

## **GROUND**

### **I. GENERAL PART**

**A. Final report on the regulatory impact assessment for a draft implementing decree concerning the type approval of certain products in the field of peaceful use of nuclear energy and ionising radiation and the carriage of radioactive or fissile material, implementing Act No X/2016, the Atomic Act (hereinafter the 'NAA')**

#### **1. Reason for submission and objectives**

##### **1.1 Title**

Draft implementing decree concerning the type approval of certain products in the field of peaceful use of nuclear energy and ionising radiation and the carriage of radioactive or fissile material.

##### **1.2 Definition of the issue**

In connection with the adoption of the NAA, it is necessary to lay down further details concerning the carriage of radioactive or fissile materials and the type approval of selected products in accordance with the authorising provisions under § 9(4)(a) and (b), § 24(7), § 137(6), § 138(6)(a) to (c), § 141(3)(a) to (e) and § 143(4). In accordance with § 238 of the NAA, Implementing Decree No 317/2002, as amended, will be repealed effective from 1 January 2017.

In addition, the purpose of the implementing decree is to implement the following into the Czech Republic's legal order:

- Commission Decision 2008/312/Euratom and to lay down standard document templates in the area of cross-border carriage of radioactive waste or spent nuclear fuel (currently the Decision is transposed by Annex 6 to Implementing Decree No 317/2002, as amended) and
- certain provisions of Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel.

##### **1.3 Description of the existing legal situation in this area**

Currently, the area of type approval of selected products and the carriage of radioactive or fissile materials is regulated by:

- Act No 18/1997 on the peaceful use of nuclear energy and ionising radiation (the Atomic Act) and on amendments to certain laws, as amended;
- Implementing Decree No 317/2002 on the type approval of packages for transport, storage and disposal of nuclear materials and radioactive materials, type approval of sources of ionising radiation and carriage of nuclear materials and specified radionuclide materials (type-approval and carriage decree), as amended by Implementing Decree No 77/2009;
- Government Order No 73/2009 on the transfer of information in connection with international carriage of radioactive waste and spent nuclear fuel.

Implementing Decree No 317/2002 on type approval and carriage regulates the following in connection with the provisions of the Atomic Act:

- type approval of packages for the carriage, storage or disposal of nuclear materials and specified radioactive materials, type approval of specified sources of ionising radiation

(i.e. it specifies products that are subject to type approval; it stipulates the particulars of a type-approval application and the particulars of a type-approval decision; it regulates the verification and certification of conformity of specified packages and sources of ionising radiation with the approved type; it stipulates test documentation for a product type approval application);

- the manner in which carriage of nuclear materials and radioactive materials is secured;
- specification of nuclear materials and radioactive materials the carriage of which is subject to authorisation;
- the content and scope of documentation that is part of an authorisation application;
- methods of international transport of radioactive waste and spent nuclear fuel including methods for producing the relevant documentation in accordance with Euratom law;
- standard documents for the carriage of radioactive waste and spent fuel.

Requirements entrenched in Implementing Decree No 317/2002 on type approval and carriage are primarily based on the principles contained in recommendations of the International Atomic Energy Agency (hereinafter the 'IAEA'), specifically IAEA recommendations - IAEA Safety Standards - IAEA Regulations for the Safe Transport of Radioactive Material (1996 edition, revised)<sup>1)</sup>.

Implementing Decree No 317/2002 on type approval and carriage transposes (along with the Atomic Act and Government Order No 73/2009) Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel and Commission Decision 2008/312/Euratom establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/Euratom.

Under the implementing decree currently in force, the following are subject to type approval:

- packages intended for the carriage, storage and disposal of nuclear materials and radioactive materials, as follows:
  1. type IP-1, IP-2, and IP-3 packages for the carriage of nuclear materials;
  2. packages for the carriage of 0.1 kg or more of uranium hexafluoride;
  3. type A packages for the carriage of nuclear materials;
  4. type B(U), B(M), and C packages for the carriage of nuclear materials and radioactive materials;
  5. type D packages intended for the disposal of spent or irradiated nuclear fuel or radioactive waste produced by processing it;
  6. type S packages intended for the storage of nuclear materials and radioactive materials, specifically for special form radioactive materials whose activity exceeds A1 or radioactive materials other than special forms whose activity exceeds A2. The values for A1 and A2 are provided in Table 1(I) in Annex 3
- special form radioactive materials that are solid, non-dispersible radioactive materials in a sealed case and
- low dispersible radioactive materials, which are radioactive materials in solid form that have limited dispersion capability or radioactive materials in a sealed case.

Pursuant to the existing implementing decree, authorisation is required for the carriage of:

1. nuclear materials, except uranium depleted of the U-235 isotope, if used as shielding in packages;

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<sup>1)</sup> IAEA Safety Standards, IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), Series No. TS-R-1 (ST-1, Rev.), International Atomic Energy Agency, Vienna, 2000.

2. special form radioactive materials with activity greater than  $3 \cdot 10^3$  times A1 and radioactive materials other than special form with activity greater than  $3 \cdot 10^3$  times A2 or radioactive materials with activity greater than 1 000 TBq, depending on which of these values is lower;
3. nuclear materials or radioactive materials in type B(M) packages that are not designed for a temperature range of minus 40 °C to plus 70 °C, or are not designed to permit occasional controlled ventilation;
4. under special conditions, when all the requirements of § 9 cannot be met, and when these requirements are replaced by special conditions that ensure the same or higher level of nuclear safety, radiation protection, and physical protection;
5. on a special-purpose vessel with a stipulated radiation protection programme;
6. nuclear materials or radioactive materials for which the values of A1 and A2 have been determined by calculation.

In accordance with IAEA recommendations - IAEA Safety Standards - IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised)1), the implementing decree stipulates the organisational and technical requirements that must be met during the carriage of nuclear materials and radioactive materials.

The existing Implementing Decree No 317/2002 on type approval and carriage is obsolete especially from a formal perspective - it contains provisions which, based on the Act, should not be regulated by implementing legislation.

Experience from the application of the decree revealed minor shortcomings - especially the vague and uncertain formulation of certain provisions, allowing for different interpretations and a certain level of confusion in the area covered.

In terms of content, the implementing decree does not correspond to the latest developments at an international level. IAEA recommendations - IAEA Safety Standards - IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised)1), on which Implementing Decree No 317/2002 on type approval and carriage was based, was gradually replaced by the 2005 edition, the 2009 edition and, most recently, by the substantially modified edition of IAEA Safety Standards - IAEA Regulations for the Safe Transport of Radioactive Material in 2012 (hereinafter 'IAEA SSR-6').

In § 23(3), the current version of the Atomic Act stipulates that for certain type-approved products, supporting documents for a decision of the Office regarding type approval includes documentation of tests performed at the applicant's expense in the case of legal persons specified by the Office. However, no legislation stipulates the requirements that these legal persons must fulfil or how these legal persons are specified by the Office. In addition, under the existing legislation, legal persons may only perform tests of type-approved products, but not calculations and analyses and their independent verification. This does not correspond to current practice, where due to advances in modern technologies, calculation programmes are increasingly used to verify the properties of type-approved products instead of tests and experiments.

#### **1.4 Identification of stakeholders**

Stakeholders include:

- manufacturers, importers, distributors or other parties requesting type approval of a product;
- parties performing tests or calculations and analyses or independent verification of these calculations and analyses (instead of tests) for products subject to type approval;

- carriers of radioactive or fissile materials.

### **1.5 Description of the target situation**

This implementing decree should, in connection with the authorising provisions in the NAA, stipulate the following in the area of carriage:

- rules for specifying radioactive or fissile materials whose carriage is subject to authorisation, their classification, and requirements they must meet;
- technical requirements for specifying a package for the carriage of radioactive or fissile materials, and requirements imposed on it;
- requirements regarding the content of documentation for authorisation of carriage of a radioactive or fissile material;
- technical and organisational conditions of carriage and transport of a radioactive or fissile material;
- requirements regarding the content, language and availability of documentation required for the carriage and transport of a radioactive or fissile material;
- the manner, scope and time limit for notification of carriage to be provided to administrative authorities and persons whom the carriage concerns;
- the manner of labelling, appearance and manner of use of safety signs for labelling radioactive packages, the means of transport used for carriage and the carriage container;
- the method of determination and maximum permissible values of the transport index, the criticality safety index, unfixed contamination and absorbed equivalent dose and the manner in which the category of the radioactive package is determined;
- standard document templates used for cross-border carriage of radioactive waste or spent nuclear fuel.

Based on the authorising provisions in the new NAA, as regards type approval the implementing decree should more closely specify products (special form radioactive materials, low dispersible radioactive materials and packages for the carriage, storage, or disposal of radioactive or fissile materials) that are subject to type approval; in addition, it should lay down

- the scope, content and method of performance of tests or calculations and analyses, and the contents of the application dossier for product type approval;
- the requirements for authorised legal persons performing tests and independent verification of tests or calculations and analyses for product type-approval applications.

In response to developments at an international level, the requirements under the existing implementing decree should be updated and brought into line with international regulations (IAEA Recommendation SSR-6). Based on experience from the application of the existing implementing decree, the discrepancies (especially formal - the absence of definitions for certain terms, difficult readability of the text) and shortcomings (the absence of a definition for a third party that would be authorised to perform tests, independent verifications and analyses; the need to clarify certain requirements for type-approved products) identified in practice should be eliminated from the legislation.

### **1.6 Risk assessment**

A failure to fulfil the authorising provisions of § 9(4)(a) and (b), § 24(7), § 137(6), § 138(6)(a) to (c), § 141(3)(a) to (e) and § 143(4) of the NAA would, from the date of entry

into force of the NAA, cause problems in the area of type approval of products and carriage of radioactive or fissile materials.

Without closer specification of products (special form radioactive materials, low dispersible radioactive materials and packages for carriage, storage or disposal of radioactive or fissile materials) the use of which is subject to type approval from the State Office for Nuclear Safety (hereinafter the 'Office'), the type approval and use of these will be impossible.

Without closer specification of radioactive or fissile materials whose carriage is subject to authorisation and without definition of the safety requirements for all carriages of radioactive and fissile materials, it would be impossible for these to take place at all.

By failing to introduce standard document templates in the area of cross-border carriage of radioactive waste or spent nuclear fuel, the Czech Republic would fail to fulfil the requirements of Council Directive 2006/117/Euratom and Commission Decision 2008/312/Euratom. If the draft implementing decree is not adopted, Article 17(5) and (6) of Council Directive 2006/117/Euratom will not be transposed into Czech legislation.

## **2. Proposed policy options**

### **2.1 Option 0**

#### ***Option A (zero option)***

The zero option is based on the assumption that the authorising provisions of the NAA in the area of type approval of specified products and in the area of carriage of radioactive or fissile materials would not be implemented and only relevant provisions of the NAA would be followed. Given that the purpose of this implementing decree is to specify more closely which products may be used based on the type approval decision and which radioactive or fissile materials may only be carried based on carriage authorisation, the implementation of the corresponding provisions of the NAA would be impossible without this implementing legislation. Similarly, without closer specification of the safety requirements for carriages of radioactive and fissile materials, it would be impossible for these to take place at all. At the same time, standard document templates in the area of cross-border carriage of radioactive waste or spent nuclear fuel would not be introduced into Czech legislation and some provisions of Council Directive 2006/117/Euratom would not be transposed.

### **2.2 Option 1**

Under Option 1, it is assumed that implementing legislation will be adopted, thereby implementing all the authorising provisions of the NAA. Compared to the current situation, the provisions of the existing Implementing Decree No 317/2002 on type approval and carriage, which have been moved to the NAA (for example, the carrier's obligations during carriage of a radioactive or fissile material, most of the provisions regarding cross-border carriage of radioactive waste or spent nuclear fuel transposing Council Directive 2006/117/Euratom, provisions regarding verification and proof that product characteristics comply with the approved type, the particulars of applications and decisions regarding product type approval, etc.) will be deleted.

