

Notice on Quantity of Radioisotopes

Specifying Standards for the Quantities, etc. of Radiation-Emitting Isotopes

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Quantities, etc. of Radiation-Emitting Isotopes

[Public Notice of the Science and Technology Agency, No. 5, October 23, 2000]

[Revised the full text of Public Notice of the Science and Technology Agency, No. 22, September 30, 1960,
“Quantities, etc. of Radiation-Emitting Isotopes”]

[Revised the full text of Public Notice of the Science and Technology Agency, No. 15, May 18, 1988,
“Quantities, etc. of Radiation-Emitting Isotopes”]

Pursuant to the provisions of the Cabinet Order for Enforcement of the Act on Prevention of Radiation Hazards Due to Radioisotopes, etc. (Cabinet Order No. 259 of 1960) and the Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc. (Ordinance of the Prime Minister's Office No. 56 of 1960), this Public Notice revising the full text of Public Notice No. 15 of the Japan Science and Technology Agency in 1988—“Specifying the Quantities, etc. of Radiation-Emitting Isotopes”— is established as follows, and comes into effect as of April 1, 2001,:

(Quantities and Concentrations of Radiation-Emitting Isotopes)

Article 1. The quantities (hereinafter referred to as “lower bound quantities” (as with “exemption levels”)) and concentrations of radiation-emitting isotopes prescribed in Article 1 of the Cabinet Order for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc. (hereinafter referred to as “the Order”) are those specified in each of the following Items separately, in accordance with each of the categories set forth in the concerned Items:

- (1) for sealed radiation-emitting isotopes: following quantities and concentrations apply to radiation-emitting isotopes in one sealed piece (or, in cases where normally used in a pair or set of materials, one pair or set), in accordance with the categories set forth in the following cases:
 - (a) in case of only one kind of radiation-emitting isotopes: The quantity and concentration set forth in the second and third columns of the Appended Table 1, respectively, in accordance with the kind set forth in the first column;
 - (b) in case of two or more kinds of radiation-emitting isotopes: The quantity of each kind of radiation-emitting isotopes for which the sum of the ratios of the quantities of the concerned radiation-emitting isotopes to the quantities set forth in the second column of the Appended Table 1 in accordance with the kinds set forth in the first column of the same Table equals to unity, and the concentration of each kind of radiation-emitting isotopes for which the sum of the ratios of the concentrations of the concerned radiation-emitting isotopes to the concentrations set forth in the third column of the same Table in accordance with the set forth in the first column of the same Table equals to unity.
- (2) for unsealed radiation-emitting isotopes: following quantities and concentrations apply to radiation-emitting

isotopes which are placed in a factory or place of business and to radiation-emitting isotopes contained in one container in accordance with the categories set forth in the following cases:

- (a) in case of only one kind of radiation-emitting isotopes: The quantity and concentration set forth in the second and third columns of the Appended Table 1, respectively, in accordance with the kind of radioisotope set forth in the first column;
- (b) in case of two or more kinds of radiation-emitting isotopes: The quantity of each kind of radiation-emitting isotopes for which the sum of the ratios of the quantities of the concerned radiation-emitting isotopes to the quantities set forth in the second column of the Appended Table 1 in accordance with the kinds set forth in the first column of the same Table equals to unity, and the concentration of each kind of radiation-emitting isotopes for which the sum of the ratios of the concentrations of the concerned radiation-emitting isotopes to the concentrations set forth in the third column of the same Table in accordance with the kinds set forth in the first column of the same Table equals to unity.

(Dose Equivalent Rate Pertaining to Radiation Generating Apparatuses)

Article 2. The dose equivalent rate specified in parts other than those set forth in each of Items of Article 2 of the Order is 600 nSv/h in terms of 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm).

(Quantities, etc. That Do Not Require Permission for Each Change of the Location of Use)

Article 3. The quantities specified by the Nuclear Regulation Authority (hereinafter, referred to as “NRA” in some cases) referred to in Article 9 Paragraph 1 of the Order, are those set forth in the second column of Appended Tables 1 to 4 and Table 6 in Public Notice to specify the Details, etc. pertaining to Technical Standards for Off-site Transport of Radioisotopes, etc. (Public Notice No. 7 of the Japan Science and Technology Agency, 1990), in accordance with the kinds or categories of radioisotopes set forth in the first column of the same Table; provided, however, that any of these quantities is 3 TBq in cases where they exceed 3 TBq or have no limitation.

2. The energy specified by the NRA referred to in Article 9 Paragraph 2 Item 1 of the Order, is 4 MeV, and that specified by the NRA referred to in Item 3 of the same Paragraph is 15 MeV.

(Dose, etc. Pertaining to Controlled Areas)

Article 4. The dose from external radiation, concentration of radiation-emitting isotopes in the air (including radiation-emitting isotopes produced by radiation from a radiation generating apparatus; hereinafter the same applies to this Article, the following Article Item 4, Article 7, Article 8, Article 14 Items 1 and 3, Article 16, Article 19, Article 24, Article 25, Article 27, Appended Tables 2 to 4, and the second column of Appended Table 7), and the density of radioisotopes on the surface of objects contaminated with radioisotopes pertaining to controlled areas prescribed in Article 1 Item 1 of the Ordinance for Enforcement of the Act on Prevention of Radiation Hazards Due to Radioisotopes, etc. (hereinafter referred to as the “NRA Ordinance”), are as follows:

- (1) the external dose is 1.3 mSv for a period of 3 months in terms of effective dose;
- (2) the average concentration of radioisotopes in the air for a period of 3 months is one-tenth of the concentration specified in Article 7;
- (3) the density of radioisotopes on the surface of an object contaminated with radioisotopes is one-tenth of the density specified in Article 8;
- (4) notwithstanding the provisions of Items 1 and 2, in cases where there is a likelihood of exposure to external radiation and of inhaling radioisotopes in the air, the effective dose and the concentration of radioisotopes in the

air are such that the sum of the ratio of the effective dose to the dose specified in Item 1 and the ratio of concentration of radioisotopes in the air to the concentration specified in Item 2 equals to unity.

(Effective Dose Limit)

Article 5. The dose limit for radiation workers in a certain period of time specified in Article 1 Item 10 of the NRA Ordinance is as follows:

- (1) 100 mSv for each 5- year period since April 1, 2001;
- (2) 50 mSv for a 1-year period beginning on April 1;
- (3) for female workers (excluding those diagnosed as being unable to become pregnant, those who have notified the permission user, notification user, or permission waste management operator in writing that they have no intention of becoming pregnant, and those prescribed in the following Item), 5 mSv for each period of 3 months beginning on April 1, July 1, October 1, and January 1, respectively, beyond what is prescribed in preceding two Items;
- (4) for pregnant workers, 1 mSv in terms of the dose due to radiation from radioisotopes taken into the human body (hereinafter referred to as “internal exposure”) during the period from the time when the permission user, notification user, or permission waste management operator was notified by a female worker of her pregnancy to the time of her delivery, beyond what is specified in Items 1 and 2.

(Equivalent Dose Limit)

Article 6. The dose limit in a certain period of time for radiation workers in each tissue or organ specified in Article 1 Item 11 of the NRA Ordinance is as follows:

- (1) for the lens of the eye, 150 mSv for a period of one year beginning on April 1;
- (2) for the skin, 500 mSv for a period of one year beginning on April 1;
- (3) for the surface of the abdominal region of a pregnant woman, 2 mSv for the period specified in Item 4 of the preceding Article.

(Concentration Limit in the Air)

Article 7. The concentration limits of radioisotopes in the air prescribed in Article 1 Item 12 and Article 14-11 Paragraph 1 Item 4 (a) and (b) of the NRA Ordinance are the concentrations specified in following Items in terms of the concentration averaged for one week:

- (1) in cases where the kind of radioisotopes (referred to the kind set forth in the first column of Appended Table 2; hereinafter the same applies to the following Item and Item 3) is identified and involving only one kind, the concentration limit is the concentration set forth in the fourth column of the same Table, in accordance with the kinds of radioisotopes set forth in the first column of the same Table;
- (2) in cases where the kind of radioisotopes is identified and involving two or more kinds, the concentration limit of each kind of radioisotopes in the air is the concentration of the concerned kind of radioisotopes for which the sum of the ratios of the concentrations of concerned radioisotopes in the air to the concentrations set forth in the preceding Item equals to unity;
- (3) in cases where the kind of radioisotopes is not identified, the concentration limit is the lowest concentration among the concentrations set forth in the fourth column of Appended Table 2 (excluding those pertaining to the kinds of radioactive materials that are evidently not contained in the air) ;
- (4) in cases where the kind of radioisotopes is identified but is not set forth in the first column of Appended Table 2, the concentration limit is the concentration set forth in the second column of Appended Table 3, in accordance with the category of radioisotopes set forth in the first column of the same Table.

(Limit of Surface Density)

Article 8. The limit of density of radioisotopes on the surface of an object that comes into contact with persons prescribed in Article 1 Item 13 of the NRA Ordinance is the concentration set forth in the right column, in accordance with the category of radioisotopes set forth in the left column of Appended Table 4.

Article 9. (Deleted)

[Public Notice No. 74 of the Ministry of Education, Culture, Sports, Science, and Technology, June 2005]

(Dose Limit Pertaining to Shielding)

Article 10. The limit of dose set forth in (a) prescribed in Article 14-7 Paragraph 1 Item 3 of the NRA Ordinance (including as applied mutatis mutandis to Article 14-8 of the NRA Ordinance; hereinafter the same applies to this Article) is 1 mSv in terms of effective dose for the period of one week.

2. The limit of dose set forth in (b) prescribed in Article 14-7 Paragraph 1 Item 3 of the NRA Ordinance is as follows:
- (1) the effective dose is 250 μ Sv for a period of 3 months (excluding cases corresponding to the following Item);
 - (2) the effective dose for sickrooms in hospitals and clinics (excluding elderly care facilities referred to in Article 8 Paragraph 27 of the Long-Term Care Insurance Act (Act No. 123 of 1997)) is 1.3 mSv for a period of 3 months.

(Quantities of Radioisotopes Pertaining to Automatic Display Systems)

Article 11. The quantity of radioisotopes prescribed in Article 14-7 Paragraph 1 Item 6 of the NRA Ordinance is 400 GBq.

(Quantities of Radioisotopes Pertaining to Interlocking Systems)

Article 12. The quantity of radioisotopes prescribed in Article 14-7 Paragraph 1 Item 7 of the NRA Ordinance is 100 TBq.

(Quantities of Radioisotopes Not Requiring the Principal Structure, etc. of Fireproof Construction, etc.)

Article 13. The quantities of radioisotopes prescribed in Article 14-7 Paragraph 4 of the NRA Ordinance is 1,000 times of the lower bound quantities (as with exemption levels).

(Concentration Limit, etc. of Radioisotopes Pertaining to the Exhaust or Drain Water)

Article 14. The limit of the average concentration of radioisotopes in the exhaust or air, or in liquid discharge or drain water prescribed in Article 14-11 Paragraph 1 Item 4 (c) i and ii and Item 5 (a) i and ii of the NRA Ordinance averaged for a period of 3 months is as specified in the following Items:

- (1) in cases where the kind of radioisotopes (referred to one of those set forth in the first column of Appended Table 2; hereinafter the same applies to the following Item and Item 3) is identified and involving only one kind, the concentration limits are those set forth in the fifth column of Appended Table 2 for concentration in the exhaust or air, and those set forth in the sixth column of the same Table for concentration in liquid discharge or drain water, in accordance with the kind of radioisotopes set forth in the first column of the same Table;
- (2) in cases where the kind of radioisotopes is identified and involving two or more kinds in the exhaust or air, or in liquid discharge or drain water, the concentration limit of each kind of radioisotopes in the air is the concentration of the concerned kind of radioisotopes for which the sum of the ratios of the concentrations of concerned

radioisotopes in the air to the concentrations set forth in the preceding Item equals to unity;

- (3) in cases where the kind of radioisotopes is not identified, the limit is the lowest concentration among the concentrations in the exhaust or air set forth in the fifth column, and the lowest concentration among the concentrations in liquid discharge or drain water set forth in the sixth column of Appended Table 2 (excluding those of the kinds of radioactive materials that are evidently not contained in the exhaust or air or in liquid discharge or drain water);
 - (4) in cases where the kind of radioisotopes is identified but not included in the first column of Appended Table 2, the limit is the concentration set forth in the third column for radioisotopes in the exhaust or air, and those set forth in the fourth column of the same Table for radioisotopes in liquid discharge or drain water, in accordance with the categories of radioisotopes set forth in the first column of Appended Table 3.
2. The dose limit prescribed in Article 14-11 Paragraph 1 Item 4 (c) iii and Paragraph 1 Item 5(a) iii of the NRA Ordinance is 1 mSv for a period of one year in terms of effective dose.
 3. The concentration limit of radioisotopes in the exhaust or air, or in liquid discharge or drain water prescribed in Article 19 Paragraph 1 Item 2 (a) and (b) and Paragraph 1 Item 5 (a) and (b) of the NRA Ordinance is the concentration specified in each Item of Paragraph 1, averaged for a period of 3 months beginning on April 1, July 1, October 1, and January 1, respectively.
 4. The dose limit prescribed in Article 19 Paragraph 1 Item 2 (c) and Item 5 (c) of the NRA Ordinance is 1 mSv in terms of effective dose for a period of one year beginning on April 1.

(Concentration Limit of Radiation-Emitting Isotopes Produced by Radiation from a Radiation Generating Apparatus Not Requiring an Exhaust Equipment)

Article 14-2. The concentration limit of radiation-emitting isotopes in the air which are produced by radiation from a radiation generating apparatus prescribed in the main clause of Article 14-11 Paragraph 1 Item 4 of the NRA Ordinance is one-tenth of the concentration specified in Article 7, averaged for 3 months.

(Quantities of Radioisotopes Pertaining to Minor Changes Not Requiring the Facility Inspection)

Article 15. The quantity prescribed in Article 14-13 Paragraph 1 Item 2 (a) and (b) of the NRA Ordinance is 100,000 times of the lower bound quantities.

(Density of Radioisotopes on the Surface of Objects Carried Outside of Controlled Areas)

Article 16. The density of radioisotopes on the surface of contaminated objects prescribed in Article 15 Paragraph 1 Item 10 of the NRA Ordinance (including as applied mutatis mutandis to Article 15 Paragraph 3 and Article 19 Paragraphs 1, 3, and 4 of the NRA Ordinance) and Article 17 Paragraph 1 Item 7 of the NRA Ordinance (including as applied mutatis mutandis to Article 17 Paragraph 2 of the NRA Ordinance) is one-tenth of the density specified in Article 8.

(Kinds and Quantities of Radioisotopes Used for Positron Emission Tomography)

Article 16-2. The quantities of radioisotopes used for positron emission tomography prescribed in Article 15 Paragraph 1 Item 10-2 of the NRA Ordinance are those set forth in the right column of the following Table in accordance with each kind of radioisotope in the left column.

Kind	Quantity
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Carbon-11	1 TBq
Nitrogen-13	1 TBq
Oxygen-15	1 TBq
Fluorine-18	5 TBq

(The Period of Storage for Disposal of Radioisotopes, etc. Used for Positron Emission Tomography)

Article 16-3. The period prescribed in Article 19 Paragraph 1 Item 13 (d) of the NRA Ordinance is 7 days from the day when concerned radioisotope has been sealed.

(Dose Limit for Workers Engaged in Waste Management)

Article 17. The dose limit for workers engaged in waste management prescribed in Article 19 Paragraph 5 Item 3 of the NRA Ordinance is the effective dose limit specified in Article 5 and the equivalent dose limit specified in Article 6.

(Dose Pertaining to the Measurement for Persons Who Temporarily Enter the Controlled Area)

Article 18. The dose pertaining to the measurement for persons who are not radiation workers and enter the controlled area temporarily prescribed in Article 20 Paragraph 2 Item 1 (e) of the NRA Ordinance is 100 μSv in terms of effective dose.

2. The dose pertaining to the measurement on internal exposure for persons who are not radiation workers and enter the controlled area temporarily prescribed in Article 20 Paragraph 2 Item 2 of the NRA Ordinance is 100 μSv in terms of effective dose from internal exposure.

(Measurement of Dose due to Internal Exposure)

Article 19. For the measurement of doses from internal exposure prescribed in Article 20 Paragraph 2 Item 2 of the NRA Ordinance, the quantities of radioisotopes taken in through inhalation or ingestion shall be calculated for each kind of radioisotopes set forth in the first column of Appended Table 2, pursuant to the provisions of the following Paragraph; provided, however, that the provisions do not apply if the measurement is performed by the method approved by the NRA.

2. The effective doses from internal exposure shall be calculated using the following equation for each kind of radioisotopes set forth in the first column of Appended Table 2. In cases where two or more kinds of radioisotopes have been inhaled or ingested, the sum of the effective doses calculated for each kind of radioisotopes is the effective dose from internal exposure.

$$E_i = e \times I$$

where, E_i , e , and I are as follows, respectively,

E_i : Effective dose from internal exposure (in mSv)

e : Effective dose coefficient for an inhaled radioisotope in the second column of Appended Table 2 and that of an ingested radioisotope in the third column of the same Table, in accordance with each kind of radioisotopes set forth in the first column of Appended Table 2 (in mSv/Bq)

I : Intakes of the radioisotopes by inhalation or ingestion (in Bq)

(Assessment of Effective Dose and Equivalent Dose)

Article 20. The effective dose prescribed in Article 20 Paragraph 4 Item 5 of the NRA Ordinance is the sum of the effective dose from exposure to external radiation prescribed in the following Item (hereinafter referred to as “external

exposure”) and effective dose from internal exposure:

- (1) effective dose from external exposure is 1-cm dose equivalent (identical to the “personal dose equivalent” defined by ICRU at $d = 10$ mm); provided, however, that in cases where the measurement was conducted pursuant to the provision of Article 20 Paragraph 2 Item 1 (b) of the NRA Ordinance, the value calculated through an appropriate method is regarded as the effective dose from external exposure;
 - (2) effective dose from internal exposure shall be calculated pursuant to the provisions of Paragraph 2 of the preceding Article.
2. The equivalent doses prescribed in Article 20 Paragraph 4 Item 5 of the NRA Ordinance are as follows:
- (1) equivalent dose for the skin is 70- μ m dose equivalent (identical to the "personal dose equivalent" defined by ICRU at $d = 0.07$ mm);
 - (2) equivalent dose for the lens of the eye is the appropriate one of either 1-cm dose equivalent or 70- μ m dose equivalent;
 - (3) the equivalent dose for the surface of the abdominal region of a pregnant female worker prescribed in Article 6 Item 3 is 1-cm dose equivalent).
3. The period prescribed in Article 20 Paragraph 4 Item 5 (b) of the NRA Ordinance is each period divided by 5 years after April 1, 2001.

(Doses, etc. for Special Provisions Pertaining to a Person Who Enters a Controlled Area Related to a Radiation Generating Apparatus)

Article 21. The dose, concentration and density specified by the NRA, prescribed in Article 22-3 Paragraph 1 of the NRA Ordinance, is the dose, concentration and density prescribed in each Item of Article 4, respectively.

(Dose Limits Pertaining to Emergency Operations)

Article 22. The dose limit pertaining to emergency operations prescribed in Article 29 Paragraph 2 of the NRA Ordinance is 100 mSv for the effective dose, 300 mSv for the equivalent dose to the lens of the eye, and 1 Sv for the equivalent dose to the skin.

(Categories of Chemical Forms, etc. of Radioisotopes Pertaining to Appended Forms)

Article 23. The categories of chemical forms, etc. of radioisotopes prescribed in Note 6 of Appended Form 1, Note 5 of Form 2, Note 6 of Form 5, Note 5 of Form 12, Note 11 of Form 18, and Note 4 of Form 19 of the NRA Ordinance and Note 6 of Appended Form 1 of Public Notice to Specify the Details of Technical Standards for the Transport of Radioisotopes, etc. Outside a Factory or Place of Business are the chemical forms, etc. set forth in the first column of Appended Table 2.

(Exclusion of Exposure for Medical Care, etc.)

Article 24. The assessment of radiation doses, effective doses or equivalent doses pursuant to the provisions of Articles 4 through 7, Article 10, Article 14, Article 14-2, Articles 17 through 20 and Article 22 shall include the exposure to electrons and X rays with energy less than 1 MeV, but shall exclude exposure for medical care and exposure to natural radiation. In cases where assessing the concentrations of radioisotopes in the air or water, radioisotopes naturally occurring in the air or water shall be excluded.

(Combination of Doses and Concentrations of Radioisotopes in the Air or Water)

Article 25. For the provisions of Article 7 and Article 10 Paragraph 1, in cases where it is likely to be exposed to external

radiation and also to inhale radioisotopes in the air, such a dose or concentration in the air that the sum of the ratios of those to respective limits concerned equals to unity is regarded as the dose limit or the concentration limit.

2. For the provisions of Article 10 Paragraph 2 and Article 14, in cases where it is likely to be exposed to external radiation and simultaneously to inhale radioisotopes in the air or to ingest water, such radiation dose or concentration in the air or water that the sum of ratios of those to the respective limits concerned equals to unity is regarded as the dose limit or the concentration limit.

(Conversion to the Effective Dose)

Article 26. The effective dose prescribed in Articles 4 and 10 may be calculated using the following equation, in accordance with the kinds of radiation (including electrons with energy less than 1 MeV and X rays; hereinafter the same applies in this Article);

- (1) for X rays or gamma rays:

$$E = f_x \times D$$

where, E, f_x and D are as follows, respectively,

E: effective dose (in Sv)

f_x : the figure in the second column of Appended Table 5 in accordance with the energy of radiation set forth in the first column of the same Table

D: air kerma free-in-air (unit: Gy)

- (2) for neutrons

$$E = f_n \times \Phi$$

where, E, f_n , and Φ are as follows, respectively,

E: effective dose (in Sv)

f_n : the figure in the second column of Appended Table 6 in accordance with the energy of radiation set forth in the first column of the same Table

Φ : neutron fluence free-in-air (unit: particles per square cm)

2. In cases where two or more kinds of radiation are involved, the sum of the effective doses calculated for each kind of radiation is regarded as the effective dose prescribed in Paragraph 1.

(Radioactivity Concentration Pertaining to Confirmation of Concentration)

Article 27. The radioactivity concentration prescribed in Article 29-2 of the NRA Ordinance is the concentration specified in each of the Items in accordance with the categories set forth in the concerned Item:

- (1) in cases where only one kind of radioisotopes is involved in the assessment (referred to the radioisotope subject to assessment prescribed in Article 24 Paragraph 1 Item 5 (b) of the NRA Ordinance; hereinafter the same applies to this Item and the following Item): in accordance with the objects for the confirmation of concentration set forth in the first column of Appended Table 7 (referred to objects for the confirmation of concentration prescribed in I Article 24 Paragraph 1 Item 5 (a) of the NRA Ordinance; hereinafter the same applies to the following Item) and the kinds of radioisotopes subject to assessment set forth in the second column of the same Table, such radioactivity concentration set forth in the third column of the same Table;
- (2) in cases where two or more kinds of radioisotopes are involved in the assessment: in accordance with the objects for the confirmation of concentration set forth in the first column of Appended Table 7, such radioactivity concentrations that the sum of ratios of concentration for each kind of radioisotopes subject to assessment set forth in the second column of the same Table to the radioactivity concentration concerned set forth in the third column of the same Table equals to unity.