

Radiation Hazards Prevention Ordinance

Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.

Issued: Prime Minister's Office Ordinance No. 56 of September 30, 1960

Latest amendment: Ordinance of the Ministry of Education, Culture, Sports, Science and Technology No. 8 of March 29, 2013

Amendment contents: Ordinance of the Ministry of Education, Culture, Sports, Science and Technology No. 8 of March 29, 2013 (April 1, 2013)

Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.

(Prime Minister's Office Ordinance No. 56 of September 30, 1960)

(Comprehensive amendment of Prime Minister's Office Ordinance No. 21 of March 31, 1958 (Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.))

The Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc., (Prime Minister's Office Ordinance No. 21 of 1958) is hereby amended in full as follows, pursuant to and in order to enforce the provisions of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc., and the Cabinet Order for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.:

Ordinance for Enforcement of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc.

CONTENTS

Chapter 1: Definitions (Article 1)

Chapter 2: Application for Permission, etc. (Articles 2 through 14)

Chapter 2-2: Application, etc., for Design Certification of Radioisotope-Equipped Devices, etc. (Articles 14-2 through 14-6)

Chapter 2-3: Standards for Usage Facilities, etc., (Articles 14-7 through 14-12)

Chapter 2-4: Facility Inspection, etc. (Articles 14-13 through 14-21)

Chapter 3: Standards for Use, etc. (Article 15 through 19-3)

Chapter 4: Obligation of Measurements, etc. (Articles 20 through 29-7)

Chapter 5: Radiation Protection Supervisor (Articles 30 through 38-3)

Chapter 6: Miscellaneous Provisions (Articles 39 through 41)

Supplementary Provisions

Chapter 1. Definitions

(Definitions of Terms)

Article 1. The definitions of terms set forth in the following Items in this Ordinance are as prescribed respectively in those Items:

- (1) controlled area: The area where the dose due to external radiation is likely to exceed the dose specified by the Nuclear Regulation Authority (hereinafter, referred to as “NRA” in some cases), the concentrations of radioisotopes in the air (including radiation emitting isotopes produced by radiation from radiation generating apparatuses; hereinafter the same applies to this Item, Items 4, 12 and 13, Article 14-7 Paragraph 1 Items 4 and 5 as applied mutatis mutandis to Article 14-8, Article 14-9 Item 4 (c) as applied mutatis mutandis to Article 14-10, Article 14-11, Article 15 Paragraph 1 Items 4 and 10, Article 17 Paragraph 1 Item 7 and Paragraph 2, Article 18 Paragraph 1 Items 1 (a) and 3, Article 18-3 Paragraph 2, Article 18-4 Item 8, Article 18-5 (excluding Item 9) ,Article 18-6, Article 18-11 Items 1 (a) and 2 (b),Article 19 Paragraph 1 (excluding Items 13 (d) and 16), Paragraph 3 and Paragraph 5 Item 2, Article 20 (excluding Paragraph 1 Items 4 (b) and (c)), Article 21 Paragraph 1 Item 4, Article 22 Paragraph 1 Item 3, Article 22-3 Paragraph 1, Article 24 Paragraph 1 Item 4 (a) and Item 5, Article 24 Paragraph 1 Item 3 and Item 7 (d) and Paragraph 2 Item 2 , Article 29 Paragraph 1 Item 4, Article 29-4 Item 1, Article 29-7 and Article 39 Paragraph 2), are likely to exceed the concentrations specified by the NRA, or the density of a radioisotope on the surface of the object contaminated with radioisotopes is likely to exceed the density specified by the NRA;
- (2) workroom: A room where unsealed radioisotopes are used or repacked, or where unsealed objects contaminated with radioisotopes or radiation emitting isotopes produced by radiation from a radiation generating apparatus (hereinafter referred to as “contaminated objects”) are repacked;
- (3) waste management workroom: A room where the residue of radioisotopes or contaminated objects (hereinafter referred to as “radioisotopes, etc.”) after being incinerated is removed from the incinerator or solidified with concrete or other solidification materials (including processes for solidification; the same applies hereinafter)
- (4) contamination inspection room: A room where inspection of contamination due to radioisotopes of human bodies or the surfaces of work wear, footwear, protective equipment, and other matters worn by persons is conducted;
- (5) exhaust equipment: Exhaust air purifiers, exhaust fans, exhaust pipes, exhaust outlets, and other equipment designed to purify and release gaseous radioisotopes, etc.;
- (6) drainage equipment: Liquid discharge equipment (referred to such structures as concentrators, separators, ion exchange devices, and other such machines or devices), drainage purification tanks (referred to such structures storage tanks, dilution tanks, sedimentation tanks, filtration tanks, and other such structures), drainage pipes, drainage outlets, and other equipment designed to purify and release liquid radioisotopes, etc.;
- (7) solidification processing equipment: Crushers, compactors, mixers, fillers, and other equipment designed to solidify radioisotopes, etc. with concrete or other solidification materials;
- (8) radiation worker: A person who is engaged in the handling, management or other relevant works of radioisotopes, etc., or radiation generating apparatuses (hereinafter referred to as “works of handling, etc.”) and who enters a controlled area;
- (9) radiation facilities: Usage facilities, waste repacking facilities, storage facilities, waste storage facilities or waste management facilities;
- (10) effective dose limit: The dose limit during a fixed period of time specified by the NRA for effective dose to a radiation worker;
- (11) equivalent dose limit: The dose limit during a fixed period of time specified by the NRA for equivalent dose to

each tissue or organ of a radiation worker.

- (12) concentration limit in the air: The limit of concentration specified by the NRA for the concentration of a radioisotope in the air a person inhales in places where a person can regularly enter within radiation facilities;
- (13) surface density limit: The limit of density specified by the NRA for the density of a radioisotope on the surface of objects that a person comes into direct contact in places where a person can regularly enter within radiation facilities.

Chapter 2. Application for Permission, etc.

(Application for the Permission of Use)

Article 2. The application form for the permission of use referred to in Article 3 Paragraph 2 of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc., (Act No. 167 of 1957; hereinafter referred to as “the Act”) is the Appended Form 1.

2. The following documents shall be appended to the application form referred to in the preceding Paragraph, pursuant to the provisions in Article 3 Paragraph 3 of the Order for Enforcement of the Act on Prevention of Radiation Hazards Due to Radioisotopes, etc., (Cabinet Order No. 259 of 1960; hereinafter referred to as “the Cabinet Order”):

- (1) for a juridical person, a certificate of registered matters;
- (2) a document describing the planned time of commencement and the planned period of use;
- (3) ground plans of the interior and the exterior of the factory or place of business with a primary focus on usage facilities, storage facilities, and waste management facilities, and with the applicable scale and orientation indicated thereon;
- (4) ground plans that outline the layout, purpose of use, the location of entranceways, controlled areas (in case where the provisions in Article 22-3 Paragraph 1 are applied, including the areas where the provisions in the same Paragraph apply) and places where signs are to be posted, of usage facilities, storage facilities and waste management facilities, with the applicable scale and orientation indicated thereon;
- (5) detailed cross-sectional drawings of usage facilities, storage facilities and waste management facilities, on which the applicable scale for their key parts of these facilities is indicated;
- (6) documents and drawings proving the conformity to the standards referred to in Article 14-7 Paragraph 1 Item 3 , Article 14-9 Item 3, or Article 14-11 Paragraph 1 Item 3, and a document outlining the situations of areas adjacent to the factory or place of business (limited to cases where measures referred to in parentheses in Article 14-7 Paragraph 1 Item 3 (b) are taken);
- (6)-2 in cases where automatically displaying devices prescribed in Article 14-7 Paragraph 1 Item 6 or the interlocking system prescribed in Item 7 of the same Paragraph is to be installed, ground plans for the room in which radioisotopes or radiation generating apparatuses are used, illustrating the locations of entranceways and the locations where automatically displaying devices or the interlocking system will be installed, as well as a document describing in detail the kinds and functions of the interlocking system to be installed;
- (7) documents and drawings proving that the exhaust equipment has the capability prescribed in Article 14-11 Paragraph 1 Item 4 (a) through (c), drawings illustrating the location of the exhaust equipment and outlining the exhaust system; in cases where the exhaust-monitoring equipment is to be installed, documents outlining the

- situations of areas adjacent to the factory or place of business (limited to cases where measures referred to in the parenthesis in (c) ii. of the same Item are taken) and a document describing the details of the exhaust monitoring equipment and drawings illustrating the location of the exhaust monitoring equipment; and, in case of adopting the exhaust equipment referred to in (c) iii. of the same Item, a document describing the reasons for the adoption;
- (8) documents and drawings proving that the drainage equipment has the capability prescribed in Article 14-11 Paragraph 1 Item 5 (a) ; drawings illustrating the location of the drainage equipment and outlining the drainage system; in cases where the drainage monitoring equipment is to be installed, documents outlining the situations of areas adjacent to the factory or place of business (limited to cases where measures referred to in the parenthesis in Item 4 (c) ii. of the same Paragraph are taken) and a document describing the details of the drainage monitoring equipment and drawings illustrating the location of the drainage monitoring equipment; and, in case of adopting the drainage equipment referred to in Item 5 (a) iii. of the same Paragraph, a document describing the reasons for the adoption;
- (9) in cases prescribed in Article 14-7 Paragraphs 2 and 3, documents describing in detail the methods for use of radioisotopes or radiation generating apparatuses and the measures to be taken to prevent radiation hazards;
- (10) in cases where unsealed radioisotopes are used outside of usage facilities pursuant to the provisions in Article 15 Paragraph 2 , drawings illustrating the location of use concerned;
- (11) a medical certificate issued by a physician concerning the person's mental disorder who intends to be granted the permission referred to in Article 3 Paragraph 1 of the Act (or, in case of a juridical person, an executive officer of business) (hereinafter referred to as "applicant").
3. In cases where the applicant is a juridical person and the NRA deems that the executive officer of business may not disrupt operation, judging from the business content, a document explaining that the executive officer does not fall under Article 5 Paragraph 2 Item 1 of the Act may be submitted, in lieu of the medical certificate set forth in Item 11 of the preceding Paragraph.

(Notification of Use)

- Article 3.** Notification of use pursuant to the provisions of Article 3-2 Paragraph 1 of the Act shall be submitted with the Appended Form 2.
2. Documents set forth in the following Items shall be appended to the notification form referred to in the preceding Paragraph, pursuant to the provisions in Article 4 Paragraph 2 of the Cabinet Order:
- (1) documents describing the planned time for the commencement and the planned period of use;
- (2) ground plans indicating the situations of the locations for use and waste management, controlled areas, places where signs are to be posted, and, for the person intending to use sealed radioisotopes, the locations of storage facilities, with the applicable scale and orientation indicated thereon;
- (3) documents and drawings proving that shielding walls and other shielding elements in storage facilities have the capability prescribed in Article 14-9 Item 3.

(Notification of Change Pertaining to Notification of Use)

- Article 4.** Notification of change pursuant to the provisions of Article 3-2 Paragraph 2 of the Act shall be submitted

with the Appended Form 3.

2. Documents set forth in the following Items shall be appended to the notification form referred to in the preceding Paragraph:

- (1) documents describing the planned time of the change;
- (2) documents and drawings pertaining to the change prescribed in Paragraph 2 Items 2 and 3 of the preceding Article

(Notification of Use of Approved Devices with Certification Label)

Article 5. Notification of use or change pertaining to use of an approved device with certification label, pursuant to the provisions of Article 3-3 Paragraph 1 or 2 of the Act, shall be submitted with the Appended Form 4.

(Notification of Dealing and Leasing Business)

Article 6. Notification of dealing and leasing business pursuant to the provisions of Article 4 Paragraph 1 of the Act shall be submitted with the Appended Form 5.

2. Documents describing the planned time of the commencement and the planned operation period of the business, and the expected quantity of each kind of radioisotopes to be dealt per year (in cases where the planned operation period of the business will be less than one year, the expected quantity to be dealt for the period) or the expected maximum quantity for lease (the maximum quantity of lease actually expected at an arbitrary point in time during the planned operation period) shall be appended to the notification form referred to in the preceding Paragraph, pursuant to the provisions in Article 6 of the Cabinet Order.

(Notification of Change Pertaining to Notification of Dealing and Leasing Business)

Article 6-2. Notification of change pursuant to the provisions of Article 4 Paragraph 2 of the Act shall be submitted with the Appended Form 6.

2. Documents set forth in the following Items shall be appended to the notification form referred to in the preceding Paragraph:

- (1) documents describing the planned time for the change;
- (2) documents prescribed in Paragraph 2 of the preceding Article relevant to the change.

(Application for the Permission of Waste Management Business)

Article 7. The application form for the permission of waste management business referred to in Article 4-2 Paragraph 2 of the Act is the Appended Form 7.

2. The provisions in Article 2 Paragraph 2 (excluding the part in the parenthesis in Item 4, Items 6-2, 9 and 10 of the same Paragraph) and Paragraph 3 apply mutatis mutandis to documents that shall be appended to the application form referred to in the preceding Paragraph pursuant to the provisions in Article 3 Paragraph 3 of the Cabinet Order, as applied mutatis mutandis pursuant to Article 7 of the Cabinet Order. In this case, the phrase “the planned time for the commencement and the planned period of use” in Article 2 Paragraph 2 Item 2 is replaced with “the planned time for the commencement and the planned operation period of business and the expected quantity of radioisotopes, etc. to be collected per year and the expected quantity of waste to be managed per year for each method of waste

management”; the terms “usage facilities, storage facilities” in Item 3 of the same Paragraph are replaced with “waste repacking facilities, waste storage facilities” and the term “factory and place of business” is replaced with “place of waste management business”; the terms “usage facilities, storage facilities” in Items 4 and 5 of the same Paragraph are replaced with “waste repacking facilities, waste storage facilities”; the terms “Article 14-7 Paragraph 1 Item 3, Article 14-9 Item 3 ” in Item 6 of the same Paragraph are replaced with “Article 14-7 Paragraph 1 Item 3, as applied mutatis mutandis pursuant to Article 14-8, Article 14-9 Item 3, as applied mutatis mutandis pursuant to Article 14-10 ”, the term “factory or place of business” is replaced with “place of waste management business”, and the term “parenthesis in Article 14-7 Paragraph 1 Item 3 (b) ” is replaced with “parenthesis in Article 14-7 Paragraph 1 Item 3 (b), as applied mutatis mutandis pursuant to Article 14-8 ”; the term “Article 14-11 Paragraph 1 Item 4 (a) through (c) ” in Item 7 of the same Paragraph is replaced with “Article 14-11 Paragraph 1 Items 4 (a) and (c) ” and the term “factory or place of business” is replaced with “place of waste management business”; the term “factory or place of business” in Item 8 of the same Paragraph is replaced with “place of waste management business”; and the term “Article 3 Paragraph 1 of the Act” in Item 11 of the same Paragraph is replaced with “Article 4-2 Paragraph 1 of the Act”.

3. In cases where the waste burial referred to in Article 4-2 Paragraph 2 Item 7 of the Act is conducted, the documents set forth in the following Items shall be appended, beyond what is prescribed in Article 2 Paragraph 2 as applied mutatis mutandis pursuant to the preceding Paragraph (excluding the part in the parenthesis in Item 4, Items 6-2, 9 and 10 of the same Paragraph) and Paragraph 3:

- (1) documents and drawings describing the meteorology, ground strength, hydrology, seismicity, social environment and other situations at the location where waste burial site is intended to be settled;
- (2) documents and drawings proving the conformity to the standards referred to in Article 14-11 Paragraph 3 Item 2 and Article 14-12 Item 2 ;
- (3) documents demonstrating a financing plan, business income and expenditure estimates, and other details establishing the existence of a financial basis adequate for the proper execution of the waste management business;
- (4) in cases where waste management business is actually ongoing, documents on the general description of the business.

(Persons Provided for in the Ordinance of the Nuclear Regulation Authority, Referred to in Article 5 Paragraph 2 Item 1 of the Act)

Article 8. A person provided for in the Ordinance of the NRA (hereinafter referred to as “NRA Ordinance”), referred to in Article 5 Paragraph 2 Item 1 of the Act, is the person who is unable to appropriately recognize, judge and communicate as required in order to take appropriate measures for the prevention of radiation hazards, due to mental dysfunction.

(Application for the Permission of Changes Pertaining to Permitted Use)

Article 9. The application form for the permission of the change pertaining to permitted use referred to in Article 8 of the Cabinet Order is the Appended Form 8.

2. The following documents shall be appended to the application form referred to in the preceding Paragraph:

- (1) documents describing the planned time of the change;
- (2) documents and drawings prescribed in Article 2 Paragraph 2 Items 3 through 10 pertaining to the change;
- (3) if construction work is involved, documents describing the planned construction period and measures to be taken concerning the prevention of radiation hazards during the period of construction.

(Minor Changes Not Requiring Permission of Change)

Article 9-2. Minor changes provided for in the NRA Ordinance, referred to in the parenthesis in Article 10 Paragraph 2 of the Act, are those set forth in the following Items:

- (1) reduction in the storage capacity of storage facilities;
- (2) reduction in the quantity of radioisotopes;
- (3) reduction in the number of units of radiation generating apparatuses;
- (4) termination of usage facilities, storage facilities, or waste management facilities;
- (5) changes in the method of use or in the location, structure or equipment of usage facilities, storage facilities, or waste management facilities, specified by the NRA;
- (6) changes in the performance of radiation generating apparatuses, specified by the NRA.

(Application for the Permission of Changes Pertaining to Waste Management Business)

Article 9-3. The provisions in Article 9 apply mutatis mutandis to the application for the permission of the change pertaining to waste management business referred to in Article 10 of the Cabinet Order. In this case, the term “Appended Form 8” in Article 9 Paragraph 1 is replaced with “Appended Form 9”; the term “planned time of the change” in Paragraph 2 Item 1 of the same Article is replaced with “planned time of the change and the expected quantities of radioisotopes, etc. to be collected per year, and the expected quantities of radioisotopes, etc. to be managed per year for each method of waste management pertaining to the change”; and the term “Article 2 Paragraph 2 Item 3 through 10” in Item 2 of the same Paragraph is replaced with “Article 2 Paragraph 2 Items 3 through 8, as applied mutatis mutandis pursuant to Article 7 Paragraph 2”.

2. In cases where the application referred to in the preceding Paragraph concerns to the waste burial referred to in Article 4-2 Paragraph 2 Item 7 of the Act, documents set forth in Article 7 Paragraph 3 Items 1 through 3 pertaining to the change shall be appended, beyond the documents set forth in each Item of Article 9 Paragraph 2 as applied mutatis mutandis pursuant to the preceding Paragraph.

(Number of the Application Form for Permission to be submitted, etc.)

Article 10. The number of the application form to be submitted referred to in Article 2 Paragraph 1, Article 7 Paragraph 1, and Article 9 Paragraph 1 (including as applied mutatis mutandis pursuant to Paragraph 1 of the preceding Article) is one original and 3 duplicates; provided, however, that documents prescribed in Article 2 Paragraph 2 (including as applied mutatis mutandis pursuant to Article 7 Paragraph 2), Article 7 Paragraph 3, Article 9 Paragraph 2 (including as applied mutatis mutandis pursuant to Paragraph 1 of the preceding Article) or Paragraph 2 of the preceding Article are not required to be appended to the duplicates.

2. Notwithstanding the provisions in the preceding Paragraph, the number of the application form pertaining to the

factory or place of business, referred to in Article 2 Paragraph 1 and Article 9 Paragraph 1, provided for in the NRA Ordinance, is one original and 4 duplicates; provided, however, that documents prescribed in Article 2 Paragraph 2 or Article 9 Paragraph 2 are not required to be appended to the duplicates.

(Notification of Changes in Name, etc.)

Article 10-2. Notification pursuant to the provisions of Article 3-2 Paragraph 3, Article 4 Paragraph 3, Article 10 Paragraph 1 or Article 11 Paragraph 1 of the Act, shall be submitted with the Appended Form 10.

(Notification of Minor Changes relevant to Permitted Use)

Article 10-3. Notification of minor changes pursuant to the provisions of Article 10 Paragraph 5 of the Act shall be submitted in the form referred to in the Appended Form 11.

2. Documents set forth in the Items of Article 9 Paragraph 2 shall be appended to the notification form referred to in the preceding Paragraph.

(Notification of Temporary Changes in the Location of Use Pertaining to Permitted Use)

Article 11. Notification of the change in the location of use pursuant to the provisions of Article 10 Paragraph 6 of the Act shall be submitted in the from referred to in the Appended Form 12.

2. The documents set forth in the following Items shall be appended to the notification form referred to in the preceding Paragraph:

- (1) documents describing the location of use and the situations in the vicinity;
- (2) ground plans with a primary focus on the location of use, indicating the controlled areas, places where signs are posted and the location of use and the vicinity with an applicable scale and orientation indicated thereon;
- (3) documents describing the measures to be taken in order to prevent radiation hazards.

(Number of the Notification Form to be submitted, etc.)

Article 12. The number of the notification form to be submitted referred to in Article 3 Paragraph 1, Article 4 Paragraph 1, Article 6 Paragraph 1 and Article 6-2 Paragraph 1 is one original and 3 duplicates; provided, however, that documents prescribed in Article 3 Paragraph 2, Article 4 Paragraph 2, Article 6 Paragraph 2 or Article 6-2 Paragraph 2 are not required to be appended to the duplicates.

2. Notwithstanding the provisions in the preceding Paragraph, the number of the application form pertaining to the factory or place of business, referred to in Article 3 Paragraph 1, Article 4 Paragraph 1, Article 6 Paragraph 1, and Article 6-2 Paragraph 1, provided for in the NRA Ordinance, is one original and 4 duplicates; provided, however, that documents pursuant to the provisions of Article 3 Paragraph 2, Article 4 Paragraph 2, Article 6 Paragraph 2 or Article 6-2 Paragraph 2 are not required to be appended to the duplicates.

3. The number of the notification form to be submitted referred to in Article 10-2 is one original and 2 duplicates.

4. The number of the notification form to be submitted referred to in Article 5, Article 10-3 Paragraph 1 and Paragraph 1 of the preceding Article is one original and one duplicate, respectively.

Article 13

[Deleted] (Prime Minister's Office Ordinance No. 45 of September 1995)

(Reissuance of a Permit)

Article 14. A person intending to have a permit reissued pursuant to the provisions in Article 12 of the Act shall submit an application form for reissuance of a permit with the Appended Form 13 to the NRA.

2. In cases where a person who has stained or damaged a permit submits an application form referred to in the preceding Paragraph, the permit concerned shall be appended thereto.
3. When a person, who lost a permit and has it reissued, finds the lost permit later, the found permit shall be returned to the NRA without delay.

Chapter 2-2. Application, etc., for Design Certification of Radioisotope-Equipped Devices, etc.

