

APRAGAZ

Revision index

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APRAGAZ

1. SCOPE

DIRECTIVE 2014/68/EU (PED) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.

- Module A2 EN ISO 17020 +t +cd
- Modules B(design) & B(prod) EN ISO 17065 +t +pk
- Modules C2, F & G EN ISO 17065 +t +pk
- Module H1 EN ISO 17065 +qa

DIRECTIVE 2014/29/EU (SPVD) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels.

- Module C EN ISO 17020
- Modules B(design) & B(prod) EN ISO 17065 +t +pk
- Modules C1 & C2 EN ISO 17065 +t +pk

EN ISO 17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection

EN ISO 17065: Conformity assessment - Requirements for bodies certifying products, processes and services

2. PURPOSE

This document defines the rules applicable to the conformity assessment procedure of a product by APRAGAZ vzw as Notified Body (NoBo) following referenced documents listed in §1

This document is based on the EN ISO 17065 standard and BELAC document 2-404 (General requirements and guidelines for the accreditation of conformity assessment bodies with activities as notified bodies)

3. STATEMENT OF THE MANAGEMENT

3.1 Impartiality

Certification activities shall be undertaken impartially.

Apragaz shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

Apragaz shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel. However, such relationships may not necessarily present Apragaz with a risk to impartiality.

3.2 Non-discriminatory conditions

The policies and procedures under which Apragaz operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants.

Apragaz shall make its services accessible to all applicants whose activities fall within the scope of its operations.

Access to the certification process shall not be conditional upon the size of the Manufacturer or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

Apragaz can decline to accept an application or maintain a contract for certification from a Manufacturer when fundamental or demonstrated reasons exist, such as the Manufacturer participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar Manufacturer-related issues.

Apragaz shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.

3.3 Confidentiality

Apragaz shall be responsible for the management of all information obtained or created during the performance of certification activities. Except for information that the Manufacturer makes publicly available, or when agreed between Apragaz and the Manufacturer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. Apragaz shall inform the Manufacturer, in advance, of the information it intends to place in the public domain.

When Apragaz is required by law or authorized by contractual arrangements to release confidential information, the Manufacturer or person concerned shall, unless prohibited by law, be notified of the information provided.

Information about the Manufacturer obtained from sources other than the Manufacturer (e.g. from the complainant or from regulators) shall be treated as confidential.

4. DEFINITIONS

Supplier: Party having the responsibility to assure that the products meet and, if necessary, continue to meet the requirements on which the certification is based.

Organization: (Manufacturer, Applicant, client,...) company, society, firm, enterprise, authority or institution, or part or combination of these, with limited liability or with any other public or private status, which has its own functional and administrative structure. Party responsible for the product and production process.

Manufacturer: means any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes;

Authorised representative: means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

Importer: means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market;

Distributor: means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market;

Economic operators: means the manufacturer, the authorised representative, the importer and the distributor;

Management system: collective name for different systems (quality assurance system, environmental management system).

Applicant: supplier and/or manufacturer applying for a certification.

Notified Body: Third party who evaluates and certifies a manufacturer in relation to the published standards described in the concerned directives/regulations (SPVD, PED). APRAGAZ is Certification Body for products, as well as Notified Body for the above mentioned directives.

Certification scheme: certification system related to specified products, to which the same specified requirements, specific rules and procedures apply (Paragraph 6 of this document).

Certification system: system having its own procedural and management rules to carry out the evaluation leading to the issuance and follow-up of a certification document. The terminology used in the Quality Manual and the specific procedures are applicable to this procedure.

Certification document: Document certifying that the products of an manufacturer is in conformity with the standards for the specified products, with all additional documentation required within the frame of the certification, and with the technical requirements of the applicable directives.

Surveillance of the production: Evaluation intended to determine the continuous conformity with the specific requirements of the certified product.

5. CERTIFICATION PROCEDURE

5.1 Certification Agreement

Apragaz shall have a legally enforceable agreement for the provision of certification activities to the manufacturer. Certification agreements shall take into account the responsibilities of Apragaz and the manufacturer. The manufacturer shall provide Apragaz a Purchase Order (PO) or a reference to a framework contract.

APRAGAZ requires that each Applicant (Manufacturer) comply with the following:

- a) The Applicant (Manufacturer) always fulfils the certification requirements, including implementing appropriate changes when they are communicated by Apragaz;
- b) If the certification applies to ongoing production, the certified product continues to fulfil the product requirements;
- c) The Applicant (Manufacturer) makes all necessary arrangements for:
 - 1) The conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and Manufacturer's subcontractors;
 - 2) Investigation of complaints;
 - 3) the participation of observers, if applicable;
- d) The Applicant (Manufacturer) makes claims regarding certification consistent with the scope of certification;
- e) The Applicant (Manufacturer) does not use its product certification in such a manner as to bring Apragaz into disrepute and does not make any statement regarding its product certification that Apragaz may consider misleading or unauthorized;
- f) Upon suspension, withdrawal, or termination of certification, The Applicant (Manufacturer) discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;
- g) If The Applicant (Manufacturer) provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;
- h) In making reference to its product certification in communication media such as documents, brochures or advertising, The Applicant (Manufacturer) complies with the requirements of Apragaz or as specified by the certification scheme;
- i) The Applicant (Manufacturer) complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;
- j) The Applicant (Manufacturer) keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to Apragaz when requested, and
 - 1) Takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;
 - 2) Documents the actions taken;NOTE Verification of item j) by Apragaz can be specified in the certification scheme.
- k) The Applicant (Manufacturer) informs Apragaz, without delay, of changes that may affect its ability to conform with the certification requirements.
NOTE Examples of changes can include the following:
 - The legal, commercial, organizational status or ownership,
 - Organization and management (e.g. key managerial, decision-making or technical staff),
 - Modifications to the product or the production method,
 - Contact address and production sites,
 - Major changes to the quality management system.

The manufacturer (Applicant) shall confirm knowledge of the Certification Agreement and provide the required information for certification written by email or letter.

5.2 Application

For application, Apragaz shall obtain all the necessary information from the Applicant (Manufacturer) to complete the certification process in accordance with the relevant certification scheme.

- The product(s) to be certified;
- The standards and/or other normative documents for which the Applicant (Manufacturer) is seeking certification;
- Name and the address(es) of its physical location(s);
- Information concerning all outsourced processes used by the Applicant (manufacturer) that will affect conformity to requirements. Apragaz can establish appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance. If such contractual controls are needed, they can be established prior to providing formal certification documentation.
- The locations where the certified product(s) are produced and contact personnel at these locations.

The manufacturer (Applicant) shall confirm knowledge of the Certification Agreement and provide the required information for certification written by email or letter.

5.3 Application review

Apragaz shall conduct a review of the information obtained to ensure that:

- a) the information about the Applicant (Manufacturer) and the product is sufficient for the conduct of the certification process;
- b) any known difference in understanding between Apragaz and the Manufacturer is resolved, including agreement regarding standards or other normative documents;
- c) the scope of certification sought is defined;
- d) the means are available to perform all evaluation activities;
- e) Apragaz has the competence and capability to perform the certification activity.

Apragaz shall ensure it has the competence and capability for all the certification activities it is required to undertake, and it shall maintain a record of the justification for the decision to undertake certification.

Apragaz shall decline to undertake a specific certification if it lacks any competence or capability for the certification activities it is required to undertake.

Following the review of the application. If accepted, an offer is drawn up by Apragaz. In case of refusal, the reasons must be documented and clearly indicated to the Applicant (Manufacturer).

In the case the applicant (Manufacturer) places direct an order (framework contract, ...), Acceptance or refusal of the order will be confirmed by email or letter to the applicant after review of the order.

5.4 Evaluation

Conformity assessment and evaluation activities will be executed according to Apragaz Quality Control Plan or Applicant's (Manufacturer) Quality Control Plan approved by Apragaz.

Apragaz planning shall assign personnel to perform each Conformity assessment and evaluation activity that it undertakes with its internal resources.

The products shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme and the Quality Control Plan.

Apragaz shall inform the Manufacturer of all nonconformities.

If one or more nonconformities have arisen, and if the Applicant (Manufacturer) expresses interest in continuing the certification process, Apragaz shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

If the Manufacturer agrees to completion of the additional evaluation tasks, Apragaz shall complete the additional evaluation tasks.

The results of all evaluation activities shall be documented in an Apragaz report prior to review.

5.5 Review & Certification

Apragaz shall be responsible for, and shall retain authority for, its decisions relating to certification

The independent review of the conformity assessment file and the certification decision are completed concurrently by an independent reviewer and certification decision maker who is independent to the file to review. He/She was not involved in the conformity assessment process and is technically familiar and competent with the product and with the applicable requirements of the directives (PED/SPVD).

Apragaz shall notify the Manufacturer of a decision not to grant certification and shall identify the reasons for the decision.

If the Manufacturer expresses interest in continuing the certification process, the certification body can resume the process for evaluation.

5.6 Certification documentation

Apragaz shall provide the Manufacturer with formal certification document that states and contains:

- a) An unique identification reference;
- b) The name and address of Apragaz;
- c) The date certification is granted and the period of validity (If any);
- d) The name and address of the Manufacturer;
- e) The scope of certification (identification of the approved type / item);
- f) The BELAC logo;

Certification documentation shall only be issued after, or concurrent with, the following:

- a) the decision to grant or extend the scope of certification has been made;
- b) certification requirements have been fulfilled;
- c) the certification agreement has been completed/signed.

