


Content

Title :	Administrative Regulations for Radioactive Material and Equipment Capable of Producing Ionizing Radiation and Associated Practice 
Date :	2009.09.30
Legislative :	Promulgated on January 22, 2003 by the Atomic Energy Council Per its decree No. Huei-Fu-Tsu-0920001511 Amendment of Article 1, Article 2, Article 4 to Article 6, Article 8, Article 9, Article 13, Article 17, Article 20, Article 22, Article 24, Article 26 to Article 28, Article 30, Article 31, Article 34 to Article 36, Article 41, Article 44, Article 49, Article 50, Article 52, Article 53, Article 55, Article 57 and Appendix on February 23, 2005 by the Atomic Energy Council per its decree No. Huei-Fu-Tsu-0940008702 Amendment of Article 4.1, Article 6.1, Article 6.2 and Table in the Appendix on December 29, 2005 by the Atomic Energy Council per its decree No. Huei-Fu-Tsu-0940039736 Amendment on October 24, 2007 by the Atomic Energy Council per its decree No. Huei-Fu-Tsu-0960028431 Amendment of Article 23, Article 25, Article 27, Article 34, Article 51 and Article 55 on July 11, 2008 by the Atomic Energy Council per its decree No. Huei-Fu-Tsu-0970010549 Amendment of Articles 13 and 14 on September 30, 2009 by the Atomic Energy Council per its Decree No. Huei-Fu-Tsu 0980016382.
Content :	<b>Section I</b> <b>General Principles</b>  Article 1 The Regulations are prescribed in accordance with the provisions of Article 29, Paragraph 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: radioactive material placed in a sealed container sufficient to provide isolation from the outside under normal use. 2. Modification: 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 the primary radiation beam of the sealed radioactive material or equipment capable of producing ionizing radiation. (2) An increase in the activity of the sealed radioactive material. (3) An increase of the nominal voltage in the X-ray unit. (4) An increase in the accelerating voltage of the accelerator. (5) A change in the radiation protective shielding. (6) Other situations as designated by the competent authority. 3. Labeling: The process of combining a radioactive nuclide with another material to form a radioactive compound.

4. Cabinet: A separate cabinet, not a part of the 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: 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.
  - (3) The use of sealed radioactive material with a activity of greater than 1,000 TBq.
6. Transit: 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 county or area via Taiwan air or sea ports.
7. Transshipment *en route*: A stop-over period with definite time parameters for unloaded goods being shipped on the same aircraft or other means of transportation that are to enter another county or area via Taiwan air or sea ports.
8. Surface contaminated object (SCO): 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 materials categorized by their degree of potential detriment against human health and environment as listed in Table I of the Appendix.

### Section II

#### Application for a Permit for Import, Transfer, Export, Transit or Transshipment *En Route*

#### Article 4

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

1. Government agency (or organization).
2. Post-secondary high (or vocational) school or academic research organization.
3. Company or other legal person.
4. Medical institution, radiology center or medical laboratory established with the approval of the public health competent authority.
5. Veterinarian medical institutions officially established in accordance with the Law Governing Veterinarian.
6. Other qualifications as approved by the competent authority.

Applicants for export permits referred to in the preceding paragraph shall meet one of the following criteria:

1. Possess a certificate of permission or registration approved by the competent authority for radioactive material or equipment capable of producing ionizing radiation.
2. Possess a permit for the production of radioactive material or a permit for the manufacture of equipment capable of producing ionizing radiation.
3. Other criteria as designated by the competent authority.

#### Article 5

For the importation of radioactive material or equipment capable of producing ionizing radiation, applicants shall fill out an application form, attach the following documents and make application to the competent authority for review and approval, after which the permit will be issued. However, they are waived for

equipment capable of producing ionizing radiation if registration for filing and reference shall be applied:

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

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

In cases where facility operators possess a certificate of permission duly issued by the competent authority or registration approved by the competent authority to use non-sealed radioactive material, the submission of all documents referred to in Paragraph 1 may be waived at the time of application for importation.