(Application for Design Certification, etc., of Radioisotope-Equipped Devices)

Article 14-2. The application form for certification referred to in Article 12-2 Paragraph 3 of the Act is the Appended Form 14.

2. Documents provided for in the NRA Ordinance, referred to in Article 12-2 Paragraph 4 of the Act are those set forth in the following Items:
 - (1) instruction documents of the method manufacturing the radioisotope-equipped device;
 - (2) documents proving the conformity of the radioisotope-equipped device to the standards referred to in Paragraph 1 Item 1 of the following Article.
3. The number of the application form to be submitted referred to in Paragraph 1 is one original and one duplicate copy.

(Standards for Certification)

Article 14-3. Technical standards for the design of the parts featuring functions to prevent radiation hazards of a radioisotope-equipped device (including the method to verify compliance with the design concerned) provided for in the NRA Ordinance, referred to in Article 12-3 Paragraph 1 of the Act, are as follows:

- (1) it has been confirmed through a prototype that the design of the part featuring the function of the radioisotope-equipped device pertaining to the application for design certification to prevent radiation hazards, conforms to the following standards:
 - (a) for a radioisotope-equipped device pertaining to the application for design certification, in cases where the concerned radioisotope-equipped device is handled according to conditions concerning the use, storage, and transport pertaining to the application concerned, the dose due to external exposure (that is, exposure to external radiation; the same applies hereinafter) must not be more than the dose limit specified by the NRA. In this case, the number of hours of use per year used for calculation of the dose must not be less than those specified by the NRA for the each kind of radioisotope-equipped devices;
 - (b) for a radioisotope-equipped device pertaining to the application for specified design certification, the 1-cm dose equivalent rate (identical to the "ambient dose equivalent rate" defined by ICRU at $d = 10$ mm) at a distance of 10 cm apart from the surface must not be more than 1 μ Sv/h;

- (c) if the concerned radioisotope-equipped device is handled according to conditions concerning the use, storage, and transport pertaining to the application concerned, exposure to radiation is unlikely to occur by the ingestion of radioisotopes into the human body;
 - (d) radioisotopes in a radioisotope-equipped device shall conform to the standards provided by the NRA for each kind of radioisotope-equipped devices;
 - (e) radioisotopes shall be stored in containers fastened to the radioisotope-equipped device or fastened to the radioisotope-equipped device with supports;
 - (f) the container in which radioisotopes are stored or the supports that are used to fasten radioisotopes shall withstand temperature and pressure changes, shocks, and vibrations to which they shall be subjected at the time of handling and must not be easily damaged.
- (2) the method to verify the compliance with the design of the part of the radioisotope-equipped device featuring the function to prevent radiation hazards pertaining to the application shall conform to the following standards:
- (a) an organization and manager tasked with the management, implementation, and verification of operations required to fulfill the obligations referred to in Article 12-4 Paragraph 1 of the Act (hereinafter referred to as “obligations of design conformity”) shall be appointed.
 - (b) the regulations concerning inspections, describing the following matters, shall be provided, and it shall be ensured that inspections are appropriately conducted according to the regulations:
 - i methods to measure whether or not the radioisotope-equipped device manufactured based on the design concerned complies with the standards referred to in (a) or (b) of the preceding Item;
 - ii methods to confirm whether or not radioisotopes in the radioisotope-equipped device manufactured based on the design concerned conform to the standards referred to in (d) of the preceding Item;
 - iii other procedures and methods for inspection of a radioisotope-equipped device required to fulfill the obligation of design conformity.
 - (c) the regulations concerning the management of measurement devices, etc., necessary for inspection of a radioisotope-equipped device shall be provided, and it shall be ensured that the management of measurement devices, etc., is appropriately conducted according to the regulations.
2. Technical standards provided for in the NRA Ordinance, referred to in Article 12-3 Paragraph 1 of the Act pertaining to the conditions concerning the use, storage, and transport of a radioisotope-equipped device shall be as follows:
- (1) for a radioisotope-equipped device pertaining to an application for design certification, measures shall be taken to ensure that a specified person does not approach within 50 cm of the surface of the concerned radioisotope-equipped device more than hours of use per year;
 - (2) any parts of the concerned radioisotope-equipped device featuring the functions to prevent radiation hazards must not be disassembled or assembled;
 - (3) the concerned radioisotope-equipped device shall be stored in a storage room or storage box referred to in Article 14-9 Item 2 or shall be stored in a designated container labeled “RADIOACTIVE” (in Japanese or English),
 - (4) in cases where the concerned radioisotope-equipped device is stored, measures shall be taken to ensure that it may not be carried without reason;
 - (5) in cases where the concerned radioisotope-equipped device is transported, the concerned radioisotope-equipped

device or the container in which the concerned radioisotope-equipped device is stored shall conform to the following standards:

- (a) it shall be equivalent to a type L package referred to in Article 18-3 Paragraph 1 Item 1;
 - (b) it shall be easily and safely handled;
 - (c) there shall be no likelihood of cracks or damage to occur caused by any anticipated changes in temperature or pressure, vibrations, etc., during its transport;
 - (d) there shall be no unnecessary protuberances on its surface and contamination on it shall be easily removed;
 - (e) there shall be no likelihood of a hazardous physical interaction or chemical reaction to occur between materials or between the material and radioisotopes that are stored or sealed therein;
 - (f) the measures to ensure that valves would not be mistakenly operated shall be taken;
 - (g) the labels “RADIOACTIVE” (in Japanese or English) and “equivalent to the type L package” shall be attached at a clearly visible position of the package; provided, however, that this does not apply to the case provided by the NRA;
 - (h) the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) on the surface must not exceed $5 \mu\text{Sv/h}$;
 - (i) the density of a radioisotope on the surface must not exceed the value of the surface density for transport packages referred to in Article 18-4 Item 8.
- (6) beyond what is pursuant to the provisions of the preceding Items, the conditions concerning the use, storage, and transport of a radioisotope-equipped device shall be adequate and reasonable for the prevention of radiation hazards.
3. A radioisotope-equipped device which contained a radioisotope therein exceeding 1,000 times of the lower bound quantity (as with “exemption level”) specified in Article 1 of the Cabinet Order (hereinafter referred to simply as “lower bound quantity”), shall conform to the following standards, beyond the standards set forth in the preceding two Paragraphs:
- (1) the radioisotope-equipped device shall be designed so that, in cases where the concerned device loses its functions to prevent radiation hazards, the person handling the concerned device can easily recognize the fact;
 - (2) the radioisotope-equipped device shall undergo an inspection each period not exceeding one year in length, conducted by the manufacturer of the concerned radioisotope-equipped device or a person who has been entrusted such an inspection thereby, in order to determine whether the function to prevent radiation hazards is maintained;
 - (3) the radioisotope-equipped device otherwise shall conform to the standards provided for by the NRA for each kind of the radioisotope-equipped devices.
4. The practical investigation of the registered certification organization referred to in Article 12-3 Paragraph 2 of the Act shall be conducted by two or more design certification personnel.

(Records of Inspection)

Article 14-4. The matters to be described in the inspection records referred to in Article 12-4 Paragraph 2 of the Act are as follows:

- (1) certification number pertaining to the inspection;

- (2) date and place of the inspection;
 - (3) name of the responsible person who conducted the inspection;
 - (4) methods of inspection;
 - (5) results of inspection.
2. The records of inspection referred to in the preceding Paragraph shall be stored for a period of 10 years from the date of the inspection.
 3. The records referred to in the preceding Paragraph may be stored by use of a recording medium pertaining to electronic or magnetic records. In this case, the electronic or magnetic record concerned shall be able to be immediately displayed as necessary using a computer or other devices.

(Labeling)

Article 14-5. On the label referred to in Article 12-5 Paragraph 1 of the Act, a design certification seal or specified design certification seal under an attached figure is affixed to and the following matters are to be described:

- (1) the characters “Nuclear Regulation Authority” in Japanese (in cases where a registered certification organization has granted a design certification or specified design certification, the title of the concerned registered certification organization or characters or symbol identifying the concerned registered certification organization);
 - (2) certification number.
2. The label referred to in the preceding Paragraph shall be attached, by the method that ensures that it must not be easily erased or removed, at the clearly visible position of the surface of the radioisotope-equipped device (in cases where it is difficult to directly label the device concerned, a designated container).

(Appended Documents)

Article 14-6. The documents referred to in Article 12-6 of the Act are those describing matters set forth in Appended Form 4, Appended Form 37 and Appended Form 36 (limited to cases involved the approved device with certification label) as well as documents describing the following matters and shall be attached to each radioisotope-equipped devices:

- (1) the fact that the Act shall apply to the concerned device;
- (2) contact address of the manufacturer of the approved device referred to in Article 12-4 Paragraph 1 of the Act;
- (3) the homepage address of the NRA to which matters pertaining to design certification or specified design certification are posted.

Chapter 2-3 Standards for Usage Facilities, etc.

(Standards for Usage Facilities)

Article 14-7. The technical standards for the location, structure, and equipping of a usage facility pursuant to the provisions in Article 6 Item 1 of the Act are as follows:

- (1) the usage facility shall be constructed at a location where the likelihood of a landslide or flooding is small.
- (2) in cases where the usage facility is pertinent to a building prescribed in Article 2 Item 1 of the Building Standards Act (Act No. 201 of 1950) or a habitable room pursuant to the provisions of Item 4 of the same Article, the main

structural section, etc. (that is, the main structural section pursuant to the provisions of Item 5 of the same Article and the walls and pillars compartmentalizing the concerned facility; the same applies hereinafter) shall be of fireproof structure (that is, fireproof structure pursuant to the provisions of Item 7 of the same Article; the same applies hereinafter) or shall be constructed with incombustible materials (that is, incombustible materials pursuant to the provisions of Item 9 of the same Article; the same applies hereinafter).

- (3) the usage facility shall be installed with shielding walls and other shielding elements required to keep each of the following doses less than or equal to the corresponding dose limit specified by the NRA:
 - (a) dose of radiation to which a person is likely to be exposed at places normally used for access by persons inside the usage facilities;
 - (b) dose of radiation at the boundary of a factory or place of business (in cases where measures to prevent persons from entering without reason the area adjacent to the boundary of a factory or place of business have been taken, the boundary of the area comprising the factory or place of business and the concerned adjacent area) and in areas where persons inhabit inside the factory or place of business.
- (4) in cases where unsealed radioisotopes are used, a workroom shall be provided pursuant to the following provisions:
 - (a) the interior walls and floor of the workroom as well as other parts that are likely to be contaminated with radioisotopes shall be of structure with few protuberances, depressions, and gaps of joints in finishing materials, etc.;
 - (b) the surfaces of the interior walls and floor of the workroom as well as other parts that are likely to be contaminated with radioisotopes shall be flat and smooth, resistant to infiltration by gases or liquids, and finished with materials resistant to corrosion;
 - (c) hoods, glove-boxes, and other devices installed in the workroom, used to prevent the spread of gaseous radioisotopes and objects contaminated with radioisotopes shall be connected to an exhaust equipment.
- (5) in cases where unsealed radioisotopes are used, a contamination inspection room shall be set up pursuant to the following provisions:
 - (a) the contamination inspection room shall be set up close to the entranceway of the usage facility normally used for access by persons or at any other location most suitable for conducting inspections of contamination by radioisotopes;
 - (b) the interior walls and floor of the contamination inspection room as well as other parts that are likely to be contaminated with radioisotopes shall conform to the standards referred to in (a) and (b) of the preceding Item;
 - (c) the contamination inspection room shall be outfitted with a washing equipment, dressing equipment, radiation measurement devices and instruments necessary to remove contamination;
 - (d) drainage pipes for the washing equipment pursuant to the provisions of (c) shall be connected to a drainage equipment.
- (6) a device automatically displaying the status that radioisotopes or radiation generating apparatuses are in use shall be provided at any entranceway normally used for access by persons to a room where sealed radioisotopes of a quantity equal to or greater than the quantity specified by the NRA or radiation generating apparatuses are used.
- (7) in cases where sealed radioisotopes of a quantity equal to or greater than the quantity specified by the NRA or

radiation generating apparatuses are used, an interlocking system to prevent entry by persons to a room without reason, when radioisotopes or radiation generating apparatuses are used, shall be provided at any entranceway normally used for access by people to the room.

(7)-2 in cases where the objects contaminated with radiation emitting isotopes produced by radiation from radiation generating apparatuses (hereinafter referred to as “activated object”) which is used as equipment or shielding material that comprises radiation generating apparatuses is stored, the activated object storage equipment shall be set up pursuant to the following provisions:

- (a) the activated object storage equipment shall be of a structure sectioned off from the outside;
- (b) any door, lid, or other component of the activated object storage equipment linked to the outside shall be installed with a lock or other system or instrument to close the concerned storage equipment;
- (c) the structure of the activated object storage equipment shall be fireproof and installed with a container that complies with the standards referred to in Article 14-9 Item 4 (including as applied mutatis mutandis pursuant to Article 14-10 ; the same applies to Article 14-11 Paragraph 1 Item 8 (c)); provided, however, that this does not apply to the cases where special measures to prevent the spread of contamination are taken, when the activated object is a large instrument, etc. and it is significantly difficult to place this large instrument, etc. inside the container.

(8) fencing and other facilities designed to prevent the entry of persons without reason shall be provided at the boundary of any controlled areas.

(9) sign shall be affixed to rooms where radioisotopes or radiation generating apparatuses are used, contamination inspection rooms, activated object storage equipment, containers pursuant to the provisions of Item 7-2 (c), and fencing and other facilities designed to prevent the entry of persons without reason provided at the boundary of any controlled areas pursuant to the provisions in the appended Table.

2. The provisions in the preceding Paragraph do not apply to the cases where radioisotopes are used being dispersed on a widespread but temporarily for the purpose of a water leakage investigation, epidemiological investigation of insects, investigation of the state of the movement of raw materials in production processes.
3. The provisions in Paragraph 1 Items 1, 2, 6 and 7 do not apply to the cases where sealed radioisotopes or radiation generating apparatuses are moved at any time as required and used accordingly.
4. The provisions in Paragraph 1 Item 2 do not apply to the cases where sealed radioisotopes of quantities less than or equal to the quantity specified by the NRA are used.
5. The provisions in Paragraph 1 Item 5 do not apply to the cases where unsealed radioisotopes are used inside a device closed tightly in order to ensure that persons and the surfaces of work clothes, footwear, and other articles worn by persons are unlikely to be contaminated with radioisotopes.
6. The provisions in Paragraph 1 Item 7 do not apply to the cases where shielding walls and other shielding materials have been set up, so as to ensure that the dose to which persons in the room where radioisotopes or radiation generating apparatuses are used might be exposed, is kept less than or equal to the dose limit related to the radiation dose set forth in Item 3 (a) of the same Paragraph.

(Standards for Waste Repacking Facilities)

Article 14-8. The provisions in Paragraph 1 of the preceding Article (excluding Items 6 through 7 (2)) apply mutatis mutandis to technical standards for the location, structure, and equipment of waste repacking facilities pursuant to the provisions of in Article 7 Item 1 of the Act. In this case, the term “factory or place of business” in Paragraph 1 Item 3 (b) of the preceding Article is replaced with “place of management business”; the phrase “unsealed radioisotopes are used” in Items 4 and 5 of the same Paragraph is replaced with “unsealed radioisotopes, etc., are repacked”; the terms “radioisotopes and objects contaminated with radioisotopes” in Item 4 (c) of the same Paragraph are replaced with “radioisotopes, etc.”; and the phrase “rooms where radioisotopes or radiation generating apparatuses are used” in Item 9 of the same Paragraph is replaced with “rooms where radioisotopes, etc., are repacked” and the terms “activated object storage equipment, containers prescribed in Item 7-2 (c) , and” are replaced with “and”.

(Standards for Storage Facilities)

Article 14-9. The technical standards for the location, structure, and equipment of storage facilities pursuant to the provisions of Article 6 Item 2 and Article 13 Paragraph 2 of the Act are as follows:

- (1) storage facilities shall be constructed at a places where the likelihood of a landslide or flooding is small.
- (2) the storage facility shall be outfitted with a storage room or storage box pursuant to the following provisions; provided, however, that this does not apply to the cases where sealed radioisotopes are placed and stored in a container of a fireproof structure:
 - (a) the main structural sections, etc. of a storage room shall be of fireproof structure and a fire prevention door equivalent to specific fire prevention equipment prescribed in Article 112 Paragraph 1 of the Cabinet Order for Enforcement of the Building Standard Act (Cabinet Order No. 338 of 1950) shall be installed at its opening section;
 - (b) the storage box shall be of fireproof structure.
- (3) the storage facility shall be outfitted with shielding walls and other shielding materials complying with the standards referred to in Article 14-7 Paragraph 1 Item 3.
- (4) the storage facility shall be outfitted with containers for radioisotopes pursuant to the following provisions:
 - (a) the container for radioisotopes that are likely to contaminate the air outside the container shall be of airtight structure;
 - (b) the container for liquid radioisotopes shall be of such a structure that liquid hardly spills out and shall be made of materials that are resistant to liquid permeation;
 - (c) for the container to store liquid or solid radioisotopes for which incidents such as cracking or damage are likely to occur, catch pans, absorbers, or other facility equipment or tools to prevent the spread of contamination by radioisotopes shall be provided.
- (5) any door, lid, or other component of storage facilities linked to the outside shall be installed with a lock or other system or instrument to close the concerned facilities.
- (6) fencing and other facilities to prevent the entry of persons without reason shall be provided at the boundary of controlled areas.
- (7) sign shall be affixed to storage rooms or storage boxes, containers prescribed in Item 4, fencing provided at the

boundary of controlled areas and other facilities to prevent the entry of persons without reason, pursuant to the provisions in the appended Table.

(Standards for Waste Storage Facilities)

Article 14-10. The provisions in the preceding Article apply mutatis mutandis to technical standards for the location, structure, and equipment of waste storage facilities pursuant to the provisions of Article 7 Item 2 of the Act. In this case, the term “radioisotopes” in Item 2 of the preceding Article is replaced with “radioisotopes, etc.,” and the phrase “into which radioisotopes are placed” in Item 4 of the same Article is replaced with “into which radioisotopes, etc., are placed”.

(Standards for Waste Management Facilities)

Article 14-11. The technical standards (excluding technical standards concerning waste burial sites) for the location, structure, and equipment of waste management facilities pursuant to the provisions of Article 6 Item 3 and Article 7 Item 3 of the Act are as follows:

- (1) waste management facilities shall be constructed at places where the likelihood of a landslide or flooding is small.
- (2) the main structural sections of waste management facilities shall be of fireproof structure or shall be constructed with incombustible materials.
- (3) waste management facilities shall be outfitted with shielding walls and other shielding materials that conform to the standards referred to in Article 14-7 Paragraph 1 Item 3.
- (4) in cases where unsealed radioisotopes, etc., are used or repacked, or in cases where radiation generating apparatuses are used (limited to cases where the concentrations of radiation emitting isotopes produced by radiation from radiation generating apparatuses in the air in a room where the concerned radiation generating apparatuses are used, are likely to exceed the limits of concentration specified by the NRA), exhaust equipment shall be provided pursuant to the following provisions; provided, however, that this does not apply to the cases where installing exhaust equipment significantly disrupts the purpose of use or renders the performance of work difficult owing to the qualities, but there is no likelihood that gaseous radioisotopes are produced or that the air is contaminated with radioisotopes:
 - (a) exhaust equipment pertaining to the use or repacking of unsealed radioisotopes, etc., shall be capable of keeping the concentration of radioisotopes in the air at places usually accessed by persons in a workroom or waste management workroom less than or equal to the limit of concentration specified by the NRA.
 - (b) exhaust equipment pertaining to the use of radiation generating apparatuses shall be capable of keeping the concentration of radiation emitting isotopes produced by radiation from radiation generating apparatuses less than or equal to the limit of concentration specified by the NRA, during the period of the suspension of the operations of the concerned radiation generating apparatuses (excluding, in cases where an interlocking system is installed to prevent the entry by a person in the room without reason where the concerned radiation generating apparatuses are used, the period during which the concerned installed interlocking system prevents person’s entry).
 - (c) exhaust equipment shall correspond to any of the followings:

- i the exhaust equipment shall be capable of keeping the concentration of radioisotopes in exhaust at an exhaust outlet less than or equal to the limit of concentration specified by the NRA;
 - ii the exhaust equipment shall be capable of keeping the concentration of radioisotopes in the air outside the boundary of a factory, place of business, or place of waste management business (hereinafter referred to as “place of business, etc.”) (in cases where measures to prevent persons from entering without reason the area adjacent to the boundary of the place of business, etc. have been taken, the boundary of the area comprising the place of business, etc. and the concerned adjacent area; hereinafter the same applies to this Item, the following Item and Article 19 Paragraph 1 Items 2 and 5) less than or equal to the limit of concentration specified by the NRA by installing exhaust monitoring equipment and monitoring the concentration of radioisotopes in the air;
 - iii in cases where it is significantly difficult to install exhaust equipment having the capability referred to in Item 1 or 2, it shall be granted approval by the NRA that the concerned exhaust equipment has the enough capability to keep the dose outside the boundary of the business office, etc., less than or equal to the dose limit specified by the NRA.
- (d) the exhaust equipment shall be of structure that the exhaust shall hardly permeate through anywhere other than the exhaust outlet and shall be made of corrosion resistant materials.
- (e) the exhaust equipment shall be installed with devices to promptly prevent the spread of air contaminated with radioisotopes in cases where it malfunctions.
- (5) in cases where liquid radioisotopes, etc., are purified or discharged, the drainage equipment shall be provided pursuant to the following provisions:
- (a) the drainage equipment shall correspond to any of the followings:
 - i the drainage equipment shall be capable of keeping the concentration of radioisotopes in waste liquid at the drain outlet less than or equal to the limit of concentration specified by the NRA;
 - ii the drainage equipment shall be capable of keeping the concentration of radioisotopes in waste liquid at the boundary of a business office, etc., less than or equal to the limit of concentration specified by the NRA, by installing the monitoring equipment and monitoring the concentration of radioisotopes in waste liquid;
 - iii in cases where it is significantly difficult to install a drainage equipment having the capability referred to in Item 1 or 2, it shall be granted approval by the NRA that the concerned drainage equipment has the enough capability to keep the dose outside the boundary of the business office, etc., less than or equal to the dose limit specified by the NRA.
 - (b) the drainage equipment shall be of structure that liquid waste hardly leaks and shall be made of materials that are resistant to permeation of liquid waste and corrosion.
 - (c) a drain purification tank shall be of such structure that waste liquid may be sampled or concentrations of radioisotopes in waste liquid may be measured. The device for adjusting the outflow of discharged waste shall be provided at the outlet of the tank. An upper opening of the outlet shall be of such structure that allows the tank to be capped. Alternatively, fencing and other facilities designed to prevent the unauthorized entry of persons shall be provided around this tank.
- (6) in cases where radioisotopes, etc. are to be incinerated, the incinerator shall be provided pursuant to the following

provisions, and also the exhaust equipment conforming to the standards referred to in Item 4, the waste management workroom conforming to the standards referred to in Article 14-7 Paragraph 1 Item 4 (including as applied mutatis mutandis pursuant to Article 14-8 ; the same applies to the following Item), and the contamination inspection room conforming to the standards referred to in Article 14-7 Paragraph 1 Item 5 (including as applied mutatis mutandis pursuant to Article 14-8 ; the same applies to the following Item) shall be provided in addition to the incinerator:

- (a) the incinerator shall be of such structure that gases hardly leak and ash hardly scatters;
- (b) the incinerator shall be of structure connected to an exhaust equipment;
- (c) the outlet of the incinerator through which incineration residue is removed shall be connected to the waste management workroom.

(7) in cases where radioisotopes, etc., are solidified with concrete or other solidification materials, the solidification processing equipment shall be provided pursuant to the following provisions, and also the exhaust equipment conforming to the standards referred to in Item 4, the waste management workroom conforming to the standards referred to in Article 14-7 Paragraph 1 Item 4 and the contamination inspection room conforming to the standards referred to in Item 5 of the same Paragraph shall be provided in addition to the solidification processing equipment:

- (a) the solidification processing equipment shall be such structure that radioisotopes, etc. hardly leak and spill, and that fine particles hardly scatter;
- (b) the solidification processing equipment shall be made of materials that are resistant to permeation of liquids and corrosion.

(8) in cases where radioisotopes, etc., are stored for disposal (excluding cases where stored for disposal pursuant to the provisions in Article 19 Paragraph 1 Item 13 (d)), the predisposal equipment shall be provided pursuant to the following provisions:

- (a) the predisposal equipment shall be of structure that is sectioned off from the outside;
- (b) any door, lid, or other component of the predisposal equipment linked to the outside shall be installed with a lock or other system or instrument to close the concerned equipment;
- (c) the predisposal equipment shall be of fireproof structure and shall be installed with a container conforming to the standards referred to in Article 14-9 Item 4; provided, however, that this does not apply in cases where special measures to prevent the spread of contamination are taken when the contaminated objects are large machines, etc. and it is significantly difficult to place these machines, etc. inside the container.

(9) fencing and other facilities designed to prevent the unauthorized entry by persons shall be set up on the boundary of any controlled areas.

(10) sign shall be affixed to the exhaust equipment, drainage equipment, waste management workrooms, contamination inspection rooms, predisposal equipment, containers prescribed in Item 8 (c) , and fencing and other facilities designed to prevent the unauthorized entry of persons as set up on the boundary of any controlled areas pursuant to the provisions in the appended Table.

2. In cases where the exhaust equipment or drainage equipment that is granted approval referred to in Item 4 (c) iii or Item 5 (a) iii of the preceding Paragraph is no longer recognized as having the capability pertaining to the permission concerned, the NRA may revoke the permission concerned.

3. The technical standards for the location, structure, and equipment of the waste management facility pursuant to the

provisions of Article 7 Item 3 of the Act pertaining to waste burial sites are as follows:

- (1) the waste burial site shall be constructed at places where the likelihood of a landslide or flooding is small.
- (2) the waste burial site shall be outfitted with shielding walls and other shielding materials that conform to the standards referred to in Article 14-7 Paragraph 1 Item 3.
- (3) in cases where waste burial is intended, outer partitioning equipment that conform to the following standards shall be set up; provided, however, that this does not apply to the cases where, among radioisotopes included in burial wastes (refer to radioisotopes, etc., that are intended to be subject to final processing by way of waste burial; the same applies hereinafter), radioactivity concentration of the kind of radioisotopes specified by the NRA must not exceed the value of radioactivity concentration specified for each kind of radioisotopes by the NRA:
 - (a) the outer partitioning equipment shall be safe in terms of structural strength against its own weight, earth pressure, seismic force, etc.;
 - (b) effective measures to prevent corrosion shall be taken according to the properties of the surface water, groundwater, and soil.
- (4) fencing and other facilities designed to prevent the unauthorized entry of persons shall be set up at the boundary of any controlled areas.
- (5) sign shall be affixed to fencing and other facilities designed to prevent the unauthorized entry of persons set up at the boundary of any controlled areas pursuant to the provisions in the appended Table.

(Review for the Permission of Waste Management Business Pertaining to Waste Burial)

Article 14-12. In cases where an application for the permission referred to in Article 4-2 Paragraph 1 of the Act or an application for the permission of change referred to in Article 11 Paragraph 2 of the Act pertaining to waste burial is submitted and the conformity of the application to Article 7 Item 4 of the Act is reviewed, the NRA reviews whether the concerned application conforms to the standards set forth in the following Items:

- (1) the burial wastes to be disposed of must not include substances that are likely to damage the soundness of wastes and otherwise shall consist only of the burial wastes that conform to the standards provided for by the NRA;
- (2) by setting up outer partitioning equipment and other equipment and systems or taking measures to prevent radiation hazards according to the decay of radioactivity referred to in Article 4 Paragraph 2 Item 7(b) of the Act, in cases where, during the planned period or after the termination of the management of the waste burial sites, the place pertaining to the concerned site is used or in other cases specified by the NRA, the dose to which persons might be exposed shall be kept less than or equal to the dose limit specified by the NRA;
- (3) the applicant shall possess a financial basis adequate to ensure the implementation of the waste management business.

Chapter 2-4. Facility Inspection, etc.

(Minor Changes Not Requiring Facility Inspection)

Article 14-13. Minor changes provided for in the NRA Ordinance referred to in Article 12-8 Paragraph 1 of the Act, are those other than the followings:

- (1) the following changes made by a permission user pertaining to sealed radioisotopes:

- (a) expansion of usage facilities where sealed radioisotopes of 10 TBq or more are used;
 - (b) expansion of storage facilities where sealed radioisotopes of 10 TBq or more are stored;
 - (c) increase in storage capacity of storage facilities (limited to the change pertaining to sealed radioisotopes of 10 TBq or more) from less than 10 TBq to 10 TBq or more;
 - (d) expansion of waste management facilities where the wastes of sealed radioisotopes are managed.
- (2) the following changes made by a permission user pertaining to unsealed radioisotopes;
- (a) expansion of usage facilities where unsealed radioisotopes of a yearly usage quantity equal to or greater than the quantity specified by the NRA are used;
 - (b) expansion of storage facilities whose storage capacity pertaining to unsealed radioisotopes is equal to or greater than the quantity specified by the NRA;
 - (c) increase in storage capacity of storage facilities pertaining to unsealed radioisotopes at the factory or place of business using the concerned storage facilities from less than the quantity of 100,000 times the lower bound quantity (as with “exemption level”) to at least the quantity of 100,000 times the lower bound quantity (as with “exemption level”) or more;
 - (d) expansion of waste management facilities where the wastes of unsealed radioisotopes are managed.
- (3) expansion of usage facilities where radiation generating apparatuses are used or the change for the newly use of radiation generating apparatuses at a facility where radiation generating apparatuses have not been used, by a permission user pertaining to radiation generating apparatuses.
2. Minor changes provided for in the NRA Ordinance referred to in Article 12-8 Paragraph 2 of the Act are the changes other than the expansion of waste repacking facilities, waste storage facilities or waste management facilities.

(Application for Facility Inspection)

Article 14-14. Any person intending to undergo facility inspection pursuant to the provisions in Article 12-8 Paragraph 1 of the Act (excluding facility inspection conducted by a registered inspection organization) shall submit an application form of the Appended Form 15, appending the following documents, to the NRA:

- (1) ground plans of the factory or place of business clearly indicating the location of the usage facility, etc.;
 - (2) measured ground plans of the usage facility, etc.;
 - (3) drawing of measured detailed cross-section of the usage facility, etc.
2. Any person intending to undergo facility inspection referred to in Article 12-8 Paragraph 1 of the Act conducted by a registered inspection organization shall submit an application form referred to in the Appended Form 15, with the appended documents set forth in the Items of the preceding Paragraph, to the concerned registered inspection organization.

Article 14-15. The provisions in the preceding Article apply mutatis mutandis to the application for facility inspection referred to in Article 12-8 Paragraph 2 of the Act. In this case, the term “usage facility, etc.” in Paragraph 1 of the preceding Article is replaced with “waste repacking facility, etc.” and the term “factory or place of business” is replaced with “place of waste management business”.

(Issuance a Facility Inspection Certificate)

Article 14-16. The Nuclear Regulation Authority or the registered inspection organization shall conduct facility inspection pursuant to the provisions in Article 12-8 Paragraph 1 or 2 of the Act and, in cases where the inspection is passed, issues a facility inspection certificate.

(Application for Periodic Inspection)

Article 14-17. Any person intending to undergo periodic inspection pursuant to the provisions in Article 12-9 Paragraph 1 of the Act (excluding periodic inspection conducted by a registered inspection organization) shall submit an application form of the Appended Form 16, with the following documents, to the NRA:

- (1) ground plans of the factory or place of business clearly indicating the location of the usage facility, etc.;
 - (2) measured ground plans of the usage facility, etc.;
 - (3) drawing of measured detailed cross-section of the usage facility, etc.
2. Any person intending to undergo facility inspection referred to in Article 12-9 Paragraph 1 of the Act conducted by a registered inspection organization shall submit an application form of the Appended Form 16, with the documents set forth in the Items of the preceding Paragraph, to the concerned registered inspection organization; provided, however, that the applicant falling under all of the following conditions, does not need to append the concerned documents:
- (1) in cases where the applicant has passed the facility inspection referred to in Article 12-8 Paragraph 1 of the Act or periodic inspection referred to in Article 12-9 Paragraph 1 of the Act conducted within the last 10 years, or has undergone periodic confirmation referred to in Article 12-10 of the Act conducted within the last 10 years, by the same registered inspection organization where the applicant intends to undergo periodic inspection pursuant to the provisions of Article 12-9 Paragraph 1 of the Act;
 - (2) in cases where the applicant has submitted the application form to the registered inspection organization or the registered periodic confirmation organization with the documents set forth in each of Items of Article 14-14 Paragraph 1, Items of the preceding Paragraph or Items of Article 14-20 Paragraph 1, at the time of undergoing facility inspection, periodic inspection or periodic confirmation referred to in the preceding Item;
 - (3) in cases where the applicant has not made any change pursuant to the provisions of Article 10 Paragraph 1 of the Act (excluding the change of the name of the representative of a juridical person among the matters set forth in Article 3 Paragraph 2 Item 1 of the Act prescribed in the same Paragraph), Paragraph 2 or Paragraph 5 of the same Article of the Act, since the applicant last passed the facility inspection or periodic inspection referred to in Item 1 or since it last underwent periodic confirmation referred to in the same Item.

Article 14-18. The provisions in the preceding Article apply mutatis mutandis to the application for period inspection referred to in Article 12-9 Paragraph 2 of the Act. In this case, the term “usage facility, etc.” in Paragraph 1 of the preceding Article is replaced with “waste repacking facility, etc.” and the term “factory or place of business” is replaced with “place of waste management business”; the term “Article 12-8 Paragraph 1 of the Act” in Paragraph 2 Item 1 of the same Article is replaced with “Article 12-8 Paragraph 2 of the Act” and the term “Article 12-9 Paragraph 1 of the Act” is replaced with “Article 12-9 Paragraph 2 of the Act”; the term “each of Items of Article 14-14 Paragraph 1” in Item 2 of the same Paragraph is replaced with “each of Items of Article 14-14 Paragraph 1 as applied

mutatis mutandis pursuant to Article 14-15 ”; and the term “Article 10 Paragraph 1 of the Act” in Item 3 of the same Paragraph is replaced with “Article 11 Paragraph 1 of the Act”, the term “Article 3 Paragraph 2 Item 1 of the Act” is replaced with “Article 4-2 Paragraph 2 Item 1 of the Act”, and the terms “Paragraph 2 or 5” is replaced with “Paragraph 2”.

(Issuance of Periodic Inspection Certificate)

Article 14-19. The Nuclear Regulation Authority or the registered inspection organization shall conduct periodic inspection pursuant to the provisions in Article 12-9 Paragraph 1 or 2 of the Act and, in cases where the inspection is passed, issues a periodic inspection certificate.

(Application for Periodic Confirmation)

Article 14-20. Any person intending to undergo periodic confirmation pursuant to the provisions in Article 12-10 of the Act (excluding periodic confirmation conducted by a registered periodic confirmation organization) shall submit an application form of the Appended Form 17, with the a documents set forth in the following Items, to the NRA:

- (1) ground plans of the place of business, etc., clearly indicating the location of the usage facility, etc., or waste repacking facility, etc.;
 - (2) measured ground plans of the usage facility, etc., or waste repacking facility, etc.;
 - (3) drawings of measured detailed cross-section of the usage facility, etc., or waste repacking facility, etc.
2. Any person intending to undergo periodic confirmation referred to in Article 12-10 of the Act conducted by a registered confirmation organization shall submit an application form of the Appended Form 17, with the documents set forth in Items of the preceding Paragraph, to the concerned registered confirmation organization; provided, however, that the applicant falling under all of the following conditions, does not need to append the concerned documents:
- (1) in cases where the applicant has passed the facility inspection referred to in Article 12-8 Paragraph 1 or 2 of the Act or periodic inspection referred to in Article 12-9 Paragraph 1 or 2 of the Act conducted within the last 10 years, or has undergone periodic confirmation pursuant to the provisions of Article 12-10 of the Act conducted within the last 10 years, by the same registered inspection organization where the applicant intends to undergo periodic confirmation referred to in Article 12-10 of the Act;
 - (2) in cases where the applicant has submitted the application form to the registered inspection organization or the registered periodic confirmation organization with the documents set forth in each of Items of Article 14-14 Paragraph 1 (including as applied mutatis mutandis pursuant to Article 14-15), Items of Article 14-17 Paragraph 1 (including as applied mutatis mutandis pursuant to Article 14-18) or Items of the preceding Paragraph, at the time of undergoing facility inspection, periodic inspection or periodic confirmation referred to in the preceding Item;
 - (3) in cases where the applicant has not made any change referred to in Article 10 Paragraph 1 of the Act (excluding the change of the name of the representative of a juridical person among the matters set forth in Article 3 Paragraph 2 Item 1 of the Act prescribed in the same Paragraph) , Paragraph 2 or Paragraph 5 of the same Article of the Act or Article 11 Paragraph 1 (excluding the change of the name of the representative of a juridical person among the matters set forth in Article 4-2 Paragraph 2 Item 1 of the Act prescribed in the same Paragraph) or Paragraph 2

since the applicant last passed the facility inspection or periodic inspection referred to in Item 1 or since it last underwent periodic confirmation referred to in the same Item.

(Issuance of Periodic Confirmation Certificate)

Article 14-21. The Nuclear Regulation Authority or a registered periodic confirmation organization, in cases where it has conducted confirmation prescribed in Article 12-10, issues a periodic confirmation certificate.

Chapter 3. Standards for Use, etc.

(Standards for Use)

Article 15. Technical standards provided for in the NRA Ordinance referred to in Article 15 Paragraph 1 of the Act, (excluding those pertaining to Paragraph 3) are as follows:

- (1) radioisotopes or radiation generating apparatuses shall be used in a usage facility; provided, however, that this does not apply in the case where a notification user uses sealed radioisotopes or in a case prescribed in Article 10 Paragraph 6 of the Act or Article 14-7 Paragraph 2 of the Act.
- (1)-2 unsealed radioisotopes shall be used in a workroom;
- (2) sealed radioisotopes shall be used in complying with the following conditions at all times:
 - (a) under normal conditions of use, there shall be no likelihood that sealed radioisotopes become unsealed or damaged;
 - (b) there shall be no likelihood of contamination through scattering caused by the leakage or permeation of sealed radioisotopes.
- (3) the doses to a radiation worker shall be kept not exceeding the effective dose limit and equivalent dose limit by taking any of the following measures:
 - (a) radiation shielding shall be implemented by using shielding walls and other shielding materials;
 - (b) an appropriate distance shall be provided between radioisotopes or a radiation generating apparatus and the human body by means of remote-handling equipment, forceps, etc.;
 - (c) the duration of time for which persons are exposed to radiation shall be shortened.
- (3)-2 in cases where radioisotopes or radiation generating apparatuses are used in a room where an interlocking system prescribed in Article 14-7 Paragraph 1 Item 7 has been provided, measures to ensure that the doors at service entrances, emergency entrances, etc. not normally used for accessing purposes by persons cannot be opened or closed from the outside and measures to ensure that persons confined inside the room can promptly escape shall be taken.
- (4) the concentration of radioisotopes in the air breathed by persons at places regularly accessed by persons or in rooms where radiation generating apparatuses are used shall be kept not exceeding the concentration limit of radioisotopes in the air by purifying or exhausting the air contaminated with radioisotopes.
- (5) ingestion of food and drinks and smoking shall be strictly prohibited in a workroom.
- (6) the surface density of radioisotopes on the objects with which persons come into direct contact in workrooms or contamination inspection rooms shall be kept not exceeding the limit of surface density of radioisotopes by removing the contamination by radioisotopes or by disposing of such objects with which persons come into contact.

- (7) persons shall work in a workroom by wearing work wear, protective equipment, etc. and shall leave the workroom with them on, without reason.
- (8) in cases where leaving the workroom, the person shall inspect the contamination by radioisotopes on his/her body, and on the surface of objects worn by the person, such as work wear, footwear, protective equipment, etc., and remove any detected contamination.
- (9) objects contaminated with radioisotopes of which the surface density of radioisotopes exceeds the limit of surface density must not be carried outside the workroom without reason.
- (10) contaminated objects of which the surface density of radioisotopes exceeds the density specified by the NRA must not be carried outside the controlled areas without reason.
- (10)-2 in cases where radioisotopes used for positron emission tomography (PET) (referred to as the radioisotopes which, for use in image diagnosis with a positron emission tomography (PET) device operated by use of radioisotopes, are produced by a device installed with a cyclotron and a function for removing impurities by chemical means (limited to devices that are inspected in order to examine whether the function to remove impurities is maintained each time they are upgraded, restructured, or changes in purifying method and once during the period not exceeding one year), of which the maximum quantity used per day for each kind of radioisotopes is less than or equal to the quantity specified by the NRA; the same applies hereinafter) have been administered to living organisms other than human beings, the concerned living organisms and any wastes discharged thereby must not be carried outside the controlled area without any reason until they have been stored in the controlled area over the period of time that ensures the number of atoms of administered radioisotopes for positron emission tomography to be less than unity.
- (10)-3 in cases where the notification of the change in the location of use is submitted to the NRA pursuant to the provisions in Article 10 Paragraph 6 of the Act and the device installed with at least 400 GBq of radioisotopes is used, the concerned device shall be installed with the mechanism to prevent dropping-out of radioisotopes.
- (10)-4 in cases where the notification of the change in the location of use is submitted to the NRA pursuant to the provisions in Article 10 Paragraph 6 of the Act and radioisotopes or radiation generating apparatuses are used, the use of radioisotopes shall be in accordance with instructions of a holder of the first-class radiation protection supervisor certificate referred to in Article 35 Paragraph 1 of the Act (hereinafter referred to as “first-class radiation protection supervisor certificate”) or a holder of the second-class radiation protection supervisor certificate referred to in the same Paragraph (hereinafter referred to as “second-class radiation protection supervisor certificate”) and the use of radiation generating apparatuses shall be in accordance with instructions by a holder of the first- class radiation protection supervisor certificate.
- (11) notices required for the prevention of radiation hazards shall be posted at clearly visible locations in a usage facility or controlled area.
- (12) measures to prevent the entry of persons into the controlled area without reason shall be taken and, if persons other than the radiation workers enter the controlled area, they shall be forced to follow instructions by radiation workers.
- (13) in cases where a notification user uses radioisotopes and where a permission user submits a notification of the change in the location of use to the NRA pursuant to the provisions in Article 10 Paragraph 6 of the Act and uses

radioisotopes or radiation generating apparatuses, sign shall be affixed in a controlled area as pursuant to the provisions of the appended Table.

(14) in cases where sealed radioisotopes are used upon being moved, the inspection to check whether there is anything abnormal about these radioisotopes, such as in terms of the loss or leakage, shall be conducted immediately after use with a radiation measurement device and, if any abnormality is found through this process, survey and other measures required to prevent radiation hazards shall be taken.

2. The provisions in Items 1, 1-2, and 3 of the preceding Paragraph do not apply to the case where outside a usage facility (limited to the outside of a usage facility as indicated with ground plans referred to in Article 2 Paragraph 2 Item 4) a permission user uses unsealed radioisotopes of the quantity not exceeding the lower bound quantity per day (limited to the case where the total quantity of unsealed radioisotopes outside a controlled area does not exceed the lower bound quantity (as with “exemption level”).

3. Beyond what is pursuant to the provisions of the following Items, the provisions of Paragraph 1 Items 1 (excluding the proviso), 3, 5, 7, 8, 10, 11, and 12 apply mutatis mutandis to technical standards provided for in the NRA Ordinance referred to in Article 15 Paragraph 1 of the Act (limited to technical standards pertaining to work which is likely to cause the contamination due to scattering of radiation emitting isotopes contained in activated object used as equipment or shielding that comprises radiation generating apparatuses (hereinafter referred to as “work” in this Paragraph)). In this case, the phrase “The use of radioisotopes or radiation generating apparatuses” in Item 1 of the same Paragraph is replaced with “work prescribed in Article 15 Paragraph 3”; the terms “Radioisotopes or radiation generating apparatuses” in Item 3 (b) of the same Paragraph are replaced with “Activated objects”; the term “workroom” in Items 5, 7, and 8 of the same Paragraph is replaced with “location where work prescribed in Article 15 Paragraph 3 is performed”; the term “contamination with radioisotopes” in Item 8 of the same Paragraph is replaced with “contamination with radiation emitting isotopes produced by radiation from radiation generating apparatuses”; and the term “Contaminated objects” in Item 10 of the same Paragraph is replaced with “Activated objects” and the term “radioisotopes” is replaced with “radiation emitting isotopes”:

(1) by using mats, catch pans, and other tools, contamination due to radiation emitting isotopes shall be prevented from spreading;

(2) after work is completed, contamination caused by the concerned work shall be removed.

Article 16. (deleted)

(Standards for Storage)

Article 17. Beyond what is pursuant to the provisions of the following Items, the provision in Article 15 Paragraph 1 Item 3 apply mutatis mutandis to the technical standards provided for in the NRA Ordinance referred to in Article 16 Paragraph 1 of the Act pertaining to a permission or notification user. In this case, the term “radiation generating apparatus” in (b) of the same Item is replaced with “activated object”:

(1) radioisotopes shall be put in containers and stored in a storage room or storage box (in cases where sealed radioisotopes are stored in containers of fireproof structure, referred to storage facility (including the place of concerned use, if sealed radioisotopes are used after the notification of the change of location of use has been

submitted to the NRA pursuant to the provisions in Article 10 Paragraph 6 of the Act)).

- (2) radioisotopes must not be stored in a storage facility in excess of its storage capacity.
 - (3) measures to prevent storage box (or, in cases where sealed radioisotopes shall be stored in a container of fireproof structure, the concerned container) from being carried without reason while radioisotopes are stored therein shall be implemented.
 - (4) in cases where radioisotopes that are likely to contaminate air are stored, the concentrations of radioisotopes in the air breathed by a person inside the storage facility shall be kept not exceeding the limit of radioisotope concentration in air.
 - (5) ingestion of food and drinks and smoking shall be strictly prohibited in places in the storage facility where oral intake of radioisotopes is likely to occur.
 - (6) the density of radioisotopes on the surface of objects with which persons come into direct contact in the storage facility shall be kept not exceeding the surface density limit by taking the following measures:
 - (a) liquid radioisotopes shall be stored in containers of such structure that liquid hardly spills out and made of materials resistant to liquid permeation;
 - (b) catch pans, absorbers, or other facility equipment or tools to prevent the spread of contamination by radioisotopes shall be provided for a container in which liquid or solid radioisotopes are placed and incidents such as cracks or damages, etc. are likely to occur therein.
 - (6)-2 materials that are activated objects and used as devices or shield structures composing a radiation generating apparatus shall be stored by any of the following methods:
 - (a) shall be stored in the activated object storage equipment, being placed in containers;
 - (b) shall be stored in the activated object storage equipment, in cases corresponding to the proviso in Article 14-7 paragraph (1) Item 7-2.
 - (7) contaminated objects of which surface density of radioisotopes exceeding the limit specified by NRA must not be carried outside the controlled area without reason.
 - (8) notices required to prevent radiation hazards shall be posted at clearly visible locations in the storage facility.
 - (9) measures to prevent the entry of persons into the controlled area without reason shall be taken and, if persons other than the radiation workers enter the controlled area, they shall be forced to follow instructions by radiation workers.
2. Beyond what is pursuant to the provisions of the following Items, provisions in Article 15 Paragraph 1 Item 3 and in items 2, 4 through 6 and 7 through 9 of the preceding Paragraph apply mutatis mutandis to the technical standards provided for in the NRA Ordinance referred to in Article 16 Paragraph 1 of the Act pertaining to a permission waste management operator. In this case, the terms “radioisotopes or radiation generating apparatuses” in Article 15 Paragraph 1 Item 3 (b) are replaced with “radioisotopes, etc.”, the terms “storage facility” and “radioisotopes” in Item 2 of the preceding Paragraph are, respectively replaced with “waste storage facility” and “radioisotopes, etc.”, the terms “radioisotopes that could contaminate air” and “storage facility” in Item 4 in the same Paragraph are, respectively replaced with “radioisotopes, etc. that could contaminate air” and “waste storage facility”, the terms “storage facility” and “radioisotopes” in Item 5 of the same Paragraph are, respectively replaced with “waste storage facility” and “radioisotopes etc.”, the terms “storage facility”, “liquid radioisotopes” and “solid radioisotopes” in Item

6 of the same Paragraph are, respectively replaced with “waste storage facility”, “liquid radioisotopes, etc.,” and “solid radioisotopes, etc.,” and the term “storage facility” in Item 8 of the same Paragraph is replaced with “waste storage facility:”:

- (1) radioisotopes, etc. shall be put in containers and stored in a storage room or storage box (or, in cases where sealed radioisotopes, etc. are stored in containers of fireproof structure, waste storage facility);
- (2) measures to prevent storage box (or, in cases where sealed radioisotopes, etc. are stored in a container of fireproof structure, the concerned container) from being carried without reason while radioisotopes are stored therein shall be implemented.

(Standards for Transport in a Place of Business, etc.)

Article 18. The technical standards provided for in the NRA Ordinance referred to in Article 17 Paragraph 1 of the Act are as follows:

- (1) in cases where radioisotopes, etc. are transported, they shall be sealed in containers; provided, however, that this does not apply to the following cases:
 - (a) the cases where contaminated objects (limited to those in which the concentration of radioisotopes contained in the concerned contaminants does not exceed the concentration specified by the NRA) are transported, for which measures to prevent radiation hazards specified by the NRA, including prevention of dispersion or leakage of radioisotopes, have been implemented;
 - (b) the cases where such contaminated objects, being extremely difficult to be transported sealed in a container for a large machine, etc. with the measures to prevent radiation hazards which have been authorized by the NRA, are transported.
- (2) the container referred to in the preceding Item shall conform to the following standards:
 - (a) each side of the rectangular parallelepiped circumscribing the container shall be not less than 10 cm;
 - (b) shall be easily and safely handled;
 - (c) there shall be no likelihood of cracking or breakage due to the anticipated changes in temperature and internal pressure, vibratory motion, etc. during transport.
- (3) it shall be ensured that the dose equivalent rates, on the surface of and at a distance of 1 m from the surface of, both the container with radioisotopes, etc. sealed therein (or, in cases where contaminated objects prescribed in Item 1 (a) or (b) pursuant to the provisions in the proviso in the same Item, are transported without being sealed in a container, the concerned contaminated objects; hereinafter referred to as “package”), and any vehicles with the concerned container loaded thereon or stored therein, or other machines or equipment (hereinafter referred to as “vehicle, etc.” in this Article) used to transport radioisotopes, etc. are kept not exceeding the corresponding dose equivalent rates specified by the NRA, respectively, and it shall be also ensured that the density of radioisotopes on the surface of the package is kept not exceeding one-tenth of the surface density limit.
- (4) the packages shall be loaded on the vehicle, etc. so that the safety of the packages is not impaired due to shifting, overturning, or falls during transport.
- (5) the packages must not be mix-loaded on the same vehicle, etc. with hazardous materials specified by the NRA.
- (6) access for persons and vehicles other than those engaged in transport shall be restricted by means of installing

sign and posting security guards along the route for transport of packages.

- (7) in cases where packages are transported with the use of a vehicle, the vehicle concerned shall drive at a slow speed.
 - (8) persons with considerable knowledge and experience concerning the handling of radioisotopes, etc., shall accompany the transport of packages and provide supervision necessary for prevention of radiation hazards.
 - (9) sign specified by the NRA shall be affixed at appropriate places both of the package (or, in cases where the package is stored in a container (in this case, it means a vehicle, etc. that have been built in order to transport loads without need of transfer of the load on the way of transport, that have the structure and strength capable of withstanding repeated use, and the mechanical mechanism for loading and unloading or a mechanism to enable fixation onto a vehicle, and that are of closed structure; the same applies hereinafter), the concerned container) and of the vehicles used for the transport.
2. In cases where it is difficult to take measures, in whole or in part, set forth in Item 2 or 3 of the preceding Paragraph, measures granted authorization by the NRA may be taken in lieu of measures set forth in Item 2 or 3 of the same Paragraph. In this case, the dose equivalent rate on the surface of the concerned package must not exceed the dose equivalent rate specified by the NRA.
 3. The provisions in Items 1 through 3 and Items 6 through 9 of Paragraph 1 do not apply to transport within the controlled area.
 4. The provision of Paragraph 1 does not apply to the case where radioisotopes, etc. are transported within usage facilities, waste repacking facilities, storage facilities, waste storage facilities or waste management facilities and the case where the time of transport is extremely short and there is no likelihood of radiation hazards.
 5. In cases where measures required for prevention of radiation hazards have been taken according to the technical standards for transport prescribed in Articles 18-3 through 18-13 and in Articles 3 through 18 of the Rules on the Vehicular Transport of Radioisotopes, etc., (Transport Ministry Ordinance No. 33 of 1977; hereinafter referred to as “Regulations for Vehicle Transport”) concerning the transport of packages, the permission or notification user or permission waste management operator may, notwithstanding the provisions in Paragraph 1, transport the concerned packages within the area of factory or place of business, etc.

(Technical Standards Pertaining to the Packages Transported by Means of Vehicle Transport)

Article 18-2. The technical standards provided for in the NRA Ordinance, referred to in Article 18 Paragraph 1 of the Act (limited to those pertaining to the packages transported by means of vehicle transport (that is, transport outside the factory or place of business by means of railway, tram, cableway, trackless train, vehicle and light vehicle; the same applies hereinafter)) are as pursuant to the provisions of the following Article through Article 18-12.

(Transport of Radioisotopes, etc. as Radioactive Package)

Article 18-3. Radioisotopes, etc. (excluding materials that do not correspond to Article 2 Item 1 (g) (1) of the Regulations for the Carriage and Storage of Dangerous Goods by Ship (Transport Ministry Ordinance No. 30 of 1957) (except for those specified by the NRA); hereinafter the same applies to Articles until Article 18-13) shall be transported as the kind of radioactive packages (that is, containers containing radioisotopes, etc. or objects in which

radioisotopes, etc. are wrapped; the same applies hereinafter) set forth in the following Items concerned, respectively, in accordance with the following classification of radioisotopes, etc.:

- (1) Type L package: radioisotopes, etc., specified by the NRA as those with an extremely small risk;
 - (2) Type A package: radioisotopes, etc., (excluding those set forth in the preceding Item) with radioactivity not exceeding the quantity specified by the NRA;
 - (3) Type BM or type BU package: radioisotopes, etc., (excluding those set forth Item 1) with radioactivity exceeding the quantity specified by the NRA in the preceding Item.
2. Notwithstanding the provisions in the preceding Paragraph, radioisotopes, etc. of low radioactivity concentrations that are specified by the NRA as of small risk (hereinafter referred to as “low specific activity radioisotopes”) as well as objects whose surface is contaminated with radioisotopes and are specified by the NRA as of small risk (hereinafter referred to as “surface-contaminated objects”) may be transported as Type IP-1, Type IP-2 or Type IP-3 package in accordance with the classification specified by the NRA.
3. The Type L, Type A, Type BM, Type BU, Type IP-1, Type IP-2 and Type IP-3 packages set forth in the preceding two Paragraphs shall conform to technical standards prescribed in Articles from the following Article through Article 18-10, respectively.

(Technical Standards Pertaining to Type L Package)

Article 18-4. The technical standards pertaining to Type L package are as set forth in the following Items:

- (1) Type L package shall be easily and safely handled;
- (2) there shall be no likelihood of cracking or breakage due to anticipated changes in temperature and internal pressure, vibratory motion, etc. during transport;
- (3) there shall be no unnecessary protuberances on its surface and contamination on it shall be easily removed;
- (4) there shall be no likelihood of a hazardous physical interaction or chemical reaction to occur between materials or between the material and radioisotopes, etc. that are stored or sealed therein;
- (5) the measures to ensure that valves would not be mistakenly operated shall be taken;
- (6) the labels “RADIOACTIVE” (in Japanese or English) shall be attached at a clearly visible position of the package at the time the package is opened; provided, however, that this does not apply to the case provided by the NRA;
- (7) the maximum value of the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) on the surface must not exceed $5 \mu\text{Sv/h}$;
- (8) the surface density of radioisotopes must not exceed the density specified by the NRA (hereinafter referred to as “surface density of package”).

(Technical Standards Pertaining to Type A Package)

Article 18-5. The technical standards pertaining to Type A package are as set forth in the following Items:

- (1) standards pursuant to the provisions of Items 1 through 5 and 8 of the preceding Article.
- (2) each side of the rectangular parallelepiped circumscribing the container shall be not less than 10 cm.
- (3) measures such as attachment of hardly broken seal, etc. shall be taken so that the package is not opened without reason and it is easily perceived in the case where the package is opened.

- (4) cracking, breakage, etc. must not occur on the components of the package at a temperature ranging -40°C through 70°C ; provided, however, that this does not apply to the case where anticipated temperature range during transport may be specified.
- (5) there must not be any leak of radioisotopes in the case where the ambient pressure is 60 kPa.
- (6) in cases where liquid radioisotopes, etc. are contained in the package, the package shall conform to the following requirements:
- (a) the package shall be installed with absorbent material capable of absorbing more than twice the volume of radioisotopes, etc. that the container may contain or a sealing system (that is, a system having the component for which sealing measures to prevent leakage of radioisotopes are implemented; the same applies hereinafter) consisting of two-fold sealing parts; provided, however, that this does not apply to the case where a container granted approval pursuant to the provision of Article 18 Paragraph 3 of the Act is used (limited to the container pertaining to Type BM package or Type BU package);
 - (b) the package shall have an appropriate space to deal with the change caused by the temperature of radioisotope, etc. and behavior of radioisotope, etc. during transport or at the time of injection into the container.
- (7) the maximum value of the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) on the surface must not exceed 2 mSv/h; provided, however, that the maximum value of the 1-cm dose equivalent rate on the surface must not exceed 10 mSv/h for the radioactive package that is transported as exclusive loading (that is, the method of loading by which a freight car of railway, tram or trolley, cableway, vehicle, light vehicle or container with each side of the rectangular parallelepiped circumscribing being not less than 1.5 m (limited to that having internal volume exceeding 3 m^3) is exclusively used by a single consignor and loading and unloading of packages is carried outside in accordance with the directions of the consignor or consignee; the same applies hereinafter) and has been granted approval by the NRA not detrimental on safety among packages that conform to the technical standards for transport prescribed in Article 4 Paragraph 2 and Article 18 Paragraphs 3 Items 1 and 2 of Regulations for Vehicle Transport.
- (8) the maximum value of the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) at a distance of 1 m from the surface of the package (for the radioactive package that uses a container or a tank (that is, a container that contains gas, liquid or solid; the same applies hereinafter) as a container and is transported not as exclusive loading, dose equivalent rate obtained by multiplying the 1-cm dose equivalent rates at a distance of 1 m from the surface by the factor specified by the NRA) must not exceed $100\ \mu\text{Sv/h}$; provided, however, that this does not apply to the case where radioactive package is transported as exclusive loading and has been granted approval by the NRA not detrimental on safety.
- (9) those other than documents or other articles necessary for use, etc. of radioisotopes (limited to those that are unlikely to impair the safety of radioactive packages) must not be contained nor packed.
- (10) in cases where the package is put under general inspection conditions pertaining to the Type A package specified by the NRA, the package shall conform to the following requirements:
- (a) radioisotopes must not leak out;
 - (b) the maximum value of the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) on the surface must not significantly increase and must not exceed 2 mSv/h (in the case

where corresponding to the proviso of Item 7, 10 mSv/h).

- (11) in cases where the package is put under additional inspection conditions pertaining to the Type A package in which liquid or gaseous radioisotopes, etc. specified by the NRA (excluding gaseous tritium and rare gas) are received or packed, radioisotopes must not leak out.

(Technical Standards Pertaining to Type BM Package)

Article 18-6. The technical standards pertaining to Type BM package are as set forth in the following Items:

- (1) standards pursuant to the provisions of Items 1 through 9 of the preceding Article; provided, however, that requirements pursuant to the provisions of Item 6 (a) of the same Article do not apply.
- (2) in cases where the package is put under general inspection conditions pertaining to Type BM package specified by the NRA, the package shall conform to the following requirements:
 - (a) requirement in Item 10 (b) of the preceding Article;
 - (b) the amount of leakage of radioisotopes per one hour must not exceed the quantity specified by the NRA;
 - (c) the surface temperature of the package in the shade must not exceed 50°C (for radioactive package transported as exclusive loading, the temperature of the surface that may be easily accessed by persons during transport (for radioactive package installed with proximity prevention frame on its surface, the surface of the proximity prevention frame) must not exceed 85 °C);
 - (d) The surface density of radioisotopes of the package must not exceed the surface density of package.
- (3) in cases where the package is put under special inspection conditions pertaining to Type BM package specified by the NRA, the package shall conform to the following requirements:
 - (a) the maximum value of the 1-cm dose equivalent rates (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) at a distance of 1 m from the surface of package must not exceed 10 mSv/h;
 - (b) the amount of leakage of radioisotopes per one week must not exceed the value specified by the NRA.
- (4) there shall be no likelihood of cracking or breakage of the package in the ambient temperature range from the lowest possible temperature anticipated during transport to 38 °C.
- (5) in cases where the radioactive package containing or packing radioisotopes, etc. having radioactivity of the quantity exceeding that specified by the NRA is put under the inspection condition specified by the NRA, the sealing system must not be damaged; provided, however, that this does not apply to the case where the package has been granted approval by the NRA not detrimental on safety.

(Technical Standards Pertaining to Type BU Package)

Article 18-7. The technical standards pertaining to Type BU package are as set forth in the following Items:

- (1) standards pursuant to the provisions of Article 18-5 Items 1 through 3, the main clause of Item 4, Item 5, Item 6 (b) and Items 7 through 9 and the main clause of Item 5 of the preceding Article;
- (2) in cases where the package is put under general inspection conditions pertaining to Type BU package specified by the NRA, the package shall conform to the requirements pursuant to the provisions of Item 2 (a) through (d) of the preceding Article;
- (3) in cases where the package is put under special inspection conditions pertaining to Type BU package specified by

the NRA, the package shall conform to the requirements pursuant to the provisions of Item 3 (a) and (b) of the preceding Article;

- (4) there shall be no likelihood of cracking or breakage of package in the ambient temperature range from -40 °C to 38 °C;
- (5) the package shall be of structure that enables filtration of internal gas or cooling of radioisotopes, etc. even without using filter or mechanical cooling devices;
- (6) the maximum operating pressure (that is, the maximum pressure (it means, gauge pressure) of gas annually generated inside the sealing system of the radioactive package in cases where special measures such as exhausting and cooling are not taken in the ambient temperature condition anticipated during transport and under direct sunlight) must not exceed 700 kPa.

(Technical Standards Pertaining to Type IP-1 Package)

Article 18-8. The technical standards pertaining to Type IP-1 package are those pursuant to the provisions of Article 18-5 Items 1, 2, 7 and 8.

(Technical Standards Pertaining to Type IP-2 Package)

Article 18-9. The technical standards pertaining to Type IP-2 Package (excluding those of which the vessel receiving radioisotopes, etc. is a container, tank or metallic intermediate container (that is, the container among metallic containers with the structure and strength withstanding the stress generated during transport, having an internal volume of 3 m³ or less and conforming to standards specified by the NRA; the same applies hereinafter)) are as set forth in the following Items:

- (1) standards pursuant to the provisions of the preceding Article;
 - (2) in cases where the package is put under general inspection conditions pertaining to IP-2 package specified by the NRA, the package shall conform to the requirements pursuant to the provisions of Article 18-5 Item 10 (a) and (b).
2. The technical standards pertaining to Type IP-2 package (limited to the package of which vessel receiving radioisotopes, etc. (limited to cases where the received radioisotopes, etc. are solid) is a container, tanks or metallic intermediate container) are as set forth in the following Items:
- (1) standards pursuant to the provisions of the preceding Article;
 - (2) standards pursuant to the provisions of Item 2 of the preceding Paragraph or equivalent standards authorized by the NRA.

(Technical Standards Pertaining to Type IP-3 Package)

Article 18-10. The technical standards pertaining to Type IP-3 package (excluding the package of which the vessel receiving radioisotopes, etc. is a container, tanks or metallic intermediate container) are as set forth in the following Items:

- (1) standards pursuant to the provisions of Article 18-5 Items 1 through 8; provided, however, that the requirements pursuant to the provisions of Item 6 (a) of the same Article do not apply;
- (2) where the package is put under general inspection conditions pertaining to Type IP-3 package specified by the

- NRA, the package shall conform to the requirements pursuant to the provisions of Article 18-5 Item 10 (a) and (b).
2. The technical standards pertaining to Type IP-3 package (limited to the package of which the vessel receiving radioisotopes, etc. (limited to cases where the received radioisotopes, etc. are solid) is a container, tank or metallic intermediate container) are as set forth in the following Items:
- (1) standards pursuant to the provisions of Article 18-8;
 - (2) the standards pursuant to the provisions of Article 18-5 Items 3 through 5, conformity to the requirements pursuant to the provisions of Item 6 (b), and standards pursuant to the provisions of Item 2 of the preceding Paragraph or equivalent standards specified by the NRA.

(Transport of Radioisotopes of Low Specific Activity and Surface-Contaminated Object That Can Be Transported as Non-Radioactive Package)

Article 18-11. Notwithstanding the provision of Article 18-3, radioisotopes of the low specific activity and surface-contaminated objects set forth in the following Items may be transported as the package deemed not to be radioactive pursuant to the provisions of Paragraphs 1 and 2 in the same Article:

- (1) radioisotopes of low specific activity specified by the NRA which conform to the following requirements:
 - (a) in normal conditions of transport, measures to prevent radioisotopes from being easily spread or leaked shall be taken;
 - (b) radioisotopes of low specific activity shall be transported as exclusive loading.
- (2) Surface-contaminated objects that are specified by the NRA which conform to the following requirements:
 - (a) requirements set forth in (a) of the preceding Item;
 - (b) surface-contaminated objects shall be transported as exclusive loading; provided, however, that this does not apply to the case where the density of the radioisotopes on the surface does not exceed the density specified by the NRA.

(Transport by Means of Special Measures)

Article 18-12. In cases where the transport pursuant to the provisions in Article 18-3 or the preceding Article is extremely difficult, and measures necessary for ensuring safe transport are taken, and in addition approval has been granted by the NRA that the safety of transport will not be impaired even if such transport is conducted without complying with these provisions, packages may be transported without complying with these provisions. In this case, the maximum value of the 1-cm dose equivalent rate (identical to the “ambient dose equivalent rate” defined by ICRU at $d = 10$ mm) on the surface of the package concerned must not exceed 10 mSv/h.

