5 Handling, storage, packaging and delivery

The Works' quality manual shall describe the precautions taken for the protection of the quality of the prestressing Steel while under the responsibility of the manufacturer. It shall include a description of the procedures used for stockholding. Delivery documentation shall allow traceability to the users.

5.5.6 Autocontrol testing of samples

5.5.6.1 Sampling and testing

The manufacturer shall operate a system of autocontrol testing for each certified type of prestressing Steel. This system shall be used to demonstrate conformity to the requirements in the relevant product specification standard. The properties to be tested, the testing methods, the minimum frequency of autocontrol testing and the conformity criteria shall be in accordance with the basic requirements given in the relevant product specification standard.

All test data shall be documented.

The reporting of test results may include the determination of the statistical characteristics for the relevant control period, i.e. number of test results, mean, minimum and maximum value, number of test results exceeding the characteristic and limit values, standard deviation and relevant fractiles.

5.5.7 Corrective action

The Works' quality manual shall document procedures for the review and adjustment of the factory production control in case of non-conformity.

The actions taken in the event of non-conformity shall be recorded in a report subject to inspection during the management review.

In the event of prestressing Steel yielding a test result not conforming to the conformity criteria specified in the relevant product specification standard, the manufacturer shall immediately determine the affected quantity, take appropriate action to prevent the dispatch of this quantity and inform the affected customer if such prestressing Steel has been released. In addition, the manufacturer shall immediately determine the causes of such non-conformity, take corrective actions and undertake a review of all relevant factory production control procedures. All such actions and findings shall be appropriately recorded in a report subject to inspection during the management review.

The notified body may require to be kept informed of these actions and findings.

5.5.7.1 Measuring and test equipment for autocontrol testing

The equipment used for autocontrol testing shall be regularly checked and calibrated in accordance with procedures and frequencies laid down in the Works' quality manual. These procedures may include comparison of test results by proficiency testing with another laboratory designated in the Works' quality manual.

The Works' quality manual shall document procedures to ensure that all personnel involved in autocontrol testing have appropriate experience and training. Appropriate records shall be retained.

Guidelines

- All equipment used for conducting autocontrol testing shall be uniquely identified and calibrated to a prescribed programme. Equipment and/or materials used as references during these calibrations need to be referenced to national or other recognised standards. Calibration records shall indicate acceptable limits of use and enable verification of the calibration status of the equipment; that out of calibration shall be marked "not for use" and isolated. Calibration procedures shall be documented. If it is found necessary to adjust data following re-calibrations,

this shall be documented and the notified body informed. This will be of importance in situations where adjustment produces a non-conformity.

- Appropriate actions shall be taken when proficiency testing shows deviating results and these shall be documented.

5.5.7.2 Quality records

The manufacturer shall retain records of the autocontrol test results and appropriate records on test equipment for at least the period required to comply with relevant legislation.

Guidelines

- Regulations valid in the country of manufacture define the minimum period of retention of all autocontrol and test equipment records and additionally this shall be for at least a period of seven years. The Works' quality manual will identify retention periods and location of all records. The records must allow traceability of the autocontrol tests to the sampling points.
- All records must be legible, identifiable, retrievable and protected from damage, deterioration or loss. Where records have been transferred to electronic or optical storage media, suitable back up copies shall be taken.

6 Tasks for the notified body

The notified body has responsibility for the functions of certification of:

- Initial Type-testing,
- Initial Inspection of factory and of the Factory Production Control,
- Continuous Surveillance, Assessment and Approval of the factory production control,
- Audit testing of samples taken at the factory.

These functions may be carried out by one body or by more than one body. The inspection function may be carried out by an inspection body.

7 Initial type-testing

7.1 Sampling

Samples shall be taken under the responsibility of the notified body according to the requirements of the relevant standard.

7.2 Properties and test methods

The mechanical, physical and chemical properties specified for testing in the relevant product specification standard shall be determined according to the indicated test methods.