#### Article 6

Applicants for the import of radioactive material of Column 1 or Column 2 as listed in Table II of the Appendix shall, after obtaining the permit referred to in the preceding Article, give a photocopy of said permit to the competent authorities of the exporting country or the exporting organization.

The applicant shall, seven days before the starting of the shipment operation at the port for the sealed radioactive material referred to in the preceding paragraph, specify the following in a written document and inform the competent authority of the:

1. Estimated date of export,
2. Name of exporting organization,
3. Name or title of the recipient,
4. Radionuclide name, quantity, activity and overall activity, and
5. Unique identifiers such as manufacturer and model number, and serial number.

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

#### Article 7

For the transfer of radioactive material or equipment capable of producing ionizing radiation, the assignee shall fill out an application form and make application to the competent authority for review and approval, after which the permit will be issued.

For the application of the transfer of radioactive material in the preceding paragraph, documents relating to the transport details shall also be enclosed.

In cases where facility operators possess a certificate of permission duly issued by the competent authority or registration approved by the competent authority for the use of non-sealed radioactive material, the enclosure of documents referred to in the preceding paragraph may be waived when the assignee makes application for the transfer of non-sealed radioactive material.

#### Article 8

For the export of radioactive material or equipment capable of producing ionizing radiation, the applicant shall fill out an application form and make application to the competent authority for review and approval, after which the permit will be issued.

For the application of the export of radioactive material in the preceding paragraph, documents relating to the transport details shall also be enclosed.

#### Article 9

Applicants for the export of significant risk sealed radioactive material of Column 1 as listed in Table II of the Appendix shall, in

addition to the documents stipulated in the preceding Article, enclose the import agreement documentation from the competent authority of the importing country and send it to the competent authority for review.

The import agreement documentation referred to in the previous paragraph shall specify the following:

1. Name or title of the recipient,
2. Recipient's residence, firm or principal place of business,
3. Radionuclide name, quantity, activity and overall activity,
4. Unique identifiers such as manufacturer, model number, and serial number, and
5. Estimated starting and ending time of shipment.

#### Article 10

Applicants for the export of significant risk sealed radioactive material of Column 1 or Column 2 as listed in Table II of the Appendix shall, seven 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, the competent authority and recipient of the importing country:

1. Estimated date of export,
2. Name or title of the applicant,
3. Name or title of the recipient,
4. Radionuclide name, quantity, activity and overall activity, and
5. Unique identifiers such as manufacturer, model number, and serial number.

#### Article 11

Applicants for a permit to import or export a surface contaminated object 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. Medical institution set up with the official approval of the public health competent authority.
5. Other qualifications as approved by the competent authority.

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

#### Article 12

For the import or export of surface contaminated objects the following documents shall be enclosed and application made to the competent authority for review and approval, after which the permit will be issued:

1. Data on the package or packaging smear test and surface dose rate.
2. Documents relating to the transport details.

#### Article 13

For the transit or transshipment *en route* of radioactive material, the shipper or carrier shall enclose the radiation protection plan and make application to the competent authority for review and approval, after which the permit will be issued. The permit is effective for a period of five years.

The shipper or carrier having obtained the permit 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.

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

In cases of the transport of radioactive material in excepted packages, the stipulations in Paragraphs 1 and 2 do not apply.

#### Article 14

Permits for import, transfer, or export are effective for a period of six months.

### Section III

#### Applications for a Permit, a Certificate of Permission or a Registration for Filing and Reference for Use, Installation, Modification or Possession

##### Article 15

Applicants for a certificate of permission or 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. Government agency (or organization).
2. Post-secondary high (or vocational) school or academic research organization.
3. Company or other legal person
4. Medical institution, radiology center or medical laboratory established with the official approval of the public health competent authority.
5. Veterinarian medical institutions officially established in accordance with the Law Governing Veterinarian.
6. Other qualifications as approved by the competent authority.

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

1. Have qualified operating personnel.
2. Possess a workplace or storage area meeting radiation safety regulations.
3. Other criteria as designated by the competent authority.

##### Article 16

For the use of the following radioactive materials, 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 of the Appendix.
2. Radioactive material that forms a component of an instrument or manufactured product and that has a 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 materials besides those mentioned in the preceding two subparagraphs with an activity less than 100 times that of the exemption level.
4. Other radioactive materials as designated by the competent authority.

