

ACCREDITATION SERVICES

SCC Requirements and Guidance - Independent Safety Assessor for Railway Systems
Accreditation Program

Standards Council of Canada



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Aussi publié en français sous le titre *Exigences et lignes directrices du CCN – Programme d'accréditation des évaluateurs indépendants de la sécurité des systèmes ferroviaires.*

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1. Scope

This document provides requirements and guidance of the Independent Safety Assessor for Railway Systems Accreditation Program that SCC operates and is a companion to ISO/IEC 17020. It outlines unique Canadian requirements of the SCC Accreditation Program for Independent Safety Assessors (ISAs) that carry out independent safety assessments of the suitability and application of both the risk management process and its results for changes to a Railway System, and that carry out independent assessments of system assurance processes for a Railway System.

In ISO/IEC 17020, the term "Inspection Body" can be read as "Independent Safety Assessor", and the term "Inspection" can be read as "independent safety assessment".

2. Normative References

- ISO/IEC 17020 Conformity assessment General criteria for the operation of various types of bodies performing inspection
- ISO/IEC 17025 General Requirements for the Competence of Calibration and Testing Laboratories
- ISO Guide 27 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- ISO/IEC Guide 7 Guidelines for drafting of standards suitable for use for conformity assessment
- ISO/IEC 17007 Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment
- ISO/IEC 17011 Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies
- EN 50126-1 Railway Applications The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 1: Generic RAMS Process
- EN 50126-2 Railway Applications The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 2: Systems Approach to Safety
- EN 50126-3 Railway Applications The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 3: Guide to the application of EN 50126-1 for rolling stock RAM
- EN 50128 Railway applications Communication, signalling and processing systems – Software for railway control and protection systems
- EN 50129 Railway applications Communication, signalling and processing systems – Safety related electronic systems for signalling
- Canadian Method for Risk Evaluation and Assessment (CMREA) for Railway Systems

Note: Unless stated otherwise, the latest revision of the documents is applicable.

3. Definitions

The definitions as presented in ISO 9000, ISO/IEC 17000, Canadian Method for Risk Evaluation and Assessment (CMREA) for Railway Systems, as well as ISO/IEC 17020 and its referenced documents, apply. The following definitions also apply:

3.1 Advisory Council

A body of concerned Canadian interests (such as regulators, manufacturers, consumers and technical specialists) developed to advise independent safety assessment Bodies in a specific program area.

3.2 Applicant

An Independent Safety Assessor that has applied to the SCC for accreditation under the Independent Safety Assessor for Railway Systems Accreditation Program but is not yet accredited.

3.3 Authority Having Jurisdiction (AHJ)

An organization, office, or individual designated with the federal, provincial, territorial, or municipal responsibility of administering and/or enforcing the requirements of legislation within the designating jurisdiction and are considered the "scheme owner" for sub programs operating in those designated regulated areas within their area of responsibility

3.4 Canadian Recognized Standard

A standard recognized by an AHJ.

3.5 Contractor

An individual retained by an Independent Safety Assessor to conduct independent safety assessments on a part time or full-time basis. Contractors operate within the Independent Safety Assessor's quality system.

3.6 Fixed Office Location

The permanent premises where independent safety assessment activities are performed and/or managed for the ISA, regardless of location and relationship with the ISA.

3.7 National Standard of Canada (NSC)

A consensus standard prepared or reviewed by an accredited Standards Development Organization and approved by SCC.

3.8 Subcontractor

An arms-length, independent legal entity retained by an Independent Safety Assessment Body to perform a service (such as independent safety assessment). Subcontractors typically operate within their own quality system.

Program Requirements

Independent Safety Assessors accredited under the Standards Council of Canada Independent Safety Assessor for Railway Systems Accreditation Program shall conduct independent safety assessments in accordance with the Canadian Method for Risk Evaluation and Assessment (CMREA) Standard for Railway Systems and in accordance with the requirements of EN 50126 part 1, 2 and 3.

