CSA N299.2:19

Quality assurance program requirements for the supply of items and services for nuclear power plants, Category 2

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Contents

Preface

This is the second edition of CSA N299.2, *Quality assurance program requirements for the supply of items and services for nuclear power plants, Category 2.* It supersedes the previous edition published in 2016.

The CSA N299 series of Standards defines quality assurance program requirements for the provision of items and services for nuclear power plants when specified in the contract between the customer and the supplier.

The most significant updates to this edition include

a) the addition of requirements on dedication in Clause 8;
b) the revision of Annex E to provide guidance on counterfeit, fraudulent, and suspect items (CFSIs);
c) the addition of Annex F to provide guidance on risk evaluation; and
d) the addition of Annex G to provide guidance on records.

This Standard has also been restructured and reordered for better readability.

Users of this Standard are reminded that civilian nuclear facilities in Canada are subject to the provisions of the *Nuclear Safety and Control Act* and its *Regulations*.

This Standard was prepared by the Subcommittee on Quality Assurance Program Requirements for Supply of Items and Services for Nuclear Power Plants, under the jurisdiction of the Technical Committee on Management Systems for Nuclear Facilities and the Strategic Steering Committee on Nuclear Standards, and has been formally approved by the Technical Committee.

Notes:

1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*
2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*
3) *This Standard was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*
4) *To submit a request for interpretation of this Standard, please send the following information to inquiries@csagroup.org and include "Request for interpretation" in the subject line:*
   a) *define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;*
   b) *provide an explanation of circumstances surrounding the actual field condition; and*
   c) *where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.*

   Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at standardsactivities.csa.ca.*
5) *This Standard is subject to review within five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:*
   a) *Standard designation (number);*
   b) *relevant clause, table, and/or figure number;*
   c) *wording of the proposed change; and*
   d) *rationale for the change.*

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0 Introduction

0.1 Background

The CSA Z299 series of Standards (referred to collectively as "CSA Z299") was selected by Ontario Hydro and AECL in the 1970s as the quality assurance standard for the procurement of items and services for their nuclear facilities. As a result, the CSA Z299 Standards were embedded in the design bases of all nuclear power stations and some utility-owned nuclear facilities licensed in Canada and continue to be used. These Standards were initially developed from Ontario Hydro quality standards and contained many of the requirements that were in force at that time. When the CSA N286 series of Standards were developed in the late 1970s, they referenced CSA Z299 as the recommended quality assurance standard for items and services. CSA Z299 was a commercial standard used by industry both nationally and internationally, and it was the pre-cursor to development of the ISO 9000 series of Standards. With the development of ISO 9001 in 1994, ISO 9001 became the commercial quality standard that was generally adopted by industry. CSA Z299 was no longer supported by the Technical Committee in charge of CSA Z299, and it was eventually withdrawn.

