



Standards Council of Canada
Conseil canadien des normes

Accreditation Services

Program Overview – Guidelines for the Development and Maintenance of Other Recognized Documents (ORDs)

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Foreword

The process described in this document has been developed to support the certification of products, processes and services in the context of regulated areas where accreditation of the certification is mandated by regulators. Although it is not meant to cover unregulated areas, this guideline document might be of interest to the unregulated areas and their stakeholders.

In addition to this document, there are requirements that must be implemented or complied with by the certification bodies. These requirements can be found in *SCC Requirements and Guidance - Product, Process, and Service Certification Body Accreditation Program*.

The Regulatory Authority Advisory Bodies and SCC are currently working to harmonize the governance related to the approval of ORDs.

Introduction

A Standards Council of Canada (SCC) accredited certification body (CB) may develop Other Recognized Documents (ORD) to provide certification services within their accredited scope in areas where Canadian Recognized Standards do not exist or are not fully applicable.

Note: see section 4.0 for details on scope of accreditation.

An ORD is intended to be used as a temporary document for certification purposes to permit time for a standard that addresses the scope of the ORD to be created or updated by an SCC accredited Standards Development Organization (SDO).

1. Scope

This guideline is for the development and maintenance of an ORD by CBs for the regulated sectors of the Canadian market. Typically this procedure has been applicable to products. However, this procedure could also be used for process or service applications.

1.1 Regulated

In regulated areas, CBs certify products to Canadian Recognized Standard(s) or National Standard(s) of Canada (NSC) where they exist. Where they don't exist, CBs may develop ORDs for use in certification activities. In regulated areas ORDs are to be acknowledged and validated by the applicable Regulatory Authority Advisory Body (RAABs) before they are used for certification.

2. References

The following referenced documents are required for the application of this document. The latest edition of the referenced document (including any amendments) applies.

- Requirements & Guidance – Accreditation of Standards Development Organizations
- Canadian Standards Development - Program Overview
- SCC Requirements and Guidance - Product, Process, and Service Certification Body Accreditation Program
- ISO/IEC 17000 Conformity Assessment – Vocabulary and general principles
- ISO/IEC 17007 Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment
- ISO/IEC 17065 Conformity assessment -- Requirements for bodies certifying products, processes and services.

3. Definitions

The definitions as presented in ISO/IEC 17065 and its referenced documents apply. The following definitions also apply.

3.1 Acknowledging Body(ies)

The Acknowledging Body is the applicable sector Regulatory Authority Advisory Body (RAAB).

3.2 Authority Having Jurisdiction (AHJ)

An organization, office, delegated authority or individual responsible, by virtue of Federal, Provincial, Territorial or Municipal authority for administration and enforcing the requirements of a legislation including a code or standard, for approving equipment, materials, an installation, or a procedure.

3.3 Canadian Recognized Standard

A standard recognized by a RAAB or an AHJ.

3.4 Certification Body (CB)

A SCC-accredited organization providing third-party written assurance that a product, process or service fulfills specified requirements.

3.5 Effective Date

The date which a CB selects to begin certifying to the ORD.

3.6 Existing Certification (on-going)

This is a certification to the requirements of the ORD, which has been granted prior to the change of status of the ORD (to expired, withdrawn or superseded).

3.7 Expired

An ORD that has exceeded its term of validity.

3.8 National Standard of Canada (NSC)

A standard prepared or reviewed by an SDO and approved by SCC, according to the NSC approval requirements.

3.9 New Certification

This is the certification of a product not previously certified to the requirements of an ORD.

3.10 Other Recognized Document (ORD)

A normative document that is developed when a Canadian Recognized Standard or National Standard of Canada does not cover some or all aspects of a product to be certified.

Note - A normative document can also be developed for situations to address changes in a Canadian Code, or a technical change in an existing standard. An ORD provides an equivalent level of safety or performance as provided for similar functions in existing standards.

3.11 Product, Process, and Service

Product

The result of a process

NOTE 1: Four generic product categories are noted in ISO 9000:2005:

- services (e.g. transport) (adopted from ISO 9000:2005, see definition in 3.6);
- software (e.g. computer program, dictionary);
- hardware (e.g. engine, mechanical part);
- processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2: Products include results of natural processes, such as growth of plants and formation of other natural resources.

NOTE 3: Adapted from ISO/IEC 17000:2004, definition 3.3.

