

ICS 01.040.23; 23.040.01; 91.140.40

English version

Plastics piping systems for the supply of gaseous fuels -
Polyethylene (PE) - Part 1 : General

Systèmes de canalisations en plastique pour la distribution
de combustibles gazeux - Polyéthylène (PE) - Partie 1 :
Généralités

Kunststoff-Rohrleitungssysteme für die Gasversorgung
Polyethylen (PE) - Teil 1 : Allgemeines

This European Standard was approved by CEN on 1 November 2002.

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Foreword

This document EN 1555-1:2002 has been prepared by Technical Committee CEN /TC 155, "Plastics piping systems and ducting systems", the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2003, and conflicting national standards shall be withdrawn at the latest by December 2004.

It has been prepared in liaison with Technical Committee CEN/TC 234 "Gas supply".

This standard is a 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.

System Standards are based on the results of the work undertaken in ISO/TC 138 "Plastics pipes, fittings and valves for the transport of fluids", which is a Technical Committee of the International Organization for Standardization (ISO).

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

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

EN 1555 consists of the following parts, under the general title *Plastics piping systems for the supply of gaseous fuels - Polyethylene (PE)*:

- *Part 1: General* (this standard)
- *Part 2: Pipes*
- *Part 3: Fittings*
- *Part 4: Valves*
- *Part 5: Fitness for purpose of the system*
- *Part 7: Guidance for assessment of conformity* (to be published as an CEN/TS).

NOTE The document dealing with recommended practice for installation which was initially submitted for CEN enquiry as prEN 1555-6 was withdrawn when EN 12007-2 TM, prepared by CEN/TC 234 "Gas supply", was published with the title "Gas supply systems - Pipelines for maximum operating pressure up to and including 16 bar - Part 2: Specific functional recommendations for polyethylene (MOP up to and including 10 bar)".

This document includes a Bibliography.

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

EN 1555-1:2002(E)

Introduction

The System Standard, of which this is Part 1, specifies the requirements for a piping system and its components made from polyethylene (PE) and which is intended to be used for the supply of gaseous fuels.

Requirements and test methods for components of the piping system are specified in EN 1555-2, EN 1555-3 and EN 1555-4. Characteristics for fitness for purpose are covered in EN 1555-5. prCEN/TS 1555-7 gives guidance for assessment of conformity. Recommended practice for installation is given in EN 12007-2, prepared by CEN/TC 234.

This part of EN 1555 covers the general aspects of the plastics piping system.

1 Scope

This part of EN 1555 specifies the general aspects of polyethylene (PE) piping systems in the field of the supply of gaseous fuels.

It also specifies the test parameters for the test methods referred to in this standard.

In conjunction with the other parts of EN 1555 (see Foreword) it is applicable to PE pipes, fittings, and valves, their joints and to joints with components of other materials intended to be used under the following conditions:

- a) a maximum operating pressure, MOP, up to and including 10 bar¹;
- b) an operating temperature of 20 °C as reference temperature.

NOTE 1 For other operating temperatures, derating coefficients should be used, see EN 1555-5.

EN 1555 covers a range of maximum operating pressures and gives requirements concerning colours and additives.

NOTE 2 It is the responsibility of the purchaser or specifier to make the appropriate selections from these aspects, taking into account their particular requirements and any relevant national regulations and installation practices or codes.

2 Normative references

This European Standard 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 this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 728, *Plastics piping and ducting systems — Polyolefin pipes and fittings — Determination of oxidation induction time*.

EN 921, *Plastics piping systems — Thermoplastics pipes — Determination of resistance to internal pressure at constant temperature*.

EN 1056, *Plastics piping and ducting systems — Plastics pipes and fittings — Method for exposure to direct (natural) weathering*.

EN 1555-2:2002, *Plastics piping systems for the supply of gaseous fuels — Polyethylene (PE) — Part 2: Pipes*.

EN 12099, *Plastics piping systems — Polyethylene piping materials and components — Determination of volatile content*.

EN 12107, *Plastics piping systems — Injection-moulded thermoplastics fittings, valves and ancillary equipment — Determination of the long-term hydrostatic strength of thermoplastics materials for injection moulding of piping components*.