Guidelines

- Other test methods than indicated may be used provided that it is demonstrated that this method yields equivalent results on the prestressing Steel in question.

7.3 Evaluation of test results

The results obtained shall be evaluated by the notified body.

7.4 Use of historic data

The Position Paper edited by SG14 on historic data is of application regarding the use of historic data.

7.5 Reports

Following each evaluation of audit test results a confidential report shall be prepared without delay.

8 Initial inspection of the factory

8.1 Inspection of a new factory

In the case of a new factory, an initial inspection of the factory and the factory production control shall be made, based on information on the factory production control and the equipment to be used to manufacture prestressing Steel. The inspection shall, among other things:

- verify that the Works' quality manual complies with the requirements;
- verify that the equipment used to manufacture and test the prestressing Steel meet the criteria.

Guidelines

- The initial inspection of a new factory shall include an examination of the whole Works' quality manual and all the related procedures.
- The initial inspection can take more than two days because of the necessity to examine if the Works' quality manual takes into account the totality of the points under reference.

8.2 Inspection of an existing factory

In the case of a new type of prestressing Steel at an existing factory, information on any significant changes concerning the factory production control and the equipment, caused by the production of the new product shall be considered. This shall form the basis to decide, based on the importance of the changes to the Works' quality manual, whether a particular inspection is necessary. In this case any new equipment which has caused a major change in the Works' quality manual shall be inspected to verify that it meets the relevant criteria.

Guidelines

- In the case of a new type of prestressing Steel at an existing factory, a new inspection of the factory is rarely necessary, except when fundamental changes have been necessary to manufacture the new type of product. The notified body shall decide if a new inspection is necessary, taking into account the modifications of the Works' quality manual and of the relevant procedures.

8.3 Criteria for the assessment of the production equipment

The inspection shall assess the suitability of the production equipment in relation to the Works' quality manual and in relation to providing the ability to meet the requirements of the relevant product specification standard. The following criteria shall be considered:

- Equipment shall be provided which is suitable for manufacturing of prestressing Steel, with sufficient accuracy to ensure that the requirements of the relevant product specification standard are met.
- Measures shall be taken to prevent the mixing of different types and qualities during storage and delivery.

8.4 Criteria for the assessment of laboratories

The laboratory responsible for carrying out the tests required for internal quality control shall have at least the equipment needed to carry out the relevant tests indicated or referred to in the Works' quality manual.

The laboratory responsible for carrying out autocontrol testing shall have at least the equipment needed to carry out tests for the properties listed in the relevant product specification standard using the test methods indicated.

The laboratories shall demonstrate the ability to provide results within a time and in a manner suitable for the manufacturer's factory production control.

8.5 Reports

Following any initial inspection, a confidential report shall be prepared and a copy sent to the manufacturer.

9 Continuous surveillance, assessment and acceptance of the factory production control

9.1 Inspection tasks

The inspection tasks include surveillance, assessment and acceptance of the factory production control operated by the manufacturer. Inspection shall include checking that any major change in the Works' quality manual which is relevant to the factory production control of prestressing Steel has been reported to the notified body by the manufacturer within one month of its implementation.

Inspection shall verify that the factory production control complies with the requirements of EN 10138 and has been carried out according to the Works' quality manual.

Guidelines

- The inspection team is normally composed of one or two persons, at least one of whom is technically competent in production and testing of prestressing Steel. The inspection normally takes between one and two days depending on the complexity of the plant and the extent covered by the factory production control.
- The inspection body examines the documents and records, interviews the relevant personnel and inspects equipment (including equipment used in production and dispatch and in the laboratory). Emphasis is laid on all measures taken by the manufacturer to ensure the required product quality.
- Before leaving the factory, the inspectors normally give a copy of their main observations to the factory's quality manager. The inspection body may ask the manufacturer to comment and countersign this document before the inspectors leave the factory.

9.2 Frequency of inspections

The inspections shall normally be carried out not less than twice per year and the notified body shall inform the manufacturer in advance when an inspection is to be made.