Process

A set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLES Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

NOTE: Adapted from ISO 9000:2005, definition 3.4.1.

Service

The result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

NOTE 1 Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied product (e.g. automobile to be repaired);
- an activity performed on a customer-supplied product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants).

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.2.

3.12 Reaffirmation

Where the validity of the ORD has been extended for a second 5 year term, having no technical revisions made to the ORD.

3.13 Regulatory Authority Advisory Body (RAAB)

A body, council or committee, consisting of representatives from various Canadian governmental organizations (Federal, Provincial, Territorial, Municipal or other) that coordinates regulations and promotes consistency among jurisdictions related to regulations, standards and enforcement practices with respect to the sale, purchase, safety, performance, use and application of consumer, commercial or industrial products within its jurisdiction(s).

Note 1: A link to a list of RAABs can be found at:

<http://www.scc.ca/en/accreditation/product-process-and-service-certification/regulatory-advisory-councils>

Note 2: In the absence of a RAAB or adequate representation in a jurisdiction, the relevant Authority Having Jurisdiction shall be consulted.

3.14 Revalidation

Where a valid ORD has been revised due to technical changes and confirmed as still valid, using the process outlined herein, for the remainder of its current term of validity.

3.15 Revision

A technical change made to a valid ORD.

3.16 Standard

A document, established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at achievement of the optimum degree of order in a given context.

Note: Standards should be based on the consolidated results of science, technology and experience and aimed at the promotion of optimum community benefits.

Note: Recognized Body: a legal or administrative entity that has specific tasks and composition, with acknowledged authority for publishing standards.

3.17 Superseded

Where an ORD has been replaced by a Canadian Recognized Standard or incorporated into another ORD with a broader scope.

3.18 Valid

An ORD that has been validated, reaffirmed or revalidated by the applicable Acknowledging Body(ies).

3.19 Validation Date

The date the ORD becomes valid and available for certification purposes in Canada.

3.20 Withdrawn

An ORD rescinded by the authoring CB.

4. General Requirements

For the accreditation requirements applicable to CB's developing ORDs, refer to the *SCC Requirements and Guidance - Product, Process, and Service Certification Body Accreditation Program*, Section 9.3.

5. Procedure

5.1 General Procedure

An SCC-accredited CB is responsible for the development of an ORD.

Note: It is recommended that the CB also work with an SCC-accredited Standards Development Organization during the ORD development phase to assist planning for disposition of the ORD. The objective is to transition the published ORD to a full consensus standard within the first 5 years of validity. Should there be reasons why the ORD has not transitioned to a standard, the Acknowledging Body(ies) may agree to another possible maintenance process for one more term of validity.

The CBs shall be responsible of informing SCC of all ORDs status changes.

No certification shall be conducted until the ORD has been validated by the appropriate Acknowledging Body(ies) and SCC has received the information described in section 4.2. There are three main stages in the existence of an ORD: creation, maintenance and disposition.

5.2 ORD Creation

5.2.1 Identification of Need for new ORD

The CB shall submit the relevant completed information package described in section 4.1.1 to the applicable Acknowledging Body(ies) to verify the need for ORD. The SCC is also informed by the authoring CB so they can post the information described in section 4.2 – Information on ORDs for public awareness.

5.2.2 Need Confirmation by Acknowledging Body(ies)

If the applicable Acknowledging Body(ies) acknowledges the need for the ORD, proceed to 5.2.3. If more information is required before a decision can be made, the Acknowledging Body(ies) shall request it from the authoring CB. The ORD status information and decision shall be shared with SCC by the submitting CB. SCC will coordinate the update of the publicly available information accordingly (see section 4.2). If the applicable Acknowledging Body(ies) does not acknowledge the need for the ORD, they shall notify the submitting CB of their decision with the rationale. The submitting CB shall notify SCC. SCC will coordinate the update of the publicly available information accordingly. The ORD creation process is terminated.

5.2.3 Potential Duplication

If the content of the proposed ORD scope is recognized as potential duplication of a published standard, a Standard under development/revision or valid ORD by any party, that party should contact the corresponding CB or SDO. The Acknowledging Body(ies) is to be informed of this potential duplication by the submitting CB. Principles for a dispute resolution process as provided in the *Canadian Standards Development - Program Overview* could be considered and if concerns persist, the complaint process of SCC could be used.