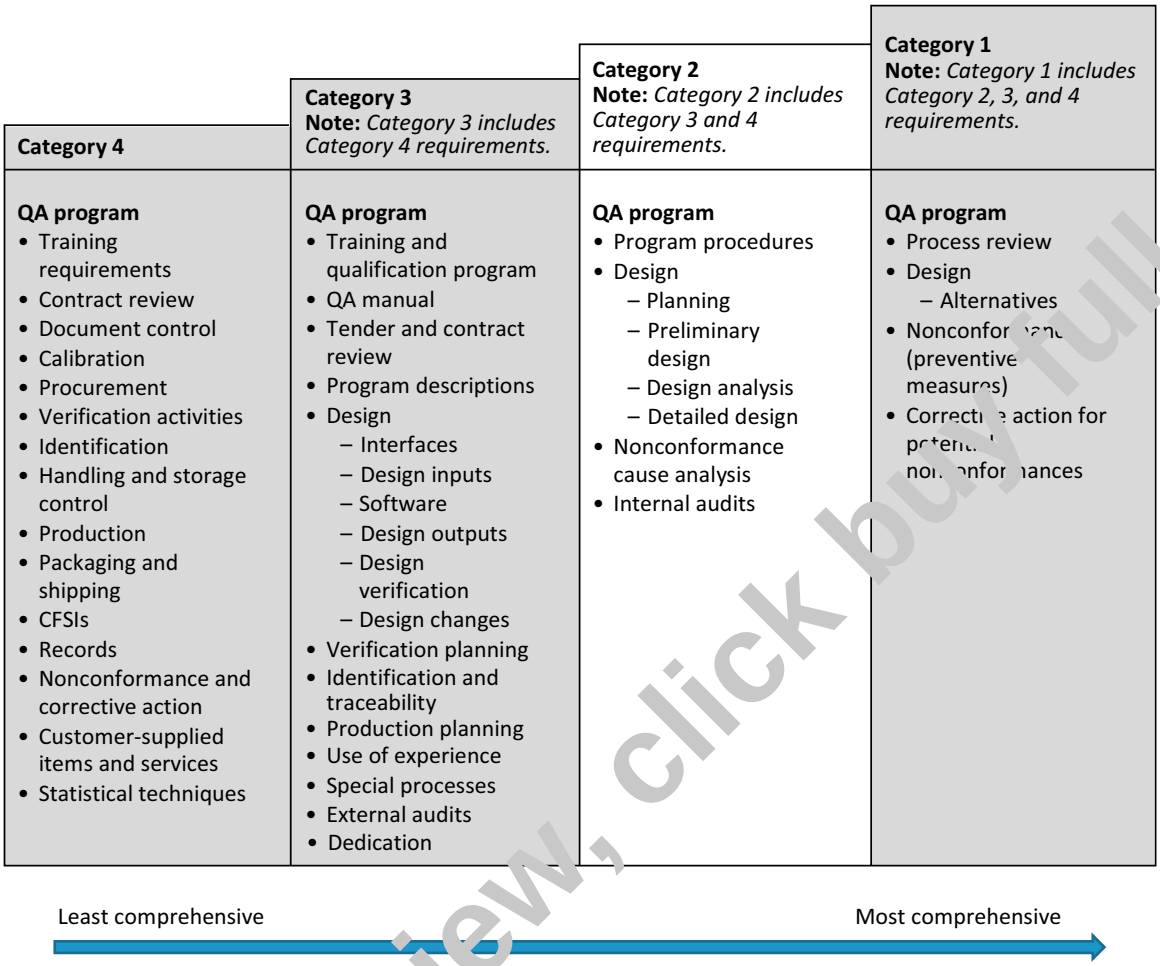
Internationally, there have been mixed approaches to creating industry-specific QA standards, such as augmenting ISO 9001 or creating completely new standards. CSA Z299 has not been issued since 1985 and needed to be updated to reflect current needs. To fulfill this need, nuclear utilities have developed, through a joint CANDU Owners Group (COG) project, a set of graded standards that align with the withdrawn CSA Z299 series so that the impact to the design basis and content transition to the new standards is minimized. These graded standards were used as the seed documents for the new CSA N299 series of Standards, which incorporates operating experience and current best practices and harmonizes, to the extent possible, with other standards (both national and international).

0.2 Category series

This is the second in a series of four Standards for the four quality assurance program categories (Category 1 to Category 4). See Figure 1 for a summary of this series of Standards and applicable elements.

This Standard was developed in response to industry's need for a quality assurance standard for items and services supplied to nuclear power plants.

Figure 1
Summary of standards and applicable elements
(See Clauses 0.2 and A.2.1.)



Category 4 is the least comprehensive, with each category in the series being more comprehensive as the category numbers decrease, and with Category 1 being the most comprehensive. The matrix comparison shows the increasing requirements by clause (see Table 1). The matrix will assist users when cross-referencing or upgrading from one category to another. When contractually required to produce an item or provide a service to one of the categories, suppliers may implement applicable additional requirements of a higher category quality assurance program.

This Standard aims at reacting to nonconforming items or services to prevent their recurrence. This is achieved by specifying feedback control to correct causes of nonconformances. This Standard is suitable for relatively high-technology items or services that require designs of lower complexity or changes to design and design verification with significant risk to safety. They also tend to have a significant number of complex processes and require production planning. Failure in service could result in significant risk to safety or the business.

The selection of any one category does not change the contractual requirements to produce an item or provide a service of the required quality. For selection of the most appropriate category, the use of Annex A within each CSA N299 series Standard is required. Selection of the appropriate category should be made by considering the parameters that are inherent to the item or service.

Table 1
Information comparison of CSA N299 category requirements
(See Clause 0.2.)

Matrix comparison of categories	Category 1	Category 2	Category 3	Category 4
1 Scope	I	II	III	IV
3 Definitions	I	I	III	IV
4 General requirements	I	I	III	IV
4.1 General	I	I	I	IV
4.2 Customer's responsibilities	I	I	I	IV
4.3 Management responsibilities				
4.3.1 Top management	I	I	III	IV
4.3.2 Management representative	I	I	I	IV
4.4 Independent verification	I	I	I	IV
4.5 Software	I	I	I	IV
4.6 Safety culture	I	I	I	N/A
4.7 Use of experience	I	I	III	N/A
4.8 Counterfeit, fraudulent, and suspect items (CFSIs)	I	I	I	I
5 QA manual/program documentation	I	I	I*	IV
6 QA program procedures/descriptions	I	I	III	N/A
7 QA program elements				
7.1 Management review	I	II	III	IV
7.2 Indoctrination, training, and qualification	I	I	III	IV
7.3 Tender and contract review	I	I	III	IV
7.4 Design	I	II	III	N/A
7.5 Documentation	I	I	I*	IV
7.6 Procurement	I	I	III	IV
7.7 Verification planning	I	I	I*	N/A
7.8 Verification activities	I	I	I	IV
7.9 Verification status	I	I	I	IV
7.10 Measuring and testing equipment (M&TE)	I	I	I*	I*
7.11 Identification and traceability	I	I	I	IV

(Continued)

Table 1 (Concluded)

Matrix comparison of categories	Category 1	Category 2	Category 3	Category 4
7.12 Handling and storage	I	I	III	IV
7.13 Production	I	I	III	IV
7.14 Special processes	I	I	I	N/A
7.15 Packaging and shipping	I	I	III	IV
7.16 Records	I	I	I	IV
7.17 Nonconformances	I	I	III	IV
7.18 Corrective action	I	II	III	III
7.19 Customer-supplied items and services	I	I	I	I
7.20 Statistical techniques	I	I	I*	IV
7.21 Quality audits				
7.21.1 Internal quality audits	I	I	III	N/A
7.21.2 External quality audits	I	I	III	N/A
8 CSA N299 dedication requirements	I	II	III	N/A

Note: *Table 1 is provided to show the differences between the standard categories.*

Legend:

I = Requirements equivalent with Category 1

II = Requirements equivalent with Category 2

III = Requirements equivalent with Category 3

IV = Requirements equivalent with Category 4

N/A = Specific clause is not applicable to the specified category

* *Descriptions rather than quality assurance procedures.*

1 Scope

1.1

1.1.1

This Standard defines minimum requirements for a supplier's quality assurance program (hereafter referred to as "QA program") for the supply of items and services to nuclear power plants — Category 2.

Notes:

1) *This Standard does not include a separate implementation guide; instead, relevant guidance is found throughout the Standard as notes, or within the relevant annex (see Annexes B through G).*
2) *The requirements in this Standard do not restrict or specify the form that suppliers' programs should take; nor do they specify how to establish such programs. The requirements only specify what these programs cover; they allow suppliers to determine how their programs should be structured in order to suit their own*

situations and objectives. The onus is on suppliers to develop programs in a consistent and systematic way that allows customers, recognized qualifying authorities, or regulatory authorities to survey and audit the programs.

3) *This Standard may provide guidance for nuclear facilities other than nuclear power plants. The operators of these facilities may determine the applicability and suitability of this Standard.*

1.1.2

The QA program is aimed primarily at controlling design, production, and verification processes, and developing corrective actions that

a) ensure items or services conform to specified requirements;
b) maintain control of, and confirm compliance to, quality and customer requirements; and

   Note: *Typically, customer requirements are found in the contract between the customer and the supplier.*

c) readily detect and control the disposition of nonconformances and prevent their recurrence.

1.2

This Standard applies to suppliers and subsuppliers when specified by the customer.

Note: *Other QA program standards or management system standards may be used provided that the requirements of this Standard are met.*

1.3

In this Standard, "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the Standard; "should" is used to express a recommendation or that which is advised but not required; and "may" is used to express an option or that which is permissible within the limits of the Standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

2 Reference publications

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below.

CSA Group

CAN/CSA-ISO 10012:03 (R2018)
Measurement management systems — Requirements for measurement processes and measuring equipment

CAN/CSA-ISO/TR 10017:03 (R2018)
Guidance on statistical techniques for ISO 9001:2000

CAN/CSA-ISO 19011:12 (R2017)
Guidelines for auditing management systems