DESIGNATION PROCEDURE

Designation and notification of Conformity Assessment Bodies; 2014/68/EU Pressure Equipment Directive

Procedure for designation and notification purposes, applicable to Notified Bodies, Recognized Third Party Organisations and User Inspectorates.

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dsb Direktoratet for samfunnssikkerhet og beredskap

CONTENT

1 INTRODUCTION

Ministry of Justice and Public Security has the formal responsibility to designate and notify conformity assessment bodies under the Pressure Equipment Directive (PED) since the Act nr. 20 of 14 June 2002 relating to the prevention of fire, explosion and accidents involving hazardous substances and the fire service (The Fire and Explosion Protection Act) is under its responsibility.

The Ministry of Justice and Public Security has delegated the designation of conformity assessment bodies to the Norwegian Directorate for Civil Protection (DSB). DSB reports to the Ministry of Justice and Public Security.

The Norwegian Ministry of Trade, Industry and Fisheries notifies designated conformity assessment bodies to the EU commission and NANDO base on behalf of the DSB.

2 SCOPE

This document contains the DSBs procedure for designation of conformity assessment bodies according to the Pressure Equipment Directive (PED) 2014/68/EU. This procedure is announced to the Commission as the official Norwegian procedure for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, recognised third-party organisations and user inspectorates, according to the PED article 23.

When this procedure is changed, existing designated bodies shall make sure that compliance with the requirements in Annex I is in place within reasonable time as a part of the ongoing monitoring by Norwegian accreditation.

3 REGULATIONS

- Act nr. 20 of 14 June 2002 relating to the prevention of fire, explosion and accidents involving hazardous substances and the fire service (The Fire and Explosion Protection Act – Brann- og eksplosjonsvernloven)
- Act nr. 20 of 16 June 1994 relating notified bodies – Lov om tekniske kontrollorgan
- Pressure Equipment Directive (PED) 2014/68/EU – Forskrift om trykkpåkjent utstyr
- Act 10 February 1967 of Public Administration – Forvaltningsloven

4 DESIGNATING AND NOTIFYING AUTHORITY

DSB is the designating authority and The Ministry of Trade, Industry and Fisheries is the notifying authority. DSB is responsible to inform The Ministry of Trade, Industry and Fisheries about every new designated conformity assessment bodies which needs to be notified further to the EU Commission.

The designation is DSBs decision, which means that the body is then formally designated in the Norway. Designation as it is, cannot be used without notification and a designated body cannot perform any kind of conformity assessment activities before they are notified and registered in the NANDO base.

5 CONFORMITY ASSESSMENT BODY

A conformity assessment body is a body that performs conformity assessment activities including calibration, testing, certification and inspection.

Pressure Equipment Directive 2014/68/EU recognizes tree types of conformity assessment bodies:

1) Notified body (NB)
2) Recognized third-party organization (RTPO)

3) User inspectorate (UI)

When applying for designation it is important to specify the requested conformity assessment body type. An applicant can be designated as both NB and RTPO.

Limitation of the scope of designation for conformity assessment bodies according to PED 2014/68/EU:

1) Notified body: Annex III conformity assessment procedures; all modules + Annex I, no. 3.1.2
2) Recognized third-party organization: Annex I, no. 3.1.2 and no. 3.1.3
3) User inspectorate: Annex III conformity assessment procedures; modules A2, C2, F and G

6 ACCREDITATION

Designation of conformity assessment bodies according to the Pressure Equipment Directive 2014/68/EU is subject to accreditation. Norwegian accreditation (NA) is responsible for accreditation in Norway. The following harmonized conformity assessment standards shall be used regarding accreditation for the purpose of notification of conformity assessment bodies:

- ISO/IEC 17020:2012 - Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17021-1:2015 - Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirement
- ISO/IEC 17024:2012 - Conformity assessment - General requirements for bodies operating certification of persons
- ISO/IEC 17065:2012 - Conformity assessment - Requirements for bodies certifying products, processes and services

Which of these standards should be used, will depends of the scope of body`s application. Annex I provides detailed requirements of which conformity assessment standards that shall be used for the different PED conformity assessment modules.

