TECHNICAL REPORT

ISO/TR 13881

First edition
2000-04-15

Petroleum and natural gas industries — Classification and conformity assessment of products, processes and services

Industries du pétrole et du gaz naturel — Classification et évaluation de la conformité des produits, procédés et services

Reference number
ISO/TR 13881:2000(E)

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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 3.

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 exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

ISO/TR 13881 was prepared by Technical Committee ISO/TC 67, *Materials, equipment and offshore structures for petroleum and natural gas industries*.

Introduction

When a user/purchaser wishes to procure a product, process or service, the user/purchaser may produce a functional specification (see ISO 13879). If so, the manufacturer/supplier provides a technical specification (see ISO 13880) as the basis for manufacturing or execution. The user/purchaser decides on the extent to which it is necessary to determine, directly or indirectly, that relevant requirements are fulfilled and states this in the contract with the manufacturer/supplier.

This document describes:

— two methodologies which enable the required degree of assurance to be determined by classification, which in turn dictates the conformity assessment system;

— a set of five conformity assessment systems which when applied can give an increasing level of confidence that the product, process or service conforms to stated requirements.

Petroleum and natural gas industries — Classification and conformity assessment of products, processes and services

1 Scope

This Technical Report describes:

— two classification methods (one based on calculated risk, the other on judgement of risk) which may be used to determine the appropriate conformity assessment system for products, processes and services;

— a set of five conformity assessment systems from which the most suitable is chosen when conformity assessment of products, processes and services is required.

NOTE Alternative classification models may be used provided their results are consistent with the conformity assessment systems to be applied.

2 References

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*.

ISO/IEC Guide 22:1996, *General criteria for supplier's declaration of conformity.*

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products.*

ISO 9001:—[1)] , *Quality management systems — Requirements*.

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 13879:1999, *Petroleum and natural gas industries — Content and drafting of a functional specification.*

ISO 13880:1999, *Petroleum and natural gas industries — Content and drafting of a technical specification.*

3 Terms and definitions

For the purposes of this Technical Report, the terms and definitions of conformity-assessment-related terms given in ISO/IEC Guide 2 apply, with the exception of the terms defined below.

3.1
class
number assigned to a product, process or service, associated with the risk of its failure during use due to design or manufacturing, process or service errors, that indicates the appropriate conformity assessment system to be adopted

1) To be published. (Revision of ISO 9001:1994)

NOTE The classification of a product, process or service does not take into consideration failure due to misuse or incorrect maintenance of the product, process or service.

3.2
probability of failure
frequency of occurrence of a product, process or service failure happening within one year divided by the total number of the particular products, processes or services in operation during the same year

3.3
consequence of failure
results of the failure of the product, process or service

NOTE In the petroleum and natural gas industries, the most commonly used measure of consequence is financial cost. This implies that the intangible aspects of the results following a failure, such as community acceptance, be translated to financial cost. The cost for failure can comprise cost for restoring the environment (i.e. damage to the environment), deferred or loss of production, reduction in efficiency, health and safety-related cost, etc.

3.4
risk of failure
probability multiplied by consequence

3.5
design review
formal, documented, comprehensive and systematic examination of a design to evaluate the design requirements and the capabilities of the design to meet these requirements

NOTE 1 In the context of the document, the acceptance criteria for the design review are defined in the functional and technical specifications (see ISO 13879 and ISO 13880).

NOTE 2 A service is also designed and can be reviewed in the same manner.

3.6
witness point
point in the chain of activities, defined in the quality or inspection plan agreed upon, to be witnessed by the conformity assessment body if deemed necessary

3.7
hold point
point, defined in an appropriate document, beyond which an activity should not proceed without the approval of a designated organization or authority

NOTE The approval to proceed beyond a hold point is usually given in written form, but it may be given by any other agreed system of authorization.

4 Classification principles

For the purposes of this Technical Report, the following classification principles apply.

— CLASS should be determined taking full account of the total life of the product, process or service, starting with its functional specification and ending with its decommissioning/demobilization.