5. Accreditation Requirements

The Independent Safety Assessor for Railway Systems Accreditation Program operates on a four-year accreditation cycle that is structured with three years of surveillance activities followed by a reassessment activity every fourth year

SCC conducts annual assessments and witness audits of each Independent Safety Assessor (ISA) to ensure continued conformance with accreditation criteria. The first annual assessment usually takes place approximately one year following the date of accreditation. Annual assessments will be rotated among ISA fixed office locations, if applicable, where equipment and independent safety assessment personnel are located. As well, there shall be a full reassessment conducted every four years at the head office locations.

The assessment team will witness at least one independent safety assessment carried out by the ISA at the time of the annual assessment activity. See Section 7 for witness audit frequency and Section 8 for the minimum complexity requirements.

6. Witness Audit Requirements

Because the most significant element of independent safety assessment activities is the competence of the independent safety assessor, the assessment activities will include the witnessing of independent safety assessors ("witness audits"). The following are considerations that may affect the number of witness audits:

- the fields and types of independent safety assessments to be covered by the scope of accreditation;
- number of independent safety assessors at the ISA inspecting in a given field;
- number of independent safety assessments the ISA conducts per year in a given field.
- subcontracting activities carried out by the ISA;
- the ISA's procedures for selecting, training, qualifying and monitoring independent safety assessors in a given field;
- internal auditing practices of the ISA;
- the geographical location of the premises from which the independent safety assessors operate;

- any regulatory requirements; and,
- the extent to which independent safety assessors exercise professional judgment.

When deciding on the types of independent safety assessment activities to be witnessed, the following factors shall be considered:

- minimum complexity requirements;
- the variety of systems covered by the independent safety assessment activity;
- the level of hazard inherent in those products;
- qualification, experience and skills needed by the independent safety assessors; and
- any regulatory requirements.

Prior to a witness audit, the equipment and documentation to be used by the witnessed independent safety assessor is examined by the SCC witnessing assessor. The witnessing assessor accompanies the independent safety assessor on-site and observes the independent safety assessor perform the independent safety assessment. The independent safety assessment report generated during or after the independent safety assessment also forms part of the witness audit. The examination of equipment and documentation used by the witnessed independent safety assessors forms part of the witness audit.

The SCC team will seek to confirm that:

- the ISA quality system generates competent independent safety assessors for the task being performed;
- the independent safety assessor demonstrates competence that is consistent with the records;
- the independent safety assessor is using the correct and up-to-date documents and equipment fit for the purpose;
- the method is properly applied by the independent safety assessor; and,
- record keeping and reporting conform to the independent safety assessment method and the ISA's procedural requirements.

In the case that the independent safety assessor does not perform on-site assessment activities, then the witness audit shall be conducted in the form of a technical review of all project elements of a given independent safety assessment.

7. Witness Audit Frequency Requirements

7.1 These are the witness audit minimum frequency requirements based on the Railway Systems program that is accredited by SCC. If an ISA is accredited for other programs by SCC, then the requirements shall still be met within each program.

Railway Systems	Minimum of one witness audit shall be
	conducted each year of accreditation.

The following are conditions applicable to witness audit frequency requirements:

- Initial accreditation (IA) will be conditionally granted with the understanding that 1 successful witness audit be completed within 6 months of initial accreditation. During this period, conditionally-accredited independent safety assessment bodies shall not make a conformity decision within the sub-program without the presence of SCC.
- Reassessment year (RA) will consist of a minimum of 1 WA and a Technical Expert office visit.
- Each witness audit must be conducted with a different independent safety assessor
 until all independent safety assessors have been witnessed (includes international
 independent safety assessors, contract independent safety assessors, and
 subcontracted independent safety assessors, if not accredited by SCC). The ISA has
 the option to request a technical desk review if all independent safety assessors in a
 given program have been witnessed within a 4-year cycle, subject to SCC approval.
- Frequency and conditions of witness audits may be increased or changed based on concerns raised from head office assessments or witness audits, changes to regulatory requirements (e.g. update to the applicable requirements and codes), or if witness audits do not meet minimum complexity requirements.
- All personnel involved in the independent safety assessment activity (e.g. analysts), if utilized, are subjected to review on a cycle similar to the witness audit cycle.

8. Witness Audit Complexity Requirements

SCC conducts witness audits of qualified independent safety assessors to ensure that the ISA's procedures are creating and maintaining competent independent safety assessors. In order for SCC to confirm the procedures are being applied effectively, equipment or process being inspected during the witness audit must be of a sufficient complexity.

8.1 Railway Systems

The witness audit in accordance with the CMREA shall be for any independent safety assessment of a system with changes classified as significant in accordance with section 4.2 of the CMREA. If an ISA is not able to provide a witness audit within the year for a system with significant changes, then the witness audit to be provided must be to the

closest complex system. Additionally, an office visit by a Technical Expert may be added to one of the cycle years.

In the case of a witness audit being completed for an independent safety assessment conducted in accordance with EN 50126 series of standards or in accordance with EN 50128 standard, safety demonstration shall be for a specific application such that competencies with systems integration and physical implementation is demonstrable.

There are no stipulated witness audit complexity requirements in the case that an independent safety assessment is being conducted in accordance with EN 50128.

9. Requirements and Guidance

Note: The following requirements and guidance statements are aligned directly to the corresponding clause in ISO/IEC 17020:2012, until Clause 9. Clause 9 contains requirements and guidance related to areas not covered by ISO/IEC 17020:2012 in any manner.

General Requirements and Guidance applicable to all programs:

ISO/IEC 17020:2		SCC GUIDANCE	
5. S	tructural Requirements		
5.1	Administrative requirements		
5.1.1.1 Independent Safety Assessors (ISAs) shall operate in accordance with federal, provincial and municipal laws and regulations and regulatory or industry association scheme rules where such schemes exist.			
6. F	6. Resource Requirements		
6.1	Personnel		
6.1.1.1	The competence criteria defined and documented by the Independent Safety Assessor shall include but not be limited to: a) (i) (A) competence in risk management: knowledge and experience of the		

- standard safety analysis techniques and of the relevant standards;
- (B) all relevant competences for assessing the parts of the railway system affected by the change;
- (C) competence in the correct application of safety and quality management systems or in auditing management systems;
- (ii) competence within the railway system, or parts of it for which an essential safety requirement exists, including the area of competence involving operation and maintenance of the railway system;
- (iii) assessment of the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole, which shall include competence in checking:
 - (A) organization, that is the arrangements necessary to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for subsystems;
 - (B) methodology, that is evaluation of the methods and resources deployed by various stakeholders to support safety at subsystem and system level; and
 - (C) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole;
- b) competence requirements stipulated in EN 50126-1 – Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 1: Generic RAMS Process;
- c) competence requirements stipulated in EN 50126-2 – Railway Applications - The

	Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 2: Systems Approach to Safety; d) competence requirements for the assessor as stipulated in EN 50128 – Railway applications – Communication, signalling and processing systems – Software for railway control and protection systems;	
6.1.3.1	The ISA shall demonstrate that it has a thorough understanding of the model codes, special codes, Canadian recognized standards and related requirements in the areas covered by the ISA's accredited scope.	The ISA should participate in an exchange of experience with other independent safety assessment bodies though accreditation, regulatory or relevant standard developing committees.
6.1.3.3	The ISA shall ensure that its independent safety assessors demonstrate the ability to apply knowledge and skills of independent safety assessment principles, procedures and techniques, to enable the independent safety assessor to apply those appropriate to different independent safety assessments and ensure that all independent safety assessments are conducted in a consistent and systematic manner.	
6.1.3.4	The ISA shall ensure that all personnel involved in the independent safety assessment process demonstrate technical knowledge, skills and abilities to appropriately apply the codes, variances, standards, and requirements related to the independently assessed system.	
6.1.3.5	The ISA shall ensure the following requirements are met for contractors: a) The ISA shall maintain a formal agreement with the contractor detailing all necessary controls and requirements. b) The ISA shall maintain a register of qualified contractors that perform	

- independent safety assessment work on its behalf.
- The ISA shall ensure the requirements of Clause 6.1 of ISO/IEC 17020 are met for all contractors.
- d) The ISA shall retain control and take full responsibility of the work performed, the independent safety assessment certificate and independent safety assessment report.
- e) The ISA shall ensure that the contractor does not further subcontract any part of an independent safety assessment.