EN 12118, *Plastics piping systems — Determination of moisture content in thermoplastics by coulometry*.

EN ISO 1043-1:2001, *Plastics - Symbols and abbreviated terms - Part 1: Basic polymers and their special characteristics (ISO 1043-1:2001)*.

EN ISO 1133, *Plastics - Determination of the melt mass-flow rate (MFR) and the melt volume-flow rate (MVR) of thermoplastics (ISO 1133:1997)*.

EN ISO 1872-1, *Plastics — Polyethylene (PE) moulding and extrusion materials — Part 1: Designation system and basis for specifications (ISO 1872-1:1993)*.

EN ISO 6259-1, *Thermoplastics pipes - Determination of tensile properties - Part 1: General test method (ISO 6259-1:1997)*.

¹bar = 0,1MPa

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EN ISO 12162, *Thermoplastics materials for pipes and fittings for pressure applications — Classification and designation — Overall service (design) coefficient* (ISO 12162:1995).

EN ISO 13478, *Thermoplastics pipes for the conveyance of fluids — Determination of resistance to rapid crack propagation (RCP) — Full-scale test (FST)* (ISO 13478:1997).

EN ISO 13479, *Polyolefin pipes for the conveyance of fluids — Determination of resistance to crack propagation Test method for slow crack growth on notched pipes (notch test)* (ISO 13479:1997).

ISO 472:1999, *Plastics — Vocabulary*.

ISO 1183, *Plastics — Methods for determining the density and relative density of non-cellular plastics*.

ISO 6259-3, *Thermoplastics pipes — Determination of tensile properties — Part 3: Polyolefin pipes*.

ISO 6964, *Polyolefin pipes and fittings — Determination of carbon black content by calcination and pyrolysis — Test method and basic specification*.

ISO/TR 9080:1992, *Thermoplastics pipes for the transport of fluids — Methods of extrapolation of hydrostatic stress rupture data to determine the long-term hydrostatic strength of thermoplastics pipe materials*.

ISO 11414:1996, *Plastics pipes and fittings - Preparation of polyethylene (PE) pipe/pipe or pipe/fitting test piece assemblies by butt fusion*.

ISO 13477, *Thermoplastics pipes for the conveyance of fluids — Determination of resistance to rapid crack propagation (RCP) — Small-scale steady-state test (S4 test)*.

ISO 13953, *Polyethylene(PE) pipes and fittings - Determination of the tensile strength and failure mode of test pieces from a butt-fused joint*.

ISO 18553, *Method for the assessment of the degree of pigment or carbon black dispersion in polyolefin pipes, fittings and compounds*.

3 Terms and definitions, symbols and abbreviations

For the purposes of this European Standard, the following terms and definitions, symbols and abbreviations apply.

3.1 Terms and definitions

In addition to the terms and definitions given below, the terms and definitions given in ISO 472:1999 and EN ISO 1043-1:2001 apply.

3.1.1 Geometrical definitions

3.1.1.1 Nominal size

3.1.1.1.1 nominal size DN

numerical designation of the size of a component, other than a component designated by thread size, which is a convenient round number, approximately equal to the manufacturing dimension in millimeters (mm)

3.1.1.1.2 nominal size DN/OD

nominal size, related to the outside diameter

3.1.1.2

nominal outside diameter (d_n)

specified outside diameter, in millimeters, assigned to a nominal size DN/OD

3.1.1.3

outside diameter (at any point) (d_o)

value of the measurement of the outside diameter through its cross-section at any point of the pipe, rounded to the next greater 0,1 mm

3.1.1.4

mean outside diameter (d_{em})

value of the measurement of the outer circumference of the pipe or spigot end of a fitting in any cross-section divided by TC (= 3,142), rounded to the next greater 0,1 mm

3.1.1.5

minimum mean outside diameter ($C_{em,min}$)

minimum value for the mean outside diameter as specified for a given nominal size

3.1.1.6

maximum mean outside diameter ($d_{em,max}$)

maximum value for the mean outside diameter as specified for a given nominal size

3.1.1.7

out-of-roundness (ovality)

difference between the maximum and the minimum outside diameter in the same cross-section of a pipe or spigot

3.1.1.8

nominal wall thickness (e_n)

numerical designation of the wall thickness of a component, which is a convenient round number, approximately equal to the manufacturing dimension in millimetres (mm)

NOTE For thermoplastics components conforming to EN 1555, the value of the nominal wall thickness, e_n , is identical to the specified minimum wall thickness at any point, e_{min} .

3.1.1.9

wall thickness (at any point) (e)

wall thickness at any point around the circumference of a component

NOTE The symbol for the wall thickness of the fittings and valves body at any point is E

3.1.1.10

minimum wall thickness (at any point) (e_{min})

minimum value for the wall thickness at any point around the circumference of a component, as specified

3.1.1.11

maximum wall thickness (at any point) (e_{max})

maximum value for the wall thickness at any point around the circumference of a component, as specified

3.1.1.12

mean wall thickness (e_m)

arithmetical mean of a number of measurements of the wall thickness, regularly spaced around the circumference and in the same cross-section of a component, including the measured minimum and the measured maximum values of the wall thickness in that cross-section

3.1.1.13

tolerance

permitted variation of the specified value of a quantity, expressed as the difference between the permitted maximum and the permitted minimum value

3.1.1.14

wall thickness tolerance (t_v)

permitted difference between the wall thickness at any point, e , and the nominal wall thickness, e_n

NOTE $e_n \leq e \leq e_n + t_v$

3.1.1.15

standard dimension ratio (SDR)

numerical designation of a pipe series, which is a convenient round number, approximately equal to the dimension ratio of the nominal outside diameter, d_n , and the nominal wall thickness, e_n

3.1.2 Material definitions

3.1.2.1 virgin material

material in a form such as granules or powder that has not been subjected to use or processing other than that required for its manufacture and to which no reprocessable or recyclable materials have been added

3.1.2.2

own reprocessable material

material prepared from clean rejected unused pipes, fittings or valves, including trimmings from the production of pipes, fittings or valves, that will be reprocessed in a manufacturer's plant after having been previously processed by the same manufacturer in the production of components by, for example injection-moulding or extrusion

3.1.2.3

compound

homogenous mixture of base polymer (PE) and additives, i.e. anti-oxidants, pigments, UV-stabilisers and others, at a dosage level necessary for the processing and use of components conforming to the requirements of this standard

3.1.3 Definitions related to material characteristics

3.1.3.1

lower confidence limit (σ_{LCL})

quantity with the dimensions of stress which represents the 97,5 % lower confidence limit of the long-term hydrostatic strength and can be considered as a property of the material under consideration. It equals the mean (average) strength or predicted mean (average) strength at a temperature T and a time t when the factor a has a value of 0,975. It is denoted as :

$$\sigma_{LCL} = \sigma(T, \log t, 0,975)$$

3.1.3.2

minimum required strength (MRS)

value of LCL, rounded down to the next smaller value of the R10 series or of the R20 series depending on the value of LCL

NOTE R10 and R20 series are the Renard number series according to ISO 3:1973^[2] and ISO 497:1973^[3]

3.1.3.3

overall service (design) coefficient or safety factor (C)

coefficient with a value greater than 1, which takes into consideration service conditions as well as properties of the components of a piping system other than those represented in the lower confidence limit

3.1.3.4

design stress (σ_s)

allowable stress, in megapascals, for a given application. It is derived from the MRS by dividing it by the coefficient C , i.e.:

$$\sigma_s = MRS / C$$

3.1.3.5

melt-mass flow rate (MFR)

value relating to the viscosity of the molten material at a specified temperature and load, expressed in grams per 10 min (g/10 min)

3.1.4 Definitions related to service conditions

3.1.4.1

gaseous fuel

any fuel which is in gaseous state at a temperature of 15 °C, at the atmospheric pressure

3.1.4.2

maximum operating pressure (MOP)

maximum effective pressure of the fluid in the piping system, expressed in bar, which is allowed in continuous use. It takes into account the physical and the mechanical characteristics of the components of a piping system

NOTE It is calculated using the following equation:

$$\text{MOP} = \frac{20 \times \text{MRS}}{\text{Cx}(\text{SDR}-1)}$$

3.1.4.3

reference temperature

temperature for which the piping system is designed. It is used as the base for further calculation when designing a piping system or parts of a piping system for operating temperatures different from the reference temperature

3.1.5 Definitions **related to joints**

3.1.5.1

butt fusion joint (using heated tool)

joint made by heating the planed ends of pipes or spigot end fittings, the surfaces of which match by holding them against a flat heating plate until the PE material reaches fusion temperature, removing the heating plate quickly and pushing the two softened ends against one another

3.1.5.2

fusion compatibility

ability of two similar or dissimilar polyethylene materials to be fused together to form a joint which conforms to the performance requirements of this standard

3.2 Symbols

| | |
|--------------|---|
| C | overall service (design) coefficient |
| d_e | outside diameter (at any point) |
| d_{em} | mean outside diameter |
| $d_{em,max}$ | maximum mean outside diameter |
| $d_{em,min}$ | minimum mean outside diameter |
| d_e | nominal outside diameter |
| E | wall thickness (at any point) of a fitting and valve body |
| e | wall thickness (at any point) of a pipe |
| e_m | mean wall thickness |
| e_{max} | maximum wall thickness (at any point) |
| e_{min} | minimum wall thickness (at any point) |
| e_n | nominal wall thickness |
| t_y | wall thickness tolerance |
| σ_S | design stress |

3.3 Abbreviations

DN : nominal size

DN/OD : nominal size, outside diameter related

LCL : lower confidence limit

| | |
|-----|--|
| MFR | melt mass-flow rate |
| MOP | maximum operating pressure |
| MRS | minimum required strength |
| PE | polyethylene |
| R | series of preferred numbers, conforming to the Renard series |
| SDR | standard dimension ratio |

4 Material

4.1 Material of the components

The pipes, fittings and valves shall be made of polyethylene compound.

4.2 Compound

4.2.1 Additives

The compound shall be made by adding to the polyethylene base polymer only those additives necessary for the manufacture of pipes, fittings and valves conforming to EN 1555-2, EN 1555-3⁵ or EN 1555-4⁶), as applicable, and for their fuseability, storage and use.

All additives shall be used according to national legislation (e.g. cadmium). They shall be uniformly dispersed.

4.2.2 Colour

The colour of the compound shall be yellow or black.

4.2.3 Characteristics

4.2.3.1 Characteristics of the compound in the form of granules

The compound in the form of granules used for the manufacture of pipes, fittings and valves shall have characteristics conforming to the requirements given in Table 1.

Table 1 —Characteristics of the compound in the form of granules

| Characteristic | Requirements ^a | Test parameters | | Test method |
|---|---|--|---|-------------|
| | | Parameter | Value | |
| Conventional density conforming to EN ISO 1872-1) | > 930 kg/m ³ (base polymer) | Test temperature Number of test pieces ^m | 23 °C Shall conform to ISO 1183 | ISO 1183 |
| Oxidation induction time (Thermal stability) | > 20 min | Test temperature Number of test pieces ^o | 200 °C ^c 3 | EN 728 |
| Melt mass-flow rate (MFR) | (0,2^MFR<1,4)g/10min Maximum deviation of ± 20 % of the nominated value ^d | Loading mass Test temperature Time Number of test pieces ^o | 5 kg 190 °C 10 min Shall conform to EN ISO 1133 | EN ISO 1133 |
| Volatile content | ≤ 350 mg/kg | Number of test pieces ⁿ | 1 | EN 12099 |
| Water content ^e | ≤ 300 mg/kg | Number of test pieces ⁶ | 1 | EN 12118 |
| Carbon black content ^f | (2 to 2,5) % (by mass) | Shall conform to ISO 6964 | | ISO 6964 |
| Carbon black dispersion | Grade S 3 | Preparation of test pieces ³ Number of test pieces ³ | Frees Shall conform to ISO 18553 | ISO 18553 |
| Pigment dispersion ^h | Grade S 3 | Preparation of test pieces ^a Number of test pieces ^a | Free a Shall conform to ISO 18553 | SO 18553 |

a Conformity to these requirements shall be proved by the compound producer.