(Technical Standards Pertaining to Simplified Transport)

Article 18-13. The technical standards provided for in the NRA Ordinance, referred to in Article 18 Paragraph 1 of the Act (limited to standards pertaining to simplified transport (that is, transport outside the place of business, etc. except for vehicle transport (excluding transport by ship or aircraft); the same applies hereinafter)) are as set forth in the following Items, beyond what is pursuant to the provisions of Articles from Article 18-3 through the preceding Article:

- (1) the maximum value of the 1-cm dose equivalent rate on the surface of the transport machine or tool (limited to those pertaining to simplified transport; hereinafter referred to as “transport apparatus”) that is loaded with or storing radioisotopes, etc. to be transported pursuant to the provisions in Articles 18-3, 18-11 or the preceding Article (hereinafter referred to as “package”) must not exceed 2 mSv/h, and the maximum value of the 1-cm dose equivalent rate at a distance of 1 m from the surface of the transport apparatus must not exceed 100 μ Sv/h.
- (2) packages (excluding Type L package; hereinafter the same applies to this Item and the following Item) shall be loaded onto the transport apparatus so that safety is not impaired due to shifting, overturning, or falls during transport.
- (3) packages must not be mix-loaded onto the same transport apparatus with hazardous materials specified by the NRA.
- (4) in cases where two or more packages (limited to those of which the maximum value of the 1-cm dose equivalent rate on the surface exceeds 5 μ Sv/h; hereinafter the same applies to this Item) are transported by loading them onto or receiving them in a single transport apparatus, the number of the packages concerned to be loaded or contained shall be limited, pursuant to the provisions specified by the NRA for the purpose of prevention of radiation hazards.
- (5) in cases where the package (excluding Type L package; hereinafter the same applies to this Item) is transported, the measures set forth in the following Items shall be taken:
 - (a) the person engaged in transport of the package concerned shall carry documents that describe the method of handling the package, measures to be taken at the time of occurrence of an accident, and other important notices concerning the transport;
 - (b) the person engaged in transport of the package concerned shall carry fire extinguishers, radiation measuring instruments, protective equipment, and other tools and devices required at the time of occurrence of an accident;
 - (c) at places where persons enter in normal conditions, the package or transport apparatus must not be placed and handling of packages including loading and unloading must not be conducted; provided, however, that this does not apply to the case where measures such as roping off and posting of sign are taken.
- (6) in cases where Type BM package is transported, the following measures shall be taken:
 - (a) a person holding the first-class radiation protection supervisor certificate, or the second-class radiation protection supervisor certificate, or having equivalent knowledge and experience, shall be forced to accompany and attend to loading, unloading, etc., and thereby to engage in radiation management of radioisotopes, etc. and exposure management of persons engaged in transport of radioisotopes, etc., and to supervise other activities necessary for safety management pertaining to radioisotopes, etc.;
 - (b) time and route with heavy traffic shall be avoided.
- (7) sign or labels specified by the NRA shall be attached to the package.
- (8) the radiation dose to radiation workers must not exceed the effective dose limit and equivalent dose limit.

(Radioisotopes, etc. Requiring Confirmation Concerning Transport)

Article 18-14. The radioisotopes, etc. provided for in the NRA Ordinance, referred to in Article 16 of the Cabinet Order are the radioisotopes, etc. prescribed in Article 18-3 Paragraph 1 Item 3 (excluding those transported pursuant to the provisions in Article 18-3 Paragraph 2 and Article 18-12).

(Application for Confirmation Concerning Transport)

Article 18-15. Any person intending to be granted package confirmation pursuant to the provision of Article 18 Item 2 of the Act (excluding confirmation by the registered package confirmation organization) shall submit an application form for confirmation using the Appended Form 18, appending the following documents to the NRA:

- (1) instruction documents concerning radioisotopes, etc. to be transported;
 - (2) instruction documents concerning structure, material and manufacturing method (hereinafter referred to as “container design”) of the container that receives radioisotopes, etc. referred to in the preceding Item (hereinafter referred to as “container” in this Article and Articles 18-17 through 18-20) as well as safety of the radioactive package in cases where the concerned radioisotopes, etc. are received in the concerned container;
 - (3) instruction documents proving that the container has been manufactured in accordance with the container design;
 - (4) instruction documents proving that the container is maintained to comply with the container design;
 - (5) instruction documents concerning inspection of radioactive package prior to transport;
 - (6) for simplified transport, instruction documents concerning transport method of radioactive package and its safety.
2. In cases where the document that proves the confirmation by Minister of Land, Infrastructure and Transport, pursuant to the provision of Article 87 Paragraph 1 of the Regulations for the Carriage and Storage of Dangerous Goods by Ship (Transport Ministry Ordinance No. 30 of 1957) has been submitted, submission of the concerned documents set forth in Items of the preceding Paragraph may be omitted.
3. In cases where radioisotopes, etc. are transported using the container that has been granted approval referred to in Article 18 Paragraph 3 of the Act, submission of documents referred to in Items 2 and 3 of Paragraph 1 may be omitted.
4. Any person intending to be granted package confirmation by the registered package confirmation organization referred to in Article 18 Paragraph 2 of the Act shall submit the application form for confirmation using the Appended Form 18, appending the documents set forth in Article 18 Paragraph 1 to the concerned registered package confirmation organization.

(Issuance of Transport Confirmation Certificate)

Article 18-16. The Nuclear Regulation Authority or the registered package confirmation organization, when it has conducted the confirmation prescribed in Article 18 Paragraph 2 of the Act, issues a transport confirmation certificate.

(Application for Approval for a Container)

Article 18-17. Application for approval pursuant to the provision of Article 18 Paragraph 3 of the Act shall be submitted with an application form for approval for a container using the Appended Form 19.

2. The application form referred to in the preceding Paragraph shall be appended by the following documents:
- (1) instruction documents concerning radioisotopes, etc. that are planned to be transported by use of a container;
 - (2) instruction documents concerning the container design and safety of radioactive package in the case where radioisotopes, etc. are received in the concerned container
 - (3) instruction documents proving that the container is manufactured to comply with the container design;

- (4) instruction documents proving that the container is maintained to comply with the container design referred to in Item 2.
3. For a vessel that may be used as a container by separating a part of a container, application referred to in Paragraph 1 for each part of the concerned container may be submitted. In this case, the instruction document referred to in Items 3 and 4 of the preceding Paragraph shall be the document for the part of the container pertaining to the application concerned.
4. When the NRA finds that, in cases where radioisotopes, etc. referred to in Paragraph 2 Item 1 are received in the concerned container of radioactive package, matters concerning the container design and safety conform to the technical standards pursuant to the provisions of Articles 18-3 through 18-12, submission of the concerned documents set forth in Paragraph 2 Item 2 may be omitted, pursuant to the provisions by the NRA.

(Issuance of Container Approval Certificate)

Article 18-18. The Nuclear Regulation Authority, when it has granted approval for a container prescribed in Article 18 Paragraph 3 of the Act, issues a container approval certificate describing the matters set forth in the following Items:

- (1) name or title and address of the applicant and, if the applicant is a juridical person, the name of a representative;
- (2) name of the container;
- (3) registration number of the approved container;
- (4) dimensions of outline and weight of the container;
- (5) type of radioactive package;
- (6) specifications of radioisotopes, etc. contained;
- (7) expiration period for use as approved container;
- (8) matters concerning maintenance of the container and handling of radioactive package.

(Renewal of Expiration Period for Use As Approved Container)

Article 18-19. A person who has received the issue of container approval certificate pursuant to the provision of the preceding Article may be granted renewal of the expiration period for use of the approved container after proving that the container concerned is maintained to comply with the concerned container design.

2. Any person intending to be granted renewal of the expiration period referred to in the preceding Paragraph shall submit the application form for renewal of expiration period for use as of the approved container using the Appended Form 20, appending instruction documents proving that the container concerned is maintained to comply with the container design to the NRA.
3. A person who has been granted renewal of the expiration period referred to in Paragraph 1 shall submit the container approval certificate without delay and have it rewritten.

(Notification of Change of Container Approval Certificate, etc.)

Article 18-20. A person who has been issued the container approval certificate pursuant to the provisions in Article 18-18, when having made any change of matters set forth in Item 1 of the same Article, shall submit a notification form using the Appended Form 21, appending the concerned container approval certificate to the NRA within 30 days

from the date of the change and have it rewritten.

2. A person who has been issued the container approval certificate pursuant to the provisions in Article 18-18, when having terminated the use of the approved container, shall submit a notification form using the Appended Form 22, appending the concerned container approval certificate to the NRA within 30 days from the date of termination of use.

(Standards for Waste Management)

Article 19. The provisions in Article 15 Paragraph 1 Items 3, 4 through 10, and 11 through 12 apply mutatis mutandis to the technical standards pertaining to the permission user and permission waste management operator provided for in the NRA Ordinance, referred to in Article 19 Paragraph 1 of the Act (excluding those pertaining to Paragraph 3), beyond what is pursuant to the provisions of the following Items. In this case, the terms “radioisotopes or radiation generating apparatuses” in (b) of Item 3 of the same Paragraph are replaced with “radioisotopes, etc.”, the phrase “places where persons regularly enter in the workroom or a room where a radiation generating apparatus is used” in Item 4 of the same Paragraph is replaced with “places where persons regularly enter in a waste management workroom”, the term “workroom” in provisions in Items 5 through 8 of the same Paragraph is replaced with “waste management workroom”, the term “objects contaminated with radioisotopes” in Item 9 of the same Paragraph is replaced with “contaminated object”, and the term “workroom” is replaced with “waste management workroom”, and the terms “usage facility or controlled area” in Item 11 of the same Paragraph are replaced with “waste management facility”:

- (1) radioisotopes, etc. in the form of the gaseous state shall be discharged after being purified or exhausted in the exhaust equipment.
- (2) in cases where discharging gaseous radioisotopes, etc. by the method referred to in the preceding Item, discharge shall be conducted as pursuant to the provisions of the following Items:
 - (a) in cases where discharge is conducted through the exhaust equipment referred to in Article 14-11 Paragraph 1 Item 4 (c) i, the concentration of radioisotopes in the discharged air at the exhaust port of the equipment concerned must not exceed the concentration limit specified by the NRA;
 - (b) in cases where discharge is conducted through the exhaust equipment referred to in Article 14-11 Paragraph 1 Item 4 (c) ii, the concentration of radioisotopes in the air outside the boundary of factory or place of business, etc. must not exceed the concentration limit specified by the NRA, by monitoring the concentration of radioisotopes in the discharged air;
 - (c) in cases where discharge is conducted through the exhaust equipment referred to in Article 14-11 Paragraph 1 Item 4 (c) iii, the radiation dose outside the boundary of factory or place of business, etc. must not exceed the radiation dose limit specified by the NRA, by monitoring the quantity and concentration of radioisotopes in the discharged air.
- (3) if intending to remove radioisotopes, etc. deposited on the exhaust equipment referred to in Item 1, the facility or tools and protective equipment such as mat, pan or absorbent shall be used for preventing spread of contamination by the radioisotopes.
- (4) liquid radioisotopes, etc. shall be discharged by any of the methods set forth in the following Items:

- (a) shall be purified or drained in the drainage equipment;
 - (b) shall be stored for disposal in the predisposal equipment, after being sealed in the container or solidified in the container by using solidification materials such as concrete in the solidification equipment;
 - (c) shall be incinerated in the incinerator;
 - (d) shall be solidified by using solidification materials such as concrete in the solidification equipment
- (5) in cases where discharging liquid radioisotopes, etc. by the method referred to in (a) of the preceding Item, discharge shall be conducted as pursuant to the provisions of the following Items:
- (a) in cases where discharging is conducted in the drainage equipment referred to in Article 14-11 Paragraph 1 Item 5 (a) i, the concentration of radioisotopes in the drain at the drain port of the concerned equipment must not exceed the concentration limit specified by the NRA;
 - (b) in cases where discharging is conducted in the drainage equipment referred to in Article 14-11 Paragraph 1 Item 5 (a) ii, the concentration of radioisotopes in the drain at the boundary of the factory or place of business, etc. must not exceed the concentration limit specified by the NRA, by monitoring the concentration of the radioisotopes in the drain;
 - (c) in cases where discharging is conducted in the drainage equipment referred to in Article 14-11 Paragraph 1 Item 5 (a) iii, the radiation dose outside the boundary of the factory or place of business, etc. must not exceed the radiation dose limit specified by the NRA, by monitoring the quantity and concentration of radioisotopes in the drain.
- (6) in cases where, accompanying the waste management conducted by the method referred to in Item 4 (a), waste liquid treatment or removal of radioisotopes, etc. such as deposit and sediment on the drainage equipment referred to in (b) of the same Item is intended, the facility or tools and protective equipment such as mat, pan or absorbent shall be used for preventing spread of contamination by radioisotopes.
- (7) in cases where, accompanying the waste management conducted by the method referred to in Item 4 (b) , liquid radioisotopes, etc. shall be sealed in a container, and the concerned container shall conform to the standards set forth in the following Items:
- (a) the container shall be of structure that liquid hardly spills out;
 - (b) the container shall be made of the material hardly permeated by liquid.
- (8) in cases where, accompanying the waste management conducted by the method referred to in Item 4 (b), liquid radioisotopes, etc. are sealed in a container and stored for waste disposal in the predisposal equipment, if any incidents such as cracking or breakage of the concerned container might occur, equipment or tools such as catch pan or absorbent shall be used to prevent the spread of contamination by radioisotopes.
- (9) in cases where, accompanying the waste management conducted by the method referred to in Item 4 (b), liquid radioisotopes, etc. are solidified in a container, the concerned container that has been integrated with the solidified liquid radioisotopes, etc. shall prevent dispersion or leakage of the liquid radioisotopes, etc..
- (10) in cases where the waste management is conducted by the method referred to in Item 4 (b), solidification of liquid radioisotopes, etc. in a container shall be conducted in a waste management workroom.
- (11) in cases where waste management is conducted by the method referred to in Item 4 (b), the work to remove the residue of incinerated liquid radioisotopes, etc. from an incinerator shall be conducted in a waste management

workroom.

- (12) in cases where waste management is conducted by the method referred to in Item 4 (d), the work to solidify liquid radioisotopes, etc. by using solidification materials such as concrete shall be conducted in a waste management workroom.
- (13) the waste of solid radioisotopes, etc. shall be managed by any of the following methods:
- (a) shall be incinerated in an incinerator;
 - (b) shall be sealed in a container or solidified in a container by using solidification materials such as concrete at a solidification equipment, and then stored for disposal in the predisposal equipment;
 - (c) in cases corresponding to the proviso of Article 14-11 Paragraph 1 Item 8 (c) , shall be stored for disposal in the predisposal equipment;
 - (d) “radioisotopes for positron emission tomography device” or shortly as “radioisotopes, etc. for PET” shall be sealed and marked with indication so that materials other than radioisotopes, etc. for positron emission tomography must not be mixed in or attached, and radioisotopes, etc. for PET shall be stored for disposal in a controlled area over the period exceeding the period specified by the NRA as the period of time that ensures the number of atoms of radioisotopes for PET to be less than unity;
 - (e) shall be disposed of by waste burial (this operation shall be implemented only by permission waste management operators granted the permission pertaining to the waste burial).
- (14) the provision of Item 11 apply mutatis mutandis to waste management by the method referred to in (a) of the preceding Item.
- (15) the provisions in Items 9 and 10 apply mutatis mutandis to waste management by the method referred to in Item 13 (b).
- (16) radioisotopes, etc. for PET that are stored for disposal pursuant to the provision of Item 13 (d) must not be regarded as radioisotopes nor objects contaminated with radioisotopes, after the period of time specified by the NRA referred to in (d) of the same Item has progressed.
- (17) the waste management by the method referred to in Item 13 (e) shall be conducted as pursuant to the provisions of the following provisions:
- (a) burial of only the wastes that conform to the following standards shall be conducted:
 - i the density of radioactivity in wastes to be buried must not exceed the maximum radioactivity density described in the application form pertaining to permission of waste management operation;
 - ii the characteristics of burial wastes including strength and sealing performance shall conform to matters described in the application form for the permission of waste management operation;
 - iii in cases where the dose equivalent rate on the surface of burial wastes exceeds limit of the dose equivalent rate specified by the NRA, the sign specified by the NRA shall be attached;
 - iv for radioactive wastes solidified in a container or other wastes specified by the NRA, the sign indicating radioactive wastes shall be attached at a clearly visible locations on the surface of burial wastes by the method that makes the sign hardly erasable;
 - v concerning the burial wastes, measures shall be taken which are able to be collated with matters described in the application form referred to in Paragraph 1 Item 1 of the following Article.

- (b) burial and soil covering shall be conducted pursuant to the following provisions:
- i by means of burial, the total quantity of radioactivity of each kind of radioisotopes in wastes buried in the waste burial site must not exceed the total quantity of radioactivity of each kind of radioisotopes listed in the application form pertaining to permission of waste management operation;
 - ii before commencement of burial, water in the location of waste burial site where burial disposal is to be conducted shall be removed, and measures shall be taken to prevent entry of rainwater, etc. in the concerned location during burial;
 - iii for burial of wastes not solidified in a container, if radioisotopes are likely to be dispersed outside the waste burial site, measures to prevent dispersion shall be taken;
 - iv in cases where circumferential walls are installed, the concerned circumferential walls shall be inspected as necessary during burial disposal, and if it is found that there is a likelihood of destruction of the concerned circumferential wall or leakage of radioisotopes, measures required for preventing destruction of the circumferential wall or leakage of radioisotopes shall be taken;
 - v the waste burial site shall be refilled dirt, etc. so that vacant space is not left after completion of burial disposal at the concerned site;
 - vi the waste burial site where burial disposal has been completed shall have the surface covered with dirt, etc. of lower permeability than that of the soil surrounding the concerned waste burial site, so that the buried wastes and equipment installed in the waste burial site do not easily come out.
- (c) the waste burial site shall be managed pursuant to the following provisions; provided, however, that this does not apply to the case where the measures referred to in Article 4-2 Paragraph 2 item 7 (b) of the Act are not taken after being granted the permission referred to in Article 4-2 Paragraph 1 of the Act or the permission of change referred to in Article 11 Paragraph 2:
- i on the waste burial site where burial disposal is completed, the notice board or other piece of equipment indicating the fact that the site is a waste burial site and other matters specified by the NRA shall be installed and kept clearly visible, and if a change is made to the notice to be indicated, necessary measures including rewriting shall be immediately taken;
 - ii in order to keep the dose prescribed in Article 14-12 Item 2 not exceeding the dose limit specified by the NRA referred to in the same Item, necessary measures including restriction of entry of persons to the waste burial site by methods such as installation of fence around the waste burial site shall be taken;
 - iii in cases where circumferential walls are installed after completion of burial disposal, leakage of radioisotopes out of the concerned circumferential wall shall be monitored and, if the occurrence of leakage is confirmed, measures necessary for preventing leakage of radioisotopes including repair of the concerned circumferential wall shall be immediately taken;
 - iv equipment capable of sampling groundwater shall be installed at locations where the influence of burial wastes on the quality of groundwater at the circumference of the waste burial site may be judged, and the measurement shall be conducted on the concentration of radioisotopes and other necessary items of the groundwater sampled from the concerned equipment pursuant to the provisions specified by the NRA;
 - v in cases where, from the result of the measurement referred to in iv, it is confirmed that there is a likelihood

of exceeding the dose limit specified by the NRA, pursuant to the provisions of Article 14-12 Item 2 or any deterioration of water quality is recognized (excluding cases where the cause of those incidents is clearly out of the waste burial site), necessary measures shall be taken as well as those to prevent the radiation dose from exceeding the dose limit specified by the NRA.

2. The provisions in Items 1 through 12 in the preceding Paragraph do not apply to the case prescribed in Article 15 Paragraph 2.
3. Beyond what is prescribed in the following Items, the provisions in Article 15 Paragraph 1 Item 1-2, Item 3, Items 4 through 10 and Item 12 apply mutatis mutandis to the technical standards (limited to those pertaining to repacking) provided for in the NRA Ordinance, referred to in Article 19 Paragraph 1 of the Act, pertaining to a permission waste management operator. In this case, the term “radioisotopes” in Item 1-2 of the same Paragraph is replaced with “radioisotopes, etc.”, the term “radioisotopes or radiation generating apparatuses” in Item 3 (b) of the same Paragraph is replaced with “radioisotopes, etc.”, the term “location or room where a radiation generating apparatus is used” in Item 4 of the same Paragraph is replaced with “location” and the term “objects contaminated with radioisotopes” in Item 9 of the same Paragraph is replaced with “contaminated objects”:
 - (1) radioisotopes shall be repacked in a waste repacking facility.
 - (2) in cases where repacking of sealed radioisotopes, etc. is conducted under the sealed condition, repacking shall be conducted for the radioisotopes, etc. being kept under the conditions complying with the following provisions, and equipment or tools such as catch pan, mat or absorbent shall be used to prevent spread of contamination by radioisotopes:
 - (a) in normal condition for use, there shall be no likelihood that sealed radioisotopes, etc. are opened or destructed;
 - (b) there shall be no likelihood that sealed radioisotopes, etc. are dispersed due to leakage, permeation or other reason and contaminate other objects.
 - (3) notices necessary to prevent radiation hazards shall be indicated at clearly visible locations in the waste repacking facility.
4. Beyond what is pursuant to the provisions of the following Items, the provisions in Article 15 Paragraph 1 Items 3, 10, 11 and 12 apply mutatis mutandis to the technical standards for waste management pursuant to the provisions of Article 19 Paragraph 1 of the Act, pertaining to a notification user. In this case, the term “radiation generating apparatus” in Item 3 of the same Paragraph is replaced with “objects contaminated with radioisotopes”, the term “contaminated objects” in Item 10 of the same Paragraph is replaced with “objects contaminated with radioisotopes” and the terms “usage facility or controlled area” in Item 11 of the same Paragraph are replaced with “controlled area”:
 - (1) wastes of radioisotopes or objects contaminated with radioisotopes shall be managed by sealing them in containers and by taking measures to prevent the occurrence of radiation hazards within a specified site marked off;
 - (2) sign shall be posted on the container or controlled area prescribed in the preceding Item pursuant to the provisions of the appended Table.
5. Beyond what is pursuant to the provisions of the following Items, the provision in Article 15 Paragraph 1 Item 3 apply to the technical standards for waste management referred to in Article 19 Paragraph 2 of the Act. In this case, the terms “radioisotopes or radiation generating apparatuses” in the same Item are replaced with “radioisotopes, etc.”:
 - (1) in cases where wastes of radioisotopes are to be managed, waste storage of wastes shall be entrusted to a

- permission user or management of wastes shall be entrusted to a permission waste management operator;
- (2) in cases where wastes of contaminated objects are to be managed, storage of disposal of wastes shall be entrusted to a permission user on whose permit the kinds of radioisotopes contained in the concerned contaminated objects are listed or management of wastes shall be entrusted to a permission waste management operator;
 - (3) the radiation dose to persons engaged in waste management (excluding radiation workers) shall be kept not exceeding the dose limit specified by the NRA.

(Application for Burial Confirmation)

Article 19-2. Any person intending to be granted confirmation of waste burial (excluding confirmation by a registered burial confirmation organization) pursuant to the provisions in Article 19-2 Paragraph 2 of the Act, according to the classification set forth in each of the following Items, shall submit the application form prescribed separately in the following Items to the NRA:

- (1) confirmation on Paragraph 1 Item 17 (a) of the preceding Article: application form according to Appended Form 23;
 - (2) confirmation on Paragraph 1 Item 17 (b) of the preceding Article: application form according to Appended Form 24.
2. Documents set forth in the following Items shall be appended to the application form referred to in Item 1 of the preceding Paragraph:
- (1) documents proving conformity to standards referred to in Paragraph 1 Item 17 (b) i of the preceding Article;
 - (2) documents describing the method used to measure the density of radioactivity contained in burial wastes and other methods used to determine the density of radioactivity.
3. Drawings set forth in the following Items shall be attended to the application form pursuant to the provisions of Paragraph 1 Item 2:
- (1) ground plan of the place of waste management business explicitly indicating the location of the waste burial site;
 - (2) ground plan of the waste burial site;
 - (3) detailed cross-section plan of the waste burial site.
4. Any person intending to be granted confirmation for waste burial by a registered burial confirmation organization referred to in Article 19-2 Paragraph 2 of the Act shall, according to the classification set forth in each of the Items in Paragraph 1, submit the application form separately pursuant to the provisions of the concerned Items, appending documents set forth in each of Items of Paragraph 2 or Items in the preceding Paragraph to the concerned registered burial confirmation organization.