— CLASS should take full account of the health, safety and environmental requirements valid for the countries in which the product, process or service is created, used and/or decommissioned/demobilized.

— CLASS, when established according to clause 5 or clause 6, should be determined using verifiable parameters.

In this Technical Report, five classes are defined, from 1 to 5, of which CLASS 1 represents the highest risk of failure and CLASS 5 represents the lowest risk of failure.

The relationship between the classes and the conformity assessment systems is defined in Table 1.

CLASS only has a meaning and/or significance in combination with one of the conformity assessment systems defined.

Table 1 — Class and conformity assessment system relationship

CLASS 1	System A
CLASS 2	System B
CLASS 3	System C
CLASS 4	System D
CLASS 5	System E

Clause 5 and clause 6 provide two different methods of CLASS determination.

5 Classification method based on calculation

5.1 General

This method can be used when specific data on costs and probabilities are available. Two sub-models are presented here. When combined, they provide a full model for classification. The sub-models are based on the assumption that cost can be allocated to the level of certainty that the product, process or service will fulfil its intended purpose without failure. Other models may be used but are not described within this Technical Report.

NOTE The classification models are used by the user/purchaser of a product, process or service to calculate and thereafter indicate which CLASS number is required to obtain the appropriate conformity assessment. The CLASS is related to the risk of failure during use of a product, process and/or service.

5.2 Explanation of the factors used in the sub-models

The sub-models are built on the following premises:

— every activity bears risks which can be translated into cost;

— the models are applicable to the design and manufacture as well as the operational life of the product, process or service.

The risks are connected with failures whereby the operational cost during the life is determined by *in situ* maintenance, periodic inspection, required level of spare parts, etc.

NOTE The risk of failure can be reduced by, for example, more frequent inspections or supervisory actions, a thorough maintenance process, a better controlled manufacturing/service process, etc.

5.3 Risk-related sub-model

$$T_r = (p_0 \cdot c_0) + (p_1 \cdot c_1) + (p_2 \cdot c_2) \quad [1]$$

where

T_r is the total risk, in monetary terms;

p_0 is the probability of failure of the product, process or service during use, due to design;

c_0 is the consequence of design-related failure;

p_1 is the probability of failure of the product, process or service during use, due to manufacturing of product or execution of services/processes;

c_1 is the consequence of manufacturing/execution-related failure;

p_2 is the probability of failure of the product, process or service during use, for other reasons such as absence of proper instructions, etc.;

c_2 is the consequence of failure related to other reasons.

The probability of failure can be obtained from historical data, preferably from a public database. In any case, a record should be kept of where the probability data was obtained.

Furthermore, for the purposes of this Technical Report, the probability factors have to be correlated to both the conformity assessment system which was adopted when producing the product or executing the service or process, and the verification of performance during the life cycle.

5.4 Integrity-related sub-model

$$T_V = C_V + C_C \quad [2]$$

where

T_V is the total cost for verification;

C_V is the planned cost for verifications during the life of the product, process or service per year;

C_C is the cost of obtaining a product, process or service using the conformity assessment system on the basis of which the probability factors have been derived.

NOTE 1 Increasing the *in situ* verifications of products, processes or services will reduce the probability of failure because failures are generally not incidents which happen suddenly but are preceded by a deterioration of the product's performance or service, process execution.

NOTE 2 These increased verifications will have a risk-limiting effect and therefore act as a compensation for the risk-related costs.

NOTE 3 The need for costs to be assessed on a yearly basis is related to the fact that the probability of failure is also based upon annual figures. Furthermore, it should be noted that the cost spent on conformity assessment will also reduce the probability of failure.

5.5 CLASS calculation

The CLASS calculation is based on the concept that the risk of failure of a product, process or service can be reduced by increasing the frequency or type of verifications during the various phases of its life cycle until the point where the risk, in monetary terms, T_r, is about equal to the total cost for verification, T_V.

