
**Plastics piping systems for hot and cold
water installations — Chlorinated
poly(vinyl chloride) (PVC-C) —**

**Part 7:
Guidance for the assessment of
conformity**

*Systèmes de canalisations en plastique pour les installations d'eau
chaude et froide — Poly(chlorure de vinyle) chloré (PVC-C) —*

Partie 7: Guide pour l'évaluation de la conformité

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 15877-7 was prepared by European Committee for Standardization (CEN) Technical Committee CEN/TC 155, *Plastics piping systems and ducting systems*, in collaboration with ISO Technical Committee ISO/TC 138, *Plastics pipes, fittings and valves for the transport of fluids*, Subcommittee SC 2, *Plastics pipes and fittings for water supplies*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This Technical Specification is part of a System Standard for plastics piping systems of a particular material for a specified application. There are a number of such System Standards.

The System Standards are consistent with general standards on functional requirements and on recommended practice for installation.

They are supported by separate standards on test methods to which references are made throughout the System Standard.

This second edition cancels and replaces the first edition (ISO/TS 15877-7:2003), which has been technically revised.

ISO 15877 consists of the following parts¹⁾, under the general title *Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C)*:

- *Part 1: General*
- *Part 2: Pipes*
- *Part 3: Fittings*
- *Part 5: Fitness for purpose of the system*
- *Part 7: Guidance for the assessment of conformity* [Technical Specification]

This Technical Specification can be used to support elaboration of national certification procedures for products conforming to the applicable part(s) of ISO 15877.

At the date of publication of this Technical Specification, System Standards for piping systems of other plastics materials used for hot and cold water installations are the following:

ISO 15874 (all parts), *Plastics piping systems for hot and cold water installations — Polypropylene (PP)*

ISO 15875 (all parts), *Plastics piping systems for hot and cold water installations — Crosslinked polyethylene (PE-X)*

ISO 15876 (all parts), *Plastics piping systems for hot and cold water installations — Polybutylene (PB)*

ISO 22391:—²⁾ (all parts), *Plastics piping systems for hot and cold water installations — Polyethylene of raised temperature resistance (PE-RT)*

1) This System Standard does not incorporate a part 4: *Ancillary equipment* or a part 6: *Guidance for installation*. For ancillary equipment, separate standards can apply. Guidance for installation of plastics piping systems made from different materials, intended to be used for hot and cold water installations, is covered by ENV 12108^[6].

2) To be published. (Revisions of ISO 22391-1:2007, ISO 22391-2:2007, ISO 22391-3:2007, ISO 22391-5:2007)

Introduction

This Technical Specification is a part of the System Standard which specifies the requirements for a piping system when made from chlorinated poly(vinyl chloride) (PVC-C). The piping system is intended to be used for hot and cold water installations and heating system installations.

In respect of potential adverse effects on the quality of water intended for human consumption caused by the product covered by ISO 15877 (all parts).

- 1) This Technical Specification provides no information as to whether the product may be used without restriction in any of the Member States of the EU or EFTA.
- 2) It should be noted that, while awaiting the adoption of verifiable European criteria, existing national regulations concerning the use and/or the characteristics of this product remain in force.

When using solvent cement, relevant national safety rules or regulations concerning their use (e.g. protection of workers) are to be observed.

Requirements and test methods for material and components are specified in ISO 15877-1, ISO 15877-2 and ISO 15877-3. Characteristics for fitness for purpose (mainly for joints) are covered in ISO 15877-5.

This Technical Specification gives guidance for the assessment of conformity of materials, components, joints and assemblies and it is intended to be used by certification bodies, inspection bodies, testing laboratories and manufacturers.

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Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C) —

Part 7: Guidance for the assessment of conformity

1 Scope

This Technical Specification gives guidance for the assessment of conformity included in the manufacturer's quality plan as part of his/her quality system.