(Issuance of Burial Confirmation Certificate)

Article 19-3. The Nuclear Regulation Authority or the registered burial confirmation organization, when it has confirmed the burial prescribed in Article 19-2 Paragraph 2 of the Act, issues a burial confirmation certificate.

Chapter 4. Obligations of Measurements, etc.

(Measurements)

Article 20. Measurements pursuant to the provisions of Article 20 Paragraph 1 of the Act are conducted pursuant to the provisions in the following Items:

- (1) the measurement of the quantity of radiation shall be made for the 1-cm dose equivalent rate or 1-cm dose equivalent (identical to the “ambient dose equivalent” defined by ICRU at $d = 10$ mm); provided, however, that at places where the 70- μ m dose equivalent rate (identical to “directional dose equivalent” defined by ICRU at $d = 0.07$ mm) is likely to exceed ten times of the 1-cm dose equivalent rate or at places where 70- μ m dose equivalent is likely to exceed ten times the 1-cm dose equivalent, the measurement of the quantity of radiation shall be made for 70- μ m dose equivalent rate or 70- μ m dose equivalent, respectively.
- (2) measurement of the quantity of radiation and condition of contamination by radioisotopes shall be made by using radiation measurement instruments; provided, however, that, in cases where the measurement using the concerned instruments is extremely difficult, the values of these quantities may be determined by calculation.
- (3) the measurement referred to in the preceding Item shall be conducted at places best suited to clarify the quantity of radiation or the condition of contamination by radioisotopes at places set forth in the right column in the following Table, respectively, corresponding to items set forth in the left column in the same Table;

Item	Place
The quantity of radiation	a) Usage facility b) Waste repacking facility c) Storage facility d) Waste storage facility e) Waste management facility f) Boundary of controlled area g) Area for residence inside of factory or place of business, etc. h) Boundary of place of business, etc.
Measurement of condition of contamination by radioisotopes	a) Workroom b) Waste management workroom c) Contamination inspection room d) Exhaust port of exhaust equipment e) Draining port of drainage equipment f) Place with exhaust monitoring equipment g) Place with drainage monitoring equipment h) Boundary of controlled area

- (4) measurements referred to in Item 2 shall be conducted once prior to starting work and as pursuant to the provisions of the following Items after the commencement of work:
 - (a) measurements of the quantity of radiation (excluding measurements in (b) and (c)) and conditions of contamination at the workroom, waste management workroom, contamination inspection room and boundary of the controlled area shall be conducted once each period not exceeding one month; provided, however, that measurements of the quantity of radiation at the boundary of the place of waste management business accompanying a waste burial site shall be conducted once each period not exceeding one week until the whole waste burial site is covered with dirt, etc.;
 - (b) measurements of the quantity of radiation (excluding measurements in (c)) at places where sealed radioisotopes or radiation generating apparatuses fixed at places are handled under the conditions of constant operational

procedure and the fixed positions of shielding objects including a shielding wall, shall be conducted once each period not exceeding 6 months;

(c) in cases where only sealed radioisotopes with the quantity less than or equal to the value of 1,000 times of the lower bound quantity (as with “exemption level”) are handled, measurements of the quantity of radiation shall be conducted once each period not exceeding 6 months;

(d) measurements of conditions of contamination with radioisotopes at the exhaust port of the exhaust equipment, the draining port of drainage equipment, the places where the exhaust monitoring equipment and the drainage monitoring equipment are installed, shall be conducted each time when the exhaust or drain water is discharged (measurements shall be conducted continuously if the exhaust or drain water is discharged continuously).

2. Measurements of the dose of radiation referred to in Article 20 Paragraph 2 of the Act shall be conducted for doses from external exposure and internal exposure (that is, exposure to radiation from radioisotopes that are taken inside human body; the same applies hereinafter) pursuant to the provisions set forth in the following Items:

(1) measurements of radiation dose from external exposure shall be conducted pursuant to the following provisions:

(a) measurements shall be conducted on the chest for the 1-cm dose equivalent and 70- μ m dose equivalent (1-cm dose equivalent for neutrons) (on the abdomen for female workers (excluding female workers who have notified the permission or notification user or permission waste management operator of themselves diagnosed as unable to become pregnant or having no intention to become pregnant in documents; provided, however, that this does not apply to the case where there is any reasonable reason)) (identical to the “personal dose equivalent” defined by ICRU at $d = 10$ mm or 0.07 mm);

(b) in cases where, among the head and neck region, the chest and arms region and the abdomen and thighs region of the body, the body region where radiation dose from external exposure is likely to be the largest is expected to be the region other than the chest and arms region (the body portion consisting of abdomen and thighs for female workers who are to have their abdomen measured in (a)), measurements for the 1-cm dose equivalent and 70- μ m dose equivalent (1-cm dose equivalent for neutrons) shall be conducted on the region where the radiation dose from the concerned external exposure is considered to be the highest in addition to the region as pursuant to the provisions of (a);

(c) in cases where the body region where the dose from external exposure is likely to be the largest is the region other than head, neck, chest, arm, abdomen and thigh, measurements of the 70- μ m dose equivalent shall be conducted on the concerned region, in addition to the regions as pursuant to the provisions of (a) and (b); provided, however, that this does not apply to measurements on neutrons;

(d) measurements shall be conducted using radiation measurement instruments; provided, however, that, in cases where the measurement using a radiation measurement instrument is extremely difficult, the values of these quantities may be determined by calculation;

(e) measurements on persons who regularly enter a controlled area shall be continuously conducted during the period of their entry; provided, however, that this does not apply to the persons who temporarily enter the controlled area and are not radiation workers, if their radiation dose from external exposure in the controlled area is unlikely to exceed the dose limit specified by the NRA.

(2) pursuant to the provisions by the NRA, measurements of the radiation dose from internal exposure shall be

conducted on persons who have inadvertently inhaled or orally ingested radioisotopes, in addition, on persons who enter the workroom or other places where there is a likelihood of inhalation or ingestion of radioisotopes, measurements also shall be conducted once each period of time not exceeding 3 months (for the woman whose pregnancy has become known to the permission or notification user or the permission waste management operator through notification by herself, etc., once each period of time not exceeding one month until her delivery); provided, however, that this does not apply to the persons who temporarily enter the workroom or other places where there is a likelihood of inhalation or ingestion of radioisotopes and are not radiation workers, if their radiation dose from internal exposure is unlikely to exceed the dose limit specified by the NRA.

3. Measurement of condition of contamination by radioisotopes pursuant to the provisions of Article 20 Paragraph 2 of the Act shall be conducted by using a radiation measurement instrument pursuant to the provisions in the following Items; provided, however, that if measurement using the concerned instrument is extremely difficult, the conditions of contamination may be determined by calculation:

- (1) measurement shall be conducted at the surface of hand, leg and other body portions that are likely to be contaminated with radioisotopes and the surface of objects worn over body such as work wear, shoes, protector that are likely to be contaminated with radioisotopes;
- (2) measurement shall be conducted on persons who enter such a radiation facility where unsealed radioisotopes are used, removed, incinerated or solidified using solidification materials such as concrete, upon their exit from the concerned facility.

4. The measures provided for in the NRA Ordinance, pursuant to the provisions of Article 20 Paragraph 3 of the Act shall be as follows:

(1) the results of measurement pursuant to the provisions of Paragraph 1 shall be recorded pertaining to the following matters at each time of measurement and the results concerned shall be stored for 5 years:

- (a) date and time of measurement;
- (b) location of measurement;
- (c) name of person who conducted measurement;
- (d) kind and model of radiation measuring instrument;
- (e) method of measurement;
- (f) results of measurement.

(2) the results of measurements of radiation dose from external exposure for each period of 3 months beginning on April 1, July 1, October 1 and January 1, respectively, and for the period of one year beginning on April 1, and, for a female worker whose pregnancy has become known to the permission or notification user or the permission waste management operator through notification by herself, for the period of each one month beginning on the first day of each month until her delivery, shall be summed on the basis of the concerned period, and the following matters shall be recorded each time of summation:

- (a) name of subject of measurement;
- (b) name of person who conducted measurement;
- (c) kind and model of radiation measuring instrument;
- (d) method of measurement;

- (e) body portion and results of measurement.
- (3) for the results of measurements of radiation dose from internal exposure, the following matters shall be recorded each time of measurement is conducted:
- (a) date and time of measurement;
 - (b) name of subject of measurement;
 - (c) name of person who conducted measurement;
 - (d) kind and model of radiation measuring instrument;
 - (e) method of measurement;
 - (f) results of measurement.
- (4) in cases where the surface of body portions such as hand, leg, etc. is contaminated with radioisotopes exceeding the surface density limit and the concerned surface cannot be easily decontaminated, the following matters shall be recorded pertaining to the results of measurement pursuant to the provisions of the preceding Paragraph:
- (a) date and time of measurement;
 - (b) name of subject of measurement;
 - (c) name of person who conducted measurement;
 - (d) kind and model of radiation measurement device;
 - (e) contamination condition;
 - (f) method of measurement;
 - (g) body portion and results of measurement.
- (5) pursuant to the provisions by the NRA, the effective dose and equivalent dose for each period of 3 months beginning on April 1, July 1, October 1 and January 1, respectively, and for the period of one year beginning on April 1, and, for a female worker whose pregnancy has become known to the permission or notification user or the permission waste management operator through notification by herself, for the period of each one month beginning on the first day of each month until her delivery shall be assessed from the measurement results pursuant to the provisions of Item 2 through the preceding Item on the basis of the concerned period, and the following matters shall be recorded each time of the assessment:
- (a) date and time of calculation;
 - (b) name of subject of measurement;
 - (c) name of person who conducted dose assessment;
 - (d) period for the assessment;
 - (e) effective dose;
 - (f) equivalent dose and name of the tissue or organ.
- (5)-2 in cases where the effective dose for one year beginning on April 1 has been found to exceed 20 mSv as the result of the assessment of effective dose pursuant to the provisions of the preceding Item, after the concerned year the cumulative effective dose (that is, the sum of effective doses assessed for each one-year beginning on April 1 pursuant to the provision of the preceding Item) for the period of time specified by the NRA, including the concerned one year, shall be summed up for the concerned period each year, and the following matters shall be recorded each time of the summation:

- (a) date of the summation;
 - (b) name of subject of measurement;
 - (c) name of person who conducted the summation;
 - (d) period for the summation;
 - (e) cumulative effective dose.
- (6) the copy of records pursuant to the provisions of Item 2 through the preceding Item shall be delivered to the subject person of the concerned measurement each time recording takes place.
- (7) the records pursuant to the provisions of Items 2 through 5-2 (including records to be stored in the case pursuant to the provisions of proviso of Article 26 Paragraph 1 Item 9) shall be stored; provided, however, that this does not apply to the case where the subject person of the concerned record has ceased to be the employee of the permission or notification user or the permission waste management operator or where the concerned record, after being kept for 5 years or longer, is transferred to the organization designated by the NRA.
- (8) necessary matters concerning the organization designated by the NRA pursuant to the provisions of the proviso of the preceding Item shall be separately specified by the NRA.

(Storage of Records by Electronic or Magnetic Means)

Article 20-2. The records of the results of measurements prescribed in Article 20 Paragraph 3 of the Act may be kept and stored by recording using an electronic or magnetic means (that is, electronic method, magnetic means or other means that cannot be recognized by human sense; the same applies hereinafter) pursuant to the provision of Paragraph 4 of the preceding Article.

- 2. In cases where the records are stored pursuant to the provision of the preceding Paragraph, it shall be ensured that the records pursuant to the provisions of the same Paragraph shall be immediately displayed as necessary by using a computer or other devices.
- 3. In cases where the records are stored pursuant to the provision of Paragraph 1, best endeavors shall be made to ensure the standard specified by the NRA.

(Radiation Hazards Prevention Program)

Article 21. The Radiation Hazards Prevention Program pursuant to the provisions of Article 21 Paragraph 1 of the Act specifies the following matters:

- (1) matters concerning the duties and organization of persons engaged in handling of radioisotopes, etc. or radiation generating apparatuses;
- (1)-2 matters concerning the duties and organization of radiation protection supervisors and other persons engaged in safety management in handling of radioisotopes, etc. or radiation generating apparatuses;
- (1)-3 matters concerning appointment of a deputy of a radiation protection supervisor;
- (1)-4 matters concerning the maintenance and management of radiation facilities (including management of persons who enter an area not regarded as controlled area pursuant to the provision of Article 22-3 Paragraph 1);
- (1)-5 matters concerning the inspection of radiation facilities (controlled area in cases where a notification user uses sealed radioisotopes or manages wastes of sealed radioisotopes or objects contaminated with radioisotopes);

- (2) matters concerning the use of radioisotopes or radiation generating apparatuses (including matters pertaining to the method for confirmation of the quantity of unsealed radioisotopes in the case prescribed in Article 15 Paragraph 2);
 - (3) matters concerning receipt, delivery, storage, transport or waste management of radioisotopes, etc. (for a notification lessor, including measures taken when radioisotopes leased to a permission or notification user are not properly stored);
 - (4) matters concerning measurements of the quantity of radiation and condition of contamination by radioisotopes and the measures for the results of the measurements pursuant to the provisions of Items of Article 20 Paragraph 4;
 - (5) matters concerning education and training required to prevent radiation hazards;
 - (6) matters concerning health surveillance;
 - (7) matters concerning measures necessary for the health of a person who has suffered or is likely to suffer radiation hazards;
 - (8) matters concerning preparation and storage of books prescribed in Article 25 of the Act;
 - (9) matters concerning measures to be taken when an earthquake, fire or other disaster occurs (excluding measures pursuant to the provisions of the following Items);
 - (10) matters concerning emergency measures;
 - (11) matters concerning report of status of radiation control;
 - (12) matters concerning measures to be taken for prevention of radiation hazards according to the decay of radioactivity in burial wastes that are buried in waste burial site (limited to the case where waste burial is conducted);
 - (13) other necessary matters concerning prevention of radiation hazards.
2. Notification pursuant to the provisions in Article 21 Paragraph 1 of the Act shall be submitted with the Appended Form 25, appended by the Radiation Hazards Prevention Program.
 3. Notification pursuant to the provisions in Article 21 Paragraph 3 of the Act shall be submitted with the Appended Form 26, appended by the Radiation Hazards Prevention Program as of after change.

(Education and Training)

Article 21-2. Education and training pursuant to the provisions in Article 22 of the Act are as pursuant to the provisions of the following Items:

- (1) education and training shall be provided to persons who enter a controlled area (including persons who enter an area not regarded as controlled area pursuant to the provisions of Article 22-3 Paragraph 1) and persons engaged in handling duties pursuant to the provisions in the following Item through Item 5.
- (2) education and training for radiation workers shall be provided before they enter the controlled area for the first time, and once each period of time not exceeding one year after they have entered the controlled area.
- (3) education and training for persons who are engaged in duties including handling, etc. and do not enter the controlled area shall be provided before they start their duties, and once each period of time not exceeding one year after they have started their duties.

- (4) education and training for persons prescribed in the preceding two Items shall be provided pertaining to the following items;
 - (a) effects of radiation on human body;
 - (b) safe handling of radioisotopes, etc. or radiation generating apparatuses;
 - (c) laws and regulations concerning the prevention of radiation hazards due to radioisotopes and radiation generating apparatuses;
 - (d) Radiation Hazards Prevention Program.
 - (5) education and training for persons other than those prescribed in the preceding Item (including persons who enter an area not regarded as controlled area pursuant to the provisions in Article 22-3 Paragraph 1) shall be provided pertaining to the matters necessary to prevent the occurrence of radiation hazards in radiation facilities where the concerned persons enter.
2. Notwithstanding the provision of the preceding Paragraph, for persons who are regarded to have sufficient knowledge and skill concerning all or part of items or matters set forth in Item 4 or 5 of the same Paragraph, education and training on the concerned items or matters may be omitted.
 3. Beyond what is pursuant to the provisions of the preceding two Paragraphs, the number of hours of education and training and other necessary matters concerning implementation of education and training are specified by the NRA.

(Health Surveillance)

Article 22. Health surveillance pursuant to the provisions of Article 23 Paragraph 1 of the Act are as pursuant to the provisions of the following Items:

- (1) health surveillance of radiation workers (excluding workers who temporarily enter a controlled area) shall be conducted before they enter a controlled area for the first time.
- (2) health surveillance of the radiation workers pursuant to the provisions of the preceding Item shall be conducted once each period of time not exceeding one year after they enter the controlled area.
- (3) notwithstanding the provision of the preceding Item, in cases where a radiation worker falls under any of the following conditions, health surveillance of the concerned radiation worker shall be conducted without delay:
 - (a) in cases where the worker has inhaled or ingested radioisotopes inadvertently;
 - (b) the worker's skin is contaminated with radioisotopes to a degree exceeding the surface density limit and cannot be easily decontaminated;
 - (c) a wounded surface of the worker's skin is contaminated or is likely to be contaminated with radioisotopes;
 - (d) the worker has been exposed or may have been exposed to radiation exceeding the effective dose limit or the equivalent dose limit.
- (4) the method of health surveillance shall be interview and medical inspection or medical examination.
- (5) interview shall be conducted for the following matters:
 - (a) whether the worker has ever received the exposure to radiation (including electrons and X rays having an energy less than 1 MeV; hereinafter the same applies to (b) in the same Item and Article 23 Item 1) or not;
 - (b) for a radiation worker with the history of exposure to radiation, place of work, contents of work, working period, radiation dose, occurrence of radiation hazards and other conditions of exposure to radiation.

- (6) medical inspection or medical examination shall be conducted for the following body portions and matters; provided, however, that for portions or matters from (a) through (c) (for health surveillance pertaining to Item 1, excluding portions or matters pursuant to the provisions of (a) and (b)), medical inspection or medical examination shall be conducted only if a physician deems it necessary:
 - (a) hemoglobin content or hematocrit value, erythrocyte count, leukocyte count, and leukocyte percentage in peripheral blood;
 - (b) skin;
 - (c) eyes;
 - (d) other portions and matters specified by the NRA.
2. Measures provided for in the NRA Ordinance, pursuant to the provisions of Article 23 Paragraph 2 of the Act, are as pursuant to the provisions of the following Items:
 - (1) the result of health surveillance shall be recorded on the following matters each time health examination:
 - (a) date of health surveillance;
 - (b) name of the subject;
 - (c) name of the physician who conducted health surveillance;
 - (d) result of health surveillance;
 - (e) measures taken in accordance with the result of health surveillance.
 - (2) the copy of the record proscribed in the preceding Item shall be issued to the person who underwent the health surveillance at each time of examinations.
 - (3) the records pursuant to the provisions of Item 1 (including the records to be stored in the case pursuant to the provisions of the proviso of Article 26 Paragraph 1 Item 9) shall be kept; provided, however, that this does not apply to cases where the person who underwent health surveillance has ceased to be the employee of the permission or notification user or the permission waste management operator or where the concerned records, after being kept for 5 years or longer, are transferred to the organization designated by the NRA.
 - (4) the necessary matters concerning the organization designated by the NRA pursuant to the provisions of the proviso of the preceding Item shall be separately provided for in the NRA Ordinance.

(Storage of Records by Electronic or Magnetic Means)

Article 22-2. Records of the results of health surveillance prescribed in Article 23 Paragraph 2 of the Act may be prepared and stored by an electronic or magnetic means in accordance with the provisions of Paragraph 2 of the preceding Article.

2. In cases where records are stored pursuant to the provision of the preceding Paragraph, it shall be ensured that the records pursuant to the provisions of the same Paragraph shall be immediately displayed as necessary by using a computer or other devices.
3. In cases where records are stored pursuant to the provision of Paragraph 1, efforts shall be made to ensure the standards specified by the NRA.

(Special Exception of Persons Who Enter a Controlled Area Pertaining to a Radiation Generating Apparatus)

Article 22-3. The whole or part of a controlled area pertaining to a radiation generating apparatus in the case where operation of the concerned radiation generating apparatus is suspended for a period of 7 days or longer due to construction, modification, repair or inspection, etc. or in the case where a radiation generating apparatus is moved out of the concerned controlled area (limited to areas where there is no likelihood that the radiation dose pertaining to external radiation exceeds the dose limit specified by the NRA, the concentration of radioisotopes in the air exceeds the concentration limit specified by the NRA, or the density of radioisotopes on the surface of objects contaminated with radioisotopes exceeds the density limit specified by the NRA) is deemed not to be the controlled area.

2. In the area deemed not to be the controlled area pursuant to the provision of the preceding Paragraph, notices that operation of a radiation generating apparatus is suspended or that the radiation generating apparatus is not installed and other necessary matters shall be posted in the vicinity of the sign pursuant to the provisions of Article 14-7 Paragraph 1 Item 9 , at the fence set up at the boundary of the concerned area, the entrance/exit of installation for preventing persons from entering the area without reason or at its vicinity.

(Measures for Persons Who Have Suffered or May Have Suffered Radiation Hazards)

Article 23. The measures that a permission or notification user, a notification user of an approved device with certification label, a notification dealer, a notification lessor and a permission waste management operator shall take, pursuant to the provisions in Article 24 of the Act, are as pursuant to the provisions of the following Items:

- (1) if radiation workers have suffered or may have suffered radiation hazards, measures such as shortening of staying time in controlled areas, prohibition of entry to controlled areas, reallocation of the concerned workers to duties less susceptible to radiation exposure shall be taken and necessary health guidance shall be provided, according to the degree of radiation hazards or possibility of radiation hazards;
- (2) if persons other than radiation workers have suffered or may have suffered radiation hazards, appropriate measures such as diagnosis by a physician and necessary health guidance, etc. shall be taken without delay.