The formal certification document shall include the signature of the reviewer and certification decision maker assigned for such responsibility.

5.7 Surveillance

If surveillance is required by the certification scheme, Apragaz shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme.

The criteria and process for surveillance activities are defined by each certification scheme.

When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it) of a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

When continuing use of a certification mark is authorized for a production process, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of the production process or requirements.

5.8 Changes affecting certification

When the certification scheme introduces new or revised requirements that affect the Manufacturer, Apragaz shall ensure these changes are communicated to all Manufacturers. Apragaz shall verify the implementation of the changes by its Manufacturers and shall take actions required by the scheme.

Apragaz shall consider other changes affecting certification, including changes initiated by the Manufacturer, and shall decide upon the appropriate action.

Changes affecting certification can include new information related to the fulfilment of certification requirements obtained by Apragaz after certification has been established.

Apragaz shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the concerned Directive, and shall determine whether such changes require further investigation. If so, Apragaz shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body (Apragaz) that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the pressure equipment with the essential safety requirements of the Directive concerned or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU- type examination certificate.

The actions to implement changes affecting certification shall include, if required, the following:

- Evaluation;
- Review & decision;
- Issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;
- Issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

These actions shall be completed in accordance with applicable parts of this document.

5.9 Termination, reduction, suspension or withdrawal of certification

When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, Apragaz shall consider and decide upon the appropriate action.

Appropriate action can include the following:

- a) Continuation of certification under conditions specified by Apragaz (e.g. increased surveillance);
- b) Reduction in the scope of certification to remove nonconforming products;
- c) Suspension of the certification pending remedial action by the Manufacturer;
- d) Withdrawal of the certification.

When the appropriate action includes evaluation, review or a certification decision, the relevant requirements in this document shall be fulfilled.

If certification is terminated (by request of the Manufacturer), suspended or withdrawn, Apragaz shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, Apragaz shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the Manufacturer and clearly specified in certification documentation and public information.

If certification is suspended, Apragaz shall communicate the following to the Manufacturer:

- Actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;
- Any other actions required by the certification scheme.

Any evaluations, reviews or decisions needed to resolve the suspension shall be completed in accordance with the relevant requirements in this document.

If certification is reinstated after suspension, Apragaz shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, Apragaz shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the Manufacturer and clearly specified in certification documentation and public information.

If applicable, APRAGAZ has the obligation to notify the competent authority of suspended, denied, falsified, revalidated or cancelled certificates. This notification is made as soon as possible.

5.10 Records

Apragaz shall retain records to demonstrate that all certification process requirements (those in this document and those of the certification scheme) have been effectively fulfilled.

Apragaz shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.

If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period defined by Apragaz.

5.11 **Complaints and appeals**

Apragaz have a documented process to receive, evaluate and make decisions on complaints and appeals. Apragaz record and track complaints and appeals, as well as actions undertaken to resolve them.

Upon receipt of a complaint or appeal Apragaz shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

Apragaz shall acknowledge receipt of a formal complaint or appeal.

Apragaz shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

Whenever possible, Apragaz shall give formal notice of the outcome and the end of the complaint process to the complainant.

Apragaz shall give formal notice of the outcome and the end of the appeal process to the appellant.

Apragaz shall take any subsequent action needed to resolve the complaint or appeal.

5.12 **Use of license, certificates and marks of conformity**

Apragaz shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.

Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.

6. CERTIFICATION SCHEME

		Directive 2014/68/EU (PED)							Directive 2014/29/EU (SPVD)				
		A2	B _(prod)	B _(design)	C2	F	G	H1	B _(prod)	B _(design)	C	C1	C2
I	Application & Application review Confirmation of order, planning of activities, specification of requirements, e.g. normative documents, and sampling, as applicable	X	X	X	X	X	X	X	X	X	X	X	X
II	Evaluation												
	Design review		X(1)	X			X	X	X(1)	X			
	Inspection (& testing)	X	X(1)		X	X(2)	X(2)		X(1)			X	
	Assessment of production process	X											X
III	Review & Decision on certification	X	X	X	X	X	X	X	X	X		X	X
IV	Attestation & Licensing												
	Issuing a certificate of conformity Or type examination certificate		X	X		X	X	X	X	X			
	Granting the right to use certificates of conformity												
	Issuing a certificate of conformity for a batch of products				X							X	
	Granting the right to use marks of conformity based on surveillance	X											X
V	Surveillance												
	Testing or inspection of samples from the factory	X			X								
	Assessment of the production	X											
	Management system audits with random test or inspections (See RPAQ4-7)							X					

Notes:

(1): First prototype

(2): Unit verification