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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Printed in Switzerland

Contents

Page

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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.