To make the text clearer, terms which have been causing problems in practice should be more clearly defined, especially with respect to the terms established in IAEA Recommendation SSR-6.

In terms of content, the text of the implementing decree should be aligned with the latest requirements at an international level (IAEA Recommendation SSR-6).

This includes:

**- identification of type-approved products:**

The requirement for type approval of a package for the carriage of a radioactive or fissile material requiring multilateral approval pursuant to international treaties by which the Czech Republic is bound should be updated. Multilateral approval is required (also in accordance with IAEA SSR-6) for a package manufactured and approved by a responsible authority pursuant to recommendations of IAEA Safety Standards, Series 6, 1973 edition or 1973 (Revised) edition, 1985 or 1985 (Revised 1990) edition.

**- identification of what carriage of radioactive or fissile materials requires authorisation:**

A requirement should be added for the need to obtain authorisation for the carriage of radioactive or fissile materials contained in a device or product and containing radionuclides, whose values for exemption were replaced by values calculated according to principles and methods contained in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements, IAEA Safety Standards Series No. GSR Part 3, and the need to obtain authorisation for the carriage of excluded fissile materials.

**- update of the requirements for technical and organisational controls of the carriage of a radioactive or fissile material**

Annex 3 “Activity Limits and Material Restrictions” to the existing Implementing Decree No 317/2002 on type approval and carriage should be updated in accordance with IAEA SSR-6 as follows:

- introduction of a classification system, which will lead to a change in the name of the annex to “Activity Limits and Classification”, and
- update of the definition of excluded fissile materials, including requirements imposed upon them.

Last but not least, a number of minor updates and clarifications should be made covering the differences between the requirements of IAEA recommendations - IAEA Safety Standards - IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised)<sup>1)</sup>, on the basis of which the existing decree was drawn up, and IAEA Recommendation SSR-6, which was used as a basis for the draft new implementing decree. The changes and additions generally arise from new findings in the given area or technical and technological developments.

Based on practical experience, the following is needed:

**- clarification of the requirements for type S packages for the storage of radioactive or fissile materials**

A type S package should not be automatically considered to meet the requirements for a type B(U) package, but depending on the specific recognised warehouse, in addition to the general requirements for all packaging and radioactive packages, it should also meet the limits and conditions for radioactive waste management and relevant acceptability criteria for the given recognised warehouse, regardless of whether they are less strict or stricter than those for a type B(U) package.

**- identification of the requirements for persons authorised to perform calculations and analyses and their independent verification and tests for type approval**

Under the current version of the Atomic Act, the legal persons that performed the tests of certain type-approved products were specified by the Office. The criteria used by the Office for this selection were not governed by any legislation. Pursuant to § 138(4) of the NAA, tests or calculations and analyses with independent verification for packages, special form

radioactive materials and low dispersible radioactive materials that are subject to approval are performed by authorised legal persons that must meet criteria stipulated by implementing legislation - i.e. this draft implementing decree. The criteria stipulated by the implementing decree should ensure professional and impartial performance of the required tests, calculations and analyses.

The implementing decree should introduce standard document templates in the area of cross-border carriage of radioactive waste or spent nuclear fuel into the Czech legal system pursuant to Commission Decision 2008/312/Euratom and should transpose certain provisions of Council Directive 2006/117/Euratom.

### **3. Assessment of costs and benefits**

#### **3.1 Identification of costs and benefits**

##### **3.1.1 Option 0 (zero option)**

For the above reasons, the status quo was not assessed.

##### **3.1.2 Option 1**

###### **Costs**

On the one hand, the following will no longer be required:

- approval of a package type for all types of nuclear materials,
- approval of carriage for all types of nuclear materials,

on the other hand, the following will be required:

- under certain conditions, authorisation for the carriage of radioactive or fissile materials contained in an instrument or product;
- authorisation for carriage of certain types of excluded fissile materials.

The new obligation of carriage authorisation will only apply to a very small number of parties (up to about 5). It can therefore be assumed that the above changes in the draft implementing decree are more likely to lead to a slight decline in the number of requests. The other changes and additions compared to the existing legislation appear to be cost-neutral.

Therefore, no negative impact on the state budget is expected and costs in the business sector are not expected to increase.

###### **Benefits**

Even though new types of permits will at first cause increased costs related to the creation of new safety documentation, the subsequent use of a simpler system of carriage with a reduced number of requirements or less strict requirements will result in cost savings over the course of repeated carriages.

### **4. Policy proposal**

#### **4.1. Ranking of the options and selection of the most suitable option**

The option recommended for further consideration is Option 1.

## **5. Implementation of the recommended option and enforcement**

The authority responsible for drawing up the draft implementing decree is the Office, which will also be responsible for implementing the legislation in the area of type approval of selected products and carriages of radioactive or fissile materials. Implementation and enforcement will primarily take place within the scope of the Office's control activities in this area.

## **6. Survey of efficiency of the legislation**

Efficacy will be reviewed regularly in the course of the exercise of state authority, primarily as part of the Office's control activities.

## **7. Consultations and data sources**

Stakeholders from the Czech Republic were consulted in the course of drafting the implementing decree. Representatives of supervisory authorities and other stakeholders from the Slovak Republic and Poland were also consulted on the draft implementing decree at the seminar: "Present and Future of Carriage of Nuclear Materials in Central Europe", which took place in 2015.

The sources for laying down the technical requirements included:

- IAEA Recommendation SSR – 6,
- experience and information from representatives of the members of EACA (European Association of Competent Authorities).

## **8. Contact details of the author of the RIA**

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## **B. Assessment of conformity of the draft legislation with the constitutional order of the Czech Republic, international treaties binding on the Czech Republic and European Union legislation, European Union case-law and the general principles of European Union law, or, if appropriate, legislative intentions and drafts of European Union legislation**

The draft implementing decree fully complies with the draft NAA and its authorising provisions in § 9(4)(a) and (b), § 24(7), § 137(6), § 138(6)(a) to (c), § 141(3)(a) to (e) and § 143(4).



The draft implementing decree is fully compatible with the relevant EU/Euratom legislation, specifically:

- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods;
- Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel;
- Commission Decision 2008/312/Euratom, establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/Euratom;
- Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

The submitted implementing decree complies with IAEA Recommendation SSR-6, which also forms basis for the relevant international treaties in this area that are binding on the Czech Republic. These are primarily:

- The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) – Annex A: General provisions and provisions concerning dangerous articles and materials, and Annex B: Provisions concerning transport equipment and transport operations (Decree of the Ministry of Foreign Affairs No 64/1987 of 26 May 1987, on the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- The Convention concerning International Carriage by Rail (COTIF) – Appendix B: Uniform Rules concerning the Contract of International Carriage of Goods by Rail (CIM), Annex 1 Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) – (Decree of the Ministry of Foreign Affairs No 8/1985 of 2 August 1984 on the Convention concerning International Carriage by Rail (COTIF), as amended);
- The Convention on International Civil Aviation (Act No 147/1947; The Convention on International Civil Aviation, as amended), Annex 18 – The Safe Transport of Dangerous Goods by Air, Technical Guidelines for the Safe Transport of Dangerous Goods by Air.

IAEA Recommendation SSR-6 is also reflected in EU legislation – Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods - via the aforementioned ADR and COTIF/CIM/RID international agreements.

**C. Expected economic and financial impact of the draft legislation on the state budget, other public budgets, the business environment in the Czech Republic, social impacts, including impacts on specific population groups, in particular socially disadvantaged persons, persons with disabilities and ethnic minorities, and environmental impact**

The draft implementing decree will not place an increased burden on the state budget or other public budgets. The Office will ensure the exercise of state authority and oversight of adherence to the requirements of the proposed implementing decree in the area of product type approval and carriage of radioactive or fissile materials to the same extent and under the same conditions as to date. The legislation will not have any negative economic and financial impacts in comparison to the current situation on economic subjects, including small and medium-size businesses. The proposed legislation will not have negative social impacts and

updated technical requirements will contribute to the protection of human health and the environment.

**D. Assessment of the current situation and impacts of the proposed solution in relation to the prohibition of discrimination**

Given its technical nature, the proposed legislation does not in any way affect the equality of subjects before the law, does not discriminate their positions, and cannot thus cause the discrimination of certain groups of individuals.

**E. Assessment of impacts of the proposed solution in relation to the protection of privacy and personal data**

The proposed legislation will have no impact on the protection of privacy and personal data.

**F. Assessment of corruption risks**

Given its technical nature, the proposed legislation does not create the opportunity for risks of corruption.

**II. SPECIAL PART**

**Re § 1**

The subject matter of the draft is defined in accordance with the authorising provisions in § 9(4)(a) and (b), § 24(7), § 137(6), § 138(6)(a) to (c), § 141(3)(a) to (e) and § 143(4) of the draft NAA.

**Re § 2**

These provisions define the basic terms used in the proposed implementing decree. They need to be defined more closely to ensure correct interpretation and application of the proposed legislation, which is very technical. Terminology that was concealed in various provisions of annexes to the existing implementing decree is now listed and explained in § 2. Definitions are primarily based on definitions stipulated in IAEA Recommendation SSR-6. For legislative reasons, the definitions in the draft implementing decree have been modified compared to the definitions in IAEA Recommendation SSR-6, for example the explanations for the terms 'confinement system' and 'containment system' do not provide for the description of these systems by the designer in an engineering-type project, nor does the definition of a low specific activity material provide the relevant activity concentration or surface contamination limits. However, this information is specified in the relevant parts of the implementing decree dealing with these systems, materials or items.

**Re § 3**

The provisions of § 3 of the draft decree implement § 9(4)(a) and (b) of the NAA and specify radioactive or fissile materials the carriage of which is subject to authorisation; for details on the classification of radioactive or fissile materials and radioactive packages and the requirements imposed on them, it refers to the corresponding provisions of Part I of Annex 1

and Annex 3 to the draft implementing decree. Cases in which international carriage must also be authorised by the relevant authorities of the states which the carriage concerns, as follows from the relevant international treaties binding on the Czech Republic, are specified in § 3(2) of the draft implementing decree.

As regards the requirement of mandatory authorisation of carriage of radioactive or fissile materials, the proposed legislation is almost identical to IAEA Recommendation SSR-6; the only difference, in the case of fissile materials, is the requirement for authorisation of carriage of certain shipments of nuclear fuel with a criticality safety index that does not exceed a value of 50.

The manner in which the carriage of radioactive or fissile materials is regulated differs depending on the risk to protected interests. Carriage where the risk to human life and health and to the environment is the highest is subject to authorisation. (Around one per cent of the total annual number of cases of carriage of radioactive or fissile materials in the Czech Republic is subject to authorisation under the existing Implementing Decree No 317/2002 on type approval and carriage). Pursuant to the draft implementing decree, authorisation is required for the carriage of nuclear fuel, certain excluded fissile materials, shipments of fissile materials with a high criticality safety index - i.e. above 50, selected fissile or radioactive materials - i.e. those with an activity greater than 3 000 A1 or 3 000 A2 or 1 000 TBq, and high-risk carriage - carriage in a type B(M) package that is not designed for a temperature range of minus 40 °C to plus 70 °C or is not designed to permit occasional controlled ventilation, carriage on special-purpose vessels for which a radiation protection programme has been specified and carriage of radioactive or fissile materials for which the necessary documentation has been produced using calculated values instead of values tabulated in the draft implementing decree.