Therefore the CLASS calculation is iterated until the following ratio is achieved:

$$T_r/T_V \leqslant 1 \quad [3]$$

When using this Technical Report in conjunction with conformity assessment, a record of the data used to calculate the class should be used.

6 Classification method based on judgement

6.1 General

This method can be used when specific data on costs and probabilities of failure are not available.

6.2 Classification process

Classification should be performed by a team of experts, from or under the responsibility of the user/purchaser, in cooperation with the manufacturer/supplier.

The team should be knowledgeable in the following areas:

— the use of the product, process or service;

— the possible consequences which can result from failure in use of the product, process or service;

— the engineering, design/manufacturing, execution and maturity/complexity of the product, process or service.

When applicable, the manufacturer/supplier should contribute appropriate experts. Input from process and future operating people may be available later in time, therefore classification may sometimes be the result of a step-by-step procedure with several iterations.

A meeting is recommended during which experts should address all relevant topics. The following should be recorded:

— meeting date;

— product, process or service identification;

— those who participated;

— the justification used to reach the final CLASS;

— unresolved issues on which consensus could not be obtained;

— the statement of CLASS.

6.3 Classification checklist

The classification checklist is used to assist the team to determine the CLASS in a structured way. The checklist gives guidance and assistance to ensure that all aspects are discussed. Although the checklist can be extended to a greater level of detail, it is not intended to be complete but to assist in the thinking process related to classification. The following topics should be ranked in terms of the required level of evidence to be collected regarding:

— intended use and reasonably foreseeable misuse;

— field-proven design;

— past use of the same product, process or service;

— effects on health;

— effects on safety;

— effects on environment;

— reliability/durability;

— effects on operational expenditure (OPEX);

— effects on capital expenditure (CAPEX);

— requirements for special skills during use;

— requirements for special skills during design, manufacturing or execution;

— the use of identical product(s), process(es) or service(s) without failure;

— confidence in manufacturer/supplier.

6.4 Determination of the CLASS

The CLASS should be determined by the user/purchaser based upon the discussion and the result of the checklist.

Annex A gives a possible model for the determination of the CLASS.

7 Limitations

The CLASS can be used to determine the required conformity assessment system if the following requirements are met:

— CLASS is determined according to the methods stated in the scope of this Technical Report or equivalent methods;

— the records, quoted in clause 5 or clause 6, can be made available to the conformity assessment body before the process of conformity assessment takes place;

— the records, quoted in clause 5 and clause 6, are kept for one year after completion of the conformity assessment.

8 Conformity assessment systems

For conformity assessment purposes, five systems, identified as systems A, B, C, D and E, are considered in this Technical Report.

These systems, one of which is specified by the user/purchaser, are intended to provide assurance that products, processes or services are in conformity with the functional, as well as the technical, specification.

It is assumed that the functional specification is a fixed document for the duration of the conformity assessment activities dealt with in this Technical Report.

These systems provide different levels of confidence that gradually decrease from system A to system E. Table 2 illustrates the main characteristics of the five systems. Design review and/or type tests are an important part of the conformity assessment systems. Type testing, including examination of a product, process or service design or testing of prototypes, or witnessing of processes or services, can provide a basis for conformity assessment of manufactured products or executed processes and services.

Type tests can be omitted and/or replaced by an examination, review or alternative calculation whenever one or both of the following conditions is relevant:

— the type test is not relevant and/or practical for the product, process or service to be assessed;

— the requirement for type testing is waived in the functional specification. The system to be adopted for each specific product, processes or service should be defined in the contract.

In addition to the documentation issued by the conformity assessment body in accordance with its conformity assessment scheme, the manufacturer/supplier should issue a declaration of conformity for the product, process or service in conjunction with a reference list of verifications that demonstrate conformity.

NOTE ISO/IEC Guide 22 provides general criteria for a supplier's declaration of conformity (SDoC) in cases where it is desirable, or necessary, that conformity of a product, process or service to normative documents be indicated, irrespective of the sector involved. The supplier may then declare under its responsibility the conformity to normative documents. ISO/IEC Guide 22 is intended for application in situations where a third party is not required.