7 PROCEDURE FOR DESIGNATION

Applicants seeking to be designated as a conformity assessment body must first make contact with the Norwegian accreditation body - Norwegian accreditation, established by the Norwegian Ministry of Trade, Industry and Fisheries. It is important to specify to Norwegian accreditation that the intention with accreditation is applying for designation according to the PED 2014/68/EU. Norwegian accreditation has application forms for accreditation and other information about accreditation schemes on their web page.

It has to be underlined that an accreditation certificate does not automatically give right to be designated. Accreditation and designation are two individual processes done by two different legal subjects, NA and DSB.

7.1 ASSESSMENT BY NORWEGIAN ACCREDITATION

Norwegian accreditation shall assess the applicant. Applicants seeking accreditation for designation purposes shall be assessed and accredited according to Annex I. It is crucial for designation purposes that the accreditation certificates refer to modules or chapters in the PED 2014/68/EU. If an applicant seeking designation meets the accreditation requirements, Norwegian accreditation will issue an accreditation certificate.

When applying for designation as a conformity assessment body, the accreditation documents shall provide sufficient documentation of professional competence according to regulatory requirements.
Applicants shall be designated within the scope of the accreditation certificate, which is related to the PED 2014/68/EU.

7.2 ASSESSMENT BY DSB

After being granted accreditation, the applicant shall send an application to DSB via e-mail: postmottak@dsb.no, with necessary documentation.
The application shall include:

a) Basic information about the applicant (Address, tel., contact person e.g.)
b) Short description of the organization
c) CVs for key personnel
d) Information about what type of conformity assessment body the applicant is seeking designation for
e) Applicants assessment of its conformity with Article 24 or Article 25 according to the PED 2014/68/EU
f) Copy of accreditation certificate
g) Copy of liability insurance policy

DSB will contact applicant if there is a need for more documents.

DSB shall then check the accreditation certificate against the publicly available information on the Norwegian accreditations website, and investigate further if necessary.

DSB shall also assess whether the requirements not covered by accreditation standards are fulfilled. These requirements will be related to the requirements in the decision letter and Norwegian legislation. These concern, but are not limited to, liability insurance, cooperation with other conformity assessment bodies, participation in standardization meetings both nationally and internationally, e.g.

8 DESIGNATION DECISION

Formal designation of designated bodies is to be understood as an individual decision under the Public Administration Act. DSB will therefore give notice of the decision with a briefing on the rights and obligations arising from designation as a conformity assessment body. The decision letter will provide the designated body a briefing on:

- The basis for the decision requirements concerning competence and activities
- Obligations to authorities
- Inspection procedures
- Circumstances that may lead to withdrawal of status as a conformity assessment body
- Information about the validity of the notification

If all requirements are met and satisfactorily documented, DSB will issue a designation decision (a letter), describing conditions and requirements related to the Pressure Equipment Directive 2014/68/EU, the Norwegian Administration Law Act, the Notified Body Act and to the designating authority (DSB).

Like all other decisions, the decision can be appealed to the Ministry of Justice and Public Security. The time limit for lodging an appeal shall be three weeks from the date on which notification of the administrative decision has reached the party concerned.

A copy of the decision will be sent to the Ministry of Justice and Public Security, the Ministry of Trade and Economy, and Norwegian accreditation.

9 NOTIFICATION

DSB will inform the Ministry of Trade and Economy about new designated conformity assessment bodies which then the Ministry will enter in to the NANDO base.

When entered into the NANDO base, the notification will then be sent to all EU/EEA states and the period for any objections is limited to two weeks. When the designated body is registered in the NANDO base, it becomes a notified conformity assessment body and can begin with conformity assessment.

10 MONITORING

DSB has the formal responsibility for monitoring of designated conformity assessment bodies. The monitoring is carried out through out the audits organized by the DSB. The designation decision will clearly state that conformity assessment bodies have a duty to inform DSB of any circumstances that can influence their notification.