6.3 Subcontracting

- 6.3.1.1 The ISA shall ensure that the following requirements are met when independent safety assessments are subcontracted in addition to the requirements provided in Clause 6.3 of ISO/IEC 17020:
 - a) Except as noted in 6.3.1.2, the ISA shall ensure the subcontractor is accredited by SCC as an ISA for the full scope of the independent safety assessment work.
 - b) The ISA shall maintain a formal agreement with the subcontractor detailing all necessary controls and requirements.
 - c) The ISA shall maintain a register of qualified subcontractors that perform independent safety assessment work on its behalf.
 - d) The ISA shall audit their subcontractors to ensure that subcontractor body is competent and complies with the applicable provisions of ISO/IEC 17020.
 - e) The ISA shall ensure the subcontractor's personnel conducting independent safety assessment activities are monitored in accordance with the applicable requirements of ISO/IEC 17020.
 - f) The ISA shall retain control and take full responsibility of the work performed, the independent safety assessment certificate and independent safety assessment report.

	g) The ISA shall ensure that the subcontractor does not further subcontract any part of an independent safety assessment.	
6.3.1.2	Notwithstanding Clause 6.3.1.1 a), if the subcontractor is without SCC ISA accreditation, the ISA shall ensure that the subcontractor is qualified to perform the subcontracted work, and that they comply with the requirements of ISO/IEC 17020 and this Requirements and Guidance document. The ISA must demonstrate knowledge and capabilities to perform assessments against ISO/IEC 17020 and this Requirements and Guidance document.	

ISO/IEC SCC REQUIREMENTS 17020:2012		SCC GUIDANCE
7. P	Process Requirements	
7.1	Independent safety assessment methods and	procedures
7.1.1.1	An ISA shall include regulatory requirements (e.g. codes) in their independent safety assessment activities if there are any applicable to the system being inspected.	It is expected that the ISA will have records to demonstrate how all applicable regulatory requirements have been considered. This can be done generically for all independent safety assessments that it performs or on a case by case basis or by some other means.
7.1.6.1	Where test data is used to demonstrate compliance with a particular independent safety assessment requirement as part of the independent safety assessment activity, the ISA shall demonstrate that any test facilities from whom it accepts test data (internal or external) meets the appropriate requirements of ISO/IEC 17025. This shall be demonstrated though objective evidence that at the time of testing the facility met one or more of the following requirements:	The verification of the data requires additional scrutiny when the data is provided by a manufacturer and not an accredited lab.

- a) A test facility accredited by SCC.
- b) A test facility accredited by an agency that is part of an organization with which SCC has signed a Mutual Recognition Agreement (MRA).
- c) An internal test facility owned or controlled by the ISA. The ISA shall demonstrate that it maintains procedures for evaluation and conducts evaluations of such facilities for conformance with the appropriate requirements of ISO/IEC 17025. Such evaluations should occur at regular intervals that shall not exceed two years.
- d) An external test facility (independent of the supplier) evaluated by the ISA. The ISA shall demonstrate that it maintains acceptable procedures to conduct evaluation, and that it evaluates those facilities for conformance to the appropriate requirements of ISO/IEC 17025. Such evaluations should occur at regular intervals and shall not exceed two years.
- e) A supplier's facility used for witness testing. The ISA shall demonstrate that it has acceptable procedures and evaluates suppliers' facilities to the appropriate requirements of ISO/IEC 17025. The ISA shall be able to demonstrate that for any use of a supplier's facility, the facility was assessed to have met the appropriate requirements of ISO/IEC 17025 at the time the testing was witnessed.

7.1.6.2 The ISA shall review and verify the integrity of all test data accepted. At a minimum this shall include the verification of the source's impartiality, its conformity to the requirements of ISO/IEC 17025 and adequacy of the information.