Table 2 — Characteristics of conformity assessment systems relevant for the petroleum and natural gas industries

Conformity assessment operation	System A	System B	System C	System D	System E
Design review(s)	x[1]				
Type test(s)	x[2]	x[2]	x[2]		
Conformity between functional and technical specification	x	x	x		
Quality system verification, using:	x ISO 9001, ISO 9002		x ISO 9002, ISO 9003		
Product, process or service surveillance by:					
— periodic inspection	x[3], and/or	—	x[3]	—	
— inspection of samples/trials	—	x, or	—	x, or	
— 100 % inspection	x	x	—	x	
Declarations of conformity by conformity assessment body, by means of:					
— certificate and/or mark of conformity	x	x	x	—	
— certificate of inspection results	—	—	—	x	
Manufacturer/supplier's declaration of conformity inclusive reference list	y	y	y	y	y

NOTE ISO/IEC Guide 28 provides a model third-party certification system of determining conformity with product specifications through initial testing, assessment of a factory quality management system and its acceptance, followed by surveillance. This model system is comprehensive and can therefore offer a basis for the development of other systems.

x Action by assessor.

x[1] Action by assessor. This action is not required if the specific product, process or service does not require design. In this case the quality system verification should be based on ISO 9002.

x[2] Action by assessor. The type test can be omitted if:

— it is not relevant and/or practical for type of product, process or service;

— the functional specification waives the requirements for type testing.

x[3] Action by assessor. This action is to be performed during the manufacturing or execution during the period of certificate validity.

y Action by manufacturer/supplier.

9 System A

9.1 General

This system describes the procedure whereby the conformity assessment body performs examinations, type tests and surveillance in order to declare that identified products, processes or services fulfil the performance requirements defined in the functional specification.

It includes the following activities:

— the design review, resulting in the issue of a design review declaration;

— the execution and/or witnessing of type tests as required;

— the verification of the manufacturer/supplier's quality system in accordance with ISO 9001. In case the specific product, process or service does not require design, ISO 9002 applies;

— the execution of product, process or service surveillance relating to the requirements of the technical specification, by both periodic inspection during the manufacturing process or execution of process or service and 100 % inspection of the product, process or service taking into account the selected characteristics identified during the design review.

9.2 Design review, type test and verification of conformity of the technical specification with the functional specification

In case the specific product, process or service does not require design, subclause 10.2 of this Technical Report applies. The manufacturer/supplier should apply to the conformity assessment body for a design review. The manufacturer/supplier should provide the necessary information, which enables conformity assessment with the functional specification. It should include:

— the technical specification, including reference to standards that have been used;

— supporting evidence of conformity with the functional specification, including relevant results of design reviews, alternative calculations and, if applicable, type tests carried out.

The conformity assessment body should:

— examine the technical documentation;

— in case of a type test, verify that the sample(s) of products, processes or services to undergo the type test have been manufactured or their execution planned in conformity with the technical documentation;

— agree with the manufacturer/supplier the location at which the inspections should be carried out;

— perform the appropriate inspections to check whether the sample(s) have the characteristics required in the functional and technical specifications.

If the design is in conformity with the functional specification and the referenced standards, and if the evidence of conformity is demonstrated, the conformity assessment body should issue a design review declaration to the applicant.

If conformity is not demonstrated, the conformity assessment body should require additional examinations, and suspend the conformity assessment process.

The design review declaration should contain the results of examinations, conditions for its validity, data for identification of the approved design and, if relevant, a description of the functioning of the product, process or service. In addition to this information, the design review declaration should make reference to the reports of the examinations of the conformity assessment body.

The manufacturer/supplier should inform the conformity assessment body about any modifications to the technical specification related to the requirements of the functional specification. These modifications should be examined by the conformity assessment body with regard to the validity of the design review declaration. The conformity assessment body should provide additional approval where modifications relate to conformity with the functional specification. Additional approval is given in the form of an addendum to the original design review declaration.

9.3 Quality system

The manufacturer/supplier should operate a certified quality system in accordance with ISO 9001 for design, development, production, installation and servicing. In case the specific product, process or service does not require design, ISO 9002 applies. The conformity assessment body should verify the validity of the certificate of conformity and the conformity assessment report(s).

If the manufacturer/supplier doesn't operate under a certified quality system, the conformity assessment body should perform an audit to convince itself that the manufacturer/supplier operates a system in accordance with ISO 9001, ISO 9002 or ISO 9003, as applicable.

9.4 Product, process or service surveillance

The manufacturer/supplier should establish, for the specific product, process or service, a quality plan that describes the production phases and the associated control measures. Inspections required to demonstrate continuous conformity with the technical specification should be taken into account.

The manufacturer/supplier should submit the quality plan to the conformity assessment body, who should identify witness and hold points on phases for which it is necessary that the conformity assessment body operate surveillance on particular products, process or services or parts thereof. Hold points relate at least to the critical parameters as stated in the functional specification and include also those stated during the design review.

Reports of inspections performed according to the quality plan should be collected and made available for the review by the conformity assessment body. Depending on the type of product, process or service, the conformity assessment body should carry out periodic inspection during the manufacturing process and/or 100 % inspection of the product, process or service, which may be unscheduled, in the manufacturer's/supplier's location of activity in order to:

— verify the validity of the design review declaration;

— verify the validity of the manufacturer's/supplier's quality system certificate;

— verify that the inspection documentation issued by the manufacturer/supplier is in conformity with the quality plan and that the associated results are satisfactory;

— verify that the non-conformities accepted during production or execution do not impair the ability of the product, process or service to meet the requirements of the functional specification;

— verify that agreed witness and hold points of the quality plan are satisfied;

— verify the inspections performed by the manufacturer/supplier at the time of the periodic inspection and/or carry out inspections or have them carried out in order to provide an impartial verification of conformity with the requirements of the technical specification.

Furthermore, the manufacturer/supplier should establish a list with regard to all modifications of the manufacturing process affecting the design. This list should include the justification and the validity considerations of each modification. As part of the product, process or service surveillance, the conformity assessment body should verify this list on a periodic basis.

9.5 Conformity assessment

After satisfactory results of the activities listed in 9.2, 9.3 and 9.4, the conformity assessment body should issue a final declaration of conformity.

The written declaration of conformity itself should include the results of the activities performed, the conditions for its validity, the necessary data for identification of the product, process or service and its main characteristics and, if relevant, a description of the functioning of the product, process or service.

Written justification should be provided by the conformity assessment body if a conformity declaration/certificate is denied.

9.6 Manufacturer/supplier's declaration of conformity

After satisfactory results of all activities identified in the functional as well as the technical specifications, the manufacturer/supplier should issue a declaration of conformity which states that the supplied product, process or service conforms with these specifications and referenced standards.

The manufacturer/supplier should maintain, for a period ending at least five years after delivery of the product, process or service, the following documentation:

— manufacturer/supplier's declaration of conformity;

— written declaration of conformity issued by the conformity assessment body;

— design review declaration or type test report, as applicable, issued by the conformity assessment body;

— reports of all verifications identified in the functional and technical specifications;

— quality system certificate.

10 System B

10.1 General

This system describes the procedure whereby the conformity assessment body verifies type tests and performs product, process or service surveillance in order to ascertain that identified products, processes or services fulfil the performance requirements defined in the functional specification.

It includes the following activities:

— the verification that the technical specification fulfils the requirements of the functional specification;

— the execution and/or witnessing of type tests as required;

— the execution of product, process or service surveillance by inspection of samples/trials or 100 % inspection.

10.2 Type test and verification of conformity of the technical specification with the functional specification

The manufacturer/supplier should apply to the conformity assessment body for an examination of the product, process or service. The manufacturer/supplier should provide the information necessary to enable conformity assessment with the functional specification. It should include:

— the technical specification, including reference to standards that have been used;

— the supporting evidence of conformity with the functional specification, including, if applicable, results of type tests carried out.

The conformity assessment body should examine the validity and applicability of the type test documentation, and if deemed necessary should:

— examine the technical documentation;

— in case of a type test, verify that the sample(s) of products, processes or services to undergo the type test have been manufactured or their execution planned in conformity with the technical documentation;

— agree with the manufacturer/supplier the location at which the inspections should be carried out;

— perform the appropriate inspections to check whether the sample(s) have the characteristics required in the functional and the technical specifications.

The type test documentation should contain the results of inspections, conditions for its validity, data for identification of the verified product, process or service and, if relevant, a description of the functioning of the product, process or service. In addition to this information, the type test documentation should include reports of the verifications of the conformity assessment body.

The manufacturer/supplier should inform the conformity assessment body about any modifications to the type-tested product, process or service. These modifications should be examined by the conformity assessment body with regard to the validity of the type test documentation. The conformity assessment body should provide additional approval where modifications relate to conformity with the functional specification. Additional approval is given in the form of an addendum to the original type test documentation.

10.3 Product, process or service surveillance

The manufacturer/supplier should establish an inspection plan for the specific product, process or service. This inspection plan should describe the inspections to be performed in order to demonstrate that the final product, process or service is in conformity with the type-tested product, process or service and with the technical specification.

The manufacturer/supplier should submit the inspection plan to the conformity assessment body, who should use this to perform surveillance after approval. Depending on the type of product, process or service, the conformity assessment body should carry out 100 % inspection or inspection of samples, as required in the functional specification, in the manufacturer/supplier's premises in order to:

— verify that the actual product, process or service does not deviate from the product, process or service type-tested;

— verify that inspections are carried out or cause them to be carried out in order to provide an impartial verification of conformity with the requirements of the technical specification.

Furthermore, the manufacturer/supplier should establish a list with regard to all modifications made to the product, process or service, which has been type-tested. This list should include the justification and the validity considerations of each modification. As part of the product, process or service surveillance, the conformity assessment body should verify this list on a periodic basis.

10.4 Conformity assessment

After satisfactory results of the activities listed in 10.2 and 10.3, the conformity assessment body should issue a final written declaration of conformity in accordance with 9.5 of this Technical Report.

Written justification should be provided by the conformity assessment body if a conformity declaration is denied.

10.5 Manufacturer/supplier's declaration of conformity

After satisfactory results of all activities identified in the functional and technical specifications, the manufacturer/supplier should issue a declaration of conformity which states that the supplied product, process or service conforms with the type test documentation, functional and technical specifications and referenced standards.

The manufacturer/supplier should maintain, for a period ending at least five years after delivery of the product, process or service, the following documentation:

— manufacturer/supplier's declaration of conformity;

— written declaration of conformity issued by the conformity assessment body;

— type test documentation and associated reports;

— reports of all inspections identified in the functional and technical specifications.

11 System C

11.1 General

This system is equivalent to the system presented in ISO/IEC Guide 28 and describes the procedure, whereby the conformity assessment body verifies type tests and performs product, process or service surveillance in order to declare that identified products, process or services fulfil the performance requirements defined in the functional specification.

It includes the following activities:

— verification, that the technical specification fulfils the requirements of the functional specification;

— execution and/or witnessing of type tests as required;

— verification of the manufacturer's/supplier's quality system in accordance with ISO 9002 or ISO 9003;

— execution of product, process or service surveillance by periodic inspection during the manufacturing or execution of a product, process or service.

11.2 Type test and verification of conformity of the technical specification with the functional specification

With regard to type test and verification of conformity of the technical with the functional specification, 10.2 of this Technical Report applies.

11.3 Quality system

The manufacturer/supplier should operate a certified quality system in accordance with ISO 9002. In case the specific product, process or service does not require process control, ISO 9003 applies.

All other provisions of 9.3 for the quality system apply.

