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Smernice za uporabo EN 197-2 "Ovrednotenje skladnosti"

Guidelines for the application of EN 197-2 "Conformity Evaluation"

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Guidelines for the application of EN 197-2 “Conformity Evaluation”

This CEN Report was approved by CEN on 13 March 2001. It has been drawn up by the Technical Committee CEN/TC 51.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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CR 14245:2001 (E)**Introduction to this Guidelines Document*****Purpose***

The purpose of this Guidelines Document is to provide explanatory detail on points not fully elaborated in EN 197-2. It is intended for use by manufacturers and by certification bodies involved in the certification of cement following EN 197-2, in particular for the issuing of an EC Certificate of Conformity.

This Document does not deal with the necessary internal procedures that the certification bodies will have.

It is an objective of this Guidelines Document that its use will assist in the establishment of equivalent procedures for certification of cement. It is expected that, following this Document, traditional good procedures and practices that may be different can continue to be used, provided that they are not in contradiction with EN 197-2 and the relevant product specification standard. Such existing good procedures and practices, applied in conjunction with these Guidelines, are not considered to be an impediment to the achievement of the uniform level of certification throughout Europe, and by different certification bodies, that is expected from the application of EN 197-2 together with these Guidelines.

This Guidelines Document is based on existing situations for production, evaluation of conformity and certification of cements. It may happen that certification bodies be confronted by a situation different to those included in this document. In such a case, specific procedures should be elaborated on a case by case situation and be approved and fully recorded by the Certification Body. These specific procedures should always fulfil the requirements of EN 197-1 and EN 197-2 and lead to the same level of confidence in product conformity that would be achieved by application of this Guidelines Document.

Arrangement

The clause numbering system of EN 197-2 is followed. The text of each of the clauses of the Standard is reproduced in full and is followed by guidance, which is provided only for those clauses where clarification or elaboration is needed.

CLAUSES OF EN 197-2

Foreword

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 51 "Cement and building limes", the secretariat of which is held by IBN.

This European Standard supersedes ENV 197-2:1995.

Annex A of EN 197-2 is normative, annex B is informative.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Swede, Switzerland and the United Kingdom.

1 Scope

EN 197-2 specifies the scheme for the evaluation of conformity of cements to their corresponding product specification standards, including certification of conformity by a certification body.

The standard provides technical rules for factory production control by the manufacturer, including autocontrol testing of samples, and for the tasks of the certification body. It also provides rules for actions to be followed in the event of non-conformity, the procedure for the certification of conformity and requirements for dispatching centres.

In EN 197-2 the word "cement" is used to refer both to common cements as defined in EN 197-1 and to other cements and binders for which the relevant product specification standard makes reference to EN 197-2 and which are submitted for certification. Such a cement is produced at a given factory and belongs to a particular type and a particular strength class, as defined and specified in the relevant product specification standard. „

Guidance

EN 197-2 deals with the evaluation of conformity of cements and binders that are submitted for certification. It deals in particular with cases where "further testing" of the product is undertaken, as is the case for attestation system 1+ under the Construction Products Directive. The products for which EN 197-2 is applicable are: the 27 common cement products, refer EN 197-1, and masonry cements, refer prEN 413-1. It will also be applicable for low heat cements, sulfate resisting cements and calcium aluminate cements when the corresponding product specification standards are adopted.

“ 2 Normative references

EN 197-2 incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to EN 197-2 only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 196-1, *Methods of testing cement - Part 1: Determination of strength.*

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EN 196-7, *Methods of testing cement - Part 7: Methods of taking and preparing samples of cement.*

EN 197-1, *Cement - Part 1: Composition, specifications and conformity criteria for common cements.*

ENV 413-1, *Masonry cement - Part 1: Specification.*

EN ISO 17025, *General requirements for the competence of testing and calibration laboratories.*

EN 45004, *General criteria for the operation of bodies performing inspection.*

EN 45011, *General criteria for certification bodies operating product certification (ISO/IEC Guide 65:1996).*

ISO 2854, *Statistical interpretation of data - Techniques of estimation and tests relating to means and variances.*

3 Definitions

For the purposes of EN 197-2, the following definitions apply:

3.1 Specific definitions**3.1.1****certificate of conformity**

document issued under the rules of this scheme for the evaluation of conformity indicating that adequate confidence is provided that cement is in conformity with the relevant product specification standard „

Guidance

The term “certificate of conformity” refers to certificates of conformity issued by a certification body under the rules of EN 197-2. This includes an EC Certificate of Conformity issued in relation to the CPD.

