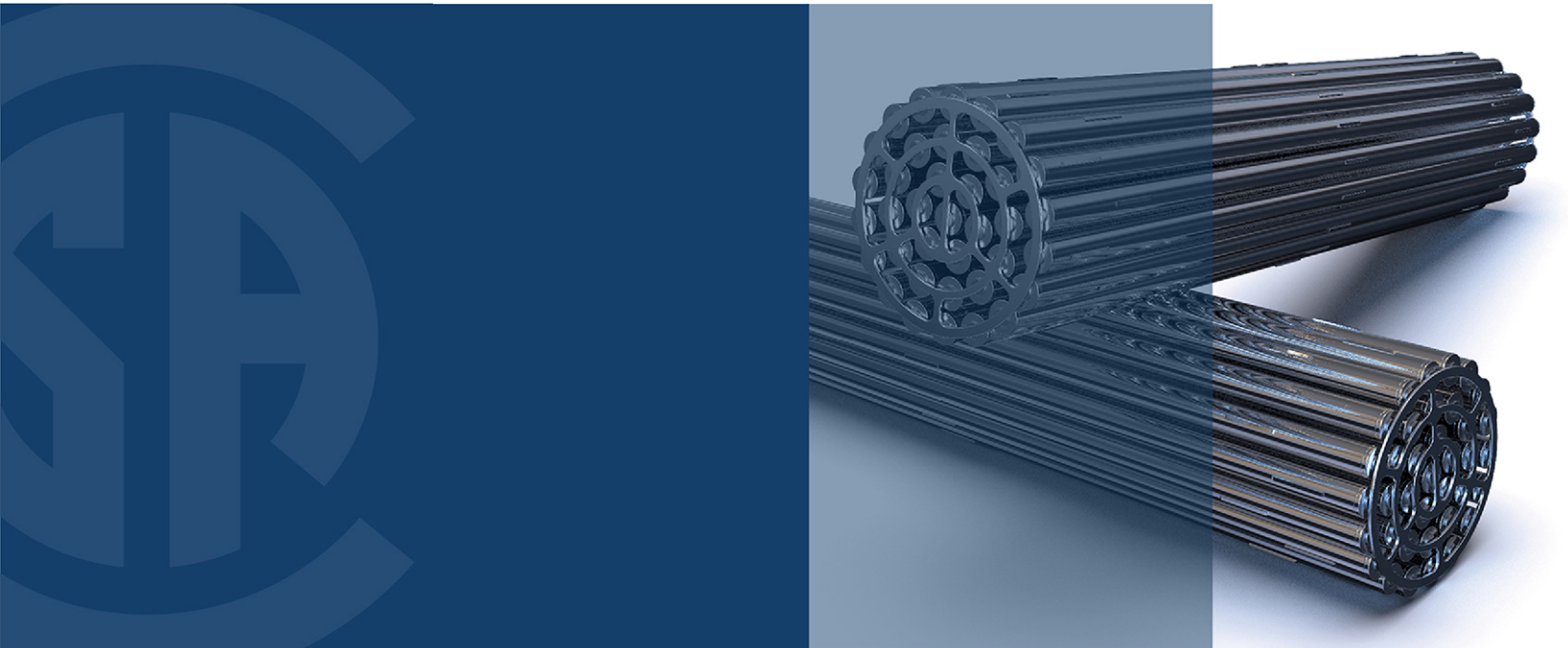


Quality assurance program requirements for the supply of items and services for nuclear power plants, Category 2



Legal Notice for Standards

Canadian Standards Association (operating as “CSA Group”) develops standards through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA Group administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document’s fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party’s intellectual property rights. CSA Group does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA Group makes no representations or warranties regarding this document’s compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA GROUP, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA GROUP HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA Group is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA Group accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA Group and the users of this document (whether it be in printed or electronic form), CSA Group is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA Group’s and/or others’ intellectual property and may give rise to a right in CSA Group and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by licence or by law, CSA Group reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA Group shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA Group for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF format.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA Group to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA Group; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.



Standards Update Service

CSA N299.2:19 December 2019

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

To register for e-mail notification about any updates to this publication

- go to store.csagroup.org
- click on **Product Updates**

The **List ID** that you will need to register for updates to this publication is **2427477**.

If you require assistance, please e-mail techsupport@csagroup.org or call 416-747-2233.

Visit CSA Group's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

CSA N299.2:19

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



®A trademark of the Canadian Standards Association, operating as "CSA Group"

*Published in December 2019 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3*

*To purchase standards and related publications, visit our Online Store at store.csagroup.org
or call toll-free 1-800-463-6727 or 416-747-4044.*

ISBN 978-1-4883-2395-9

*© 2019 Canadian Standards Association
All rights reserved. No part of this publication may be reproduced in any form whatsoever
without the prior permission of the publisher.*