Guidelines

- The inspection body, when delegated by the certification body, takes an initiative to agree with the manufacturer a date for the inspection.
- The notified body, at its own discretion, may request to be included in the distribution list of the controlled versions of the Works' quality manual. When the notified body is not on the distribution list it is appropriate that it requests an up-to-date copy of the Works' quality manual before the date of the inspection.
- The interval between two consecutive visits shall be not greater than 6 months; nevertheless, inspections are to be made in every certified factory twice per calendar year.

9.3 Reports

Following each inspection, a confidential report shall be prepared and sent to the manufacturer. The manufacturer shall, if appropriate, advise the notified body of any corrective actions taken or planned to be taken following receipt of the report.

The notified body shall then make a decision on its final assessment.

Guidelines

- The confidential report shall not be restricted to discrepancies but shall contain all relevant observations.
- The importance of any observations and the time within which corrections must be made shall be clearly mentioned in the report.
- The report shall be sent to the factory as soon as possible after the inspection, taking account of any needs for urgent action.

- Within a time specified in the inspection report, the manufacturer has to inform the notified body in writing about the corrective actions that he has taken or that he intends to take and the time for their implementation.

9.4 Evaluation of the results of autocontrol testing of samples

9.4.1 Evaluation tasks

Surveillance, assessment and acceptance of the factory production control includes evaluation of the test results of the manufacturer's autocontrol testing to check conformity to the statistical conformity criteria and single result limit values in the relevant product specification standard.

9.4.2 Number and timing of evaluations

The number of evaluations of the results of autocontrol testing of samples shall be at least two per year. The timing of the evaluations should be decided in advance.

Guidelines

- The certification body should specify the frequency for the sending of data by the manufacturer. The frequency and sequence of evaluations should follow a specified procedure. The certification body should establish normal periods of evaluation regularly distributed over the year taking into account the minimum frequency of two evaluations per year. In the case of a non-conformity (statistical or single result) or when test results from the autocontrol or from the audit testing lead to doubtful interpretation, the number of evaluations may be increased for a certain time to identify the reasons and monitor the effectiveness of corrective actions if needed.

9.4.3 Evaluation of test results

Each evaluation shall be made on the test results obtained on all autocontrol samples of a given certified prestressing Steel, without selection, taken during the control period preceding the date of the evaluation or during the initial period as the case may be.

Guidelines

- It should be checked whether all results of autocontrol testing are correctly documented. If there are obvious omissions or typing errors these should be remedied before carrying out the evaluation. If differences to the results of audit testing occur actions have to be taken.

10 Audit testing of samples taken at the factory

10.1 Sampling

Spot samples shall be taken under the responsibility of the certification body at the points of release of prestressing Steel from the factory or depots supplied with prestressing Steel by the factory. These are taken principally in order to provide a check on the accuracy of the manufacturer's test results. Representatives of the certification body shall be granted access to the factory and depots at any time without giving prior notice in order to allow the samples to be taken.

Guidelines

In order to make it possible that sampling can take place without prior notice, the certification body or its sub-contractor should make arrangements with the factory about the person(s) and their deputies to be contacted on entering the factory/depot in case of sampling. It is essential that sampling should be carried out in the presence of the representative of the certification body by the employees of the factory/depot that normally carry out that task.

10.2 Number of samples, properties and test methods

The number of samples taken shall be in accordance with the standard as well as properties to assess and test methods.

10.3 Evaluation of test results

The results obtained shall be evaluated by the certification body.

10.4 Reports

Following each evaluation of audit test results a confidential report shall be prepared without delay and a copy sent to the manufacturer.

11 Actions in the event of non-conformity

11.1 Actions to be taken by the manufacturer

The control of non-conforming prestressing Steel and the corrective actions to be taken are the full responsibility of the manufacturer, who shall document the detailed procedures in the Works' quality manual.

Guidelines

- In the event of a non-conformity it is the responsibility of the manufacturer to take adequate measures in accordance with the relevant detailed procedures documented in the Works' quality manual.

12 Questionnaire regarding FPC

Questions are included in the Table reproduced hereunder.

| Questions |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| For which product/product family a factory production control has been established and an initial inspection has been performed? |
| Did the methods of producing the products or the technical specification change since the latest continuous surveillance of the before-mentioned products/product family? |
| If yes, did the producer adapt the documentation accordingly? |

| |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Does the producer still apply a quality management system according to ISO 9000 which covers the factory production control of the certified products, and is that proved by a valid certificate? |
| Is the machinery equipment still maintained correctly and regularly and is the relevant documentation in existence and updated? |
| Are the personnel involved in the production still sufficiently qualified and trained to operate and maintain the machinery equipment? |
| Have there been alterations in the staff since the initial or the last continuous surveillance? |
| Are all processes and procedures of the production still recorded at regular intervals or continuously (automatically)? |
| Have there been changes in the manner of recording or documenting since the initial or the last continuous surveillance? |
| Does the producer still carry out for the certified products a traceable documentation of the production process from the purchasing or delivery of the basic materials until the storage and the delivery of the finished products? |
| Have the provisions for procurement of the basic materials and/or the suppliers been changed? |
| Is an inspection of the incoming material still carried out and have there been any changes in the way and/or intervals? |
| Are manner, extent and frequency of factory production control still in accordance with the provisions of the technical specification? |
| Have any changes been made concerning test methods and/or testing equipment? |
| Have appropriate comparable measurements been performed and documented? |
| Do the findings of these tests still correlate with the test methods laid down in the technical specification for initial type-testing or testing in the frame of the surveillance, respectively? |
| Is the testing equipment still correctly maintained and calibrated to ensure constant accuracy of the tests performed during factory production control and surveillance? |
| Does the producer still apply a documentation system which allows the detection of defects and deviations fast enough to identify and mark unambiguously products which are not in accordance with the product specification in order to eliminate them? |
| Does the producer maintain a complete documentation of all incoming complaints (internal concerning the factory production control and external) concerning his certified products? |
| Complaints with regard to certified products are considered in case of lacks of confidence concerning the conformity with the technical specification. Have appropriate measures for corrections also been introduced and are these measures documented? |
| Have complaints received by the producer been reported to full extent to the certification body ? |
| Are the products duly marked with the CE marking? |
| Do the values measured during factory production control correspond with those values determined |

| |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| on products within the initial type-testing? |
| Besides the CE marking, is the marking of prestressing Steel according to clause “Marking” inside the standard rightly addressed? |
| <p>Does the FPC rightly addresses:</p> <ul style="list-style-type: none"> ▪ The control of all the harmonised properties? ▪ The control of the dimensions? ▪ The verification of the raw materials? |
| <p>Conclusion made by the notified body:</p> <ul style="list-style-type: none"> ▪ Appraisal of the results, ▪ Listing of the measures to be taken for necessary correction, ▪ Proposal for future certification. |

13 Identification

Identification of the prestressing Steels regarding the Producer (country and works number) and the product (product number) are stringently ruled by EN10138 with reference to a database held by a European organisation.

A Position Paper has been edited by SG14 on this matter and is of application.

14 Certification procedure

14.1 Manufacturers not holding an ISO 9000 certificate

14.1.1 Initial type-testing of the product by the notified body

In so far as historic data may be used and after having received the agreement of the certification body in this regard, the manufacturer shall prepare for the attention of the certification body a certification application dossier detailing the content of the initial type-testing of all related products according to the requirements of the technical specifications and the present operating procedure. This dossier shall then be completed by the cares of the notified body by the further information that is requested according to the standard.

14.1.2 Factory production control by the manufacturer

The manufacturer shall document a factory production control and demonstrate its right application to the notified body during initial inspection and continuous surveillance.