“ 3.1.2**conformity mark**

protected mark applied on the basis of the certificate of conformity (see 3.1.1) „

Guidance

The term “protected mark” includes registered mark, regulated mark and CE marking.

“ 3.1.3**certified cement**

cement for which a certificate of conformity (see 3.1.1) has been issued

3.1.4**initial period**

immediate period after the first issuing of the certificate of conformity for a cement

3.1.5**certification body**

impartial body, governmental or non-governmental, possessing the necessary competence and responsibility to carry out conformity certification according to given rules of procedure and management

3.1.6**factory production control**

permanent internal control of cement production exercised by the manufacturer consisting of internal quality control complemented by autocontrol testing

3.1.7**factory**

facility used by a manufacturer for the production of cement using equipment which is suitable for continuous mass production of cement including, in particular, equipment for adequate grinding and homogenization and the necessary silo capacity for the storage and dispatch of each cement produced. This equipment and the production control applied allow the control of production with sufficient accuracy to ensure that the requirements of the relevant product specification standard are met „

Guidance

According to clause 4 of EN 197-1, common cements (CEM cements) consist of different materials and are statistically homogeneous in composition resulting from quality assured production and material handling processes. A high degree of uniformity in all cement properties is obtained through continuous mass production processes, in particular, adequate grinding and homogenisation processes. Similar considerations apply for other cements.

Three categories of “factory” are recognised:

- Traditional full cement factories, where clinker and cement are produced on the same site;
- Grinding plants, where cement is produced by grinding supplied cement constituents;
- Blending plants, where ground cement constituents, which may be received already combined as cement, are blended to produce finished cement.

The following operating steps, which apply for all of these types of factory, are essential in the manufacturing process. These steps are needed to ensure the necessary uniformity, continuity and suitability of the cement properties as well as the ability to meet the other requirements of the relevant product specification standard:

- Use of separate and adequate storage for the cement constituents;
- Controlling the cement constituents – including, where relevant, their fineness and particle size distribution, and therefore their grinding – to achieve a performance of the cement compatible with the requirements of the product specification standard;
- Proportioning the cement constituents in order to achieve the target composition of the cement;
- Homogenisation of the cement constituents by grinding, or by mixing where relevant;
- Storage of finished product, in silos of adequate capacity, allowing proper identification of mass quantities of product and giving the possibility of taking spot samples at any time without prior notice.

Factories can only be operated by manufacturers which have personnel with sufficient experience and knowledge in all operating steps important for cement

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quality and which have the people and test equipment to test, evaluate and correct the cement being produced. The definition of factory in EN 197-2 takes it, therefore, for granted that all operating steps listed above are carried out in effect under the same quality responsibility.

“ 3.1.8**new factory**

factory which is not already producing cement(s) certified under this scheme

3.1.9**existing factory**

factory which is already producing cement(s) certified under this scheme

3.1.10**depot**

bulk cement handling facility (not located at the factory) used for the dispatch of cement (whether in bulk or bagged) after transfer or storage where the manufacturer has full responsibility for all aspects of the quality of the cement ,,

Guidance

It is important to point out the difference between a depot and a dispatching centre. The difference consists essentially of the linkage to the factory and the responsibility for the quality of the cement. In the case of a depot the facility is strictly linked to the factory and is included in the factory Works' quality manual. The manufacturer has full responsibility for the quality of the cement released from the depot. In a dispatching centre, in contrast, the facility is not at all linked to the factory and it is an intermediary (an entity taking certified cement, acting independently and operating between the manufacturer and a subsequent customer) who has full responsibility for the quality of the cement dispatched. A dispatching centre, being independent from the factory cannot be included in a Works' quality manual, but it has to ensure, using appropriate rules, that the quality of an already certified cement does not undergo any change.

Depots are included in the Works' quality manual. An entity other than the manufacturer may own and operate the depot but it does this on behalf of and under the strict quality management responsibility of the manufacturer.

“ 3.1.11**dispatching centre**

bulk cement handling facility (not located at the factory) used for the dispatch of cement after transfer or storage where an intermediary has full responsibility for all aspects of the quality of the cement ,,

Guidance

See guidance under 3.1.10 and 9.1.