Contents

Technical Committee on Management Systems for Nuclear Facilities	4
Subcommittee on Quality Assurance Program Requirements for Supply of Items and Services for Nuclear Power Plants	6
Preface	8
0 Introduction	9
0.1 Background	9
0.2 Category series	9
1 Scope	12
2 Reference publications	13
3 Definitions	15
4 General requirements	19
4.1 General	19
4.2 Customer's responsibilities	20
4.3 Management responsibilities	21
4.3.1 Top management	21
4.3.2 Management representative	21
4.4 Independent verification	21
4.5 Software	22
4.5.1 Software employed in work methods or tools	22
4.5.2 Embedded software	22
4.5.3 Design analysis software	22
4.6 Safety culture	22
4.7 Use of experience	22
4.8 Counterfeit, fraudulent, and suspect items (CFSIs)	23
5 QA manual	23
5.1 General	23
5.2 QA manual contents	23
6 QA program procedures	24
7 QA program elements	24
7.1 Management review	24
7.2 Indoctrination, training, and qualification	25
7.2.1 Indoctrination	25
7.2.2 Training	25
7.2.3 Qualification	25
7.3 Tender and contract review	26
7.3.1 Review of tendering requirements	26
7.3.2 Review of contractual requirements	26

7.4	Design	27
7.4.1	Application	27
7.4.2	Design planning	27
7.4.3	Work assignment	27
7.4.4	Interfaces	27
7.4.5	Design inputs	28
7.4.6	Preliminary design	28
7.4.7	Design analysis software	28
7.4.8	Detailed design	28
7.4.9	Design output	28
7.4.10	Design verification	28
7.4.11	Design changes	30
7.5	Documentation	30
7.6	Procurement	31
7.6.1	Selection	31
7.6.2	Use of customer's approved suppliers	32
7.6.3	Subcontract requirements	32
7.6.4	Reviews	33
7.6.5	Inspection, surveillance, and audit of sub-suppliers	33
7.6.6	Amendments to subcontracts	33
7.7	Verification planning	33
7.8	Verification activities	35
7.9	Verification status	36
7.9.1	Verification status for items	36
7.9.2	Verification status for services	36
7.10	Measuring and testing equipment (M&TE)	36
7.11	Identification and traceability	38
7.11.1	Identification	38
7.11.2	Traceability	38
7.12	Handling and storage	38
7.13	Production	39
7.13.1	Planning	39
7.13.2	Process procedures	39
7.13.3	Process verification	39
7.13.4	Work control	40
7.14	Special processes	40
7.15	Packaging and shipping	40
7.16	Records	40
7.16.1	General requirements	41
7.16.2	Generation of records	41
7.16.3	Authentication of records	41
7.16.4	Maintenance and storage of records	41
7.16.5	Record retention periods	42
7.17	Nonconformances	42
7.17.1	General nonconformance requirements	42
7.17.2	Specific nonconformance requirements for items and services	43
7.18	Corrective action	43
7.19	Customer-supplied items and services	44
7.20	Statistical techniques	44

7.21	Quality audits	44
7.21.1	Internal quality audits	44
7.21.2	External quality audits	45
8	CSA N299 dedication requirements	46
8.1	Application	47
8.2	Dedication eligibility	48
8.3	Planning	48
8.4	Work assignment	48
8.5	Identification and maintaining traceability	48
8.6	Design evaluation	48
8.7	Acceptance	49
8.7.1	Acceptance criteria and control areas	49
8.7.2	Control Area 1: QA program augmentation	50
8.7.3	Control Area 2: Verification activities	50
8.7.4	Control Area 3: Supplier performance	52
8.8	Conduct acceptance activities	52
8.9	Dedication outputs	53
8.10	Dedication changes	53

Annex A (normative)	— Category selection	54
Annex B (informative)	— Guidance on QA program procedures	63
Annex C (informative)	— Guidance on design	66
Annex D (informative)	— Guidance on measuring and test equipment	70
Annex E (informative)	— Counterfeit, fraudulent, and suspect items (CFSIs)	73
Annex F (informative)	— Risk evaluation	75
Annex G (informative)	— Records	76

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.*

CSA N299.2:19

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

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 broadly 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	Category 3 Note: Category 3 includes Category 4 requirements.	Category 2 Note: Category 2 includes Category 3 and 4 requirements.	Category 1 Note: Category 1 includes Category 2, 3, and 4 requirements.
QA program <ul style="list-style-type: none"> • Training requirements • Contract review • Document control • Calibration • Procurement • Verification activities • Identification • Handling and storage control • Production • Packaging and shipping • CFSIs • Records • Nonconformance and corrective action • Customer-supplied items and services • Statistical techniques 	QA program <ul style="list-style-type: none"> • Training and qualification program • QA manual • Tender and contract review • Program descriptions • Design <ul style="list-style-type: none"> – Interfaces – Design inputs – Software – Design outputs – Design verification – Design changes • Verification planning • Identification and traceability • Production planning • Use of experience • Special processes • External audits • Dedication 	QA program <ul style="list-style-type: none"> • Program procedures • Design <ul style="list-style-type: none"> – Planning – Preliminary design – Design analysis – Detailed design • Nonconformance cause analysis • Internal audits 	QA program <ul style="list-style-type: none"> • Process review • Design <ul style="list-style-type: none"> – Alternatives • Nonconformance (preventive measures) • Corrective action for potential nonconformances



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 sub-suppliers 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