For the use of radioactive materials other than those stipulated in the preceding paragraph, application for a certificate of permission shall be made to the competent authority.

##### Article 17

For the use of the following equipment capable of producing ionizing radiation, the applicant shall apply 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.
3. Other equipment as designated by the competent authority.

For the use of equipment capable of producing ionizing radiation other than those stipulated in the preceding paragraph, application for a certificate of permission shall be made to the competent authority.

#### Article 18

Applicants for the use of sealed radioactive material or equipment capable of producing ionizing radiation for which a permit application shall be made shall, when applying for import or transfer, fill out an application form, attach the following documents and make application to the competent authority for review. In cases requiring installation, installation permits will be issued after review and approval; in cases not requiring installation, following the issuance by the competent authority of an import or transfer permit, the documents referred to in Paragraph 2 shall be enclosed to the competent authority for review, inspection and approval, after which the certificate of permission for use will be issued:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Photocopy of relevant operating personnel credentials and certificate of employment.
3. Workplace radiation safety assessment. In cases not requiring installation, a shielding planning need not be enclosed.
4. Radiation protection plan and radiation safety operation guidelines.
5. Photocopy of authorization certificate 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.
6. For the use of sealed radioactive materials of Category I and Category II as listed in Table I of the Appendix, documents regarding security measures shall be submitted.

Only after applicants referred to in the preceding paragraph have obtained an installation permit can installation begin in accordance with the officially approved workplace radiation safety assessment, floor plans and 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 certificate of permission for use will be issued:

1. Radiation safety survey report (hereinafter referred to as "survey report" ).
2. For sealed radioactive material conforming with the stipulations referred to in Article 54, Paragraph 1, the sealed radioactive material smear test report shall be submitted (hereinafter referred to as "smear test report" ).
3. For sealed radioactive material, a photocopy of the original certifying document of radioactive material shall be submitted.

#### Article 19

For unsealed radioactive material or re-packaged and labeled radioactive material whose use requires a permit, the applicant shall fill out an application form, enclose the following documents and make application to the competent authority for review and approval, after which the installation permit will be issued:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Photocopy of relevant operating personnel credentials and certificate of employment.
3. Workplace radiation safety assessment.
4. 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.
6. In conformity with the stipulations in the Standards for Establishment of Radiation Protection Management Organizations

and Radiation Protection Personnel, a photocopy of the authorization certificate of radiation protection personnel shall be submitted.

After obtaining permit for installation, the preceding applicant may process installation in accordance with the approved workplace radiation safety assessment. Within 30 days after completion of installation, the test report shall be enclosed to the competent authority for review, inspection and approval, after which a certificate of permission for use will be issued.

#### Article 20

The workplace radiation safety assessment referred to in Article 18, Paragraph 1, Subparagraph 3 and in Paragraph 1, Subparagraph 3 of the preceding Article, shall consider the following items as appropriate for assessment 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 radioactive material or equipment capable of producing ionizing radiation in a mobile configuration.
4. Personal dose assessment.

#### Article 21

A certificate of permission for use is effective for a maximum period of five 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 a renewed certificate of permission for use will be issued:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Original certificate of permission for use.
3. A survey report done within the last 30 days.
4. For sealed radioactive materials qualifying regulations set forth in Paragraph 1 of Article 54, the latest smear test report shall also be enclosed.

#### Article 22

Facility operators who have obtained a certificate of permission for the 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 permit will be issued:

1. Workplace radiation safety assessment in accordance with the stipulations of Article 20.
2. Photocopy of the credentials of the operating personnel.
3. Original certificate of permission for use.

In cases where the modification referred to in the preceding paragraph involves a change in radiation safety, the radiation protection plan or radiation safety operating guidelines shall be enclosed. Only after a facility operator obtains the permit for modification may the modification work proceed in accordance with the approved workplace radiation safety assessment. Within 30 days after the work is completed, the following documents shall be enclosed to the competent authority for review, inspection and approval, after which the certificate of permission for use will be issued:

1. Survey report.
2. For sealed radioactive material in conformity with the stipulations referred to in Article 54, Paragraph 1, a smear test report shall be provided.

