

## 英譯法規內容

法規名稱(Title) : Administrative Regulations for Radioactive Material and Equipment Capable of Producing Ionizing Radiation and Associated Practice

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Amendment of Articles 7 and 46 on December 24, 2012 by the Atomic Energy Council Per its decree No. Huei-Fu-Tsu 1010020806

## 法規內文(Content) :

## Section I General Principles

## Article 1

The Regulations are prescribed in accordance with the provisions

of Paragraph 29.5 of the Ionizing Radiation Protection Act (hereinafter referred to as "this Act").

## Article 2

The definitions for terms used in the Regulations are as follows:

1. Sealed radioactive material refers to radioactive material placed in a sealed container sufficient to provide isolation from the outside under normal use.
2. Modification refers to any one of the following situations involving radioactive material, equipment capable of producing ionizing radiation or the workplace:
  - (1) a change in the direction of primary radiation beam of sealed radioactive material or equipment capable of producing ionizing radiation;
  - (2) an increase in the activity of sealed radioactive material;
  - (3) an increase in the nominal voltage of an X-ray unit;
  - (4) an increase in the accelerating voltage of an accelerator;
  - (5) a change in the radiation protective shielding; or
  - (6) other situations as designated by the Competent Authority.
3. Labeling refers to the process of combining a radioactive nuclide with another material to form a radioactive compound.
4. Cabinet refers to a separate cabinet, not a part of a building, originally designed or constructed with appropriate shielding that, when in use, prevents entry by personnel and in which radioactive material or equipment capable of producing ionizing radiation is placed.
5. High-level radiation facility refers to a facility characterized by one of the following:
  - (1) equipment capable of producing ionizing radiation with a rated accelerating voltage of greater than 30 MV
  - (2) equipment capable of producing ionizing radiation with a particle energy rating of greater than 30 MeV; or
  - (3) the use of sealed radioactive material with an activity of greater than 1,000 TBq.
6. Transit refers to a stop-over period with definite time parameters for goods not yet unloaded being shipped on the

same aircraft or means of transportation that are to enter another country or area via Taiwan air or sea ports.

7. Transshipment en route refers to a stop-over period with definite time parameters for unloaded goods being shipped on the same or other aircraft or means of transportation that are to enter another country or area via Taiwan air or sea ports.
8. Surface contaminated object (SCO) refers to a solid substance that, itself not radioactive, has been contaminated on the surface by a radioactive material, but this does not include radioactive waste.

### Article 3

There are five types of sealed radioactive material categorized by their degree of potential detriment against human health and environment as listed in Table I.

## Section II Application for a Permission of Import, Transfer, Export, Transit or Transshipment En Route

### Article 4

#### Paragraph 4.1

Applicants who apply for a permission of import, transfer or export for radioactive material or for equipment capable of producing ionizing radiation shall possess one of the following qualifications:

1. a government agency (or organization);
2. a post-secondary high (or vocational) school or academic research organization;
3. a company or other legal person;
4. a medical institution, radiology center or medical laboratory established with the approval of the public health competent authority;
5. a veterinarian medical institution officially established in accordance with the Law Governing Veterinarian; or

6.other qualifications as approved by the Competent Authority.

#### Paragraph 4.2

The applicants who apply for the permission of export referred to in Paragraph 4.1 shall meet one of the following criteria:

- 1.possessing a permit or a registration approved by the Competent Authority for radioactive material or equipment capable of producing ionizing radiation;
- 2.possessing a permission for production of radioactive material or for manufacture of equipment capable of producing ionizing radiation; or
- 3.other criteria as designated by the Competent Authority.

### Article 5

#### Paragraph 5.1

For import of radioactive material or equipment capable of producing ionizing radiation, applicants shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review and approval, after which the permission will be granted:

- 1.results of radiation safety tests done by the original manufacturer, Chinese or English version; and
- 2.a catalog and explanatory diagrams.
- 3.For radioactive material, documents relating to the transport details shall also be enclosed.

#### Paragraph 5.2

The documents in Subparagraphs 5.1.1 and 5.1.2 shall be kept by the applicants themselves and the submission of the documents to the Competent Authority for review and approval may be waived for equipment capable of producing ionizing radiation if the registration of import for filing and reference is applied.

#### Paragraph 5.3

For re-applications for import of radioactive material or equipment capable of producing ionizing radiation of the same model and brand previously reviewed and approved, the submission of all the documents in Paragraph 5.1 may be waived.

#### Paragraph 5.4

In cases where facility operators possess a duly issued by the Competent Authority or a registration approved by the Competent Authority to use unsealed radioactive material, the submission of all the documents referred to in Paragraph 5.1 may be waived at the time of applying for import.

## Article 6

### Paragraph 6.1

Applicants who apply for import of radioactive material of Column 1 or Column 2 as listed in Table II shall, after obtaining the permission referred to in Article 5, give a photocopy of the said permission to the competent authority of the exporting country or the exporting organization.

### Paragraph 6.2

The applicant shall, seven (7) days before the starting of shipment operation at the port for the sealed radioactive material referred to in Paragraph 6.1, specify the following in a written document and inform the Competent Authority:

- 1.estimated date of export;
- 2.name of the exporting organization;
- 3.name or entire title of the recipient;
- 4.radionuclide name, quantity, activity and total activity; and
- 5.unique identifiers such as manufacturer, model and serial number, etc.