“ 3.1.12**intermediary**

natural or legal person who takes from the manufacturer bulk cement certified according to EN 197-2 and bearing the conformity mark, who undertakes full responsibility for maintaining in a bulk handling facility all aspects of the quality of the cement and who supplies the cement onwards to a further person

3.1.13

confirmation autocontrol testing

continual testing carried out by an intermediary which consists of testing of samples taken by the intermediary at the point(s) of release from the dispatching centre

3.1.14**works' quality manual**

document that provides information on the factory production control which is applied by a manufacturer at a particular factory to ensure conformity of the cement with the requirements of the relevant product specification standard

3.2 General definitions

See annex B (informative).

4 Factory production control by the manufacturer**4.1 General requirements****4.1.1 Concept**

Factory production control means the permanent internal control of cement production exercised by the manufacturer and consists of internal quality control (see 4.2) complemented by autocontrol testing of samples of cement taken at the point of release ¹⁾ (see 4.3).

NOTE The requirements of EN 197-2 as regards factory production control take account of those clauses of EN ISO 9002 which are relevant to the production, process control and testing of cement.

Guidance

The purpose of factory production control is to ensure that the cement is manufactured in a controlled way to meet all of the requirements of the relevant product specification standard. In order that a certification 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 197-2 requirements are addressed. See also the Note in 4.1.2 of the Standard.

As depots are under the direct responsibility of the cement manufacturer, the factory production control system must include them and appropriate procedures should be produced, where relevant.

“ 4.1.2 Works' quality manual

¹⁾ This testing corresponds also to the “further testing of samples” mentioned in Annex III Section 2 point (i) of the Construction Products Directive 89/106/EEC.

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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:

- a) 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 (see 4.1.3);
- b) the manufacturing and quality control techniques, processes and systematic actions that will be used (see 4.2.1, 4.2.3 and 4.3.2);
- c) the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out (see 4.2.2, 4.3.1 and 4.3.3).

The Works' quality manual prepared by the manufacturer for each factory shall include an adequate system of documentation (see 4.1.4 and 4.3.4).

The Works' quality manual shall address and document the procedures operated to ensure that the manufactured cement conforms 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.

NOTE In the case of an existing quality management system according to EN ISO 9002, the certification body may examine if the corresponding quality manual meets all the requirements of EN 197-2 which are relevant to the factory production control of cement. Provided all the requirements are included, this quality manual may also be applied for product certification.

Guidance

The Works' quality manual is the fundamental document that describes the factory production control system operated by the cement factory. It should clearly state the scope of the factory production control system and must describe how each of the elements of the system, as outlined in clauses 4.1 to 4.3.4, 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 cement factory, showing very clearly the lines of reporting and this is best achieved by one or more simple diagrams. The manual should 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 should pay particular attention to the level of authority to check, assess, verify and pass conforming product during the stages of clinker and cement and, if appropriate under the selected scope of factory production control, of raw materials, raw meal and/or kiln feed.

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| <p>Illustrative Example of Responsibilities - For Information Only</p> |
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Quality Manager

The Quality Manager has two overall responsibilities: to ensure that adequate quality procedures exist and to ensure that the procedures are carried out. The Quality Manager is responsible to the Factory Manager for:

- The co-ordination, monitoring and updating of the Works' quality manual procedures.
- Ensuring all personnel at every level are kept informed of working methods, procedures, specifications and quality targets.
- Setting the requirements for process control and supervising their written transmission to the appropriate personnel.
- Assessing the conformity of raw materials to the relevant specifications.
- Controlling of off-specification constituents and non-conforming cements.
- The identification and resolution of non-conformities in the factory production control system.
- Supervising the recording and processing of relevant data and consequent approval.
- Provide senior personnel with periodic reports on the compliance status of the cement.

There needs to be a quality plan for the production of conforming cement 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 should also be documented.

Regarding the NOTE at the end of 4.1.2, in the case of an existing quality management system in accordance with EN ISO 9002 it should be clearly stated in the Works' quality manual that the system is also used for factory production control according to EN 197-2 and the relevant product specification standard. EN ISO 9002 is currently under revision and will be incorporated in EN ISO 9001.

“ 4.1.3 Management systems**4.1.3.1 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. „

Guidance

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 should 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 should 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 should be documented. A route for feedback should be established to aid understanding of the policy.

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In the case of an existing quality management system in accordance with EN ISO 9002 (see comment in the guidance under 4.1.2 regarding the revision of this standard), the quality policy statement should include a commitment to the attainment of cement quality in relation to the relevant product specification standard.