(Recording)

Article 24. Details of the matters that shall be described in the books prepared by a permission or notification user, a notification dealer, a notification lessor or a permission waste management operator pursuant to the provisions in Article 25 Paragraph 1, 2 or 3 of the Act are as pursuant to the provisions of the following Items:

- (1) a permission or notification user shall describe the following matters:
 - (a) kind and quantity of radioisotopes, etc. pertaining to receipt or delivery;
 - (b) date of receipt or delivery of radioisotopes, etc. and the name or title of the counterparty;
 - (c) kind and quantity of radioisotopes, etc. pertaining to use (excluding repacking; hereinafter the same applies to this item);
 - (d) kind of a radiation generating apparatus pertaining to use;
 - (e) date, purpose, method and place of use of radioisotopes or a radiation generating apparatus;
 - (f) name of a person engaged in use of radioisotopes or a radiation generating apparatus (including persons who confirmed the quantity of unsealed radioisotopes in the case prescribed in Article 15 Paragraph 2);
 - (g) kind and quantity of radioisotopes to be stored in storage facilities and activated objects to be stored in a

- activated object storage equipment;
 - (h) period, method and location of storage of radioisotopes in storage facilities and activated objects in activated object storage equipment;
 - (i) name of a person engaged in storage of radioisotopes in storage facilities and activated objects in activated object storage equipment;
 - (j) date, method, and name or title of consignee or consignor of transport of radioisotopes, etc. outside the factory or place of business, and name of a person engaged in transport or name or title of the contractor of transport;
 - (k) kind and quantity of radioisotopes, etc. pertaining to waste management;
 - (l) date, method and location of waste management of radioisotopes, etc.;
 - (m) name of a person engaged in waste management of radioisotopes, etc.
 - (n) in cases where radioisotopes, etc. are to be disposed of at sea and radioisotopes, etc. are sealed in containers or solidified in containers, the number and specific gravity of the concerned containers and method of sealing or solidification;
 - (o) date and results of inspection of a radiation facility (refer to a controlled area in cases where a permission or notification user uses sealed radioisotopes or manages the wastes of sealed radioisotopes or objects contaminated with radioisotopes), contents of measures associated therewith, and name of a person who implemented the inspection;
 - (p) date and items of education and training to persons who enter radiation facilities, and names of persons who received the concerned education and training;
 - (q) names of persons who entered the area deemed to be not a controlled area pursuant to the provision of Article 22-3 Paragraph 1.
- (2) a notification dealer and notification lessor shall describe the following matters:
- (a) kind and quantity of radioisotopes pertaining to acquisition (including recovery and lease; hereinafter the same applies to this Item), dealing or other transfer (including return; hereinafter the same applies to this Item), or leasing;
 - (b) date of acquisition, dealing or other transfer, or leasing of radioisotopes, and the name or title of the counterparty;
 - (c) date, method and name or title of consignee or consignor of transport of radioisotopes or objects contaminated with radioisotopes, and name of a person engaged in the transport or name or title of the entrustee of the transport;
 - (d) kind and quantity of radioisotopes of which storage is entrusted;
 - (e) date, period of entrustment of storage of radioisotopes, and name or title of entrustee;
 - (f) kind and quantity of radioisotopes or objects contaminated with radioisotopes whose waste management is entrusted;
 - (g) date of entrustment of waste management of radioisotopes or objects contaminated with radioisotopes and name or title of the entrustee.
- (3) a permission waste management operator (excluding a person who conducts waste burial) shall describe the following matters:
- (a) kind and quantity of radioisotopes, etc. pertaining to receipt or delivery;

- (b) date of receipt or delivery of radioisotopes, etc. and the name or title of the counterparty;
 - (c) kind and quantity of radioisotopes, etc. pertaining to storage;
 - (d) period of time, method and place of storage of radioisotopes, etc.;
 - (e) name of a person engaged in storage of radioisotopes, etc.;
 - (f) date, method and name or title of consignee or consignor of transport of radioisotopes, etc. outside the place of waste management, and name of a person engaged in transport or name or title of the trustee of transport;
 - (g) matters set forth in Items 1 (k) through (p).
- (4) a permission waste management operator who conducts waste burial shall describe the following matters;
- (a) kind and quantity of wastes buried in waste burial site and concentration and quantity of each kind of radioisotopes contained in the concerned burial wastes;
 - (b) date and location that wastes were buried in waste burial site;
 - (c) name of a person engaged in waste burial;
 - (d) date of implementation of monitoring or measurement prescribed in Article 19 Paragraph 1 Item 17 (c) iii and iv, results of the monitoring or measurement and contents of measures associated therewith, and name of a person who conducted monitoring or measurement;
 - (e) date and results of inspection of radiation facility, and contents of measures associated therewith, and name of a person who conducted inspection;
 - (f) matters set forth in Items 1 (k) through (n) (provided ,however, that in Items 1 (k) through (m), excluding matters pertaining to waste burial);
 - (g) matters set forth in Items 3 (a) through (f).
- (5) any person intending to be granted confirmation of radioactivity concentration pursuant to the provision of Article 33-2 Paragraph 1 of the Act shall describe the following matters, beyond what is pursuant to the provisions of the preceding Items:
- (a) kind, date of production and location of objects for radioactivity concentration confirmation (that is, contaminated objects to be granted confirmation of radioactivity concentration pursuant to the provision of Article 33-2 Paragraph 1 of the Act; the same applies hereinafter);
 - (b) weight of each mass unit for evaluation (in cases where, dividing the object for radioactivity concentration confirmation into two or more assemblies, the measurement and evaluation of radioactivity concentration are conducted on each assembly, it means the concerned each assembly, or in cases where measurement and evaluation of radioactivity concentration are conducted on the whole object deemed to be one assembly, it means the concerned whole object; the same applies hereinafter) and concentration of each kind of radioisotopes (that is, radioisotopes measured and evaluated by the methods of radioactivity concentration measurement and evaluation having been granted approval pursuant to the provisions of Article 33-2 Paragraph 2 of the Act; the same applies hereinafter) contained in the concerned mass unit for evaluation;
 - (c) in cases where using the composition ratio of radioisotopes for determining radioactivity concentration, results of measurement of the composition ratio;
 - (d) in cases where radioactivity concentration has been determined by calculation, the conditions and results of the calculation;

- (e) in cases where decontamination of the object for radioactivity concentration confirmation has been carried out in order to determine radioactivity concentration, results of measurement of radioactivity concentration as of after decontamination;
 - (f) radiation measurement devices and measurement conditions used for measurement of radioactivity concentration;
 - (g) results of inspection and calibration of radiation measurement devices;
 - (h) method and location of storage of objects for radioactivity concentration confirmation.
2. A permission or notification user, a notification dealer, a notification lessor or a permission waste management operator pursuant to the provisions in Article 25 Paragraph 1, 2 or 3 of the Act shall close the book, pursuant to the provisions of the preceding Paragraph, on March 31 of each year or the day of revocation of permission, on the day of the termination of use, dealing, leasing or waste management business, or on the day of death, dissolution or split (limited to cases where succession pursuant to the provisions of Article 26-2 Paragraph 1 or 2 or Paragraphs 4 through 7 of the Act or Article 26-3 Paragraph 1 did not take place).
 3. The storage period of book pursuant to the provision of Article 25 Paragraph 4 of the Act is 5 years after closing of book prescribed in the preceding Paragraph; provided, however, that the storage period of the book pursuant to the provisions of (a) through (d) and (e) (limited to the part pertaining to waste burial site) of Paragraph 1 Item 4 and the book pursuant to the provisions of Item 5 of the same Paragraph is the period until the end of waste management business and 5 years after the book has been carried outside the place of business, etc., respectively.

(Storage of Records by Electronic or Magnetic Means)

- Article 24-2.** In cases where matters set forth in each of Items of Paragraph 1 of the preceding Article are recorded by an electronic or magnetic means and the concerned records are stored so as to be immediately displayed as necessary by using a computer or other devices, storage of book describing the matters prescribed in Article 25 Paragraph 4 of the Act may be replaced with the storage of the concerned records.
2. In cases where records are stored as pursuant to the provisions of the preceding Paragraph, efforts shall be made to ensure the standards specified by the NRA.

(Merger, etc.)

- Article 24-3.** An application form pertaining to approval of merger or split pursuant to the provisions of Article 26-2 Paragraph 1 or 2 of the Act is the Appended Form 27.
2. Documents set forth in the following Items shall be appended to the application form pursuant to the provisions of the preceding Paragraph:
 - (1) a copy of the merger agreement or split agreement;
 - (2) where one of parties to the merger is not a permission user or a permission waste management operator, the certificate of registered matters of the juridical person;
 - (3) for a person intending to be granted approval for merger or split pursuant to the provisions of Article 26-2 Paragraph 2 of the Act (limited to merger or split of a juridical person who is a permission waste management operator to conduct waste burial), financial plan and business income and expenditure estimates of the juridical

person that succeeds the position of the permission waste management operator after merger or split, and other documents clarifying that the juridical person to succeed the position of the permission waste management operator after merger or split has a financial base sufficient for appropriately implementing waste management business.

Article 24-4. Notification pursuant to the provisions of Article 26-2 Paragraph 8 of the Act shall be submitted with the Appended Form 28 or Appended Form 29.

(Succession of Permission Waste Management Operator)

Article 24-5. Notification pursuant to the provisions of Article 26-3 Paragraph 2 of the Act shall be submitted with the Appended Form 30.

(Reception of a Waste Burial Site)

Article 24-6. An application form for permission pertaining to reception of a waste burial site pursuant to the provisions of Article 20 of the Ordinance is as the Appended Form 31.

2. Documents as set forth in the following Items shall be appended to the application form pursuant to the provisions of the preceding Paragraph:

- (1) documents and drawings prescribed in Article 2 Paragraph 2 as applied mutatis mutandis to Article 7 Paragraph 2 (excluding the proviso of Item 4, Item 6-2, and Items 9 and 10 of the same Paragraph) and Paragraph 3;
- (2) documents and drawings proving conformity to standards pursuant to the provisions of Article 14-11 Paragraph 3 Item 2 and Article 14-12 Item 2;
- (3) financial plan, business income and expenditure estimates, and other documents clarifying a financial base sufficient for appropriately implementing waste management business;
- (4) where management business is currently operated, a document concerning the general description of the business.

(Number of an Application Form to Be Submitted Pertaining to Merger, etc.)

Article 24-7. The number of an application form pursuant to the provisions of Article 24-3 Paragraph 1 and Paragraph 1 of the preceding Article and a notification form pursuant to the provisions of Article 24-4 (excluding the notification form of the Appended Form 29) , and a notification form pursuant to the provisions of Article 24-5, is one original and 2 duplicates, respectively; provided, however, that documents prescribed in Article 24-3 Paragraph 2 and Paragraph 2 of the preceding Article are not required to be appended to the duplicates.

2. The number of the notification form pursuant to the provisions of Article 24-4 (limited to the notification form of the Appended Form 29) is one original.

(Notification of Termination of Use, etc.)

Article 25. Notification pursuant to the provisions of Article 27 Paragraph 1 of the Act (excluding notification pertaining to the user of an approved device with certification label) shall be submitted without delay with the Appended Form 32.

2. Notification pursuant to the provisions of Article 27 Paragraph 3 of the Act (excluding notification pertaining to the

- user of an approved device with certification label) shall be submitted without delay with the Appended Form 33.
3. A notification form pursuant to the provisions of Paragraph 1 or Paragraph 2 shall be submitted with a permit; provided, however, that this does not apply to the notification pursuant to the provisions of Article 27 Paragraph 3 of the Act as applied pursuant to the provision in Article 28 Paragraph 7 of the Act.
 4. The number of the notification form pursuant to the provisions of Paragraph 1 or Paragraph 2 is one original and two duplicates, respectively.

(Measures Associated with Revocation of Permission, the Termination of Use, etc.)

Article 26. Measures that a revoked permission user, etc. prescribed in Article 28 Paragraph 1 shall take pursuant to the provisions in the same Paragraph (hereinafter referred to as “decommissioning measures” in this Article) are as pursuant to the provisions of the following Items; provided, however, that the provisions in Items 6 and 9 do not apply to revoked permission users, etc. who are involved with a prior notification dealer or notification lessor prescribed in Article 28 Paragraph 7 of the Act (hereinafter referred to as “revoked dealer, etc.” or “revoked lessor, etc.,” respectively, in this Article), and provisions in Items 6 through 9 do not apply to revoked permission users, etc. who are involved with a prior user of an approved device with certification label prescribed in the same Paragraph (hereinafter referred to as “revoked user of approved devices with certification label, etc.” in this Article and the following Article):

- (1) to export owned radioisotopes, to transfer them to a permission or notification user, a notification dealer, a notification lessor or a permission waste management operator, or to manage the waste of them.
- (2) to export rented radioisotopes, or to return them to a permission or notification user, a notification dealer, a notification lessor or a permission waste management operator.
- (3) to remove contamination by radioisotopes; provided, however, that this does not apply where the place of business, etc. pertaining to decommissioning measures is transferred to a permission user or a permission waste management operator; (limited to the case where all radioisotopes, etc. or radiation generating apparatuses and radiation facilities pertaining to the concerned decommissioning measures are transferred as a set).
- (4) to take measures required for ensuring no radiation hazards caused by burial wastes, in case of the termination of management of waste burial site, notwithstanding the provision in the preceding Item.
- (5) to transfer contaminated objects to a permission user or a permission waste management operator (limited to such a person receiving the place of business, etc. in the case prescribed in proviso of Item 3) or to manage the waste of them.
- (6) to conduct measurements pursuant to the provisions in Article 20 Paragraphs 1 through 3 (excluding provisions in Paragraph 1 Item 4 (a) through (c) of the same Article) and to record the result of the measurements. In this case, to conduct measurements pursuant to the provisions of Paragraph 1 of the same Article (excluding measurement in Item 4 (d) of the same Paragraph) before and after decontamination prescribed in Item 3.
- (7) to prepare a book and describe the following matters therein:
 - (a) kind and quantity of radioisotopes exported or transferred pursuant to the provision in Item 1 and the date and name or title of the opposite party;
 - (b) kind and quantity of radioisotopes of which wastes are managed pursuant to the provision in Item 1 and the

- date, method and location;
- (c) kind and quantity of radioisotopes exported or returned pursuant to the provision in Item 2 and the date and name or title of the opposite party;
 - (d) kind and quantity of contaminated objects produced in cases where contamination by radioisotopes was decontaminated pursuant to the provision in Item 3;
 - (e) kind and quantity of contaminated objects transferred pursuant to the provision in Item 5 and the date and name or title of the opposite party;
 - (f) kind and quantity of contaminated objects of which wastes are managed pursuant to the provision in Item 5 and the date, method and location;
 - (g) where a revoked permission user, etc. intending to have radioactivity concentration confirmed, matters listed in Article 24 Paragraph 1 Item 5.
- (8) to request a person falling under any of the following conditions to supervise decommissioning measures:
- (a) a person prescribed separately in Items of Article 34 Paragraph 1 of the Act according to the classification in each of the concerned Items as of the day of revocation of permit, the day of the termination of use, dealing, leasing or waste management business, or the day of death, dissolution or split (excluding the day of death, dissolution or split pertaining to a person which shall make notification referred to in Article 27 Paragraph 3 of the Act, as applied pursuant to the provisions in Article 28 Paragraph 7 of the Act; hereinafter referred to as “revocation day, etc.”) (including a physician or a dentist when a radioisotope or a radiation generating apparatus has been used for diagnosis, and a pharmacist when radioisotope or a radiation generating apparatus has been used at a manufacturing facility of drugs, quasi-drugs, cosmetic and medical equipment prescribed in Article 2 of the Act on Ensuring Quality, Effectiveness and Safety of Pharmaceuticals and Medical Devices, etc. (Act No. 145 of 1960));
 - (b) Any person who has knowledge and experience equivalent or superior to those of the person listed in (a).
- (9) to pass the records pursuant to the provisions of the main clause of Article 20 Paragraph 4 Item 7 and the main clause of Article 22 Paragraph 2 Item 3 to an organization designated by the NRA; provided, however, that this does not apply to the case where the person pertaining to the notification pursuant to the provisions of Article 27 Paragraph 1 of the Act stores the concerned records continuously as a permission or notification user or a permission waste management operator.
- (10) necessary matters concerning the organization designated by the NRA pursuant to the provisions of the main clause of the preceding Item are separately provided for in the NRA Ordinance.
2. A decommissioning plan pursuant to the provisions in Article 28 Paragraph 2 of the Act includes the matters as pursuant to the provisions of the followings:
- (1) methods to export, transfer, return radioisotopes or to manage wastes of them;
 - (2) methods to remove contamination by radioisotopes (for measures pertaining to the termination of management of waste burial site, measures for ensuring no radiation hazards caused by burial wastes);
 - (3) methods to transfer contaminated objects and to manage wastes of them;
 - (4) measures to be taken concerning the prevention of spreading of contamination and other radiation hazards;
 - (5) planned period for decommissioning.

3. Decommissioning measures shall be taken within the planned period of the decommissioning plan.
4. Notification pursuant to the provisions of Article 28 Paragraph 2 of the Act (excluding notification pertaining to a revoked user of an approved device with certification label, etc.) shall be submitted without delay with the Appended Form 34, appended by a decommissioning plan.
5. Notification pursuant to the provisions of Article 28 Paragraph 3 of the Act (excluding notification pertaining to a revoked user of an approved device with certification label, etc.) shall be submitted with the Appended Form 35, appended by a changed decommissioning plan.
6. A document pertaining to the report referred to in Article 28 Paragraph 5 of the Act (excluding the report pertaining to a revoked user of an approved device with certification label, etc.) is submitted with the Appended Form 36, appended by the copy of the document set forth in the following Items; provided, however, that a document pertaining to a revoked dealer, etc. or a revoked lessor, etc. is submitted with the concerned form, appended by the copies of the documents pursuant to the provisions of Items 1, 3, 4 and 5:
 - (1) documents proving that the measure pursuant to the provisions of Paragraph 1 Items 1 and 2 has been taken;
 - (2) documents proving that the measure pursuant to the provisions of Paragraph 1 Item 3 has been taken;
 - (3) documents proving that the measure pursuant to the provisions of Paragraph 1 Item 5 has been taken;
 - (4) a book pursuant to the provisions of Paragraph 1 Item 7(excluding a part pertaining to (g) of the same Item);
 - (5) a book pertaining to the storage (including storage for disposal) and rent of radioisotopes, etc. among books pursuant to the provisions of Article 25 Paragraph 4 of the Act in the fiscal year including the date of the revocation.
7. A revoked permission user, etc. who used sealed radioisotopes only and owned or possessed all the sealed radioisotopes listed in the permit or notified on the day of revocation, etc. may not append a copy of the document pursuant to the provisions of Item 5 of the preceding Paragraph.
8. The number of notification forms to be submitted, pursuant to the provisions of Paragraphs 4 and 5, is one original and one duplicate, respectively.
9. The number of documents to be submitted pertaining to the report prescribed in Paragraph 6 is one original and 2 duplicates; provided, however, that the duplicates do not require the documents pursuant to the provisions of Items of the same Paragraph to be appended.

(Notification, etc. of Revocation of Use, etc. Pertaining to Approved Devices with Certification Label)

- Article 26-2.** Notification pursuant to the provisions of Article 27 Paragraph 1 or 3 of the Act (limited to notification pertaining to a user of an approved device with certification label) shall be submitted without delay with the Appended Form 37 or Appended Form 38, respectively.
2. Notification pursuant to the provisions of Article 28 Paragraph 2 of the Act (limited to notification pertaining to a user of an approved device with certification label) shall be submitted without delay with the Appended Form 37 by a person or an organization who is required to notify pursuant to the provisions of Article 27 Paragraph 1 of the Act or with the Appended Form 38 by a person or an organization who is required to notify pursuant to the provisions of Paragraph 3 of the same Article.
 3. Notification pursuant to the provisions of Article 28 Paragraph 3 of the Act (limited to notification pertaining to a user of an approved device with certification labels) shall be submitted with the Appended Form 35, appended by a

changed decommissioning plan.

4. A document pertaining to the report pursuant to the provisions of Article 28 Paragraph 5 of the Act (limited to notification pertaining to a user of an approved device with certification label) is submitted with the Appended Form 36, appended by a copy of the document proving that measures pursuant to the provisions of Paragraph 1 Items 1 and 2 of the preceding Article have been taken.
5. The number of the document to be submitted for notification, pursuant to the provisions of Paragraphs 1 through 3 and that of the document pertaining to the report pursuant to the provisions of Paragraph 4 is one, respectively.

(Restriction on Transfer)

Article 27. Transfer of radioisotopes pursuant to the provisions of Article 29 Item 6, 7 or 8 of the Act shall be conducted within 30 days from the day of revocation of permission, the day of the termination of use, dealing, leasing or waste management business, or the day of death, dissolution or split.

(Restriction on Possession)

Article 28. The period in which radioisotopes may be possessed pursuant to the provisions in Article 30 Items 6 through 10 of the Act is 30 days from the day of revocation of permission, the day of the termination of use, dealing, leasing or waste management business, or the day of death, dissolution or split.

(Person Provided for in the NRA Ordinance, Pursuant to the Provisions of Article 31 Paragraph 1 Item 2 of the Act)

Article 28-2. The provisions in Article 8 apply mutatis mutandis to a person provided for in the NRA Ordinance, pursuant to the provisions of Article 31 Paragraph 1 Item 2 of the Act.

(Emergency Measures)

Article 29. Emergency measures that shall be taken by a permission or notification user, a notification user of an approved device with certification label, a notification dealer, a notification lessor and a permission waste management operator as well as a person who is entrusted the transport by those persons pursuant to the provisions in Article 33 Paragraph 1 of the Act are as pursuant to the provisions of the following Items:

- (1) in cases where a fire has occurred at a radiation facility or in radioactive packages or the fire is likely to spread to these objects, efforts shall be made to extinguish the fire or to prevent its spread, and the fact shall be immediately reported to a fire station or a location designated by a municipal mayor pursuant to the provisions in Article 24 of Fire Service Act (Act No. 186 of July 24, 1948);
- (2) in cases where occurrence of radiation hazards needs to be prevented, a warning shall be issued to evacuate persons inside a radiation facility, persons engaged in the transport of radioactive packages, or other persons in the vicinity;
- (3) in cases where there is a person who has suffered or who could suffer radiation hazards, he/she shall be promptly rescued and evacuated and other emergency measures shall be taken;
- (4) in cases where contamination by radioisotopes has occurred, the spread shall be immediately prevented and the

contamination shall be immediately removed;

(5) in case where there is time to move radioisotopes, etc. to another location, the concerned radioisotopes, etc. shall be moved to a safe location as required, and persons other than concerned persons shall be prohibited from entering by roping off or posting sign and security guards around the concerned location;

(6) other measures required to prevent radiation hazards shall be taken.

2. In cases where emergency works as set forth in Items in the preceding Paragraph are taken, the radiation dose of persons engaged in emergency works shall be decreased as much as possible by using shielding tool, forceps or protective equipment, shortening the time of exposure to radiation, or by other method. In this case, radiation workers (for female workers, limited to those who notified a permission or notification user or a permission waste management operator of themselves diagnosed as unable to become pregnant or having no intention to become pregnant in a document) are tolerated to be exposed to radiation up to the dose limit specified by the NRA, notwithstanding the provisions in Article 15 Paragraph 1 Item 3 (including as applied mutatis mutandis to Article 17 Paragraphs 1 and 2 and Article 19 Paragraphs 1, 3, 4 and 5) and Article 18-13 Item 8.
3. Any person prescribed in Article 33 Paragraph 1 of the Act shall notify of the following matters pursuant to the provisions in Paragraph 3 of the same Article:
 - (1) date, location, and cause of the occurrence of the event pursuant to the provisions of Article 33 Paragraph 1 of the Act;
 - (2) status of radiation hazards that has occurred or are likely to occur;
 - (3) contents of emergency measures that are taken or going to be taken.