### Paragraph 6.3

When the significant risk sealed radioactive material of Column 1 as listed in Table II reaches the port of destination, the applicant or its designator shall pick up the goods forthwith, and shall not store them in the warehouse of the port without the permission of the Competent Authority.

## Article 7

### Paragraph 7.1

For the transfer of radioactive material or equipment capable of producing ionizing radiation, assignors and assignees shall jointly fill out an application form and apply to the Competent

Authority for review and approval, after which permission may be granted.

#### Paragraph 7.2

For the applications of transfer of radioactive material referred to in Paragraph 7.1, documents relating to the transport details shall also be enclosed.

#### Paragraph 7.3

In cases where facility operators possess a permit duly issued by the Competent Authority or registration approved by the Competent Authority for the use of unsealed radioactive material, the enclosure of the documents referred to in Paragraph 7.2 may be waived when applying for the transfer of unsealed radioactive material.

### Article 8

#### Paragraph 8.1

For export of radioactive material or equipment capable of producing ionizing radiation, applicants shall fill out an application form and make an application to the Competent Authority for review and approval, after which the permission will be granted.

#### Paragraph 8.2

For the applications of the export of radioactive material referred to in Paragraph 8.1, documents relating to the transport details shall also be enclosed.

### Article 9

#### Paragraph 9.1

Applicants who apply for export of significant risk sealed radioactive material of Column 1 as listed in Table II shall, in addition to the documents stipulated in Article 8, enclose the import agreement documentation from the competent authority of the importing country and send it to the Competent Authority for review.

#### Paragraph 9.2

The import agreement documentation referred to in Paragraph 9.1 shall specify the following:

- 1.name or entire title of the recipient;
- 2.recipient's residence, firm or principal place of business;
- 3.radionuclide name, quantity, activity and total activity;
- 4.unique identifiers such as manufacturer, model and serial number, etc; and
- 5.estimated starting and ending time of shipment.

## Article 10

Applicants for export of significant risk sealed radioactive material of Column 1 or Column 2 as listed in Table II shall, seven (7) days before the starting of shipment operation at the port for the sealed radioactive material, specify in a written document the following and inform the Competent Authority and the competent authority as well as the recipient of the importing country:

- 1.estimated date of export;
- 2.name or entire title of the applicant;
- 3.name or entire title of the recipient;
- 4.radionuclide name, quantity, activity and total activity; and
- 5.unique identifiers such as manufacturer, model and serial number, etc.

## Article 11

### Paragraph 11.1

Applicants who apply for a permission to import or export a surface contaminated object shall possess one of the following qualifications:

- 1.a government agency (or organization);
- 2.a university, college or academic research organization;
- 3.a company or other legal person;
- 4.a medical institution set up with the official approval of the public health competent authority; or
- 5.other qualifications as approved by the Competent Authority.

### Paragraph 11.2

Applications for import or export of surface contaminated objects shall conform with the Regulations for the Safe Transport of

Radioactive Material.

## Article 12

For import or export of surface contaminated objects, the following documents shall be enclosed and an application shall be made to the Competent Authority for review and approval, after which the permission will be granted:

- 1.data on the package or packaging smear test and surface dose rates;
- 2.documents relating to the transport details.

## Article 13

### Paragraph 13.1

For transit or transshipment en route of radioactive material, the shipper or the carrier shall enclose the radiation protection plan and make an application to the Competent Authority for review and approval, after which the permission will be granted. The permission is effective for a period of five (5) years.

### Paragraph 13.2

The shipper or the carrier having obtained the permission shall enclose the transport documents to the Competent Authority for filing and reference prior to transit or transshipment en route of any batch of radioactive material.

### Paragraph 13.3

Transit or transshipment en route of radioactive material shall conform with the Regulations for the Safe Transport of Radioactive Material.

### Paragraph 13.4

In cases of transport of radioactive material in excepted packages, the stipulations in Paragraphs 13.1 and 13.2 do not apply.

## Article 14

The Permission of import, transfer, or export is effective for a period of six (6) months.

Section III Applications for a Permission, a Permit or a  
Registration for Filing and Reference for Use,  
Installation, Modification or Possession

Article 15

Paragraph 15.1

Applicants who apply for a permit or a registration for filing and reference for the use of radioactive material or equipment capable of producing ionizing radiation shall possess one of the following qualifications:

- 1.a government agency (or organization);
- 2.a post-secondary high (or vocational) school or academic research organization;
- 3.a company or other legal person;
- 4.a medical institution, radiology center or medical laboratory established with the official approval of the public health competent authority;
- 5.a veterinarian medical institution officially established in accordance with the Law Governing Veterinarian; or
- 6.other qualifications as approved by the Competent Authority.

Paragraph 15.2

In the case of an application for the use referred to in Paragraph 15.1, the applicants shall meet the following criteria:

- 1.having qualified operating personnel;
- 2.possessing a workplace or storage area meeting radiation safety regulations; and
- 3.other criteria as designated by the Competent Authority.