14.1.3 Initial inspection of factory and factory production control by the notified body

The notified body shall evaluate:

- the capacity of the manufacturer to apply the foreseen factory production control,

- the capability of the foreseen factory production control and its fulfilment with the requirements of the present operating procedure,
- the fact that the factory production control really addresses the requirements of the EN 10138 standard,
- the right working of the factory production control as regards all its requirements,
- the capacity of the manufacturer to take part in the initial type-testing.

14.1.4 Continuous surveillance, assessment and approval of the factory production control by the notified body

The notified body shall evaluate:

- the capacity of the manufacturer to apply the foreseen factory production control,
- the capability of the foreseen factory production control and its fulfilment with the requirements of the present operating procedure,
- the fact that the factory production control really addresses the requirements of the EN 10138 standard,
- the right working of the factory production control as regards all its requirements.

14.2 Manufacturers already holding an ISO 9000 certificate

14.2.1 Initial type-testing of the product by the notified body

In so far as historic data may be used and after having received the agreement of the certification body in this regard, the manufacturer shall prepare for the attention of the certification body a certification application dossier detailing the content of the initial type-testing of all related products according to the requirements of the technical specifications and the present operating procedure. This dossier shall then be completed by the cares of the notified body by the further information that is requested according to the standard.

14.2.2 Factory production control by the manufacturer

The manufacturer shall compile in a certification dossier to be sent to the notified body before the initial inspection the features of its factory production addressing the requirements of the EN 10138 standard. A copy of the ISO 9000 certificate will be included.

14.2.3 Initial inspection of factory and factory production control by the notified body

Prior to the initial inspection, the notified body shall evaluate the certification dossier prepared by the manufacturer relating to initial type-testing and factory production control and will have requested necessary complementary information.

The initial inspection shall be conducted after acceptance of the certification dossier and will aim at visualizing and consolidating its content.

14.2.4 Continuous surveillance, judgement and assessment of the factory production control by the notified body

The manufacturer shall keep his certification dossier updated. Prior to the periodical inspection, the notified body shall evaluate the updating of the certification dossier prepared by the manufacturer relating to initial type-testing and factory production control and will have requested necessary complementary information.

The periodical inspection shall be conducted after acceptance of the certification dossier and will aim at visualising and consolidating its content.

15 Application for certification

The manufacturer, who intends to grant for a certification shall address a demand to OCAB-OCBS.

Upon receipt of this demand, OCAB-OCBS will transmit to the manufacturer a proposal with a set of documents including:

- The specific procedure for use and control of CE marking in the sector of construction products,
- The present operating procedure,
- A copy of the certification agreement,
- The applicable tariff and fees.

The manufacturer, who wishes to start the certification procedure, sends back the duly signed and approved proposal to OCAB-OCBS. The certification process is then started.

16 Example of EC Certificate

SG14 has edited a Position Paper on the models of certificate . This document is of application.

An example of certificate forwarded is illustrated below.

Certificate of Conformity (EC Certificate)

1+



Avenue Arianelaan, 5

B 1200 BRUSSELS

1148 - CPD - 200XNN

By the Belgian Law on the application of the directive 89/106/EEC of the Council of European Communities of 21 December 1988 relating to the construction products (Construction Products Directive - CPD), it has been stated by OCAB-OCBS (Notified Body N°1148) and LIN/MET/SECO/INFRABEL (Notified Body N°1147/1593/1612/0000) that

Name of the Producer**Full address**in its factory of **FACTORY**

applies a

**Factory Production Control (FPC) according to EN 10138
for Prestressing Steel.**

The notified body has performed the **Initial Type-testing** of the products, the **Initial Inspection** of the factory and of the factory production control and performs the **Continuous Surveillance, Assessment and Approval** of the factory production control as well as the **Audit Testing** laid down in the harmonized standard EN 10138: 200X.

This certificate attests that all provisions concerning the attestation of conformity described in Annex ZA of the standard were applied. This certificate remains valid for five years from the hereunder mentioned date and as long as the conditions laid down in the harmonized standard or the manufacturing conditions in the factory or the FPC itself have not changed significantly.

<City, Date>

<Authorized signatures AND NAMES>