b The numbers of test pieces given indicate the numbers required to establish a value for the characteristic described in the table. The numbers of test pieces required for factory production control and process control should be listed in the manufacturer's quality plan. For guidance see prCEN/TS 1555-7[^].

c Test may be carried out at 210 °C providing that there is a clear correlation with the results at 200 °C. In case of dispute the reference temperature shall be 200 °C.

d Nominated value given by the compound manufacturer.

e Only applicable, if the measured volatile content is not in conformity to its specified requirement. In case of dispute the requirement for water content shall be used. As an alternative method, ISO 760:1978 ⁴⁾ may apply.

f Only for black compound, g In case of dispute, the test pieces shall be prepared by the compression method, h Only for yellow compound.

4.2.3.2 Characteristics of the compound in the form of pipe

Unless otherwise specified by the applicable test method, the test pieces shall be conditioned at (23 ± 2) °C before testing in accordance with Table 2.

The compound in the form of pipe used for the manufacture of pipes, fittings and valves, shall have characteristics conforming to the requirements given in Table 2.

Table 2 — Characteristics of compound in the form of pipe

| Characteristic | Requirements a | Test parameters | | Test method |
|--|---|--|---|--|
| | | Parameter | Value | |
| Resistance to gas condensate | No failure during the test period of all test pieces | End caps Test temperature Orientation Number of test pieces ^b Circumferential (hoop) stress Pipe dimensions: d_n e_n Type of test Test period Conditioning period | Type a) 80 °C Free 3 2,0 MPa 32 mm 3 mm Synthetic condensate ^c in water 20 h 1500 h in air at 23 °C | EN 921 (incl. corrigendum of 1995) |
| Resistance to weathering ^d | The weathered test pieces shall fulfil the requirements of the following characteristics: | Preconditioning (weathering): Cumulative solar radiation Number of test pieces ^b | 2 3,5 GJ/m ² See below | EN 1056 |
| a) oxidation induction time ^e ; b) hydrostatic strength (165 h at 80 °C); c) elongation at break | a) shall conform to Table 1 b) shall conform to Table 4 of EN 1555-2:2002 c) shall conform to Table 4 of EN 1555-2:2002.. | | | a) EN 728 b) EN 921 (incl. corr. of 1995) c) EN ISO 6259-1 and ISO 6259-3 |
| Resistance to rapid crack propagation (Critical pressure, p_t) ($e > 15$ mm) | $p_c > 1,5$ MOP with $P_c = 3,6 p_{CIS4} + 2,6^f$ | Test temperature Number of test pieces ^b | 0 °C Shall conform to ISO 13477 | ISO 13477 |
| Resistance to slow crack growth (d_n : 110 mm or 125 mm-SDR 11) | No failure during the test period | Test temperature Internal test pressure: for PE 80 PE 100 Test period Type of test Number of test pieces ^b | 80 °C 8,0 bar 9,2 bar 165 h Water-in-water Shall conform to EN ISO 13479 | EN ISO 13479 |
| <p>a Conformity to these requirements shall be proved by the compound producer.</p> <p>b The numbers of test pieces given indicate the numbers required to establish a value for the characteristic described in the Table.</p> <p>The numbers of test pieces required for factory production control and process control should be listed in the manufacturer's quality plan. For guidance see prCEN/TS 1555-7^g.</p> <p>c 50 % (by mass) n-decane and 50 % (by mass) 1-3-5 trimethylbenzene.</p> <p>d Only for yellow compound.</p> <p>e Before sampling for oxidation induction time test, 0,2 mm from the surface should be taken off.</p> <p>f Full scale/S4 correlation factor is equal to 3,6 and is defined as the full scale/S4 critical absolute pressure ratio: $(P_{c,full\ scale} + 1) = 3,6 (p_{CIS4} + 1)$.</p> <p>NOTE Attention is drawn to the fact that the correlation factor may be modified, when revising this Standard, according to the result of work of ISO/TC 138/SC4 "Plastics pipes, fittings and valves for the supply of gaseous fuels".</p> <p>If the requirement is not met or S4 test equipment not available, then (re)testing by using the full scale test shall be performed in accordance with EN ISO 13478. In this case: $p_c = p_{CIS4}$.</p> | | | | |

4.3 Fusion compatibility

4.3.1 The compounds conforming to Table 1 shall be fusible. This shall be demonstrated by the compound manufacturer for each compound of his own product range by checking that the requirement on tensile strength given in Table 3 is fulfilled for a butt fusion joint prepared by using the parameters as specified in annex A of ISO 11414:1996 at an ambient temperature of $(23 \pm 2) ^\circ\text{C}$ from pipes both manufactured from that compound.