Article 16

Paragraph 16.1

For use of the following radioactive material, a registration application shall be made to the Competent Authority for filing and reference:

- 1.sealed radioactive material of Category IV and Category V as listed in Table I;
- 2.radioactive material that forms a component of an instrument or manufactured product and that has an activity less than 1,000 times that of the exemption level and that under normal usage has a surface dose rate at an accessible distance of 5 cm of less than 5 micro-sieverts ( $\mu\text{Sv}$ ) per hour;
- 3.radioactive material besides those mentioned in Subparagraphs 16.1.1 and 16.1.2 with an activity less than 100 times that of the exemption level; or
- 4.other radioactive material as designated by the Competent Authority.

#### Paragraph 16.2

For use of radioactive material other than those stipulated in Paragraph 16.1, an application for a permit shall be made to the Competent Authority.

### Article 17

#### Paragraph 17.1

For use of the following equipment capable of producing ionizing radiation, applicants shall apply for a registration to the Competent Authority for filing and reference:

- 1.nominal voltage is less than 150 kV or particle energy is less than 150 keV;
- 2.cabinet or baggage inspection X-ray machine, ion implanter, electron beam welding machine or static eliminator that under normal usage has a surface dose rate at an accessible distance of 5 cm of less than 5 micro-sieverts ( $\mu\text{Sv}$ ) per hour; or
- 3.other equipment as designated by the Competent Authority.

#### Paragraph 17.2

For use of equipment capable of producing ionizing radiation other than those stipulated in Paragraph 17.1 or for non-medical use of those stipulated in Subparagraph 17.1.1 with direct irradiation on human bodies, an application for a permit shall be made to the Competent Authority.

## Article 18

### Paragraph 18.1

Applicants for use of sealed radioactive material or equipment capable of producing ionizing radiation for which a permission application shall be made shall, when applying for import or transfer, fill out an application form, enclose the following documents and make an application to the Competent Authority for review. In cases that shield engineering is involved in the installation, the installation permission will be granted after review and approval; in cases that shield engineering is not involved in the installation, following the grant of permission by the Competent Authority for import or transfer, the documents referred to in Paragraph 18.2 shall be enclosed to the Competent Authority for review, inspection and approval, after which the permit for use will be issued:

- 1.a photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations);
- 2.photocopies of the relevant operating personnel credentials and the certificates of employment;
- 3.workplace radiation safety assessment. In cases that shield engineering is not involved, a shielding planning need not to be enclosed;
- 4.a radiation protection plan and radiation safety operation guidelines;
- 5.photocopies of the certificates of radiation protection personnel shall be submitted in conformity with the stipulations in the Standards for Establishment of Radiation Protection Management Organizations and Radiation Protection Personnel; and
- 6.for use of sealed radioactive material of Category I and Category II as listed in Table I, a security planning shall be submitted.

### Paragraph 18.2

Only after the applicants referred to in Paragraph 18.1 have obtained the installation permission can installation begin

in accordance with the officially approved workplace radiation safety assessment, the floor plans and the shielding planning. Within 30 days after completion of the installation, the following documents are to be enclosed to the Competent Authority for review, inspection and approval, after which the permit for use will be issued:

- 1.a radiation safety survey report (hereinafter referred to as "survey report");
- 2.for sealed radioactive material conforming with the stipulations referred to in Paragraph 54.1, a sealed radioactive material smear test report shall be submitted (hereinafter referred to as "smear test report"); and
- 3.for sealed radioactive material, a photocopy of the original certifying document of radioactive material shall be submitted.

## Article19

### Paragraph 19.1

For unsealed radioactive material or re-packaged and labeled radioactive material whose use requires a permission, applicants shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review and approval, after which the installation permission will be granted:

- 1.a photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations);
- 2.photocopies of the relevant operating personnel credentials and the certificates of employment;
- 3.workplace radiation safety assessment;
- 4.a radiation protection plan and radiation safety operation guidelines;
- 5.for the labeling of radioactive material, information on the physical and chemical properties of the radioactive material as well as on the handling process used shall be submitted; and
- 6.in conformity with the stipulations in the Standards for

Establishment of Radiation Protection Management Organizations and Radiation Protection Personnel, photocopies of the certificates of radiation protection personnel shall be submitted.

#### Paragraph 19.2

Only after the applicants referred to in Paragraph 19.1 have obtained the installation permission can the shield engineering installation begin in accordance with the officially approved workplace radiation safety assessment. Within 30 days after completion of the installation, a radiation safety survey report is to be enclosed to the Competent Authority for review, inspection and approval, after which the permit for use will be issued.

#### Article 20

The workplace radiation safety assessments referred to in Subparagraph 18.1.3 and Subparagraph 19.1.3 shall deliberate the following items for appropriate assessing, in accordance with the scale and nature of the radiation practice:

1. workplace floor plans and shielding planning;
2. measures for handling radioactive contaminants;
3. protective measures on mobile radioactive material or equipment capable of producing ionizing radiation; and
4. personnel dose assessment.

#### Article 21

The permit for use is effective for a maximum period of five (5) years. Facility operators shall fill out an application form 60 to 30 days before the expiration date and enclose the following documents to the Competent Authority for review, inspection and approval, after which renewal of the permit for use will be issued:

1. a photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations);
2. the original permit for use;

- 3.a survey report done within the last 30 days; and
- 4.for sealed radioactive materials conforming with the stipulations referred to in Paragraph 54.1, the latest smear test report shall also be enclosed.

## Article 22

### Paragraph 22.1

Facility operators who have obtained the permit for use of radioactive material or equipment capable of producing ionizing radiation shall fill out an application form before making modifications and enclose the following documents to the Competent Authority for review and approval, after which the modification permission will be granted:

- 1.workplace radiation safety assessment in accordance with the stipulations of Article 20.;
- 2.photocopies of the relevant operating personnel credentials;  
and
- 3.the original permit for use.

### Paragraph 22.2

In cases where the modification referred to in Paragraph 22.1 involves a change in radiation safety, a radiation protection plan or radiation safety operating guidelines shall be enclosed.

### Paragraph 22.3

Only after the facility operator obtains the modification permission may the modification proceed in accordance with the approved workplace radiation safety assessment. Within 30 days after completion of the modification, the following documents shall be enclosed to the Competent Authority for review, inspection and approval, after which the permit for use will be issued:

- 1.a survey report; and
- 2.for sealed radioactive material in conformity with the stipulations referred to in Paragraph 54.1, a smear test report shall be submitted.

## Article 23

### Paragraph 23.1

For use of sealed radioactive material that the use requires a registration for filing and reference approved by the Competent Authority, applicants shall, when applying for import or transfer, fill out an application form, enclose the following documents and make an application to the Competent Authority for review. If shield engineering is involved in the installation, the installation permission will be granted after review and approval; if shield engineering is not involved in the installation, after the Competent Authority grants the permission of import or transfer, the documents referred to in Paragraph 23.2 are to be enclosed to the Competent Authority for review and approval, after which the registration will be approved:

1. photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations);
2. photocopies of the relevant operating personnel credentials and the certificates of employment;
3. workplace floor plans and shielding planning; the shielding planning may be waived if shield engineering is not involved or Subparagraph 16.1.2 is qualified; and
4. a radiation protection plan.

### Paragraph 23.2

Only after the applicants referred to in Paragraph 23.1 have obtained the modification permission may the modification proceed in accordance with the approved workplace floor plans and shielding planning. Within 30 days after completion of the modification, the following documents shall be enclosed to the Competent Authority for review and approval, after which the registration will be approved:

1. a photocopy of the original radioactive material certification;
2. a survey report; and
3. for sealed radioactive material in conformity with the

stipulations referred to in Paragraph 54.1, a smear test report shall be submitted.

#### Paragraph 23.3

For use of equipment capable of producing ionizing radiation that the use requires a registration for filing and reference approved by the Competent Authority, applicants shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review prior to the use of the equipment, after which a registration will be approved:

- 1.name and number of the certification of establishment or the registration approved;
- 2.name and number of the relevant operating personnel credentials;
- 3.survey report related information; and
- 4.a radiation protection plan.

#### Article 24

For unsealed radioactive material or re-packaged, labeled radioactive material, whose use requires a registration, applicants shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review and approval, after which a registration will be approved:

- 1.photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations);
- 2.photocopy of the relevant operating personnel credentials and the certificate of employment;
- 3.workplace floor plans and shielding planning;
- 4.a radiation protection plan; and
- 5.for the labeling of radioactive material, information on the physical and chemical properties of the radioactive material as well as on the handling process used shall be submitted.

#### Article 25

Once every five (5) years, the facility operators who have the

registration approved by the Competent Authority for radioactive material or equipment capable of producing ionizing radiation one (1) month prior to or after the day equivalent to the approved registration date, shall conduct a radiation safety survey and record the results for future reference.

## Article 26

### Paragraph 26.1

When the radioactive material for which the registration has been permitted is to be modified, the facility operators shall fill out an application form before modification and enclose the following documents to the Competent Authority for review and approval, after which a modification permit will be issued:

- 1.workplace floor plans and shielding planning; and
- 2.photocopy of the relevant operating personnel credentials.

### Paragraph 26.2

Only after the facility operators have obtained the modification permit may the modification work proceed in accordance with the approved workplace floor plans and shielding planning. Within 30 days after the work is completed, the following documents shall be enclosed to the Competent Authority for review, after which a registration will be approved:

- 1.survey report; and
- 2.for sealed radioactive material in conformity with the stipulations referred to in Paragraph 54.1, a smear test report shall be submitted.

### Paragraph 26.3

The facility operators who have the registration approved by the Competent Authority for equipment capable of producing ionizing radiation shall, within 30 days after the modification work is completed, fill out an application form and the following information, enclosed to the Competent Authority for review and approval, after which a registration will be approved:

- 1.name and number of the relevant operating personnel credentials.
- 2.survey report related information and radiation detection data.

#### Paragraph 26.4

If, after modification, the energy level of the equipment capable of producing ionizing radiation or the total activity of the radioactive material reaches the level stipulated that the certificate of permission shall be applied for, then matters shall proceed in accordance with the stipulations referred to in Article 22.

#### Article 27

##### Paragraph 27.1

For radioactive material or equipment capable of producing ionizing radiation, if there will be a movement to a new location or a change of the workplace and therefore an installation or modification is involved, the facility operators shall fill out an application form and apply for a certificate of permission for use or a registration for filing and reference separately in accordance with the installation or modification stipulations referred to in Article 18, Article 22 and Article 23.