Monitoring shall also be done by the Norwegian accreditation, which will check every year whether accreditation requirements are still fulfilled. Summary of final reports from Norwegian accreditation shall be forwarded to DSB. Norwegian accreditation shall continuously and in reasonable time inform DSB about serious and/or recurrent deviations, which may affect notification. The Norwegian accreditation shall immediately inform DSB if any accreditation decisions related to the notified conformity assessment bodies have been suspended or withdrawn. Suspension or withdrawal of the accreditation decision will cause suspension or withdrawal of DSBs designation decision and notification in the NANDO base.

In case of violation of the designation conditions, designation will be either suspended or withdrawn by DSB. These decisions can be appealed within a three weeks deadline to the Ministry of Justice and Public Security. ESA/the European Commission and the other Member States will be informed about any changes in the notification.

11 PUBLICATION AND CHANGES

This designation procedure is published on DSBs website. When the procedure is updated, Norwegian accreditation and relevant Norwegian conformity assessment bodies will be informed

12 REFERENCES

1) Decision No 768/2008/EC on a common framework for the marketing of products
2) European Commission: The ‘Blue Guide’ on the implementation of EU products rules
3) EA-2/17: 2020 - EA Document on Accreditation for Notification Purposes
4) https://www.dsb.no/
5) https://www.akkreditert.no/
6) https://ec.europa.eu/growth/tools-databases/nando/
7) https://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment_en

Annex I: Conformity assessment standards for PED conformity assessment modules

The table below summarize the allowable conformity assessment standards to be used for accreditation for notification purposes. The conformity assessment body may choose from the given standards for the corresponding conformity assessment module. The list is in line with EA 2/17 M:2020 Annex B, Table 3.

Conformity assessment module	Accreditation standard*
A2 - Internal production control plus supervised product checks at random intervals	• EN ISO/IEC 17065 + t • EN ISO/IEC 17020 + t + cd
B - EC type examination	• EN ISO/IEC 17065 + t + pk • EN ISO/IEC 17020 + t + cd
C2 - Conformity to type based on internal production control plus supervised product checks at random intervals	• EN ISO/IEC 17065 + t + pk • EN ISO/IEC 17020 + t + cd
D - Conformity to type based on quality assurance of the production process D1 - Quality assurance of the production process	• EN ISO/IEC 17065 + qa • EN ISO/IEC 17020 + qa • EN ISO/IEC 17021-1 + pk
E - Conformity to type based on product quality assurance E1 - Quality assurance of final product inspection and testing	• EN ISO/IEC 17065 + qa • EN ISO/IEC 17020 + qa • EN ISO/IEC 17021-1 + pk
F - Conformity with type based on product verification F1 - Conformity based on product verification	• EN ISO/IEC 17065 + t + pk • EN ISO/IEC 17020 + t + cd
G - Conformity based on unit verification	• EN ISO/IEC 17065 + t + pk • EN ISO/IEC 17020 + t + cd
H - Conformity based on full quality assurance H1 - Conformity based on full quality assurance plus design examination	• EN ISO/IEC 17065 + qa • EN ISO/IEC 17020 + qa • EN ISO/IEC 17021-1 + pk
Annex I, 3.1.2 - Approval of Permanent Joining Personnel	• EN ISO/IEC 17024
Annex I, 3.1.2 - Approval of Permanent Joining Procedures	• EN ISO/IEC 17020
Annex I, 3.1.3 - Approval of NDT personnel	• EN ISO/IEC 17024

*	Additional requirements to chosen accreditation standard
t	Additional applicable requirements of EN ISO/IEC 17025 if **t**esting is required. To this end fulfilment of the applicable requirements of clause 6 and 7 (except 7.9) in EN ISO/IEC 17025:2017 shall be demonstrated.
cd	**C**apability of and procedures for judging and **d**eciding based on results of tests and/or inspections, if the essential requirements are fulfilled and/or the Harmonised Standards have been applied when required. To this end, fulfillment of clauses 4.1.2, 4.1.3, 7.5 and 7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.
pk	Ability – based on **p**roduct **k**nowledge - to make professional judgments related to product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.
qa	Ability to assess and approve manufacturer's **qu**a**l**ity systems where required. To this end, fulfillment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and 9.1 to 9.4 and 9.6 in EN ISO/IEC 17021-1:2015 shall be demonstrated.

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