This Technical Specification includes:

- a) provisions for materials, components, joints and assemblies given in the applicable part(s) of ISO 15877;
- b) provisions for the manufacturer's quality system, which can conform to ISO 9001^[2];
- c) definitions and procedures applied if certification is involved; in which case, the certification body can be accredited to ISO/IEC Guide 65^[5] or ISO/IEC 17021^[3], as applicable.

In conjunction with the other parts of ISO 15877, this Technical Specification is applicable to chlorinated poly(vinyl chloride) (PVC-C) piping systems intended to be used for hot and cold water installations within buildings for the conveyance of water, whether or not intended for human consumption (domestic systems), under design pressures and temperatures appropriate to the class of application (see Table 1 of ISO 15877-1:2009).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15877-1:2009, *Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C) — Part 1: General*

ISO 15877-2:2009, *Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C) — Part 2: Pipes*

ISO 15877-3:2009, *Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C) — Part 3: Fittings*

ISO 15877-5:2009, *Plastics piping systems for hot and cold water installations — Chlorinated poly(vinyl chloride) (PVC-C) — Part 5: Fitness for purpose of the system*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptable quality limit (AQL) for lot-by-lot inspection*

ISO 3951-1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

ISO 3951-2, *Sampling procedures for inspection by variables — Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection of independent quality characteristics*

3 Terms, definitions and abbreviated terms

For the purposes of this Technical Specification, the definitions, symbols and abbreviations given in ISO 15877-1, ISO 15877-2 and ISO 15877-3 apply, together with the following.

3.1 Terms and definitions

3.1.1

certification body

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

3.1.2

inspection body

impartial organization or company, approved by a certification body as possessing the necessary competence to verify and/or to carry out initial type testing, audit testing and inspection of the manufacturer's factory production control in accordance with the relevant standard

3.1.3

testing laboratory

laboratory which measures, tests, calibrates or otherwise determines the characteristics of the performance of materials and products

3.1.4

quality system

organizational structure, responsibilities, procedures, processes and resources for implementing quality management

See ISO 9000^[1].

3.1.5

quality plan

document setting out the specific quality practices, resources and sequence of activities relevant to a particular product or range of products

3.1.6

type testing

TT
testing performed to prove that the material, component, joint or assembly is capable of conforming to the requirements given in the relevant standard

3.1.7

preliminary type testing

PTT
type testing carried out by or on behalf of the manufacturer

3.1.8

initial type testing

ITT
type testing carried out by or on behalf of a certification body for certification purposes

3.1.9**batch release test****BRT**

test performed by the manufacturer on a batch of components, which has to be satisfactorily completed before the batch can be released

3.1.10**process verification test****PVT**

test performed by the manufacturer on materials, components, joints or assemblies at specific intervals to confirm that the process continues to be capable of producing components conforming to the requirements given in the relevant standard

NOTE Such tests are not required to release batches of components and are carried out as a measure of process control.

3.1.11**audit test****AT**

test performed by or on behalf of a certification body to confirm that the material, component, joint or assembly continues to conform to the requirements given in the relevant standard and to provide information to assess the effectiveness of the quality system

3.1.12**indirect test****IT**

test performed by the manufacturer, different from that specified for that particular characteristic, having verified its correlation with the specified test

3.1.13**witness testing****WT**

testing accepted by a certification body for initial type testing and/or audit testing, which is carried out by or on behalf of the manufacturer and supervised by a representative of the certification body, qualified in testing

3.1.14**material or compound batch**

clearly identifiable quantity of a particular material or compound

3.1.15**production batch**

clearly identifiable collection of units, manufactured consecutively or continuously under the same conditions, using material or compound conforming to the same specification

3.1.16**lot**

clearly identifiable sub-division of a batch for inspection purposes

3.1.17**sample**

one or more units of product drawn from a batch or lot, selected at random without regard to their quality

NOTE The number of units of product in the sample is the sample size.

3.1.18**acceptable quality level****AQL**

when a continuous series of lots or batches is considered, the quality level which for the purpose of sampling inspection is the limit of a satisfactory process average

See ISO 2859-1, ISO 3951-1 and ISO 3951-2.