##### Paragraph 27.2

If the facility operators, who have obtained the certificate of permission or the registration approved by the Competent Authority for the use of unsealed radioactive material, will increase the number of workplaces, the number of nuclides or activity used, they shall apply for a certificate of permission for use or a registration for filing and reference separately in accordance with the stipulations referred to in Article 19 and Article 24.

#### Article 28

##### Paragraph 28.1

For use of a high-level radiation facility, applicants shall fill out an application form and enclose the following documents to the Competent Authority for review and approval, after which a permit for installation will be issued:

- 1.a photocopy of the certification of establishment or the

- registration approved; waived for government agencies (or organizations);
2. workplace radiation safety assessment;
  3. radiation protection plan and radiation safety operation guidelines;
  4. the structure of workplace shielding and machinery and an earthquake enduring level certification;
  5. operational training and practical operational training plan;
  6. pre-operational test plan and schedule;
  7. for sealed radioactive material, a photocopy of the original radioactive material certification and security planning shall be enclosed; and
  8. procedure for dealing with accidents.

#### Paragraph 28.2

The workplace radiation safety assessment referred to in Subparagraph 28.1.2 shall contain the following information:

1. workplace floor plans and shielding planning;
2. facility radiation dose assessment and protection measures;
3. measures for handling radioactive contaminants (including activated products); and
4. other information as designated by the Competent Authority.

#### Paragraph 28.3

Only after the applicants have obtained the permit for installation may the work proceed in accordance with the approved radiation safety assessment, the floor plans, and the shielding planning. Within 30 days after completion of the work, a survey report shall be enclosed to the Competent Authority for review, inspection and approval, after which a pre-operational test permit will be issued.

#### Paragraph 28.4

After the completion of the pre-operational test, the applicants shall enclose, within 30 days, a radiation safety analysis report that includes the following items to the Competent Authority for review, inspection and approval, after which a certificate of permission for use will be issued:

1. the area monitoring results;

- 2.the personal dose monitoring results;
- 3.the record of the pre-operational test; and
- 4.other items as designated by the Competent Authority.

#### Article 29

The certificate of permission for use of a high-level radiation facility is effective for a maximum period of five (5) years. The facility operators shall fill out an application form 60 to 30 days before the expiration date and enclose the following documents to the Competent Authority for review, inspection and approval, after which a renewed certificate of permission for use will be issued:

- 1.a photocopy of the certification of establishment or the registration approved; waived for government agencies (or organizations); and
- 2.the survey report done within the last 30 days.

#### Article 30

For installation or modification of radioactive material or equipment capable of producing ionizing radiation, the work shall be completed within the time frames as specified below. If the work is not completed within the specified time frame, an application for extension may be made to the Competent Authority one (1) month prior to the deadline:

- 1.a high-level radiation facility shall be completed within two (2) years of the approved installation or modification date.
- 2.work involving the use of radioactive material or equipment capable of producing ionizing radiation to which the permit shall be applied, other than that referred to in Article 30.1, shall be completed within one (1) year of the approved installation or modification date.
- 3.work involving the use of equipment capable of producing ionizing radiation to which the registration for filing and reference is to be applied shall be completed within one (1) year of the approved import or transfer date.

## Article 31

### Paragraph 31.1

Those who are engaged in radiation protection service businesses shall not possess sealed radioactive material.

However, the following circumstances with the permission of the Competent Authority are excluded:

- 1.those who sale sealed radioactive material referred to in Subparagraph 16.1.2; or
- 2.those who are engaged in sales service businesses or radiation protection detection businesses replace the sealed radioactive material for facility operators and do temporary storage of the material before export or transfer.

### Paragraph 31.2

Applicants who apply for possession of sealed radioactive material according to the stipulations in Subparagraphs 31.1.1 and 31.1.2 shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review, inspection and approval, after which a possession permit will be issued:

- 1.the permit of radiation protection service businesses;
- 2.application documentation on the brand, model, nuclide ,activity and quantity of the sealed radioactive material in possession;
- 3.radiation protection plan; and
- 4.radiation safety assessment on an appropriate storage area and shielding planning. They shall be finished according to the maximum holding of the radioactive material estimated for the appropriate storage area.

### Paragraph 31.3

Those who are permitted by the Competent Authority to engage in the sales of equipment capable of producing ionizing radiation may possess the equipment capable of producing ionizing radiation according to the approved items.

## Article 32

### Paragraph 32.1

For any of the following situations, the applicants shall apply for a possession permit:

- 1.inability to complete the installation or the modification within the time frame stipulated in Article 30;
- 2.subsequent to the approval by the Competent Authority for import or transfer, inability to proceed the installation following the delivery; or
- 3.other situations as approved by the Competent Authority.

#### Paragraph 32.2

The applicants shall, 30 days prior to the deadline stipulated in Article 30 or within 30 days from the delivery of the radioactive material or the equipment capable of producing ionizing radiation, enclose the following documents and make an application to the Competent Authority for review. After the equipment capable of producing ionizing radiation is reviewed and approved, a possession permit will be issued; after the radioactive material is reviewed, inspected and approved, a possession permit will be issued:

- 1.reasons for possession;
- 2.radiation protection plan;
- 3.the storage area. For radioactive material, the floor plans and the shielding planning shall be submitted; and
- 4.for sealed radioactive material in conformity with the stipulations of Paragraph 54.1, a smear test report shall be submitted.

#### Paragraph 32.3

The possession permit referred to in Paragraph 32.2 is effective for a maximum of two (2) years.

#### Paragraph 32.4

The facility operator may, within 60 to 30 days prior to the expiration of the possession permit of the radioactive material or the equipment capable of producing ionizing radiation, fill out an application form and enclose all the documents provided in Paragraph 32.2 to the Competent Authority for extension, which is subject to a maximum of one (1) time.

## Article 33

### Paragraph 33.1

For the certificate of permission for radioactive material or equipment capable of producing ionizing radiation or the designated items in the registration approved by the Competent Authority, if there is change of the printed items or loss or damage of the certificate of permission, the facility operator shall, within 30 days of the occurrence, fill out an application form and apply to the Competent Authority for change, reissue or renewal.

### Paragraph 33.2

The period of effectiveness for the permit is the same as that for the original one.

## Article 34

### Paragraph 34.1

When a facility operator replaces the X-ray tube or the accelerator tube of equipment capable of producing ionizing radiation, he/she shall proceed according to the following stipulations. However, the following stipulations are not applicable to the replacement of the X-ray tube of static eliminators:

1. for that who obtains the permit for use, a survey report shall be enclosed to the Competent Authority for filing and reference within 15 days after the replacement.
2. for the registration approved by the Competent Authority, the survey report shall be independently kept.

### Paragraph 34.2

If a facility operator removes and replaces radioactive material for which he/she possesses the permit for use or the registration approved by the Competent Authority, he/she shall fill out an application form and enclose the following documents prior to effecting the replacement, and submit to the Competent Authority for review; and within 15 days following the replacement, he/she shall enclose a smear test report and a photocopy of the original certifying documentation of the newly

installed radioactive material to the Competent Authority for filing and reference:

- 1.the documents relating to the transport details; and
- 2.method of processing the original radioactive material after the replacement.

#### Paragraph 34.3

For the replacement of radioactive material provided in Paragraph 34.2, if the container is replaced at the same time, the application shall be filed in accordance with the stipulations set forth in Article 18 and Article 23 before the replacement.

### Section IV Application for a Permission for Temporary or Permanent Cease of Use

#### Article 35

##### Paragraph 35.1

In cases where the use of radioactive material or equipment capable of producing ionizing radiation must be ceased, the facility operator shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review. After the equipment capable of producing ionizing radiation is reviewed and approved, a permission for cease of use will be granted; after the radioactive material is reviewed, inspected and approved, the permission for cease of use will be granted:

- 1.the original permit for use, for those who have already said issued; and
- 2.description of the storage area. For radioactive material, a floor plan of the storage area and the shielding planning shall be enclosed.

##### Paragraph 35.2

The permission referred to in Paragraph 35.1 are effective for a maximum period of two (2) years.

##### Paragraph 35.3

The facility operator may, within 60 to 30 days prior to the

expiration of ceased use of the radioactive material or the equipment capable of producing ionizing radiation, fill out an application form and enclose all the documents provided in Subparagraph 35.1.2 to the Competent Authority for extension.

## Article 36

### Paragraph 36.1

In cases where an application is made to resume the use of the radioactive material or the equipment capable of producing ionizing radiation that has previously obtained the approval for cease of use, the procedure shall follow the stipulations in Article 18 or Article 23; however, an application for a permission for installation may be waived in the case of use that will occur in the location originally approved by the Competent Authority.

### Paragraph 36.2

If the reason for the approved cease of use referred to in Paragraph 36.1 is the lack of qualified operating personnel, the facility operator shall, when making an application for the resumption of use, fill out an application form, attach qualified operating personnel credentials, and make an application to the Competent Authority for review and approval, after which the permit for use will be issued or the registration will be approved.

## Article 37

### Paragraph 37.1

When a facility operator permanently ceases the use of radioactive material and treats it as radioactive waste, he/she shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review and approval, after which the permission will be granted:

1. discard plan of sealed radioactive material;
2. a photocopy of the originally certifying documents of the radioactive material; and

3.documents relating to the transport details.

#### Paragraph 37.2

Following the approval of the application referred to in Paragraph 37.1 by the Competent Authority, the facility operator shall, within three (3) months, transport the radioactive waste to the receiving unit. Within 30 days of receipt of the said material, a radiation workplace monitoring certificate, receipt documentation and the original permit for use for those who have already said issued shall be enclosed and submitted to the Competent Authority for filing and reference.

### Article 38

#### Paragraph 38.1

When a facility operator permanently ceases the use of radioactive material or equipment capable of producing ionizing radiation and disposes of it by shipping overseas, he/she shall fill out an application form, submit the documents relating to the transport details in the case of exporting radioactive material and make an application to the Competent Authority for review and approval, after which the permission will be granted.

#### Paragraph 38.2

After the application referred to in Paragraph 38.1 is approved by the Competent Authority, the facility operator shall, within 30 days after exportation, enclose a photocopy of the export documentations, the original permit for use for those who have already said issued, and the radiation workplace monitoring certificate in the case of exporting radioactive material, and submit to the Competent Authority for filing and reference.

### Article 39

#### Paragraph 39.1

When a facility operator permanently ceases the use of equipment capable of producing ionizing radiation and disposes of it by transfer, the assignee shall proceed as follows:

- 1.for equipment capable of producing ionizing radiation designated as requiring an application for a permission,

he/she shall proceed in accordance with the stipulations of Articles 7 and 18.

2.for equipment capable of producing ionizing radiation designated as requiring an application for registration for filing and reference, he/she shall proceed in accordance with the stipulations of Articles 7 and 23.

#### Paragraph 39.2

If the assignee referred to in Paragraph 39.1 is applying for possession, he/she shall proceed in accordance with the stipulations of Articles 7 and 32.

#### Article 40

When a facility operator permanently ceases the use of equipment capable of producing ionizing radiation and disposes of it by discard, he/she shall fill out an application form, enclose the original permit for use for those who have already said issued and make an application to the Competent Authority for review and approval, after which he/she will independently render inoperable such parts of said equipment as designated by the Competent Authority and will either take a photograph for filing and reference or request the Competent Authority to send an official to conduct an inspection.

#### Article 41

##### Paragraph 41.1

When a facility operator permanently ceases the use of unsealed radioactive material, he/she shall fill out an application form, enclose the following documents and make an application to the Competent Authority for review and approval, after which he/she shall complete the decontamination in accordance with the approved plan and request the Competent Authority to conduct an inspection:

- 1.the original permit for use for those who have already said issued; and
- 2.decontamination plan.

##### Paragraph 41.2

The decontamination plan referred to in Subparagraph 41.1.2 shall include decontamination schedule, decontamination method, disposition method for radioactive waste, division of the decontamination area and measures for personnel control.

## Section V Application for Display or Lease Permits

### Article 42

#### Paragraph 42.1

Applicants who apply for a permission for display of radioactive material or equipment capable of producing ionizing radiation shall possess one of the following criteria:

1. applicants must be a business representative recognized by the Competent Authority to engage in sales service of radioactive material or equipment capable of producing ionizing radiation;
2. applicants must possess the permission for manufacturing of equipment capable of producing ionizing radiation, issued according to the stipulations in Paragraph 30.1 of this Act;  
or
3. other applicants approved by the Competent Authority.

#### Paragraph 42.2

The period of display referred to in Paragraph 42.1 shall not exceed two (2) months.

### Article 43

For a static display of equipment capable of producing ionizing radiation, applicants shall enclose the following documents and make an application to the Competent Authority for review and approval, after which the permission will be granted:

1. catalog and explanatory diagrams; and
2. display plan and schedule.

### Article 44

#### Paragraph 44.1

For the following radioactive material or equipment capable of

producing ionizing radiation, an application may be made for dynamic display:

1. radioactive material provided in Subparagraph 16.1.1 that forms a component of an instrument or manufactured product;
2. radioactive material provided in Subparagraph 16.1.2;
3. equipment capable of producing ionizing radiation provided in Subparagraphs 17.1.1 and 17.1.2; or
4. others as designated by the Competent Authority.

#### Paragraph 44.2

For the display referred to in Paragraph 44.1, the applicant shall enclose the following documents and make an application to the Competent Authority for review and approval, after which the permission will be granted:

1. catalog, explanatory diagrams and information regarding radiation safety;
2. radiation protection plan;
3. a photocopy of credentials of relevant qualified operating personnel; and
4. display plan and schedule.

### Article 45

#### Paragraph 45.1

Applicants who apply for a lease permission for radioactive material or equipment capable of producing ionizing radiation shall possess one of the following qualifications:

1. government agency (or organization);
2. university, college or academic research organization;
3. company or other legal person;
4. a medical institution, radiology center or medical laboratory;
5. a veterinary medical institution; or
6. other qualifications as approved by the Competent Authority.

#### Paragraph 45.2

For the application for a lease referred to in Paragraph 45.1, the following criteria shall be met:

1. the lessee or the borrower has qualified operating personnel or the personnel are supplied by the lessor or the lender;

- 2.the applicant possesses an appropriate workplace or storage area; and
- 3.radioactive material or equipment capable of producing ionizing radiation must be mobile, carried-in-a-cabinet, carried-on-a-car or the radioactive material used for calibration purposes.

## Article 46

### Paragraph 46.1

In an application for leasing radioactive material or equipment capable of producing ionizing radiation, the lessee or the borrower shall explain the reasons for leasing, enclose the following documents and make an application to the Competent Authority for review and approval, after which the permission will be granted:

- 1.a photocopy of the original permit for those who have already said;
- 2.the lease contract specifying the proposed period of lease;
- 3.a workplace radiation safety assessment carried out in accordance with Article 20. For registration of radioactive material or equipment capable of producing ionizing radiation to be applied, said assessment may be waived;
- 4.radiation protection plan and radiation safety operation guidelines;
- 5.a photocopy of certification of establishment or registration approved; waived for government agencies (or organizations); and
- 6.photocopies of relevant qualified operating personnel credentials and certificate of employment.

### Paragraph 46.2

The duration of the lease permission referred to in Paragraph 46.1 is up to two (2) years. When the lease period is over for the radioactive material or the equipment capable of producing ionizing radiation referred to in Paragraph 46.1, the lessee or the borrower shall immediately return the material or the equipment to the lessor or the lender and shall, within one (1)

month, enclose a survey report and submit to the Competent Authority for filing and reference. For the sealed radioactive material conforming with the stipulation of Paragraph 54.1, a smear test report shall be submitted.

