

Message 001

Communication from the Commission - TRIS/(2025) 2590

Directive (EU) 2015/1535

Notification: 2025/0531/CZ

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahtuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20252590.EN

1. MSG 001 IND 2025 0531 CZ EN 23-09-2025 CZ NOTIF

2. Czechia

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví

Biskupský dvůr 1148/5

110 00 Praha 1

tel: +420 221 802 216

e-mail: eu9834@unmz.gov.cz

3B. Státní úřad pro jadernou bezpečnost

Senovážné náměstí 9,

110 00 Praha 1

Tel.:+420 221 624 746

e-mail: pravni.oddeleni@sujb.gov.cz

4. 2025/0531/CZ - B20 - Safety

5. Draft Decree amending Decree No 358/2016 on requirements for quality assurance and technical safety and assessment and verification of conformity of selected equipment

6. selected equipment (in the field of peaceful uses of nuclear energy), packaging for transport, storage or disposal of radioactive or fissile substances

7.

8. The amendment to Decree No 358/2016 is prompted by the need to adapt current practice to the expected deployment of new nuclear sources. Proposed amendments:

- Formally and materially, there is a distinction between the processes of 'repair' and 'maintenance', which, especially in the operation of selected equipment, has not always been sharply and clearly delineated in practice.
- Implementation of the concept of 'part of selected equipment' introduced by the amendment to Act No 83/2025.
- Addition of measures to prevent so-called counterfeit or fraudulent items. This is equipment for which compliance with technical requirements was not adequately assessed, inadequate tests were carried out with varying degrees of planning or intent, inadequate documents were produced, and this equipment was subsequently delivered and deployed in the operation of the nuclear installation as fully-fledged and fully legally compliant selected equipment.
- Changes in conformity assessment procedures (e.g. the operator of the nuclear installation, and thus of selected equipment, is accepted as a conformity assessment body for its own needs. This concept was introduced by the aforementioned amendment to the Atomic Act and is further developed in the Decree).
- Newly established framework requirements for persons carrying out conformity assessments.
- Amendments to the annexes to the Decree, namely in specific areas of technical requirements, where individual requirements are clarified, as well as in specific conformity assessment procedures, where new conformity assessment procedures are introduced in part, e.g. for assessing the conformity of parts of selected equipment by the operator. At the same time, certain changes are being made to existing conformity assessment procedures as required by practice.

The mutual recognition clause is set out in the Atomic Act (Act No 263/2016).

Keywords: technical safety, quality assurance, conformity assessment, selected equipment, packaging for transport, storage or disposal of radioactive or fissile materials

9. Decree No 358/2016 is implementing legislation, in particular for § 57, 58 and 59 of the Atomic Act. In these provisions, the Atomic Energy Act regulates the area of so-called technical safety, meaning requirements for selected equipment that has a particularly significant impact on ensuring nuclear safety because it contributes to the performance of safety functions. In nuclear installations, this selected equipment is of key importance, as its correct functioning and the correct fulfilment of the required characteristics contributes to ensuring nuclear safety. The Decree lays down not only the technical requirements for certain types of this selected equipment, but in particular, in connection with the Atomic Act, it regulates the way in which the conformity of this equipment with the technical requirements imposed on it is assessed during the design, production, assembly and commissioning of this selected equipment.

This conformity assessment is carried out by accredited persons, authorised persons or, where applicable, the manufacturer or importer of this selected equipment. The Decree lays down both the scope and methods of conformity assessment depending on the safety classes in which the selected equipment classified. Last but not least, the Decree regulates so-called technical safety or conformity testing, which means that in a situation where selected equipment is already being used in the operation of a nuclear installation, its permanent conformity with technical requirements must be continually assessed.

Based on practical experience, it is currently necessary to supplement the Decree in several respects. Further to the amendment to the Atomic Act No 83/2025, some concepts are being broadened, some requirements are being relaxed in the case of parts of selected equipment, and a number of new possibilities related to the involvement of the operator of the selected equipment in conformity assessment procedures are also being introduced.

10. Reference(s) to basic text(s): 2016/0299/CZ

The basic texts were forwarded with an earlier notification:
2016/0299/CZ

11. No

12.

13. No

14. No

15. Yes

16.

TBT aspects:

The draft is a technical regulation or a conformity assessment

SPS aspects: No

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu