



3 November 2025

(25-7098)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: CZECH REPUBLIC

If applicable, name of local government involved (Articles 3.2 and 7.2):

2. Agency responsible:

State Office for Nuclear Safety
Senovážné náměstí 9
110 00 Prague 1
Telephone: +420 221 624 746
Email address: pravni.oddeleni@sujb.gov.cz

3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:

4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Sources of ionising radiation (including radionuclide sources) and workplace equipment with sources of ionising radiation.

Sources of ionising radiation used in healthcare.

ICS: Nuclear energy engineering (ICS code(s): 27.120); ICS: 27.120.99 other standards

5. Details of notified document(s) (title, number of pages and languages, means of access): Draft decree amending Decree No 422/2016 on radiation protection and security of radionuclide sources; (163 page(s), in English), (156 page(s), in Czech)

Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:

https://members.wto.org/crnattachments/2025/TBT/CZE/25_07385_00_e.pdf
https://members.wto.org/crnattachments/2025/TBT/CZE/25_07385_00_x.pdf

<https://technical-regulation-information-system.ec.europa.eu/en/notification/27328>
<https://technical-regulation-information-system.ec.europa.eu/cs/notification/27328>

6. Description of content: 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 State Office for Nuclear Safety 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.

7. Objective and rationale, including the nature of urgent problems where applicable: In relation to the amendment to the Atomic Act, 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").; Protection of human health or safety

8. Relevant documents:

Basic legislation - Act No 263/2016, Decree No 422/2016

9. Proposed date of adoption: 1 February 2026

Proposed date of entry into force: 1 February 2026

10. Provision of comments

Final date for comments: 3 January 2026

[] 60 days from notification

Contact details of agency or authority designated to handle comments regarding the notification:

Czech Office for Standards, Metrology and Testing

WTO/TBT Enquiry Point

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Telephone: +420 221 802 194

Email address: wto.tbt@unmz.gov.cz

<https://unmz.gov.cz/en/international-relations-2/wto-tbt/information-centre-wto-tbt/>