Verification of the integrity of information should include at a minimum the following:

- Impartiality of the body providing the test data
- Competency of personnel performing testing, adequacy of the facilities and equipment used to perform the tests

		Adequacy of the information included in the test reports (e.g. model number, product description, photographs, critical component list, serial number, sampling technique employed to ensure representative sample of the unit/batch under independent safety assessment has been tested).
7.1.6.3	The ISA shall ensure that if the impartiality of the source for the accepted test data cannot be verified that the ISA shall conduct complete testing of the product or perform a sampling of tests using sound sampling principles (see Clause 7.1.2 of ISO/IEC 17020), to ascertain the integrity of the data.	SCC should be able to follow the logic and steps that were used to accept the data.
	Independent safety assessment reports and in certificates	ndependent safety assessment
7.4.1.1	The ISA shall make the conformity decision and issue an attestation, in the form of a certificate or a report or a combination of the two. This decision may be made on site at a client's facilities or at other specified locations, including the location of equipment/system installation by an independent safety assessor.	
7.4.1.2	The ISA shall ensure that the conformity decision is made only by qualified individuals and shall be based on their first-hand knowledge of applicable model codes, specific codes, Canadian recognized standards and related requirements referenced within this Requirements and Guidance Document.	
7.4.1.3	The ISA shall ensure that when errors and omissions in the report or certificate are discovered after the unit or system is approved, the ISA shall issue an amended report or certificate and advise the AHJ	

	whenever the AHJ was provided with the original documents.	
7.4.1.4	The ISA shall ensure that each system, or process is assessed individually. If an ISA utilizes any sampling methodologies, the independent safety assessment report shall include a technical justification for conducting such sampling.	
7.4.2.1	The ISA shall ensure that in addition to the elements contained in ISO/IEC 17020:2012 cl. 7.4.2 and any requirements stipulated by the Normative References, any reports of the independent safety assessor include all of the following: a) name and location of the customer whose equipment/system is being independently assessed, the customer being the organization or individual who has requested the independent safety assessment; b) a statement that the assessment report shall not be reproduced, except in full; c) information on where the independent safety assessment was carried out; d) demonstrated assessment of the impact of variant environmental conditions on the system being reviewed during normal operation. e) identification or brief description of the independent safety assessment method(s) and procedure(s) used, mentioning the deviations from, additions to or exclusions from required standards, methods or procedures; f) Results of the review of the verification and validation tasks that would have been completed throughout the phases of the lifecycle of the RAMSInformation on any nonconformities and their resolution,	In addition to the elements contained in ISO/IEC 17020:2012 cl. 7.4.2, the independent safety assessment report should include, where possible and appropriate, other support information such as photographs etc. The independent safety assessment report should include all the results of examinations and the determination of conformity made from these results as well as all information needed to understand and interpret them.

	including resolutions that will be required to be done. g) Steps, as may be required, identified by the ISA for demonstration of conformity. conditions of acceptability where relevant; and h) calibration dates of the test equipment used for evaluation if applicable. i) Conclusion of the complete review and recommendations on conformity.	
7.4.2.5	The ISA shall keep on file all required evidence and support documents including clear photographs and drawings of the assessed system/equipment.	
7.5	Complaints and appeals	
7.5.1.1	The ISA shall inform independent safety assessment clients that SCC is the final level of appeal in disputes with an ISA regarding conformity with accreditation criteria. ISAs shall abide by all SCC decisions pertaining to accreditation criteria.	

ISO/IEC SCC REQUIREMENTS 17020:2012		SCC GUIDANCE	
8. N	lanagement System Requirements		
8.4	Control of records (Option A)		
8.4.1.1	The ISA shall safely store all independent safety assessment records for the intended lifecycle of the approved system, as recommended by the manufacturer or designer, plus five years or as required by law, whichever is longer.		
8.4.1.2	The ISA shall provide independent safety assessment reports to SCC or the AHJ in a timely manner when requested by SCC or the AHJ.	To do so with the understanding that delays can affect system approval/rejection and that AHJs may or may not be tracking incidents for reporting and safety purposes.	

8.6 Internal Audits (Option A)

8.6.1.1 The ISA shall establish procedures for internal audits to verify that it fulfils the mandatory requirements of this Requirements and Guidance and that the management system is effectively implemented and maintained.

Internal audits should cover all locations listed on the scope of accreditation (head office and all fixed office locations).