5.2.4 ORD Development and Submission for Validation

The authoring CB of the ORD shall consult available published standards or ORDs, and should consult the applicable SDO(s) regarding technical content as part of the ORD development.

The authoring CB submits the ORD final draft document to relevant Acknowledging Body(ies) for validation. An ORD providing safety requirements shall comply with Requirements & Guidance – Accreditation of Standards Development Organizations clause 4.15 for safety markings where applicable.

A CB associated with a SDO may submit ORDs that are verbatim copies successfully approved as a Canadian Recognized Standard (e.g. approved by the balanced matrix committee). The submission must be done in accordance with section 5.2.5 described here.

The ORD shall be submitted for balloting to the Acknowledging Body within 9 months from the date the Acknowledging Body(ies) confirms the need for the ORD.

Note: Exceptions to this requirement will be addressed on a case by case basis between the CBs and the Acknowledging Body(ies) and SCC will be kept informed.

The information package shall include as a minimum:

- evaluation criteria applied;
- any information previously submitted as in 4.1.1 and 4.1.2 that has changed;
- new relevant information; and
- final draft of ORD.

5.2.5 Validation Decision

If validated by the Acknowledging Body, proceed to 5.2.6.

If more information is required before a decision can be made, the Acknowledging Body(ies) shall request it of the authoring CB. If not validated by the Acknowledging Body(ies), the authoring CB is informed and provided with the rationale.

The authoring CB may request the Acknowledging Body(ies) to consider combining steps described in 5.2.2, 5.2.4 and 5.2.5. However, should the Acknowledging Body(ies) agree to combine these steps, the final validation status shall not be considered complete until the information described in section 4.1.2 has been provided to SCC so it is publicly available and stakeholders have an opportunity to raise issues of potential duplication as described in 5.2.3 above. Where there may be more than one Acknowledging Body(ies) involved, these steps should be taken serially.

5.2.6 Validation Status Publicized by SCC

The ORD validation status and scope information shall be shared with the SCC by the authoring CB. SCC will coordinate the update of the publicly available information accordingly.

The responsible CB shall

- immediately advise stakeholders how the ORD may be purchased or obtained
- provide information to SCC as outlined in section 4.1.2

- make an official request to the appropriate SDO within 30 days to amend an existing standard where one exists, or create a standard where none exists

5.2.7 ORD Term of Validation

ORD's may be used for certifications purposes for up to 5 years from date of initial validation, or revalidation, unless superseded or withdrawn.

5.3 ORD Maintenance

5.3.1 General

Acknowledging Body(ies) may permit an ORD to be reaffirmed once for a period of up to 5 years. If the reaffirmation process has been initiated but not completed within the term of validity, an extension of the validation date may be granted by the Acknowledging Body(ies) and communicated back to the CB and SCC.

On an exception basis, provided a draft standard is at an advanced stage, the ORD may be reaffirmed one additional time for no more than one year, if accepted by the Acknowledging Body(ies).

The ORD will be valid for certifications for up to 5 years from the date of reaffirmation or revalidation, unless it is superseded or withdrawn. An ORD that has expired cannot be reaffirmed.

Note: The justification provided by the authoring CB for reaffirmation and/or revalidation should describe the extent of use and application of the ORD and the progress made towards its incorporation into a standard. If insufficient progress is being made towards its incorporation, the justification should include the reasons for the lack of progress.

5.3.2 ORD Reaffirmation

For a reaffirmation, there shall be no technical changes to the ORD. The authoring CB shall provide the information package to the same Acknowledging Body(ies) that originally validated the ORD and shall include as a minimum the information outlined below and in sections 4.1.1 and 4.1.2 as applicable:

- key issues
- outline timing and approach needed (ie: phased in transition or effective date to permit manufacturer to update for production line changes)
- reasons why it has not become a standard
- indicate if editorial changes are expected

The Acknowledging Body(ies) may request additional information as necessary.

If the Acknowledging Body(ies) confirms reaffirmation, the Acknowledging Body(ies) informs the CB. The authoring CB informs SCC with the completed 4.1.2 information package. SCC will coordinate the update of the publicly available information accordingly. The period of ORD reaffirmation commences at the expiration of the previous period.

If the request to reaffirm is not granted by the Acknowledging Body(ies) the ORD expires. Go to 5.4.2 for notification process.

5.3.3 ORD Revision - Revalidation

Where technical revisions are being proposed, the authoring CB shall provide the information package described in 4.1.1 and additionally the bullets in 5.3.2 to the same Acknowledging Body(ies) that originally validated the ORD. This information shall include as a minimum a summary of proposed revisions (technical and administrative changes) and the supporting rationale.

If the applicable Acknowledging Body(ies) confirms justification for an ORD revision, proceed to 5.2.3 through 5.2.7 for development and revalidation of the ORD. A decision by the Acknowledging Body(ies) to approve or reject the revision request shall be communicated to SCC by the authoring CB. SCC shall coordinate the update of the publicly available information accordingly. If more information is required before a decision can be made, the Acknowledging Body(ies) shall request it from the authoring CB.

When a revised ORD has been revalidated or rejected, the Acknowledging Body(ies) shall inform the authoring CB of the decision. The authoring CB shall submit a completed 4.1.2 information package to SCC. SCC shall coordinate the update of the publicly available information. All CBs that have granted certifications to this ORD shall inform their clients of the revised or rejected ORD.

All CBs that have existing certifications to the original ORD shall inform their clients of the revalidated ORD. Existing certifications shall be transitioned through an evaluation to the revalidated ORD requirements or the certifications should be withdrawn.

The revalidated ORD can be used by CBs for certification for the remainder of the original ORDs term of validity.

When a revised ORD has been rejected, the Acknowledging Body(ies) shall inform the authoring CB of the decision and consider if the original ORD should be withdrawn as per Section 5.4.3. The authoring CB shall inform the SCC of the revalidated ORD rejection. SCC shall coordinate the update of the publicly available information.

5.4 ORD Disposition

ORDs are subject to being superseded, expired or withdrawn. The following procedures will describe the process steps.

5.4.1 ORD Superseded

An ORD is superseded when it is incorporated or replaced by a standard that is published and becomes effective, or another ORD is validated by an Acknowledging Body(ies) that covers the scope of an existing ORD before it expires.

The authoring CB of the superseded ORD shall initiate its withdrawal once the standard is published and becomes effective or the superseding ORD has been validated.

No new certifications to the superseded ORD shall be issued after the effective date of the new standard or superseding ORD. Existing certifications shall be transitioned through an evaluation to the new standard or superseding ORD requirements, or the certifications shall be withdrawn.

5.4.2 ORD Expired

An ORD is considered expired when it has passed its term of validity and has not been revalidated or reaffirmed. The authoring CB shall inform the Acknowledging Body(ies) and SCC of the expiration. SCC shall coordinate the update of the publicly available information accordingly.

CBs shall inform their clients of the new status.

All certifications issued to this document while it was valid are still acceptable. No new and existing certification to the expired ORD shall be issued as an expired ORD is not a valid certification document.

5.4.3 ORD Withdrawal

5.4.3.1 Acknowledging Body(ies) initiated ORD withdrawal

An Acknowledging Body(ies) may request of the authoring CB to withdraw a valid ORD. The Acknowledging Body(ies) shall specify the nature and provide justification for the request.

The Acknowledging Body(ies) shall inform the SCC of the request. SCC shall coordinate the update of the publicly available information listing concerning the nature of the request to withdraw an ORD. Where there is a disagreement to the request for withdrawal, the appropriate appeal process of the Acknowledging Body involved should be used.

When a final decision has been made by a Acknowledging Body(ies) for withdrawal of the ORD, the Acknowledging Body(ies) shall inform SCC and authoring CB. All CBs shall take action in accordance with their accreditation as appropriate.

When a final decision has been made for withdrawal, see 5.4.3.2 for procedures.

All CBs that have certified to this ORD shall:

- inform its affected clients
- withdraw all existing certifications based on the withdrawn ORD and remove them from the certification directory

- issue a public notification
- not issue any new certifications to the withdrawn ORD.

5.4.3.2 Non-RAAB initiated ORD withdrawal

A request for withdrawal of an ORD can also be initiated by any of the following relevant stakeholders: CB, or SDO, and shall be sent to the Acknowledging Body(ies) with copy to the authoring CB.

Note: An SDO may request a withdrawal when a standard is published that now covers the complete scope of the ORD, or the appropriate Standards Development Committee formally rejects an ORD for technical reasons.

For a requesting CB or SDO, this ORD shall be within their general SCC accredited scope. The organization that initiated the withdrawal shall provide justification as to why it should be rescinded.