## Section VI Controls

### Article 47

The workplace and the shielding planning for radioactive material or equipment capable of producing ionizing radiation shall be made in accordance with its scale and nature, and refer to the stipulations set forth in Appendix I .

### Article 47-1

#### Paragraph 47-1.1

For the security planning for sealed radioactive material of Category I and Category II, its contents shall refer to the matters stipulated in Appendix 2.

#### Paragraph 47-1.2

The security level and their functions of sealed radioactive material of Category I and Category II shall be in accordance with the stipulations set forth in Table 3.

### Article 47-2

Prior to the implementation of the security planning for sealed radioactive material of Category I and Category II, should sealed radioactive material of Category I and Category II having been set and the permitted associated practice be not in accordance with the stipulations set forth in Article 47-1, they shall be improved within one (1) year since the date of promulgation of the amendment to the Regulations. However, this period may be extended after permission by the Competent Authority. The extension shall be limited to one (1) year.

### Article 48

If the practice of radioactive material or equipment capable of

producing ionizing radiation has one of following conditions, the Competent Authority may cancel its permission, permit or registration:

- 1.the Competent Authority ordered to suspend all its practices twice in one (1) year; or ordered to suspend part of its practices three times in one (1) year; or
- 2.the Competent Authority recognizes that there is concern about radiation safety of radioactive material or equipment capable of producing ionizing radiation, which may be detrimental to human health, safety or environmental ecology and that the situation can never be improved, the material or the equipment can never be used, or the situation cannot be improved within a specified time for over half a year.

#### Article 49

The radiation safety survey for radioactive material or equipment capable of producing ionizing radiation and the smear test for sealed radioactive material shall be conducted by a radiation protection measuring company authorized by the Competent Authority or radiation protection personnel designated by the facility operator.

#### Article 50

If the facility operator uses unsealed radioactive material, he/she shall, each week or after each use, conduct a measuring of the workplace contamination once and make a record. At least twice a year, samples of the released wastewater shall be taken and a nuclide analysis shall be conducted.

#### Article 51

With regard to the radioactive material or the equipment capable of producing ionizing radiation specified in the following documents, the facility operator shall check and verify the inventory account and the status of use every six (6) months, make a record of this and keep the record for filing and reference:

- 1.the permit for use or the permission for possession of radioactive material, and the registration approved by the Competent Authority.
- 2.the permit for use or the permission for possession of equipment capable of producing ionizing radiation.

## Article 52

### Paragraph 52.1

A facility operator who uses, ceases to use or possesses sealed radioactive material shall report to the Competent Authority within the first 15 days of each month on the status of use, cease of use or possession in the preceding month with regard to the said material.

### Paragraph 52.2

The report referred to in Paragraph 52.1 may be filed via the Internet.

## Article 53

After permission for the import of radioactive material has been granted by the Competent Authority, the applicant shall, upon arrival of the material, confirm the integrity of the packaging and the package surface, measure the surface dose rate, conduct a smear test and make a record of them. However, the above requirement does not apply to the radioactive material with an activity or an activity concentration less than 100 times the exemption level, excepted packages, or the radioactive material that itself is a noble gas.

## Article 54

### Paragraph 54.1

If a facility operator uses or possesses a sealed radioactive material with a half-life of more than 30 days that itself is a beta or gamma emitting nuclide with an activity of exceeding 3.7 MBq or is an alpha emitting nuclide with an activity of exceeding 370 kBq, he/she shall conduct a sealed radioactive material smear test within the time period stipulated in

Paragraph 54.3 and keep a record for filing and reference.

Paragraph 54.2

The following sealed radioactive material may be excepted from the smear test referred to in Paragraph 54.1:

- 1.sealed radioactive material that is contained in a liquid scintillation counter and used for calibration;
- 2.sealed gaseous radioactive material; or
- 3.other materials as designated by the Competent Authority.

Paragraph 54.3

Smear test reports of sealed radioactive material shall be made by the facility operator according to the times stipulated below:

- 1.once every six (6) months for sealed radioactive material in teletherapy equipment and remote after-loading brachytherapy equipment;
- 2.once a year for sealed radioactive material of other uses;
- 3.once every three (3) years for americium-241 contained in toxic gas detectors; or
- 4.other actions announced by the Competent Authority shall be completed according to the stipulated times.

Paragraph 54.4

If the radioactive nuclide referred to in Paragraph 54.1 is radium,the smear test shall include a test for radon leakage.

Paragraph 54.5

If the smear test results referred to in Paragraph 54.1 exceed 185 Bq, the facility operator shall cease the uses immediately and report to the Competent Authority within seven (7) days.

Article 55

The stipulated radiation survey report, smear test report, measuring records of liquid waste samples, measuring records of workplace and periodic check records of inventory account shall all be kept for five (5) years.

Section VII Supplementary Provisions

#### Article 56

In making an application for or applying for renewal of the various purposes of permission, permits or registration for filing and reference in conformity with the Regulations, the documents for review or the information to be filled out that the applicant shall enclose may, besides those have been stipulated in the Regulations, be designated and announced by the Competent Authority as needed.

#### Article 57

(Deleted)

#### Article 58

The format for all the documents and the forms stipulated in the Regulations shall be determined by the Competent Authority.

#### Article 59

The Regulations come into force upon the promulgation.