

Message 001

Communication from the Commission - TRIS/(2025) 2738

Directive (EU) 2015/1535

Notification: 2025/0563/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 - Atidējimai 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: 20252738.EN

1. MSG 001 IND 2025 0563 CZ EN 08-10-2025 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. 2025/0563/CZ - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5. Draft decree amending Decree No 422/2016 on radiation protection and security of radionuclide sources

6. Sources of ionising radiation (including radionuclide sources) and workplace equipment with sources of ionising radiation.

Sources of ionising radiation used in healthcare.

7.

8. The draft decree reflects changes in legislation in the field of radiation protection and security of radionuclide sources, in particular changes made by amendment No 83/2025. These changes primarily consist of:

- reflecting legal provisions that have not been accurately implemented, or also reflecting newly amended legal provisions in the amendment to the Atomic Energy Act;
- adjustment of the calculation of derived limits for radiation workers;
- individual adjustments in the categorisation of sources of ionizing radiation;
- adjustment of the regulation of acceptance tests, long-term stability tests and operational stability tests;
- individual adjustments of the rules of record-keeping of sources of ionising radiation by the licence holder and the registrant;
- in connection with statutory authorisation, the stipulation of an excessive number of workplaces where a supervising entity carries out continual supervision;
- changes to the entry of persons into controlled and monitored zones;
- individual adjustments to the radiation protection programme and other documentation for permitted activity and documentation for registered activity;
- changes to the job description of personnel overseeing the radiation protection of the registrant;
- changes to the regulation of personal monitoring of radiation workers and the vicinity of the workplace;
- regulation of requirements for a source of ionising radiation used in medical exposure, a workplace with a source of ionising radiation intended for medical irradiation;
- new provisions on notification to SONS of the submission of an application for authorisation of a clinical trial of radiopharmaceuticals;
- new provisions on the details of regulation of radiological events;
- clarification of certain rules in relation to natural sources of ionising radiation and in the context of existing exposure situations;
- regulation of the consumption and distribution of locally produced or unprotected foodstuffs in areas affected by a radiation accident and the distribution and marketing of products located in areas affected by a radiation accident;
- introduction of details in the field of radionuclide source security culture;
- amendments to annexes – in particular adjusting conversion factors for the conversion of volumetric activity, radiological events, content of documentation or registration forms.

The draft does not contain any references to standards or technical regulations.

Keywords:

ionising radiation, radionuclide source, radiation protection, natural radionuclide, radiation worker, workplace

with a source of ionising radiation.

9. In relation to the amendment to the Atomic Act (notification 2024/0259/CZ), an analysis of the suitability and necessity of amending legislation implementing the Atomic Act was carried out. The main objective of the amendment to Decree No 422/2016 is to respond to the amendment to the Atomic Act, which, in the area of radiation protection, consists primarily of minor (but rather numerous) amendments to the procedures for ensuring radiation protection. This must be ensured within the scope of a wide range of activities associated with sources of ionising radiation. These include, in particular, activities involving sources of ionising radiation in the context of industrial activity, medical use (treatment and diagnosis) or mineral extraction. The draft decree builds on the experience gained by the State Office for Nuclear Safety in the application of the decree in the context of its monitoring activities, in the context of international expert missions (the IAEA mission in the field of IPPAS – 2021 or IRRS – 2023 security) and also in the context of suggestions from addressees of obligations in the field of radiation protection and security of radionuclide sources and other public authorities involved in this system.

The current Decree No 422/2016 transposes into the Czech legal code the requirements of the legislation of the European Atomic Energy Community, namely Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (hereinafter “Directive 2013/59/Euratom”) and Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption (hereinafter “Directive 2013/51/Euratom”).

Basic legislation - Act No 263/2016 - attached as part of notification 2024/0259/CZ. The versions uploaded to the TRIS database are effective until 31.12.2025 and from 1. 1.2026.

Decree No 422/2016, which is being changed by the amendment, was notified under number 2016/0477/CZ.

10. References to basic texts: 2016/0477/CZ,2024/0259/CZ

The basic texts were forwarded with an earlier notification:

2016/0477/CZ

2024/0259/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