NOTE The designation of an AQL does not imply that a manufacturer has the right knowingly to supply any non-conforming unit of product.

3.1.19

inspection level

relationship between the lot or batch size and the sample size

See ISO 2859-1.

3.1.20

group

collection of similar components from which samples are selected for testing purposes

3.2 Abbreviated terms

NOTE The abbreviated terms are the same in the three languages (en: English, fr: French, de: German).

AQL en : acceptable quality level
fr : niveau de qualité acceptable
de : annehmbare Qualitätsgrenzlage

AT en : audit test
fr : essai d'audit
de : Überwachungsprüfung

BRT en : batch release test
fr : essai de libération de campagne de fabrication
de : Freigabeprüfung einer Charge

IT en : indirect test
fr : essai indirect
de : indirekte Prüfung

ITT en : initial type testing
fr : essai de type initial
de : Erst-Typprüfung

PTT en : preliminary type testing
fr : essai de type préliminaire
de : vorausgehende Typprüfung

PVT en : process verification test
fr : essai de vérification du procédé de fabrication
de : Prozeßüberprüfung

TT en : type test
fr : essai de type
de : Typprüfung

WT en : witness testing
fr : essai témoin
de : Prüfung unter Aufsicht

4 Requirements

4.1 General

4.1.1 Materials, components, joints and assemblies shall conform to the requirements given in ISO 15877-1, ISO 15877-2, ISO 15877-3 and ISO 15877-5, as applicable.

4.1.2 Components and/or assemblies shall be produced by the manufacturer under a quality system which includes a quality plan.

4.2 Testing and inspection

4.2.1 Grouping

For the purposes of this Technical Specification, the following groups apply.

4.2.1.1 Pressure groups

The pressure group is a group of design pressures, from which one individual design pressure, p_D , shall be selected for testing purposes.

Two pressure groups shall be designated as given in Table 1.

Table 1 — Pressure groups

| Pressure group | Design pressure, p_D bar |
|----------------|-------------------------------|
| 1 | 4; 6 |
| 2 | 8; 10 |

4.2.1.2 Size groups

The size group is a group of nominal diameters of pipes and fittings, from which one individual nominal diameter, d_n , shall be selected for testing purposes.

Two size groups shall be designated as given in Table 2.

Table 2 — Size groups

| Size group | Nominal diameter, d_n mm |
|------------|-------------------------------|
| 1 | $12 \leq d_n \leq 63$ |
| 2 | $63 < d_n \leq 160$ |

4.2.1.3 Fitting groups

The fittings group is a group of fittings having a similar design, from which one individual fitting shall be selected for testing purposes.

Four fitting groups shall be designated as given in Table 3.

Table 3 — Fitting groups

| Fitting group | Type of fitting |
|---------------|---|
| 1 | Bends |
| 2 | Elbows, tees |
| 3 | Reducers, couplers, double-sockets, end caps |
| 4 | Unions, flange adaptors, adaptor pieces and/or their plastics parts |

4.2.2 Type testing

4.2.2.1 General

Type testing (TT) shall demonstrate that the products conform to all requirements for the characteristics given in Table 5 to Table 7, as applicable.

In addition, relevant type tests shall be carried out whenever there is a change in design, in material and/or in the production method, other than routine in-process adjustments, and/or to extensions of the product range.

For the purposes of defining a change of material, Table 4 applies. The dosage level of ingredients of the material or compound shall not exceed the tolerance bands given in Table 4. The values for X (see Table 4) shall be specified by the manufacturer in his/her quality plan.

If any characteristic is changed or any level exceeds the dosage band, this variation in formulation constitutes a change in material and the relevant characteristics given in Table 5 to Table 7, as applicable, shall be retested. If certification is involved, retesting shall be agreed on between the certification body and the manufacturer.

A change in the material supplier does not necessarily constitute a change in material.