The values A1 and A2 for the individual radionuclides (as provided in Table 2 of Annex 3 to the draft implementing decree) that are used to stipulate activity limits for the purposes of carriage were laid down on the basis of the following assumptions:

- accident scenarios under normal carriage conditions (when packaging for an excluded package or a type IP-1 package is completely destroyed and its radioactive content dispersed, unless it is a special form radioactive material, and when a type IP-2, IP-3, A, B or C package prevents the loss or dispersal of radioactive contents and maintains sufficient shielding) and under the conditions of an accident during carriage (when a package for excluded shipments or type IP-1, IP-2, IP-3 or A package is completely destroyed and its radioactive contents dispersed, unless it is a special form radioactive material, and when a type B(U), B(M) or C package prevents the loss or dispersal of radioactive contents to A2/week and maintains sufficient shielding),
- five critical methods contributing to the irradiation of persons (1. external irradiation by gamma radiation; 2. external irradiation by beta radiation; 3. external irradiation after inhalation of radionuclides released through the destruction of a radioactive material other than special form material; 4. external or internal irradiation due to skin contamination caused by the handling of a damaged package, where the irradiation is caused by radionuclides released through the destruction of a radioactive material other than special form material; 5. external or internal irradiation due to inhalation, ingestion or contamination due to presence in a room with a damaged package, where the irradiation is caused by radionuclides in a gaseous state that were released through the destruction of a radioactive material other than special form material),
- specification of parameters for transport workers and representative persons regarding their distance from the source and the duration of their presence in the area under consideration.

Activity limits A1 a A2 were laid down for individual radionuclides so that under normal carriage conditions and under the conditions of an accident during carriage, the transport worker does not receive a dose higher than the limit for an exposed worker (i.e. 20 mSv for the sum of effective doses from external radiation and committed effective doses from internal irradiation) and the representative person does not receive a dose greater than 1 mSv for the sum of effective doses from external radiation and committed effective doses from internal irradiation.

Other cases of carriage of radioactive or fissile materials are also regulated; they are, however, not subject to authorisation. Depending on their classification (classification of radioactive or fissile materials and radioactive packages and the requirements imposed on them are listed in points 1 and 8 to 34 of Annex 3 and in Part I of Annex 1 to the draft implementing decree), radioactive or fissile materials must be transported in packages intended for this purpose (and, in defined cases, type-approved).

#### **Re § 4**

The provisions of § 4 of the draft implementing decree implement § 9(4)(a) and (b) of the NAA, define the individual types of packages for the transport of radioactive or fissile materials, lay down the requirements for their specification and stipulate the requirements that individual packages must meet, depending on type and radioactive contents. As regards the details of the requirements for the specification of individual types of packages, it refers to Annex 3 of the draft implementing decree; for the requirements for individual types of packages for the transport of a radioactive material or a fissile material, it refers to Annex 1 of the draft implementing decree; and for the requirements for packages for storage or disposal of a radioactive or fissile material, it refers to Annex 2 of the draft implementing decree.

Pursuant to § 141(1)(k), for the carriage of a radioactive or fissile material, carriers may only use a package type that meets the technical requirements for design, safety functions and package labelling and the requirements for handling depending on the radioactive contents. The individual types of packaging for the carriage of radioactive or fissile materials (and individual types of corresponding radioactive packages) are as follows:

- *package for an excluded shipment* (must meet the general requirements stipulated for all packages, i.e. the requirements under points 7 to 18 of Annex 1 to the draft implementing decree) intended for excluded packages (excluded packages are specified in point 22 of Annex 3 to the draft implementing decree. An empty package that once contained radioactive materials may be transported as an excepted package; an instrument or product whose activity does not exceed the activity limits for excluded packages in Table 4 of Annex 3 to the draft implementing decree; a product made of natural uranium, depleted uranium or natural thorium; a radioactive material whose activity does not exceed the activity limits for excluded packages in Table 4 of Annex 3 to the draft implementing decree; less than 0.1 kg of uranium hexafluoride that is not a fissile material and whose activity does not exceed the limits listed in the column "Materials - limits for radioactive shipments" in Table 4 of Annex 3 to the draft implementing decree);
- *type IP-1 package* (must meet the requirements of points 7 to 18 and of point 36 of Annex 1 to the draft implementing decree) intended for group LSA-I solid radioactive materials with a low specific activity (LSA-I materials are defined in point 9(2) of Annex 3 to the draft implementing decree. These are uranium and thorium ores, concentrates of these ores and other ores containing naturally occurring radionuclides; natural or depleted uranium, natural thorium or their compounds and mixtures that

have not been irradiated and that are in solid or liquid form; a radioactive material for which the value of A2 is unlimited, unless it is a fissile material, in which case only an excluded fissile material may be included; other radioactive materials in which activity is distributed equally throughout their volume and their calculated average activity concentration does not exceed 30 times the activity concentration limit for the exemption, unless it is a fissile material, in which case only an excluded fissile material may be included.) and for a surface contaminated item in group SCO-I (surface contaminated items in group SCO-I are defined in point 13(2) of Annex 3 to the draft implementing decree);

- *type IP-2 package* (must meet the requirements for an IP-1 package and, after undergoing a drop test pursuant to point 22 and a stacking test pursuant to point 23 in Part II of Annex 1 to the draft implementing decree, there must be no loss or dispersal of radioactive contents and the maximum absorbed equivalent dose must not increase by more than 20 % in an arbitrary location on the outside surface) intended for a group LSA-I liquid radioactive material with a low specific activity, for a group LSA-II solid radioactive material with a low specific activity (LSA-II materials are defined in point 9(3) of Annex 3 to the draft implementing decree. It is water with tritium with a concentration not exceeding 0.8 TBq/l and other materials in which activity is distributed equally throughout their volume and the calculated average activity concentration does not exceed  $10^{-4}$  A2/g for solids and gases and  $10^{-5}$  A2/g for liquids) and for a surface contaminated item in group SCO-II (group SCO-II surface contaminated items are defined in point 13(3) of Annex 3 to the draft implementing decree);
- *type IP-3 package* (must meet the requirements for an IP-1 package and the requirements under points 37 to 49 of Annex 1 to the draft implementing decree) intended for a group LSA-II liquid radioactive material with a low specific activity and for a group LSA-III radioactive material with a low specific activity (LSA-II materials are defined in point 9(4) of Annex 3 to the draft implementing decree);
- *type A package* (must meet the requirements under points 7 to 18 and points 36 to 51 of Annex 1 to the draft implementing decree) is intended for a special form radioactive material with activity not exceeding A1 and for radioactive materials other than special form materials with activity not exceeding A2;
- *type B(U) package* (must meet the requirements under points 7 to 18, 36 to 47, 48(b), 49 and 53 to 66 of Annex 1 to the draft implementing decree) is intended for radioactive or fissile materials not exceeding the activities specified in type-approval decisions;
- *type B(M) package* (must meet the requirements laid down for type B(U) packages, except for cases specified in point 67(2) of Annex 1 to the draft implementing decree. In cases defined in point 67(2), some requirements for a type B(U) package need not be met) intended for radioactive or fissile materials up to activities stipulated in type-approval decisions;
- *type C package* (must meet the requirements under points 7 to 21, 36 to 47, 48(b), 49, 53 to 57, 61 to 66 and 70 to 72 of Annex 1 to the draft implementing decree) is intended for radioactive or fissile materials not exceeding the activities specified in type approval decisions (it is used primarily for air transport).

### **Re § 5**

In connection with § 24(7) of the NAA, § 5 lays down the particulars of the documentation for authorisation of a particular case of carriage, which is carriage of radioactive materials

contained in an instrument or product, where the material contains radionuclides for which the values for exemption of the consignment were substituted with values calculated according to principles and methods contained in the document Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements, IAEA Safety Standards Series No. GSR, Part 3, International Atomic Energy Agency, Vienna, 2014. Knowledge of the above information is necessary for the Office to verify the submitted calculations of basic values of the radionuclides carried, in this case values for exemption of the consignment.

### **Re § 6**

§ 6 of the draft decree governs the manner in which the transport index, the criticality safety index and the *radioactive package category - I-WHITE, II-YELLOW, or III-YELLOW* are determined (with reference to the detailed rules in Annex 1 and Annex 4 to the draft implementing decree). § 6 also governs, referring to the detailed provisions in Annex 4 to the draft implementing decree, the maximum permissible values of the transport index, the criticality safety index, equivalent absorbed dose and non-fixed contamination for radioactive packages, overpacks and means of transport. This section is in compliance with statutory authorisation contained in § 141(3)(a) of the NAA.

*The transport index (TI) and radioactive package category* quantify the hazardousness of the radioactive contents of a radioactive package (as opposed to its weight or volume) and are used to limit the exposure of radiation workers and the population to ionising radiation.

*The criticality safety index (CSI)* is the degree to which fissile materials are accumulated in a package, overpack, container, cistern or a means of transport and is used to ensure that the amount of fissile materials in a given space remains sub-critical, thus avoiding the occurrence of an uncontrolled fission chain reaction.

### **§ 7**

Based on the authorising provisions in § 141(3)(b) of the NAA, § 7 and Annex 4 to the draft implementing decree lay down detailed technical and organisational requirements for the carriage and transport of radioactive or fissile materials. Specific requirements are laid down which must be met:

- prior to the first and then prior to each further carriage of a radioactive or fissile material,
- for the carriage of individual types of radioactive packages;
- for the safe segregation of radioactive packages, overpacks or containers containing radioactive materials and some unpackaged radioactive materials from transport workers, the population, unexposed photographic film and other dangerous items during transport and storage in transport;
- for the safe stowage of radioactive packages on or in the means of transport and during storage in transport;
- for the safe mutual segregation of groups of radioactive packages containing fissile materials during transport and storage in transport.

Annex 4 also contains requirements for carriage documents, marking and labelling radioactive packages with safety warnings, large-format safety warnings and placards, and requirements for individual modes of transport - i.e. for carriage by rail or road, vessels, air and by post.

### **Re § 8**

The provisions of § 8, which are based on the authorising provisions in § 141(3)(c) of the NAA, refer to the corresponding provisions of Annex 4 to the draft implementing decree, which describe the specific requirements for documentation needed for the carriage and transport of radioactive or fissile materials. In addition, in accordance with Article 17 of Directive 2006/117/Euratom, this section stipulates that in the course of cross-border transport of radioactive waste or spent nuclear fuel under § 9(4)(d) of the NAA, the accompanying documentation must also include completed forms A-1 or B-1 (carriage authorisation application), A-4a or B-4a (authorisation from the relevant cross-border transport authority) and A-5 or B-5 (a description of the consignment and list of packaging containers) listed in Annex 5 to the draft implementing decree.

### **Re § 9**

This section implements the authorising provisions in § 141(3)(d) of the NAA and, referring to specific provisions of Annex 4 to the draft implementing decree, lays down the manner, scope and time period for informing administrative authorities of the given shipment.

### **Re § 10**

The provisions of § 10 of the draft implementing decree govern the marking of radioactive shipments with UN numbers, the use and filling in of safety warning signs for the labelling of radioactive package and the use of large-format safety warnings and placards to designate an overpack, container and means of transport. Annex 4, to which § 10 refers, stipulates detailed rules for the marking required, with the trefoil radioactivity symbol, safety warnings, large-format safety warnings and placards and their dimensions depicted in Figures 1 to 7. The provisions of this section are based on the authorising provisions in § 141(3)(e) of the NAA.

### **Re § 11**

In connection with the authorising provisions in § 137(6) of the NAA, this section more closely specifies the types of packages for carriage, storage or disposal of radioactive or fissile materials, including radioactive waste, that are subject to type-approval. Paragraph (2) further stipulates that all special form radioactive materials with properties referred to in points 2 to 4 of Part I of Annex 1 to the draft implementing decree and low dispersible radioactive materials with properties referred to in point 5 of Part I of Annex 1 to the draft implementing decree are subject to type approval. The requirements of § 11 of the draft implementing decree for these products are no different than those in existing legislation and the draft legislation thus complies with the requirements in IAEA Recommendation SSR-6.

### **Re § 12**

§ 12 implements the authorising provisions in § 138(6)(a) and (b) of the NAA and governs the particulars of the product type-approval application dossier – i.e. the scope, contents, and method of performance of tests or calculations and analyses for the product type-approval application, and the contents of documentation for these tests and analyses. Paragraph (1) contains a reference to Part II (Test Procedures) of Annex 1 to the draft implementing decree, which governs in detail the scope, contents and method of performance of tests for the individual product types under § 11. Paragraph (2)(a) then lists specific requirements for the contents of test documentation for individual types of packages for the carriage of radioactive

or fissile materials, with references to the relevant provisions of Part II (Test Procedures) of Annex 1 to the draft implementing decree. Letters (b) and (c) specify the requirements for the contents of test documentation for special form radioactive materials and low dispersible radioactive materials, with references to the relevant provisions of Part II (Test Procedures) of Annex 1 to the draft implementing decree.

### **Re § 13**

The provisions of § 13 implement the authorising provisions in § 138(6)(c) of the NAA and governs the requirements for authorised legal persons who perform calculations and analyses or independent verification of these calculations and analyses for product type-approval applications. § 13 is a new part in the draft and the criteria to be met by authorised legal persons should ensure the professional and impartial performance of the required tests, calculations and analyses.

### **Re § 14**

These provisions implement § 143(4) of the NAA. In connection with Article 17(2) of Directive 2006/117/Euratom, a decision of the Commission laid down unified standard document templates for all Euratom Member States for the carriage of radioactive waste and spent fuel in the area of cross-border carriage. Standard document templates are being introduced into Czech legislation through Annex 5 to the draft implementing decree.

### **Re § 15**

The implementing decree is a technical regulation within the meaning of Article 1(1)(f) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, and as such the draft must be notified to the Commission and other EU Member States in accordance with the procedure contained in the Directive.

### **Re § 16**

This decree is a measure implementing the NAA and should therefore enter into force on the same day as the Act, i.e. on 1 January 2017.

### **Regarding the annexes**

Annex 1	Requirements and Test Procedures for Type Approval
Annex 2	Requirements for Type D and S packages
Annex 3	Activity Limits and Classification
Annex 4	Requirements and Controls for Transport
Annex 5	Standard document templates
Annex 6	Requirements for the Calculation of Activity Values for Exemption of a Package for the Carriage of Radioactive Materials in Instruments or Products

### **Re Annexes 1 to 4**

Annexes 1 to 4 of the draft implementing decree are based on international regulations in this area (IAEA Recommendation SSR-6). This structure of these annexes corresponds with this –



the individual points of the annexes correspond to a large extent to the provisions of IAEA Recommendation SSR-6. Compared to the existing legislation, the technical requirements listed in the annexes were updated in accordance with SSR-6.

Regarding point 3(c) of Part I and point 11(b) of Part II of Annex 1: the text refers to ISO 9978:1992 (E) Radiation protection – Sealed radioactive sources – Leakage test methods, International Organisation for Standardization, Geneva, 15 February 1992.

Regarding points 26(b), 27(b) and 30(b) of Part I of Annex 1: the text refers to the UN Recommendations on the Transport of Dangerous Goods – Model Regulations, rev. 17, (ST/SG/AC.10/1/17), UN, 2011.

Regarding point 29(c) of Part I of Annex 1: the text refers to ISO 1496:1990(E) Series 1 freight containers – Specification and testing – Part 1: General cargo containers for general purposes, International Organization for Standardization, Geneva, 15 August 1990.

Regarding points 31, 32(a) and 34(a) of Part I of Annex 1: the text refers to ISO 7195:2005(E) Nuclear energy – Packaging of uranium hexafluoride (UF<sub>6</sub>) for transport, International Organization for Standardization, Geneva, 1 September 2005.

Regarding point 9(a) and (b) of Part II of Annex 1: the text refers to ISO 2919:2012(E) Radiological protection – Sealed radioactive sources – General requirements and classification, International Organization for Standardization, Geneva, 14 February 2012.

Structure of the Annexes:

Annex 1        Requirements and Test Procedures for Type Approval

Part I:

## **I. REQUIREMENTS FOR RADIOACTIVE OR FISSILE MATERIALS, PACKAGING AND RADIOACTIVE PACKAGES**

### **I. 1. REQUIREMENTS FOR RADIOACTIVE OR FISSILE MATERIALS**

I. 1. 1. Requirements for group LSA-III radioactive materials with low specific activity

I. 1. 2. Requirements for special form radioactive materials

I. 1. 3. Requirements for low dispersible radioactive materials

I. 1. 4. Requirements for excluded fissile materials

### **I. 2. GENERAL REQUIREMENTS FOR PACKAGES AND RADIOACTIVE PACKAGES**

### **I. 3. ADDITIONAL REQUIREMENTS FOR RADIOACTIVE PACKAGES TRANSPORTED BY AIR**

### **I. 4. REQUIREMENTS FOR EXCLUDED PACKAGES**

### **I. 5. REQUIREMENTS FOR INDUSTRIAL PACKAGES**

I. 5. 1. Requirements for type IP-1

I. 5. 2. Requirements for type IP-2

I. 5. 3. Requirements for type IP-3

I. 5. 4. Alternative requirements for type IP-2 and type IP-3

I. 6. REQUIREMENTS FOR RADIOACTIVE PACKAGES CONTAINING URANIUM HEXAFLUORIDE

I. 7. REQUIREMENTS FOR TYPE A RADIOACTIVE PACKAGES

I. 8. REQUIREMENTS FOR TYPE B(U) RADIOACTIVE PACKAGES

I. 10. REQUIREMENTS FOR TYPE C RADIOACTIVE PACKAGES

I. 11. REQUIREMENTS FOR RADIOACTIVE PACKAGES CONTAINING FISSILE MATERIALS

I. 11. 1. Content specifications for assessments of radioactive package designs containing fissile materials

I. 11. 2. Geometry and temperature requirements

I. 11. 3. Assessment of individual radioactive packages in isolation

I. 11. 4. Assessment of arrays of radioactive packages under normal transport conditions

I. 11. 5. Assessment of arrays of radioactive packages under accident conditions during transport

I. 11. 6. Specification of the criticality safety index

Part II:

**II. TEST PROCEDURES**

II. 1. DEMONSTRATION OF COMPLIANCE

II. 2. LEACHING TESTS FOR LOW SPECIFIC ACTIVITY MATERIALS IN GROUP LSA-III AND LOW DISPERSIBLE RADIOACTIVE MATERIALS

II. 3. TESTS FOR SPECIAL FORM RADIOACTIVE MATERIALS

II. 3. 1. General requirements

II. 3. 2. Test methods

II. 3. 3. Leaching and volumetric leakage test methods

II. 4. TESTS FOR LOW DISPERSIBLE RADIOACTIVE MATERIALS

II. 5. TESTS FOR RADIOACTIVE PACKAGES

II. 5. 1. Test specimen preparation

II. 5. 2. Testing of the integrity of the containment system and shielding and assessing of criticality safety

II. 5. 3. Target for drop tests

II. 5. 4. Test for radioactive packages designed to contain uranium hexafluoride

II. 5. 5. Tests demonstrating the ability to withstand normal conditions of transport

II. 5. 6. Additional tests for type A radioactive packages designed for liquids and gases

II. 5. 7. Tests demonstrating the ability to withstand accident conditions during transport

II. 5. 8. Extended water immersion test for type B(U) and type B(M) radioactive packages

II. 5. 9. Water immersion test for radioactive packages containing fissile materials

II. 5. 10. Tests for type C radioactive packages

Annex 3 Activity Limits and Classification

1. GENERAL REQUIREMENTS

2. BASIC RADIONUCLIDE VALUES

3. DETERMINATION OF BASIC RADIONUCLIDE VALUES

4. CLASSIFICATION OF MATERIAL

4. 1. Material with low specific activity
4. 2. Surface contaminated item
4. 3. Special form radioactive material
4. 4. Low dispersible radioactive material
4. 5. Fissile material
4. 6. Uranium hexafluoride

5. CLASSIFICATION OF RADIOACTIVE PACKAGES

5. 1. Classification as an excluded package
5. 2. Additional safety requirements for the carriage of empty packages
5. 3. Classification as a type A radioactive package
5. 4. Classification as a type B(U), B(M) and C radioactive package

6. TRANSPORT UNDER SPECIAL ARRANGEMENTS

Annex 4 Technical and organisational conditions of carriage and transport of a radioactive or fissile material

1. REQUIREMENTS BEFORE THE FIRST SHIPMENT

2. REQUIREMENTS BEFORE EACH SHIPMENT

3. TRANSPORT OF OTHER GOODS

4. OTHER DANGEROUS PROPERTIES OF CONTENTS

5. REQUIREMENTS AND CONTROLS FOR CONTAMINATION AND LEAKING PACKAGES

6. REQUIREMENTS AND CONTROLS FOR TRANSPORT OF PACKAGE EXCEPTIONS

7. REQUIREMENTS AND CONTROLS FOR TRANSPORT OF LOW SPECIFIC ACTIVITY MATERIAL AND SURFACE CONTAMINATED ITEMS IN INDUSTRIAL PACKAGES OR UNPACKAGED

8. DETERMINATION OF TRANSPORT INDEX

9. DETERMINATION OF THE CRITICALITY SAFETY INDEX FOR FREIGHT CONTAINERS, OVERPACKS AND CONSIGNMENTS

## 10. LIMITS ON TRANSPORT INDEX, CRITICALITY SAFETY INDEX AND ABSORBED EQUIVALENT DOSE FOR RADIOACTIVE PACKAGES AND OVERPACKS

### 11. CATEGORIES

#### 12. MARKING, LABELLING, AND PLACARDING

- 12. 1. Marking
- 12. 2. Labelling
- 12. 3. Labelling for radioactive contents
- 12. 4. Labelling for criticality safety
- 12. 5. Placarding

#### 13. CONSIGNOR'S RESPONSIBILITIES

- 13. 1. Particulars of consignment description in the carriage document
- 13. 2. Consignor's declaration
- 13. 3. Information for carriers
- 13. 4. Notification of administrative authorities
- 13. 5. Documents and operating rules the carrier must have available

#### 14. TRANSPORT AND STORAGE IN TRANSIT

- 14. 1. Segregation during transport and storage in transit
- 14. 2. Stowage on or in the conveyance during transport and storage in transit
- 14. 3. Additional transport and storage requirements during transport of fissile material
- 14. 4. Additional requirements relating to transport by rail and road
- 14. 5. Additional requirements relating to transport by vessels
- 14. 6. Additional requirements relating to air transport
- 14. 7. Transport by post

### 15. OTHER REQUIREMENTS

### 16. CARRIAGE DOCUMENTS KEPT BY AND AVAILABLE FROM THE CARRIER

#### Re Annex 5

The obligation to authorise cross-border carriage of radioactive waste or spent nuclear fuel was implemented into our legislation by transposing Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel. Pursuant to § 9(4)(d) of the NAA, carriers are required to request the issue of authorisation for cross-border carriage of radioactive waste or spent nuclear fuel if its activity and the activity concentration of radionuclides contained in it exceed the exemption level in the form of a standard document as stipulated by Commission Decision 2008/312/Euratom. Commission Decision 2008/312/Euratom also contains templates of other standard documents used in the area of cross-border carriage of radioactive waste or spent nuclear fuel, which are being incorporated into the Czech Republic's legislation through Annex 5.

#### Re Annex 6

Annex 6 introduces the document of the International Atomic Energy Agency (Radiation

Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements, IAEA Safety Standards Series No. GSR, Part 3, International Atomic Energy Agency, Vienna, 2014), according to which activities for exemption of a consignment of radioactive or fissile materials in instruments or products are calculated in accordance with § 3(2)(b) and § 5 and activity concentration limits for exemption of materials and activity limits for exemption of a consignment in accordance with point 3 of Annex 3 to the draft implementing decree.