4.3.2 Compounds conforming to Table 1 are considered fusible to each other. If requested, the compound manufacturer shall demonstrate this by checking that the requirement on tensile strength given in Table 3 is fulfilled for a butt fusion joint prepared by using the parameters as specified in annex A of ISO 11414:1996 at an ambient temperature of $(23 \pm 2) ^\circ\text{C}$ from two pipes manufactured from the compounds from his own range covered by this request.

Table 3 — Characteristic of compound in the form of butt fusion joint

| Characteristic | Requirement | Test parameters | | Test method |
|--|---|--|-------------------------------------|-------------|
| | | Parameter | Value | |
| Tensile strength for butt fusion (A: 110 mm or 125 mm-SDR 11) | Test to failure : Ductile - pass Brittle - fail | Test temperature Number of test pieces ^a | 23 °C Shall conform to ISO 13953 | ISO 13953 |
| <p>a The conformity to these requirements shall be proved by the compound producer.</p> <p>b The numbers of test pieces given indicate the numbers required to establish a value for the characteristic described in the Table.</p> <p>The numbers of test pieces required for factory production control and process control should be listed in the manufacturer's quality plan. For guidance see prCEN/TS 1555-7¹.</p> | | | | |

4.4 Classification and designation

Compounds shall be designated by the type of PE material. The level of minimum required strength (MRS) shall conform to Table 4 when tested in the form of pipe.

Table 4 — Classification and designation of compounds

| Classification by MRS (MPa) | Designation |
|-----------------------------|-------------|
| 8.0 | PE 80 |
| 10.0 | PE 100 |

The compound shall be evaluated in accordance with ISO/TR 9080:1992 where a pressure test is made in accordance with EN 921 to find the a_{LCL} . The MRS-value shall be derived from the a_{LCL} and the compound shall be classified by the compound producer in accordance with EN ISO 12162.

The conformity of the designation of the compound to the classification given in Table 4 shall be demonstrated by the compound producer.

Where fittings are manufactured from the same compound as pipes, then the material classification shall be the same as for pipes.

For the classification of a compound intended only for the manufacture of fittings, the test piece shall be an injection-moulded pipe in accordance with EN 12107.

4.5 Overall service (design) coefficient and design stress

The minimum value of the overall service (design) coefficient, C , for pipes, fittings and valves for the supply of gaseous fuels shall be 2, or a higher value according to national legislation.

The maximum value for the design stress, σ_s , **shall** be for PE 80, 4,0 MPa and for **PE** 100, 5,0 MPa.

4.6 External reprocessable and recyclable material

Reprocessable material obtained from external sources and recyclable material shall not be used.

Bibliography

- [1] EN 12007-2:2000, *Gas supply systems - Pipelines for maximum operating pressure up to and including 16 bar - Part 2: Specific functional recommendations for polyethylene (MOP up to and including 10 bar)*;
- [2] ISO 3:1973, *Preferred numbers — Series of preferred numbers*.
- [3] ISO 497:1973, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*.
- [4] ISO 760:1978, *Determination of water — Karl Fischer method (General method)*.
- [5] EN 1555-3, *Plastics piping systems for the supply of gaseous fuels — Polyethylene (PE) — Part 3: Fittings*.
- [6] EN 1555-4, *Plastics piping systems for the supply of gaseous fuels — Polyethylene (PE) — Part 4: Valves*.
- [7] prCEN/TS 1555-7, *Plastics piping systems for the supply of gaseous fuels - Polyethylene (PE) - Part 7: Guidance for the assessment of conformity*.