Table 4 — Conditions for change of material

| Type of material change | Tolerance band |
|--|----------------|
| Change in chlorine content of the resin | $X \pm 0,5 \%$ |
| Change in additive level (e.g. pigments) | $X \pm 20 \%$ |

For the purposes of defining a change in design, the following characteristics are relevant:

- a) dimensions;
- b) geometry of the component;
- c) jointing system.

In the quality plan of the manufacturer, the geometry, dimensions and the applied tolerances at least according and in addition to the requirements given in the relevant part(s) of ISO 15877 shall be specified.

If one or more of these characteristics exceed(s) the defined specifications, the relevant characteristics given in Table 5, Table 6 and Table 7, as applicable, shall be retested. If certification is involved, retesting shall be agreed on between the certification body and the manufacturer.

For a change of production method and/or for an extension of the product range, the relevant characteristics given in Table 5 or Table 6, as applicable, shall be retested. If certification is involved, retesting shall be agreed on between the certification body and the manufacturer.

Table 5 — Characteristics of material and pipes that require type testing

| Characteristic | Reference to part, clause and table of ISO 15877 | Initial/changes/extension ^a | | | | | Sampling procedure |
|--|--|---|---|---|---|---|--|
| | | I | D | M | P | E | |
| Density | ISO 15877-1:2009, 5.2 | + | - | + | - | - | One evaluation per material |
| Chlorine content | ISO 15877-1:2009, 5.3 | + | - | + | - | - | One evaluation per material |
| Verification of T_{mal} (95 °C, 100 h) | ISO 15877-1:2009, 5.5 | + | - | + | - | - | One evaluation per material |
| Influence on water intended for human consumption | ISO 15877-1:2009, 5.6 | + | - | + | - | - | According to national regulations |
| Hydrostatic stress properties of material ^b | ISO 15877-2:2009, 4.3 | + | - | + | - | - | One evaluation per material |
| Appearance | ISO 15877-2:2009, 5.1 | + | - | + | - | + | One test piece per d_n and pressure group |
| Opacity ^c | ISO 15877-2:2009, 5.3 | + | - | + | - | - | One test piece with the smallest wall thickness produced |
| Dimensions | ISO 15877-2:2009, Clause 6, Tables 2 and 3 | + | + | - | - | + | One test piece per d_n and pressure group |
| Resistance to internal pressure | ISO 15877-2:2009, 7.1 Table 5 or 6 | + | - | + | - | + | Three test pieces on one d_n per size group |
| Impact resistance | ISO 15877-2:2009, 7.2 Table 7 | + | - | + | + | + | One evaluation per size group and pressure group |
| Tensile strength | ISO 15877-2:2009, 7.3 Table 9 | + | - | + | - | - | One evaluation per size group and pressure group |
| Vicat softening temperature (VST) | ISO 15877-2:2009, Clause 8 Table 10 or 11 | + | - | + | - | - | One evaluation per material |
| Longitudinal reversion | ISO 15877-2:2009, Clause 8 Tables 10 or 11 | + | - | + | + | + | Three test pieces on one d_n per size group |
| Thermal stability | ISO 15877-2:2009, Clause 8 Table 10 or 11 | + | - | + | - | - | One test piece per material |
| Marking | ISO 15877-2:2009, Clause 11 | + | - | - | + | + | One test piece per d_n and pressure group |
| ^a | | I: initial type test in case of new system; D: change in design; M: change of material; | | P: change of production method; E: extension of the product range; +: test to be carried out. | | | |
| ^b | | If the material supplier has evaluated the hydrostatic stress properties specified in ISO 15877-2:2009, the manufacturer of pipes only has to check conformity with the reference curves for the expected hydrostatic strength given in Figure 1 of ISO 15877-2:2009 by testing three test pieces at two different stress levels at 95 °C. The lowest stress level shall give failure times of approximately 2 500 h. All failure points shall be on or above the relevant reference curve of Figure 1 of ISO 15877-2:2009. | | | | | |
| ^c | | If required. | | | | | |