The Quality Policy should be reviewed periodically to ensure changes in aims are incorporated.

“ 4.1.3.2 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 197-2 for the evaluation of conformity are implemented and maintained. „

Guidance

The Management Representative should be clearly shown to have the necessary dedication, time and authority to ensure that cement 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 should at least include maintenance of the Works' quality manual, the operation of process and autocontrol and the evaluation of the cement 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 cement are not necessarily held by the same person.

The Works' quality manual should state to whom the responsibility is transferred in the absence of the management representative.

“ 4.1.3.3 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 197-2, the manufacturer shall perform at least once per year:

- a) internal audits covering the scope of this clause 4 and 6.1;
- b) a management review of the factory production control, taking into account records of the internal audits. „

Guidance

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 should 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 cement constituents and cements with standard requirements and in-process specifications.

“ 4.1.3.4 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. „

Guidance

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 should 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 should indicate the minimum educational level required for each role. Training can be external, as well as internal - details of these should be recorded.

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

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“ 4.1.4 System of documentation [log/standards/sist/ee8b84de-c933-4239-8b1a-1bbde5f4f59c/sist-tp-cr-14245-2004](#)

4.1.4.1 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. „

Guidance

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 should 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.

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The principles of the document control are the same as those of ISO 9002, which can therefore be used as guidelines.

“ 4.1.4.2 Quality records

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

Guidance

All factory production control records should be kept for a minimum period of three 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 cement should 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 should be taken.

“ 4.2 Internal quality control**4.2.1 Process control****4.2.1.1 General**

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

Guidance

Process control should be designed to prevent non-conformities arising. This cannot be achieved by testing only. To ensure that cement complies with the relevant product specification standard, planning of the production process is required and should address the following:

- A process flow description/diagram to illustrate the important production elements and show how each stage is interrelated. This should include all stages covered by the selected scope of the factory production control. It should also indicate measurement points, sampling points for the relevant tests and storage areas;
- 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, for example, specific surface area;
- Method and frequency of data collecting and processing;
- Procedures to cover 4.2.1 to 4.3.4 with particular reference to those in the cases of changing conditions such as start/stop operations, cement and silo changeovers;
- Prevention of contamination of cement, cement constituents (including clinker) and all materials covered by the selected scope of the factory production control, during production, handling and dispatch.

In following the requirements of EN 197-2, all categories of factory (see guidance under 3.1.7) should have, in particular, the following equipment and procedures:

- Separate storage for incoming materials, normally for powdered materials and adequate other forms of storage for granular materials;

- Testing and control of all cement constituents, the degree of which being adapted to the level of influence of the constituent to the ultimate quality of the product;
- Adequate blending and homogenisation equipment and procedures;
- Silo(s) for each product awaiting dispatch;
- A procedure ensuring no direct loading;
- Adequate testing and control of intermediate products.

For grinding plants and full factories there should also be:

- Adequate grinding equipment and procedures.

In the case of blending plants, because the grinding facilities are located at a site that is remote from the plant, special consideration has to be given, on a case by case basis, to the equipment and to the factory production control to verify their suitability for producing cement in accordance with the requirements of the relevant product specification standard. For blending plants, in addition to the equipment and procedure items listed above for all types of factory, there should also be:

- Arrangements to ensure that cement constituents are produced, supplied and received in accordance with the requirements of the blending plant for the purpose of designing the cement and controlling its properties;
- Documented procedures showing full traceability and control of the cement constituents whether received separately or in a combined form, for instance as cement.

“ 4.2.1.2 Constituents and composition of cement

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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 cement to be produced meeting the technical specification.

The Works' quality manual shall describe the methods used by the manufacturer to ensure that the composition of the cement produced conforms to the relevant product specification standard, including appropriate test methods. „

Guidance

Incoming supply should be assessed against a previously agreed specification and will generally involve sampling and testing. Procedures may include those to establish suitability of different sources of all constituents including additives.

Adequate stocks must be maintained and discrete, protected storage should be available for each constituent. If any material is unsatisfactory, there must be an adequate procedure for disposal and possible controlled use. This is particularly important for off-specification clinker or clinker that has been stored outside.

Determination of cement composition also includes the amount of minor additional constituent.

The target level values of all constituents should be specified and recorded.

“ 4.2.1.3 Control of off-specification production

The Works' quality manual shall contain procedures to ensure that off-specification production is adequately managed. „