11.4 Product surveillance

The manufacturer/supplier should establish an inspection plan for the specific products, processes or services. This inspection plan describes the inspections to be performed in order to demonstrate conformity with the technical specification.

The manufacturer/supplier should submit the inspection plan to the conformity assessment body for approval. Reports of inspections performed according to the inspection plan should be collected and made available for the review of the conformity assessment body. The conformity assessment body should carry out periodic inspection, which may be unscheduled, in the manufacturer/supplier's location of activity in order to:

— verify that the actual product, process or service does not deviate from the product, process or service type tested;

— verify the validity of manufacturer/supplier’s quality system certificate;

— verify that the inspection documentation issued by the manufacturer/supplier is in conformity with the inspection plan and that the associated results are satisfactory;

— verify that the non-conformities accepted during production do not impair the ability of the product, process or service to meet the requirements of the functional specification;

— verify the inspections performed by the manufacturer/supplier at the time of periodic inspection and/or carry out inspections, or cause them to be carried out, in order to provide an impartial verification of conformity with the requirements of the technical specification.

The manufacturer/supplier should establish a list with regard to all modifications made to the product, process or service, which has been type-tested. This list should include the justification and the validity considerations of each of these modifications. The conformity assessment body should inspect this list.

11.5 Conformity assessment

After satisfactory results of the activities listed in 11.2, 11.3 and 11.4, the conformity assessment body should issue a final written declaration of conformity in accordance with 9.5 of this document.

Written justification should be provided by the conformity assessment body if a conformity declaration is denied.

11.6 Manufacturer/supplier’s declaration of conformity

After satisfactory results of all activities identified in the functional and technical specifications, the manufacturer/supplier should issue a declaration of conformity which states that the supplied product, process or service conforms with these specifications and referenced standards.

12 System D

12.1 General

This system describes the procedure whereby the conformity assessment body performs product surveillance of the final product, process or service.

12.2 Product surveillance

The manufacturer/supplier should apply to the conformity assessment body for product, process or service surveillance.

The manufacturer/supplier should establish for the specific product, process or service, an inspection plan. This plan should describe the inspections to be performed in order to demonstrate conformity of identified characteristics with the technical specification.

The manufacturer/supplier should submit the inspection plan to the conformity assessment body, who should use this to operate surveillance. The conformity assessment body causes the inspections to be carried out on selected characteristics as required in the technical specification in order to provide an impartial verification of conformity of these characteristics to the requirements. The inspections performed by the conformity assessment body may be either 100 % inspection or inspection of samples.

12.3 Conformity assessment

After satisfactory results of the inspections with regard to product surveillance, the conformity assessment body should issue a written declaration of inspection. The declaration itself should include the results of the inspections. In addition, a reference list should be included relating to the conformity assessment body's reports. Written justification should be provided by the conformity assessment body if conformity assessment is denied.

12.4 Manufacturer/supplier's declaration of conformity

After satisfactory results of all activities identified in the functional and technical specifications, the manufacturer/supplier should issue a declaration of conformity which states that the supplied product, process or service conforms with the specifications and referenced standards.

The manufacturer/supplier should maintain, for a period ending at least five years after the delivery of the product, process or service, the following documentation:

— manufacturer/supplier's declaration of conformity;

— declaration of inspection issued by the conformity assessment body;

— reports of all inspections identified in the functional and technical specifications.

13 System E

13.1 General

This system describes the procedure whereby the manufacturer/supplier performs design examinations (if necessary), type tests, verification of conformity of the technical specification with the functional specification, and product surveillance. It may include the implementation of a quality system, the preparation of quality or inspection plans, etc.

13.2 Manufacturer/supplier's declaration of conformity

After satisfactory results of all activities identified in the functional and technical specifications, the manufacturer/supplier issues a declaration of conformity which states that the supplied product, process or service conforms with the functional and technical specifications and referenced standards.

The manufacturer/supplier should maintain, for a period ending at least five years after the delivery of the product, process or service, the following documentation:

— manufacturer/supplier's declaration of conformity;

— reports of all verifications.