Table 6 — Characteristics of material and fittings that require type testing

| Characteristic | Reference to part, clause and table of ISO 15877 | Initial/changes/extension ^a | | | | | Sampling procedure |
|--|--|--|---|---|---|---|---|
| | | I | D | M | P | E | |
| Density | ISO 15877-1:2009, 5.2 | + | – | + | – | – | One evaluation per material |
| Chlorine content | ISO 15877-1:2009, 5.3 | + | – | + | – | – | One evaluation per material |
| Verification of T_{mal} | ISO 15877-1:2009, 5.5 | + | – | + | – | – | One evaluation per material |
| Influence on water intended for human consumption | ISO 15877-1:2009, 5.6 | + | – | + | – | – | According to national regulations |
| Hydrostatic stress properties of material ^b | ISO 15877-3:2009, 4.3 | + | – | + | – | – | One evaluation per material |
| Appearance | ISO 15877-3:2009, 5.1 | + | – | + | – | + | One test piece per d_n and fitting group |
| Opacity ^c | ISO 15877-3:2009, 5.2 | + | – | + | – | – | One test piece with the smallest wall thickness produced |
| Dimensions | ISO 15877-3:2009, Clause 6 | + | + | + | – | + | One test piece per d_n and fitting group |
| Resistance to internal pressure | ISO 15877-3:2009, 7.1 Table 14 | + | + | + | – | + | Three test pieces on one d_n per size group and fitting group |
| Vicat softening temperature (VST) | ISO 15877-3:2009, 4.4 Table 1 or 2 | + | – | + | – | – | One evaluation per material |
| Effects of heating | ISO 15877-3:2009, 4.4 Table 1 or 2 | + | – | + | + | + | Three test pieces on one d_n per size group and fitting group |
| Thermal stability | ISO 15877-3:2009, Clause 4 Tables 1 and 2 | + | – | + | – | – | One test piece per material |
| Marking | ISO 15877-3:2009, Clause 11 | + | – | – | + | + | One test piece per d_n and fitting group |
| <p>^a I: initial type test in case of new system; P: change of production method; D: change in design; E: extension of the product range; M: change of material; +: test to be carried out.</p> <p>^b If the material supplier has evaluated the hydrostatic stress properties specified in ISO 15877-3, the manufacturer of fittings only has to check conformity with the reference curves for the expected hydrostatic strength given in Figure 1 of ISO 15877-3:2009 by testing three test pieces at two different stress levels at 80 °C. The lowest stress level shall give failure times of approximately 2 500 h. All failure points shall be on or above the relevant reference curve of Figure 1 of ISO 15877-3:2009.</p> <p>^c If required.</p> | | | | | | | |

Table 7 — Characteristics of fitness for purpose of the system that require type testing

| Characteristic | Reference to part, clause and table of ISO 15877 | Initial/changes/extension ^a | | | Sampling procedure |
|--|--|--|---|---|---|
| | | I | D | E | |
| Resistance to internal pressure | ISO 15877-5:2009, 4.2 | + | + | + | One evaluation per size group and jointing system for the relevant design pressure and appropriate application class |
| Resistance to pull-out | ISO 15877-5:2009, 4.3 | + | + | + | One evaluation for the smallest and largest d_n per size group and jointing system for the relevant design pressure and appropriate application class |
| Resistance to thermal cycling | ISO 15877-5:2009, 4.4 | + | + | + | One evaluation per d_n and jointing system for the relevant design pressure and appropriate application class |
| Resistance to pressure cycling | ISO 15877-5:2009, 4.5 | + | + | + | One evaluation per size group and jointing system for the relevant design pressure |
| Leaktightness under vacuum | ISO 15877-5:2009, 4.6 | + | + | + | One evaluation per size group and jointing system per pressure group |
| ^a I: initial type test in case of new system; D: change in design; E: extension of the product range; +: test to be carried out. | | | | | |

4.2.2.2 Preliminary type testing

For preliminary type testing (PTT), the manufacturer shall demonstrate that the products conform to all requirements of the characteristics given in Table 5 to Table 7, as applicable.