The authoring CB shall inform the SCC of the request. SCC shall coordinate the update of the publicly available information indicating the withdrawal request.

Where there is a disagreement to the request for withdrawal, the relevant Acknowledging Body(ies) shall make the final determination. This process would be facilitated through the complaint process of SCC. SCC would provide its recommendations to the relevant Acknowledging Body for decision.

The withdrawal of a superseded ORD may need to be deferred in view of need for a transition period to allow for manufacturers to update their production to come into compliance with the new requirements.

Once the decision to withdrawal is final, the relevant details about this ORD are provided to SCC by the authoring CB. SCC shall coordinate the update of the publicly available information indicating the new status and relevant details.

All CBs that have certified to this ORD shall:

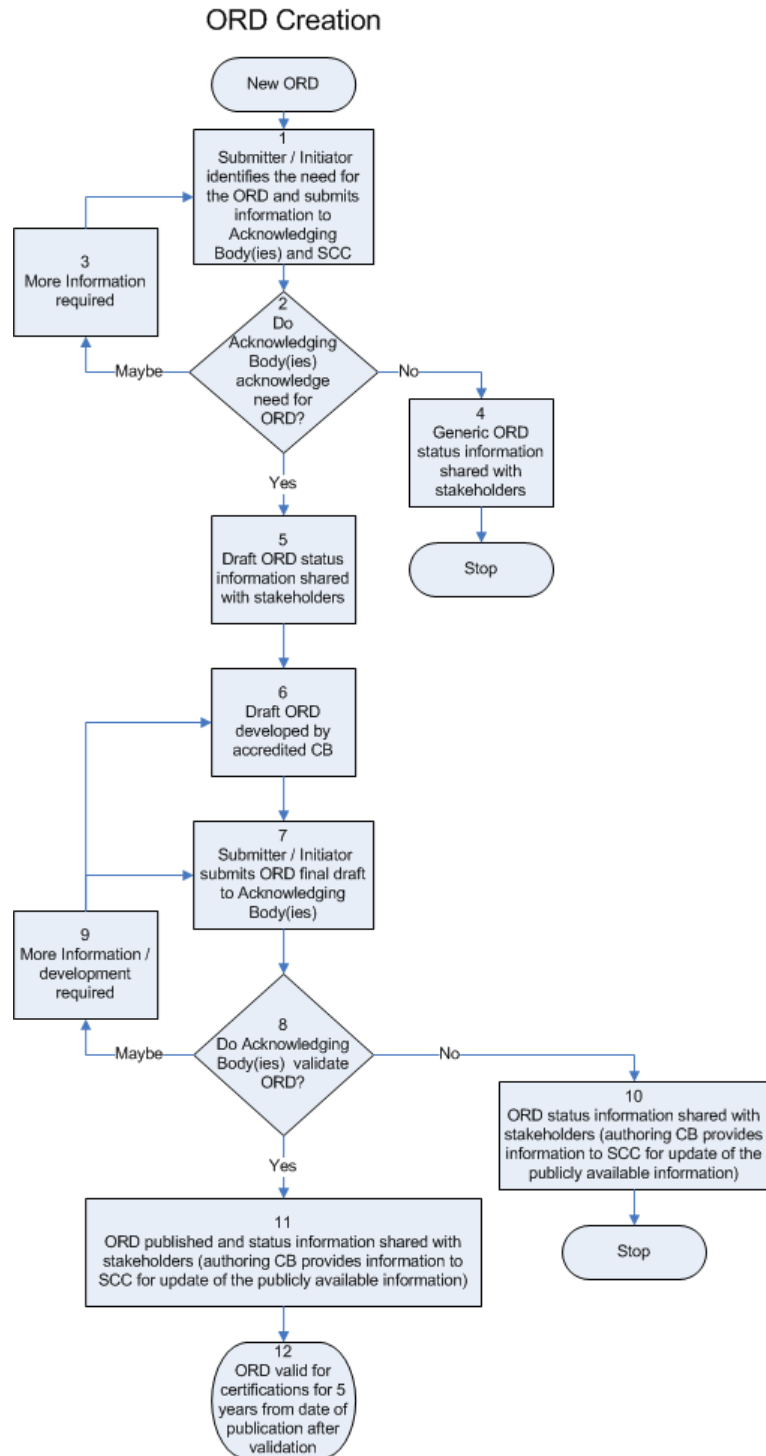
- inform its affected clients
- cease all existing certifications based on the withdrawn ORD and remove them from the certification directory
- issue a public notification.
- not issue any new certifications to the withdrawn ORD

6. Dispute resolution

Where there is a disagreement with the application of the ORD process (e.g.; creation, maintenance, disposition), the relevant Acknowledging Body(ies) shall make the final determination. This process would be facilitated through the complaint process of SCC. SCC would provide its recommendations to the relevant Acknowledging Body for decision.