#### Article 23

For the use of sealed radioactive material that 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, attach the following documents and make application to the competent authority for review. If installation is required, the installation permit will be issued after review and approval; if installation is not required, after the competent authority issues the import or transfer permit, the documents in Paragraph 2 are to be enclosed to the competent authority for review and approval, after which the registration will be approved:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).;
2. Photocopy of relevant qualified operating personnel credentials and certificate of employment.
3. Workplace floor plans and shielding planning. Shielding planning may be waived if installation is not required or Paragraph 2 of Article 16 is qualified.
4. Radiation protection plan.

Only after the applicant referred to in the preceding paragraph has obtained the permit for modification may the modification 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 and approval, after which the registration will be approved:

1. Photocopy of the original radioactive material certification.
2. Survey report.
3. For sealed radioactive material in conformity with the stipulations referred to in Article 54, Paragraph 1, a smear test report shall be submitted.

For the use of equipment capable of producing ionizing radiation that 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 application to the competent authority for review prior to use of the equipment, after which the registration will be approved:

1. Name and number of certification of establishment or registration approved.
2. Name and number of relevant qualified operating personnel credentials.
3. Survey report related information.
4. Radiation protection plan.

#### Article 24

For unsealed radioactive material or re-packaged, labeled radioactive material, whose use requires registration, the applicant shall fill out an application form, attach the following documents and make application to the competent authority for review and approval, after which the registration will be approved:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Photocopy of relevant qualified operating personnel credentials and certificate of employment.
3. Workplace floor plans and shielding planning.
4. Radiation protection plan.
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 years, facility operators who have registration approved by the competent authority for radioactive material or equipment capable of producing ionizing radiation one month prior to or after the day equivalent to approved registration date, shall conduct a radiation safety survey and record the results for future reference.

#### Article 26

When radioactive material for which the registration has been permitted is to be modified, 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 the modification permit will be issued:

1. Workplace floor plans and shielding planning.
2. Photocopy of relevant qualified operating personnel credentials.

Only after 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 the registration will be approved:

1. Survey report.
2. For sealed radioactive material in conformity with the stipulations referred to in Article 54, Paragraph 1, a smear test report shall be provided.

Facility operators who have registration approved by the competent authority for radioactive material or equipment capable of producing ionizing radiation shall fill out application form and following documents and enclose to the competent authority for review and approval, after which the registration will be approved:

1. Name and number of relevant qualified operating personnel credentials.
2. Survey report related information and radiation exam data.

If, after modification, the energy level of the equipment capable of producing ionizing radiation or the overall 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

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

If facility operators who have obtained a certificate of permission or 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 separately for a certificate of permission or registration for filing and reference for use in accordance with the stipulations referred to in Article 19 and Article 24.

#### Article 28

For the use of a high-level radiation facility, the applicant 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. Photocopy of certification of establishment or 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 documents relating to security procedures shall be enclosed.
8. Procedure for dealing with accidents.

The workplace radiation safety assessment referred to in the preceding paragraph, Subparagraph 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).
4. Other information as designated by the competent authority.

Only after the applicant has obtained the permit for installation may the work proceed in accordance with the approved radiation safety assessment, floor plans, and shielding planning. Within 30 days of 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.

After the completion of the pre-operational test, the applicant 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 the certificate of permission for use will be issued:

1. Area monitoring results.
2. Personal dose monitoring results.
3. Record of the pre-operational test.
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 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 a renewed certificate of permission for use will be issued:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Survey report done within the last 30 days.

#### Article 30

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

1. A high-level radiation facility shall be completed within two 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 the preceding Subparagraph, shall be completed within one 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 year of the approved import or transfer date.

#### Article 31

In the case of the sale of sealed radioactive material referred to in Article 16, Paragraph 1, Subparagraph 2 and an application for possession of said item, the applicant shall fill out an application form, enclose the following documents and make application to the competent authority for review, inspection and approval, after which the possession permit will be issued:

1. Permit of sales service businesses.

2. Applying documentation on the brand, model, nuclides, activity and quantity of the radioactive material in possession.
  3. Radiation protection plan.
  4. Radiation safety assessment on appropriate storage area.
- Those who are permitted by the competent authority to engage in sales of equipment capable of producing ionizing radiation may possess approved equipment capable of producing ionizing radiation.

#### Article 32

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

1. Inability to complete the installation or modification within the time frame stipulated in Article 30.
2. Subsequent to approval by the competent authority for import or transfer, inability to proceed with installation following delivery of material or equipment.
3. Other situations as approved by the competent authority.

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

1. Reason for possession.
2. Radiation protection plan.
3. Storage area. For radioactive material, the floor plans and shielding planning shall be submitted.
4. For sealed radioactive material in conformity with the stipulations of Article 54, Paragraph 1, a smear test report shall be submitted.

The possession permit referred to in the preceding paragraph is effective for a maximum of two years.

Facility operator may, within 60 to 30 days prior to expiration of the possession permit of radioactive material or equipment capable of producing ionizing radiation, fill out an application form and enclose all documents provided in Paragraph 2 to the competent authority for extension, which is subject to a maximum of one time.

#### Article 33

For a certificate of permission for radioactive material or equipment capable of producing ionizing radiation or designated items in the registration approved by the competent authority, if there is change of 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 a change, replacement or renewal. The period of effectiveness for the certificate of permission is the same as that for the original certificate.

#### Article 34

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

1. For those who obtain a certificate of permission for use, a testing report shall be enclosed to the competent authority for filing and reference within 15 days after the replacement.
2. For registration approved by the competent authority, the testing report shall be independently kept.

If a facility operator removes and replaces radioactive material for which he possesses a certificate of permission or registration approved, he shall fill out an application and enclose the following

documents prior to effecting the replacement, and enclose to the competent authority for review and within 15 days following the replacement and 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. Documents relating to the transport details,
2. Method of processing the original radioactive material after replacement

For replacement of radioactive materials provided in the preceding paragraph and the container at the same time, the application shall be filed in accordance with stipulations set forth in Article 18 and Article 23 before replacement.

#### **Section IV**

#### **Application for a Permit for Temporary or Permanent Cease of Use**

##### **Article 35**

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 application to the competent authority for review. After the equipment capable of producing ionizing radiation is reviewed and approved, the permit for cease of use will be issued; after the radioactive material is reviewed, inspected and approved, the permit for cease of use will be issued:

1. The original certificate of permission for those who already have said certificate.
2. Description of storage area. For radioactive material, a floor plan of the storage area and the shielding planning shall be submitted.

The permits referred to in the preceding paragraph are effective for a maximum period of two years.

The facility operator may, within 60 to 30 days prior to expiration of ceased use of radioactive material or equipment capable of producing ionizing radiation, fill out an application form and enclose all documents provided in Paragraph 1 Subparagraph 2 to the competent authority for extension.

##### **Article 36**

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

If the reason for the approved cease of use referred to in the preceding paragraph is the lack of qualified operating personnel, the facility operator shall, when making application for the resumption of use, fill out an application form, attach qualified operating personnel credentials, and make application to the competent authority for review and approval, after which the certificate of permission will be issued or registration will be approved.

##### **Article 37**

When a facility operator permanently ceases the use of radioactive material and treats it as radioactive waste, he shall fill out an application form, enclose the following documents and make application to the competent authority for inspection and approval, after which a permit will be issued:

1. Sealed radioactive material discard plan.
2. Photocopy of original certifying document of radioactive

material.

### 3. Documents relating to the transport details.

Following approval of the application referred to in the preceding paragraph by the competent authority, the facility operator shall, within three months, transport the radioactive waste to the receiving unit. Within 30 days of receipt of said material, a radiation workplace monitoring certificate, receipt documentation and the original certificate of permission for those who already have said certificate shall be enclosed and sent to the competent authority for filing and reference.

### Article 38

When a facility operator permanently ceases use of radioactive material or equipment capable of producing ionizing radiation and disposes of it by shipping overseas, he shall fill out an application form, documents relating to the transport details shall be submitted for exporting radioactive material and make application to the competent authority for review and approval, after which the permit will be issued.