ISO/IEC S 17020:2012		CC REQUIREMENTS	SCC GUIDANCE
9.	Areas not co	vered by ISO/IEC 17020:2012	
9.1	Non-conform	ming products	
9.1.1		The ISA shall ensure that the agreement between the ISA and its client requires the client to take corrective action, if the approved system is subsequently found to be non-conforming or to be hazardous. The ISA shall apply the corrective action principles in ISO/IEC Guide 27 in the design of their corrective action response.	For the purposes of this clause, in ISO/IEC Guide 27 replace the term "certification body" with the term "Independent Safety Assessment Body".
9.1.2		The ISA shall require independent safety assessment clients to notify it of any situation where an approved system could lead to a potential hazard.	
9.1.3		The ISA shall have documented procedures to handle, record, and report any reported misuse of independent safety assessment certificates, according to the requirements of ISO/IEC Guide 27.	
9.1.4		The ISA shall have documented procedures to handle, record, and report any reported situations in which a conformant system is subsequently found to be hazardous, according to the requirements of ISO/IEC Guide 27.	For the purposes of this clause, in ISO/IEC Guide 27 replace the term "certification body" with the term "Independent Safety Assessment Body".

9.1.5	The ISA shall advise the relevant AHJ of any known safety related system hazards, incidents, or safety related recalls involving systems that were independently assessed for the Canadian marketplace in a timely manner. The notification shall be in writing and be provided in both of Canada's official languages. Notifications shall be provided before the public notice is issued. The ISA shall copy SCC on all such correspondence.	This includes, but not limited to: Systems approved by the ISA Systems independently assessed but not approved and NCRs not corrected
9.1.6	The ISA shall advise the relevant AHJ of any known misuse of independent safety assessment certificates in a timely manner. The notification shall be in writing and be provided in both of Canada's official languages. The ISA shall copy SCC on all such correspondence.	
9.1.7	The ISA shall advise the relevant AHJ of any situation where the client does not take corrective action to resolve any nonconformities identified by the ISA following an independent safety assessment resulting in an unapproved non-conformant system. The notification shall be in writing and be provided in both of Canada's official languages. The ISA shall copy SCC on all such correspondence.	
9.2 Relationship	ps with Authorities Having Jurisdiction	
9.2.1	The ISA shall establish working relationships with applicable AHJs in the intended market of the inspected product or system, for each regulated area of accreditation. This liaison shall: a) provide the AHJ an opportunity to discuss independent safety assessment issues and regulatory	ISAs may establish such working relationships with an advisory body to an AHJ rather than with each jurisdiction (provincial,

	requirements with ISAs (to accomplish this, ISAs shall agree to attend meetings with Regulatory Authorities as required by the Authority). b) enable ISAs to confirm regulatory requirements and processes	territorial or municipal) when such an advisory body exists.
9.2.2	The ISA shall abide by the requirements of the AHJs or their designated advisory bodies.	
9.2.3	The ISA shall comply with any requirements in the bulletins issued by AHJs, the regulatory authorities or SCC.	
9.2.4	In regulated areas, the ISA shall independently assess products in accordance with Standards, or other normative documents recognized by an AHJ.	
9.2.5	In unregulated areas, the ISA shall inspect systems to an NSC or to a standard developed in accordance with ISO/IEC 17007. For systems operated in Canada, Canadian Recognized Standards shall be applied.	
9.2.6	The ISA shall permit SCC and relevant AHJs to examine reports and any other information used in making conformity decisions. Such examination may be conducted at the independent safety assessment client's premises or at the ISA's premises.	
9.2.7	The ISA shall require independent safety assessment clients to make necessary arrangements for the participation of observers, as required.	

9.3	Language		
9.3.1		ISAs operating programs for the evaluation of systems destined for the Canadian market shall have a documented procedure to demonstrate dual official language capability.	
9.3.2		Core documents utilized by the ISA in communication with the client shall be available in both official languages. These shall include as a minimum:	The ISA should take into consideration the provincial variation on contract language legality.
9.3.3		The ISA shall include requirements for dual language safety labeling with the products/installations assessed, if so required by the standard or by the AHJ.	