(Standard for Radioactivity Concentration)

Article 29-2. The standard for radioactivity concentration provided for in the NRA Ordinance, pursuant to the provisions of Article 33-2 Paragraph 1 of the Act, is the radioactivity concentration specified by the NRA as the upper limit of the average radioactivity concentration for all of radioisotopes, respectively, that are contained in each mass unit for evaluation.

(Application for Confirmation of Radioactivity Concentration)

Article 29-3. Any person intending to be granted the confirmation of radioactivity concentration pursuant to the provision in Article 33-2 Paragraph 1 of the Act (excluding the confirmation granted by a registered concentration confirmation organization) shall submit an application form according to the Appended Form 39 to the NRA, appending documents proving that measurements and evaluation have been conducted in accordance with the measurement and evaluation methods for the radioactivity concentration that have been granted approval pursuant to the provisions of Article 33-2 Paragraph 2 of the Act.

2. The number of the application form pursuant to the provisions of the preceding Paragraph is one original and one duplicate copy.
3. Any person intending to be granted the confirmation of radioactivity concentration by a registered concentration confirmation organization pursuant to the provisions of Article 33-2 Paragraph 1 of the Act shall submit an application form according to the Appended Form 39, appending documents pursuant to the provisions of Paragraph 1 to the

concerned registered concentration confirmation organization.

4. The number of the application form pursuant to the provisions of the preceding Paragraph 1 is one original and two duplicates.

(Concentration Confirmation)

Article 29-4. The Nuclear Regulation Authority or a registered concentration confirmation organization confirms the following matters pursuant to the provision in Article 33-2 Paragraph 1 of the Act:

- (1) measurement and evaluation of the concentrations of radioisotopes contained in the object for concentration confirmation have been conducted in accordance with the method that has been granted approval pursuant to the provisions of Article 33-2 Paragraph 2 of the Act;
- (2) concentrations of radioisotopes contained in the object for concentration confirmation do not exceed the standard for radioactivity concentrations prescribed in Article 29-2.

(Issuance of Concentration Confirmation Certificate)

Article 29-5. The Nuclear Regulation Authority or a registered concentration confirmation organization, when it conducted confirmation prescribed in Article 33-2 Paragraph 1 of the Act, issues a certificate of concentration confirmation.

(Application for Approval of Measurement and Evaluation Methods)

Article 29-6. Any person intending to be granted approval of measurement and evaluation methods of radioactivity concentration shall submit an application form according to Appended Form 40, appending documents describing the following matters to the NRA pursuant to the provisions in Article 33-2 Paragraph 2 of the Act:

- (1) matters concerning facilities pertaining to measurement and evaluation of radioactivity concentration;
 - (2) matters concerning the situation of occurrence, material, contamination condition and estimated amount of the object for concentration confirmation;
 - (3) matters concerning the mass unit for evaluation;
 - (4) matters concerning selection of radioisotopes subject to evaluation;
 - (5) matters concerning the method to determine radioactivity concentration;
 - (6) matters concerning selection of the instrument for radiation measurement and setting of measurement conditions, etc.
 - (7) matters concerning measures to ensure reliability of measurement and evaluation of radioactivity concentration;
 - (8) beyond the matters set forth in the preceding each Item, matters regarded as necessary by the NRA.
2. The number of the application form pursuant to the provisions of the preceding Paragraph one original and one duplicate copy.

(Standard for Approval of Measurement and Evaluation Methods)

Article 29-7. In cases where application for approval of measurement and evaluation methods of radioactivity concentration pursuant to the provisions of Article 33-2 Paragraph 2 of the Act is submitted, the NRA, when it finds

the application conforms to the following standards, shall grant approval pursuant to the provisions of the same Paragraph in the case where, :

- (1) the mass unit for evaluation shall have an appropriate weight in consideration of uniformity of distribution of radioactivity concentration therein and anticipated radioactivity concentration.
- (2) radioisotopes subject to evaluation shall be important among radioisotopes contained in the mass unit for evaluation, in evaluating the radiation dose.
- (3) radioactivity concentration shall be determined by an appropriate method in consideration of the condition of contamination of the object for radioactivity concentration confirmation; provided, however, that in cases where measurement using a radiation measurement instrument is difficult, radioactivity concentration shall be determined by calculation using the composition ratio of radioisotopes set appropriately and other methods.
- (4) selection of radiation measurement instrument and setting of measurement conditions shall be conducted as follows:
 - (a) radiation measurement instrument shall be appropriate in accordance with the shape, material, mass unit for evaluation and contamination condition of the object for concentration confirmation;
 - (b) conditions of measurement of radioactivity concentration shall be such that judgment may be properly made as to whether the concentration within the standard prescribed in Article 29-2 or not.
- (5) appropriate measures to prevent mixing of other substances and contamination by radioisotopes, are implemented on the object for concentration confirmation.

Chapter 5. Radiation Protection Supervisors

(Appointment of Radiation Protection Supervisors)

Article 30. The number of radiation protection supervisors whom a permission or notification user, a notification dealer, a notification lessor and a permission waste management operator shall appoint, pursuant to the provisions in Article 34 Paragraph 1 of the Act, is at least one person per factory or place of business or per place of waste management business in case of a permission or notification user or permission waste management operator, and at least one person in case of a notification dealer or notification lessor.

2. Appointment pursuant to the provisions in Article 34 Paragraph 1 of the Act shall be made by the time when radioisotopes are carried in a usage facility or a storage facility, or a radiation generating apparatus is installed in the usage facility or when dealing or leasing business of radioisotopes or waste management business of radioisotopes, etc. is commenced.

(Notification of Appointment of Radiation Protection Supervisors, etc.)

Article 31. Notification of appointment or dismissal of radiation protection supervisors pursuant to the provisions in Article 34 Paragraph 2 of the Act shall be submitted with the Appended Form 41.

(Periodic Training)

Article 32. Persons provided for in the NRA Ordinance, pursuant to the provisions of Article 36-2 Paragraph 1 of the Act, are those as set forth in the following Items:

- (1) permission or notification users;
 - (2) notification dealers and notification lessors (excluding persons who deal or lease approved devices with certification label only and persons who do not transport nor are entrusted to transport radioisotopes or objects contaminated with radioisotopes);
 - (3) permission waste management operators.
2. The period provided for in the NRA Ordinance, pursuant to the provisions of Article 36-2 Paragraph 1 of the Act is the period specified separately in the following Items according to the classification of the persons set forth in each of the following Items:
- (1) radiation protection supervisors who have not undergone periodic training after being appointed as a radiation protection supervisor (excluding persons who underwent periodic training within one year prior to the appointment as a radiation protection supervisor): within one year from the day of the appointment as a radiation protection supervisor;
 - (2) radiation protection supervisors (excluding the persons set forth in the preceding Item): within 3 years from the day of the previous periodic training (within 5 years for a notification dealer and notification lessor).
2. Registered periodic training organizations shall implement periodic training at least twice each year.
3. Beyond what is pursuant to the provisions of the preceding three Paragraphs, the number of hours of periodic training and other detailed particulars are separately specified by the NRA.

(Appointment of a Deputy of a Radiation Protection Supervisor, etc.)

- Article 33.** The provisions in Article 30 Paragraph 1 apply mutatis mutandis to the appointment of a deputy of a radiation protection supervisor pursuant to the provisions of Article 37 Paragraph 1 of the Act.
- 2. Notification of the appointment and dismissal of a deputy of a radiation protection supervisor pursuant to the provisions in Article 37 Paragraph 3 of the Act shall be submitted with the Appended Form 42.
 - 3. In cases where the period during which a radiation protection supervisor cannot implement his/her duties is less than 30 days, notification pursuant to the provisions in Article 37 Paragraph 3 of the Act is not required.

(Frequency of Examination, etc.)

- Article 34.** Examinations for the first-class radiation protection supervisor and for the second-class radiation protection supervisor (hereinafter referred to as “examination”) is conducted at least once each year, and the matters necessary to implement examinations such as the date, location and other particulars are, in advance, noticed publicly in the Official Gazette by the NRA.

(Procedures for Taking Examination)

- Article 35.** Any person intending to take the examination shall submit an application form for the examination for a radiation protection supervisor using the Appended Form 43, appending a photograph of the person (photograph of front image of the upper half of the body without a cap or hat taken within one year prior to the application for examination with the date taken and the person’s name written on the back side) to the NRA (or, in cases where the registration pursuant to the provisions of Article 35 Paragraph 2 of the Act has been made, the registered examination

organization)

(Issuance of Certificate of Passing Examination, etc.)

Article 35-2. The Nuclear Regulation Authority issues the certificate of the Appended Form 44 to persons who passed the examination (hereinafter referred to as “certificate of passing”) and, at the same time, notices publicly the persons’ names in the Official Gazette.

(Reissuance of Certificate of Passing)

Article 35-3. A person who has smeared, damaged or lost his/ her certificate of passing and intends to have it reissued shall submit an application form for reissuance of certificate of passing examination for radiation protection supervisors using the Appended Form 45 to the NRA.

2. In cases where a person who has smeared, damaged or lost his/her certificate of passing intends to have it reissued pursuant to the provisions in the preceding Paragraph, the smeared or damaged certificate of passing shall be appended to the application form pursuant to the provisions of the same Paragraph.
3. In cases where a person who lost his/her certificate of passing and received reissued the certificate of passing pursuant to the provisions in Paragraph 1 has found the lost certificate of passing, the concerned certificate of passing shall be immediately returned to the NRA.

(Qualification for Attending Training)

Article 35-4. A person who has passed the examination for the first-class radiation protection supervisor may attend the training for the first-class radiation protection supervisor.

2. A person who has passed the examination for the second-class radiation protection supervisor may attend the training for the second-class radiation protection supervisor.

(Procedures for Attending Training)

Article 35-5. Any person intending to attend the qualification training pursuant to the provisions of Article 35 Paragraph 8 of the Act (excluding a person who intends to attend the qualification training implemented by a registered certification training organization) shall submit an application form for attending qualification training for a radiation protection supervisor pursuant to the provisions of the Appended Form 46, appending a copy of certificate of passing to the NRA; provided, however, that a person intend to attend the qualification training for the third-class radiation protection supervisor is not required to append the copy of certificate of passing.

2. Any person intending to attend the qualification training implemented by a registered qualification training organization shall submit an application form pursuant to the provisions of the Appended Form 46, appending a copy of certificate of passing to the concerned registered qualification training organization; provided, however, that a person intending to attend the qualification training for the third-class radiation protection supervisor is not required to append a copy of certificate of passing.

(Issuance of a Qualification Training Completion Certificate)

Article 35-6. The Nuclear Regulation Authority or a registered qualification training organization issues a certificate of completion of qualification training for the radiation protection supervisor pursuant to the provisions of the Appended Form 47 (hereinafter referred to as “qualification training completion certificate”) to the person who has completed the qualification training.

(Reissuance of a Qualification Training Completion Certificate)

Article 35-7. A person who has smeared, damaged or lost his/her qualification training completion certificate (excluding a qualification training completion certificate pertaining to the qualification training implemented by a registered qualification training organization; the same applies to the following Paragraph) and intends to have the certificate reissued shall submit an application form for reissuance of certificate of completion of qualification training for a radiation protection supervisor pursuant to the provisions of the Appended Form 48 to the NRA.

2. In cases where a person who has smeared, damaged or lost his/her qualification training completion certificate intends to have the certificate reissued pursuant to the provisions in the preceding Paragraph, the smeared or damaged qualification training completion certificate shall be submitted with the application form pursuant to the provisions of the same Paragraph.
3. A person who has smeared, damaged or lost his/her qualification training completion certificate pertaining to a qualification training implemented by a registered qualification training organization and intends to have it reissued shall submit an application form pursuant to the provisions of the Appended Form 48 to the concerned registered qualification training organization.
4. In cases where a person, who lost his/her qualification training completion certificate and received a reissued qualification training completion certificate pursuant to the provisions in Paragraph 1 or 3, has found the lost qualification training completion certificate, the person shall immediately return the found qualification training completion certificate to the NRA or the registered qualification training organization concerned.

(Details of Qualification Training)

Article 35-8. Beyond what is pursuant to the provisions of Article 35-4 through the preceding Article, the number of hours of qualification training and other details are separately specified by the NRA.

(Format of Certificate)

Article 36. The format of the certificate for a radiation protection supervisor (hereinafter referred to as “certificate”) is as pursuant to the provisions of the Appended Form 49.

(Issuance of Certificate)

Article 36-2. A person intending to have his/her certificate be issued shall submit an application form for issuance of the certificate for a radiation protection supervisor using the Appended Form 50, appending the certificate of passing and the qualification training completion certificate (or, in the case pertaining to the certificate for the third-class radiation protection supervisor pursuant to the provisions of Article 35 Paragraph 1 of the Act, qualification training completion certificate) to the NRA. In this case, the NRA may have the person intending to have a certificate be

issued, submit a copy of his/her residence certificate pursuant to the provisions in Article 30-7 Paragraph 3 of Residential Basic Book Act (Act No. 81 of 1967), if the personal identification information on the person involved prescribed in Article 30-5 Paragraph 1 of the same Act (referred to as “personal identification information” in the following Article) is unable to be used.

(Correction of Certificate)

Article 37. The person to whom has been issued a certificate, in cases where any changes occurred in matters mentioned in a certificate, shall submit an application form for correction of the certificate for radiation protection supervisors using the Appended Form 51, appending the certificate to the NRA, without delay. In this case, the NRA may have a person involved submit a copy of his/her residence certificate pursuant to the provisions in Article 30-7 Paragraph 3 of Residential Basic Book Act, if personal identification information is unable to be used.

(Reissuance of Certificate)

Article 38. A person who has smeared, damaged or lost his/ her certificate and intends to have it reissued shall submit an application form for reissuance of the certificate for a radiation protection supervisor using the Appended Form 52 to the NRA.

2. In cases where a person who has smeared, damaged or lost his/her certificate, intends to have it reissued pursuant to the provisions in the preceding Paragraph, the smeared or damaged certificate shall be submitted, appended by the application form pursuant to the provisions of the same Paragraph.
3. In cases where the person prescribed in Paragraph 1 who had it reissued, has found the lost certificate, the person shall immediately return the concerned certificate to the NRA.

(Issuance of Training Completion Certificates)

Article 38-2. The Nuclear Regulation Authority issues training completion certificates pursuant to the provisions of the Appended Form 53 to persons who have completed the training pursuant to the provisions of Article 36-3 Paragraph 2 of the Act.

(Subjects of Training, etc.)

Article 38-3. Beyond what is pursuant to the provisions of the preceding Article, subjects and number of hours of training and other matters necessary for training are specified by the NRA each time when it gives directions pursuant to the provisions in Article 36-1 Paragraph 1 of the Act.

Chapter 6. Miscellaneous Provisions

(Collection of Reports)

Article 39. A permission or notification user, a notification user of an approved device with certification label, a notification dealer, a notification lessor or a permission waste management operator, or a person entrusted transport by any of these persons, in cases where the event corresponding to any of the following Items arises, shall notify the NRA of the fact promptly and the situations and the measures taken within 10 days:

- (1) radioisotopes have been stolen or missing.
 - (2) in cases where the exhaust has been discharged after the gaseous radioisotopes, etc. being purified in the exhaust equipment or exhausted, the concentration of radioisotopes in the air or radiation dose has exceeded the respective limit specified in Article 19 Paragraph 1 Item 2.
 - (3) in cases where the drain has been discharged after liquid radioisotopes, etc. being purified in the drainage equipment or drained off, the concentration of radioisotopes in the drain or radiation dose has exceeded the respective limit specified in Article 19 Paragraph 1 Item 5.
 - (4) in cases where there has been a leakage of radioisotopes, etc. outside a controlled area (excluding the case where unsealed radioisotopes have been used outside a controlled area pursuant to the provisions in Article 15 Paragraph 2).
 - (5) in cases where there has been a leakage of radioisotopes, etc. inside a controlled area; provided, however, that this does not apply to the case corresponding to any of the following cases (excluding the case where leaked materials have spread beyond the controlled area):
 - (a) leaked liquid radioisotopes, etc. have not yet spread beyond shuttering for preventing the spread of leakage that have been installed around the equipment involved in the concerned leakage;
 - (b) in cases where gaseous radioisotopes, etc. have leaked, there is no likelihood that the concentrations of radioisotopes in the air exceed the concentration limit in air.
 - (6) the dose limits specified in Article 14-7 Paragraph 1 Item 3 have been or are likely to be exceeded.
 - (7) in cases where unplanned exposure has occurred in use, dealing, leasing, waste management or other handling of radioisotopes, etc. and the effective dose of the concerned exposure has exceeded or is likely to exceed 5 mSv for a radiation worker (including persons engaged in waste management; hereinafter the same applies to this Paragraph) or 0.5 mSv for a person other than a radiation worker.
 - (8) radiation workers have been exposed to radiation that exceeds or is likely to exceed the effective dose limit or equivalent dose limit.
 - (9) the dose limit pursuant to the provisions of Article 14-12 Item 2 is likely to be exceeded.
2. A permission or notification user or a permission waste management operator (excluding the person deemed to be a permission or notification user or a permission waste management operator pursuant to the provisions in Article 28 Paragraph 7 of the Act), if the person has decommissioned a radiation facility, shall notify the NRA of removal of contamination by radioisotopes and other measures taken, with the form pursuant to the provisions of the Appended Form 54 within 30 days of the decommissioning.
 3. A permission or notification user, a notification dealer, a notification lessor or a permission waste management operator (excluding the person deemed to be a permission or notification users, notification dealer, a notification lessor, or a permission waste management operator pursuant to the provisions in Article 28 Paragraph 7 of the Act) shall prepare a report in the form pursuant to the provisions of the Appended Form 55 for the period of time from April 1 of each year to March 31 of the following year and submit the report to the NRA within 3 months after the concerned period has elapsed.
 4. Persons set forth in each of the following Items, pertaining to sealed radioisotopes that are specified by the NRA as those that are likely to cause a serious influence on human health (hereinafter referred to as “specific radioisotopes”

in this Article), in cases where they have conducted acts prescribed separately in the following Items concerned or conducted waste management shall notify the NRA of the fact and the details of the specific radioisotopes concerned, with the forms pursuant to the provisions of the Appended Form 56 for the acts and in the Appended Form 57 for the waste management within 15 days from the day of implementation of the concerned acts; provided, however, that in cases where the concerned act is any of the acts pursuant to the provisions of the following Items (excluding manufacture, import and export) that are conducted between a permission or notification user or a notification user of approved devices with certification label and a notification dealer or a notification lessor, and where, pertaining to the acts, the factory or place of business of the permission user, a notification user or a notification user of approved devices with certification label and the place of business of the notification dealer or the place of business of the notification lessor are identical, the report for notification may be omitted:

- (1) permission or notification user: manufacture, import, receipt, export or delivery;
- (2) notification user of approved devices with certification label: receipt or delivery;
- (3) notification dealer or notification lessor: import, receipt (including completion of collection, lease and entrustment of storage), export or transfer (including return, lease and entrustment of storage).

5. In cases where a permission user or a notification user has changed the details of specific radioisotopes that have been notified pursuant to the provisions in the preceding Paragraph or where the concerned radioisotopes have no more classified as specific radioisotopes due to the change, it shall notify the NRA of the fact and details of the specific radioisotopes concerned with the Appended Form 57 within 15 days from the day of the change. In this case, in cases where receipt or delivery was conducted in a series of acts, the report for notification pursuant to the provisions of the preceding Paragraph may be submitted together.
6. A permission or notification user or a notification user of approved devices with certification label (excluding the person deemed to be a permission or notification user or a notification user of approved devices with certification label pursuant to the provisions in Article 28 Paragraph 7 of the Act) shall notify the NRA of the specific radioisotopes it possesses as of March 31 each year, within 3 months after the same date, with the Appended Form 58.
7. Beyond the cases pursuant to the provisions of the preceding Paragraphs, a permission or notification user, a notification user of approved devices with certification label, a notification dealer, a notification lessor or a permission waste management operator, or a person who is entrusted transport by any of these persons, in cases where the NRA requests them to report about the matters set forth in the following Items by designating a certain time limit, shall notify it of the concerned matters within the concerned time limit:
 - (1) status of radiation management;
 - (2) stock of radioisotopes and status of increase and decrease;
 - (3) status of waste management or transport of radioisotopes, etc. conducted outside the factory or place of business.

(Certificate for Removal of Radioisotopes, etc.)

Article 40. In cases where a radiation inspector removes radioisotopes, etc. pursuant to the provisions in Article 43-2 Paragraph 1, certificate for removal shall be issued to the person whose radioisotopes, etc. have been removed.

(Identification Card of a Radiation Inspector)

Article 41. Identification card of a radiation inspector who conducts on-site inspection pursuant to the provisions in Article 43-2 Paragraph 1 of the Act, pursuant to the provisions of Paragraph 3 of the same Article and identification cards of the personnel who conduct on-site inspection pursuant to the provisions in Paragraph 2 of the same Article shall conform with the provisions of the Appended Form 59 and Appended Form 60, respectively.

(Special Provisions for Liaison)

Article 41-2. Notification or reports provided for in the NRA Ordinance prescribed in Article 47 Paragraph 2 of the Act are notification pursuant to the provisions of Article 3-3 of the Act, and notification pursuant to the provisions of Article 27 Paragraphs 1 and 3 of the Act pertaining to approved devices with certification label, and reports pursuant to the provisions of Article 28 Paragraph 5 of the Act.

(Procedures by Using Flexible Disks)

Article 42. Pursuant to the provisions by the NRA, submission of documents set forth in the following Items may be substituted by submitting a flexible disk which records the matters to be stated in the concerned documents and a flexible disk submission form of the Appended Form 61 (referred to as “flexible disk, etc.” in the following Paragraph):

- (1) notification pursuant to the provisions of Article 10-2;
- (2) notification pursuant to the provisions of Article 31 Paragraph 1;
- (3) notification pursuant to the provisions of Article 33 Paragraph 2;
- (4) report pursuant to the provisions of Article 39 Paragraph 3.

2. In cases where a flexible disk, etc. is submitted in lieu of submission of the documents set forth in Item 1 of the preceding Paragraph pursuant to the provisions in the preceding Paragraph, the terms “one original and 2 duplicates” in Article 12 Paragraph 3 are replaced with “one floppy disk and 3 floppy disk submission forms”.

Supplementary Provisions (Excerpt)

(omitted)