After the preceding application is approved by the competent authority, the facility operator shall, within 30 days after exportation, enclose a photocopy of the export documentations, the original certificate of permission for those who already have said certificate, the radiation workplace monitoring certificate shall also be attached for exporting radioactive material and submitted to the competent authority for filing and reference.

### Article 39

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 permit, he 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 shall proceed in accordance with the stipulations of Articles 7 and 23.

If the assignee referred to in the preceding paragraph is applying for possession, he 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 discards it, he shall fill out an application form, enclose the original certificate of permission for those who already have said certificate and make application to the competent authority for review and approval, after which he 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 will request the competent authority to send an official to conduct an inspection.

### Article 41

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

1. The original certificate of permission for those who already have said certificate.
2. Decontamination plan.

The decontamination plan referred to in the preceding paragraph, subparagraph 2, shall include the decontamination schedule, decontamination method, method for the treatment of radioactive

waste, division of the decontamination work area, and measures for personnel control.

## Section V Application for Display or Leasing Permits

### Article 42

Applicants for the display of 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. Other qualifications as approved by the competent authority.

The application referred to in the preceding paragraph shall meet the following criteria:

1. Applicant must be a business representative recognized by the competent authority to engage in sales and service of radioactive material or equipment capable of producing ionizing radiation.
2. The period of display shall not exceed two months.

### Article 43

For a static display of equipment capable of producing ionizing radiation, the applicant shall enclose the following documents and make application to the competent authority for review and approval, after which the permit will be issued:

1. Catalog and explanatory diagrams.
2. Display plan and schedule.

### Article 44

For the following radioactive material or equipment capable of producing ionizing radiation, application may be made for dynamic display:

1. Radioactive material provided in Paragraph 1, Subparagraph 1 of Article 16 that forms a component of an instrument or manufactured product.
2. Radioactive material provided in Paragraph 1, Subparagraph 2 of Article 16.
3. Equipment capable of producing ionizing radiation provided in Paragraph 1, Subparagraph 1 and 2 of Article 17.
4. Others as designated by the competent authority.

For the display referred to in the preceding paragraph, the applicant shall attach the following documents and make application to the competent authority for review and approval, after which the permit will be issued:

1. Catalog, explanatory diagrams and information regarding radiation safety.
2. Radiation protection plan.
3. Photocopy of credentials of relevant qualified operating personnel.
4. Display plan and schedule.

### Article 45

An applicant for a leasing permit 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 established with the approval of the public health competent authority.
5. A veterinary hospital established in accordant with the Law Governing Veterinarian.

6. Other qualification as approved by the competent authority.
- For the application for leasing referred to in the preceding paragraph, the following criteria shall be met:
1. The lessee or borrower has qualified operating personnel or the personnel is supplied by the lessor or lender.
  2. The applicant possesses an appropriate workplace or storage area.
  3. Radioactive material or equipment capable of producing ionizing radiation must be either mobile, carried-on-a-car or the radioactive material is used for calibration purposes.

#### Article 46

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 application to the competent authority for review and approval, after which the permit will be issued:

1. Photocopy of the original of the certificate of permission for those who already have said certificate.
2. 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. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
6. Photocopy of relevant qualified operating personnel credentials and certificate of employment.

When the lease period is over for the radioactive material or equipment capable of producing ionizing radiation referred to in the preceding paragraph, the lessee or borrower shall immediately return the material or equipment to the lessor or lender and shall, within one month, submit a survey report to the competent authority for filing and reference. For sealed radioactive material conforming with the stipulations of Article 54, Paragraph 1, a smear test report shall be submitted.

### Section VI Controls

#### Article 47

The workplace and 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 the Appendix.

#### Article 48

If practice of radioactive material or equipment capable of producing ionizing radiation has one of following conditions, the competent authority may cancel its permission, certificate of permission, or registration:

1. The competent authority ordered to suspend all its practices twice in one year; or ordered to suspend part of its practices three times in one year.
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 the situation cannot be improved, the material or equipment cannot be used, or the situation cannot be improved within a specified time for over one half 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 monitoring 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 shall, each week or after each use, conduct a monitoring of the workplace contamination once and make a record.

At least twice a year, expelled wastewater samples shall be taken and a survey analysis of the nuclides shall be conducted.

#### Article 51

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

- 1.A certificate of permission for use or possession permit of radioactive material or registration approved by the competent authority.
- 2.A certificate of permission for use or possession permit of equipment capable of producing ionizing radiation.

#### Article 52

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 said material. The report referred to in the preceding paragraph 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 surface of the packaging and the package and shall make a record of the surface dose rate and a smear test. However, the above requirement does not apply to radioactive material with activity or activity concentration less than 100 times the exemption level, excepted packages, or if the radioactive material is a noble gas.

#### Article 54

If a facility operator uses or possesses a sealed radioactive material with a half-life of more than 30 days, and that is beta or gamma emitting nuclide with activity exceeding 3.7 MBq or is alpha emitting nuclide with activity exceeding 370 kBq, he shall conduct a sealed radioactive material smear test within the time period stipulated in Paragraph 3 and keep a record for future reference. The following sealed radioactive materials are excepted from the smear test referred to in the preceding paragraph:

- 1.Sealed radioactive material used for calibration that is contained in a liquid scintillation counter.
- 2.Sealed gaseous radioactive material.
- 3.Other materials as designated by the competent authority.

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

- 1.Once every six months for sealed radioactive material in teletherapy equipment and remote afterloading brachytherapy equipment.
- 2.Once a year for sealed radioactive material of other uses.
- 3.Once every three years for americium-241 contained in toxic gas detectors.
- 4.Other actions announced by the competent authority shall be

completed according to the stipulated times.  
If the radioactive nuclide referred to in Paragraph 1 is radium, the smear test shall include a test for radon leakage.  
If the smear test results referred to in Paragraph 1 exceed 185 Bq, the facility operator shall cease use immediately and report to the competent authority within seven days.

#### Article 55

The stipulated radiation survey report, smear test report, wastewater sample monitoring record, workplace monitoring record and periodic inventory account check record shall all be kept for five years.

### Section VII Supplementary Provisions

#### Article 56

In applying for, or applying for renewal of, the various permits, certificates of permission or registration for filing and reference in conformity with the Regulations, the applicant shall enclose the documents or filled-out information for review; besides those stipulated in the Regulations, the competent authority may designate and announce others as needed.

#### Article 57

Licenses for radioactive material or equipment capable of producing ionizing radiation granted by the competent authority prior to the implementation of this Act may continue to be used until their expiration dates. In the case of use after the expiration date, the facility operator shall, 60 to 30 days prior to the deadline, fill out an application form, attach the following documents and apply to the competent authority for a renewed certificate of permission or registration for filing and reference. In the case of an application for a permit, following review, inspection and approval, the certificate of permission for use will be issued; in the case of an application for registration, following review and approval, the registration will be approved:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Photocopy of relevant qualified operating personnel credentials and certificate of employment.
3. Original license for equipment capable of producing ionizing radiation or radioactive material.
4. Survey report done in the last 30 days.

In the case of license application, prior to the implementation of this Act, were exempted or excepted by public announcement and, subsequent to the implementation of this Act, application is required to be made for a permit or registration, the applicant shall, within two years of the implementation of this Act, fill out an application form, attach the following documents and make application to the competent authority for review and approval, after which the certificate of permission will be issued or registration will be approved:

1. Photocopy of certification of establishment or registration approved; waived for government agencies (or organizations).
2. Photocopy of qualified operating personnel credentials and certificate of employment.
3. Survey report.
4. Radiation protection plan. For a certificate of permission, radiation safety operation guidelines shall also be enclosed.

In cases where the renewal or application for radioactive material referred to in the preceding two paragraphs as stipulated in Article 54, Paragraph 1, a smear test report shall be enclosed.

#### Article 58

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

Article 59

The Regulations come into force upon promulgation.

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Attachments : 980930管理辦法英譯附件.doc  
980930管理辦法英譯附表一.doc  
980930管理辦法英譯附表二.doc

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