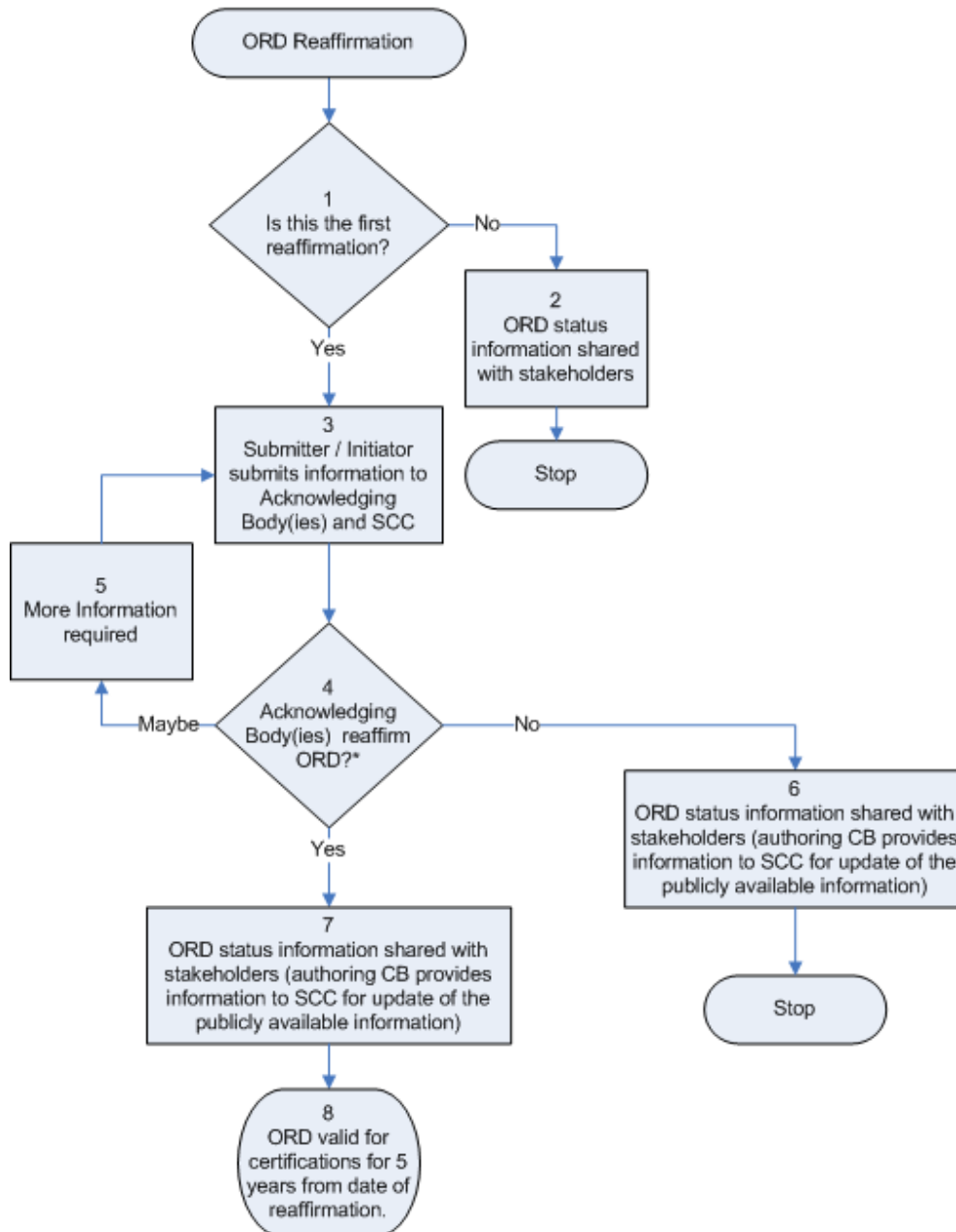
Annex A – Process Flowcharts

A.1. ORD Creation



A.2. ORD Maintenance – Reaffirmation

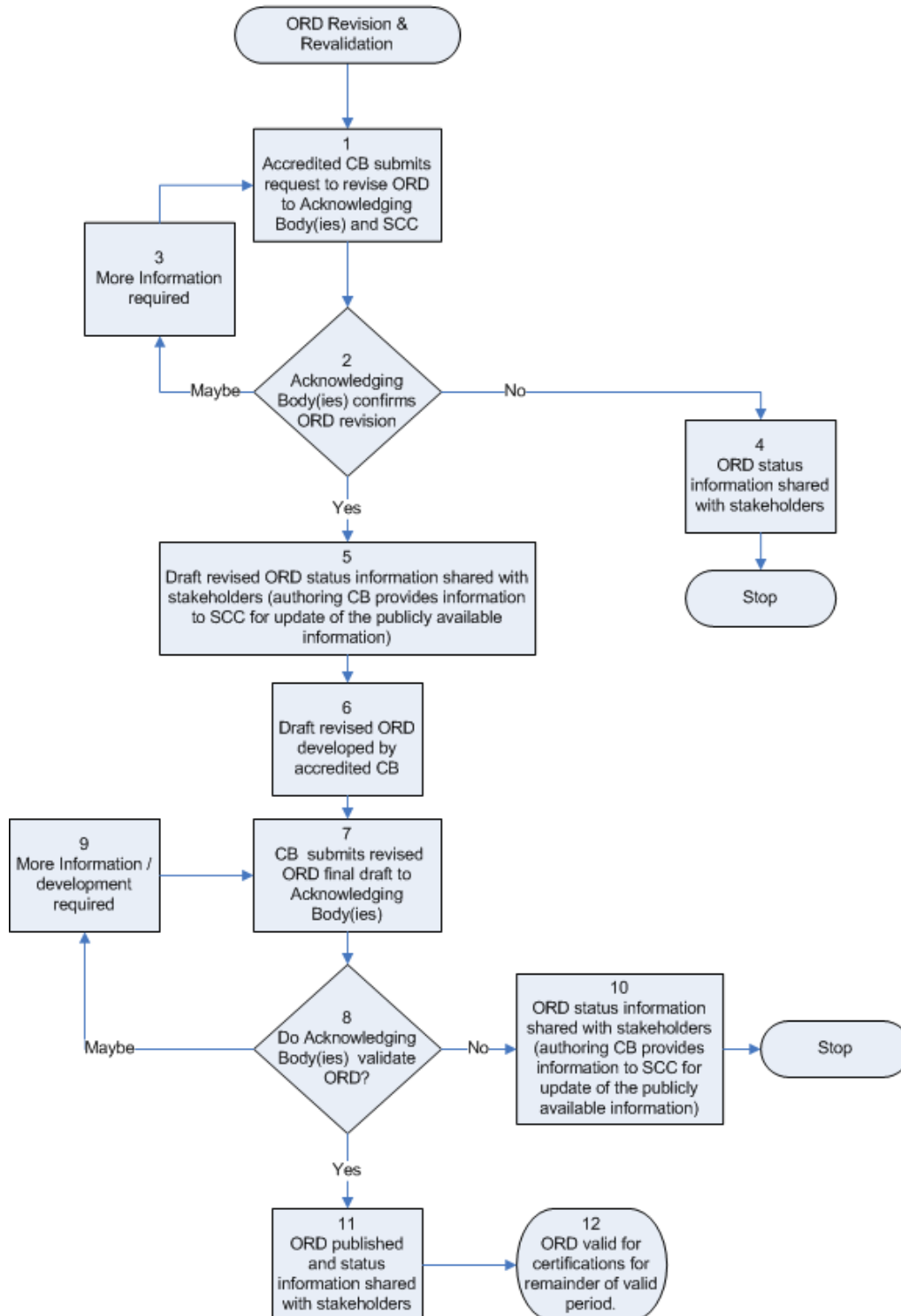
ORD Maintenance - Reaffirmation



** On an exception basis, provided a draft standard is at an advanced stage, the ORD may be reaffirmed one additional time for no more than one year, if accepted by the Acknowledging Body(ies).*

A.3. ORD Maintenance – Revision and revalidation

ORD Maintenance – Revision & Revalidation



A.4. ORD Disposition

ORD Disposition