4.2.2.3 Initial type testing

If certification is involved in initial type testing (ITT), the certification body shall assess the conformity of a product to all requirements for the characteristics given in Table 5 to Table 7, as applicable.

The assessment shall be performed by validation or testing, using the sampling procedure given in Table 5 to Table 7, as applicable and grouping according to 4.2.1, in an approved testing laboratory or by witness testing.

NOTE An approved testing laboratory is one working in accordance with ISO/IEC 17025^[4].

Preliminary test data including long-term characteristics, supplied by the manufacturer and traceable to material and process, validated by the certification body, shall be taken into account for initial type testing.

4.2.3 Batch release tests

In batch release testing (BRT), those characteristics specified in ISO 15877-2 and ISO 15877-3 and listed in Table 8 shall be batch release tested with the minimum sampling frequency given in Table 8.

Table 8 — Characteristics and minimum sampling frequencies for BRT

| Characteristic | Reference to part, clause and table of ISO 15877 | Minimum sampling frequency ^a | Retest procedure |
|---|--|---|------------------|
| Pipes | | | |
| Appearance | ISO 15877-2:2009, 5.1 | One test piece per 8 h per machine | A or B |
| Dimensions: - outside diameter - wall thickness | ISO 15877-2:2009, Tables 2 and 3 | One test piece per 8 h per machine | A |
| Resistance to internal pressure (95 °C, 165 h) | ISO 15877-2:2009, 7.1 Table 5 or 6 | One test piece per week per machine | A or B |
| Impact resistance | ISO 15877-2:2009, 7.2 Table 7 | One test piece per week per machine | A or B |
| Longitudinal reversion | ISO 15877-2:2009, Clause 8 Tables 10 and 11 | One test piece per week per machine | A or B |
| Marking | ISO 15877-2:2009, Clause 11 | One test piece per 8 h per machine | A or B |
| Fittings | | | |
| Appearance | ISO 15877-3:2009, 5.1 | One test piece per 8 h per cavity | A or B |
| Dimensions: - outside diameter - wall thickness - socket dimensions | ISO 15877-3:2009, Clause 6 | One test piece per 8 h per cavity | A |
| Resistance to internal pressure ^b a) 20 °C, 1 h or b) 60 °C, 1 h | ISO 15877-3:2009, Clause 7 | One test piece per week per machine | A or B |
| Effects of heating | ISO 15877-3:2009, 4.4 Tables 1 and 2 | One test piece per week per machine | A or B |
| Marking | ISO 15877-3:2009, Clause 11 | One test piece per 8 h per cavity | A or B |
| ^a Alternatively, the manufacturer may use the sampling procedures detailed in either ISO 2859-1 with a minimum inspection level S-2 or ISO 3951 with a minimum inspection level S-3, as appropriate. In any case, an AQL not greater than 6,5 % shall be used. ^b In case of dispute, testing at 20 °C shall be done. | | | |

The manufacturer shall specify a batch or lot in his/her quality plan.

A batch or lot shall only be released for supply when all the relevant tests and inspections have been carried out at least once at the specified frequencies and the requirements have been conformed to.

If a product fails in respect of any characteristic given in Table 8, the batch or lot shall be rejected or the retest procedure shall be performed for the characteristic on which the product failed.

The retest procedure shall conform to Table 8 and shall be either procedure A or procedure B, as follows:

Procedure A:

Find the last product, which conforms to the requirements as specified in ISO 15877-2 and ISO 15877-3, as applicable. Release all products produced before that point and reject the products produced after that point;

Procedure B:

Use a sampling procedure in accordance with ISO 2859-1 or ISO 3951-1 and 3851-2, as applicable, based on a maximum AQL of 4 % and a minimum inspection level S-3.