#### PREFACE

Upon publication of the English version

of

"The Act on Prevention of Radiation Hazards due to Radioisotopes, etc."

Upon translating "The Act on Prevention of Radiation Hazards due to Radioisotopes, etc. (hereinafter referred to as "the Radiation Hazards Prevention Act", or simply as "the Act")" to the English version, the following conditions are taken into account:

- 1. The provisions in Japanese laws and regulations should be translated into English as literally as possible.
- 2. As far as possible, terms and standards should be identical to those conforming to the International Basic Safety Standard (IAEA No. GSR Part 3, hereinafter referred to as "IAEA BSS") and the IAEA Safety Glossary (2007 Edition).

Consequently, some problems on the English expression of the Japanese Provisions have been found here and there. For example, the meaning or expression of the terms "disposal, waste or discharge" and on the dose pertaining to the measurement of radiation in the provisions concerned, such as "1-cm dose equivalent" in the Act are not always identical to those used internationally as is in the IAEA documents.

The explanation on such confusing expressions different from the international standards or those that more attention should be paid for is summarized in the SHORT NOTE at the end of the English version of the Radiation Hazards Prevention Act.

In cases where the Radiation Hazards Prevention Act of the English version is referred, the SHORT NOTE might be helpful to understand well the legal framework for the prevention of radiation hazards in Japan.

Concurrently, appended regulations relevant to the Act, which are "the Cabinet Order for enforcement of the Act" and "the Ordinance for enforcement of the Act" and the "Public Notice to specify the Quantities, etc. of Radioisotopes" which specifies numerical standards of these laws and regulations, are translated into English. For the English version of these regulations, are also applied the conditions for translation and the SHORT NOTE mentioned above.

# English Translation Working Group of the Act on Prevention of Radiation Hazards due to Radioisotopes, etc. and its relevant Ordinances

(Chair) Kenichi Ijiri (University of Tokyo) Sakae Kinase (JAEA / Ibaraki University) Seiichi Shibata (RIKEN) Shogo Higaki (University of Tokyo) Yoshihisa Matsumoto (Tokyo Institute of Technology)

## (Secretariat of the Working Group)

Japan Radioisotope Association Radiation Regulations Office, Secretariat of Nuclear Regulation Authority

#### SHORT NOTE

#### Radiation

This term as used in the Act and its relevant Ordinances means, as is defined in Articles of Atomic Energy Basic Act and relevant Cabinet Order, ionizing radiation only, which includes alpha particles, protons, deuterons, other heavy charged particles, beta particles, neutrons, gamma rays, characteristic X rays (limited to characteristic X rays generated, accompanied by Electron Capture), electrons and X rays of the energy exceeding 1 MeV.

#### Radioisotopes, etc. (Title of this Act)

This term as used in the Act includes radioisotopes, contaminated objects provided for in the Ordinance for Enforcement of the Act, and radiation generating apparatuses; provided, however, that this term as used in the Ordinance for Enforcement of the Act does not include radiation generating apparatuses.

#### Contaminated Object (Act, Article 1)

This term as used in the Act and relevant Ordinances means, as is defined in Article 1 of the Act, the material or object contaminated with radioisotopes or radiation-emitting isotopes induced by radiation generating apparatuses, including the **activated object** (Ordinance, Article 14 -7 (7) - 2.

#### Activated Object (Ordinance, Article 14 -7 (7) - 2)

This term as used in the Act and relevant Ordinances means, as is defined in Article14-7 Paragraph 1 Item 7-2 of the Ordinance for enforcement of the Act, the **material activated or contaminated** with radiation-emitting isotopes induced by radiation generated from radiation generating apparatuses or the **object containing such materials**, which are designated in the Act and its relevant Ordinances or by a regulatory body as being subject to regulatory control and required to be stored in a storage facility; provided, however, that materials irradiated for the specific purpose, such as target material in low energy accelerators, are out of the above requirement.

#### **Contamination** (Act, Article 12 - 10 (1))

This term as used in the Act and relevant Ordinances means, **radioactive substances** on surfaces, or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or **the process** (Ordinance, Article 1 (3), (7)) giving rise to their presence in such materials.

#### Lower bound quantity (Ordinance, Article 14 – 3 para. 3), (Notice, Article 1)

This term means the lower limit of the activity or activity concentration of radionuclides, equal to or more than that laws and regulations for the prevention of radiation hazards should be applied. The quantity corresponds to the **activity** or **activity concentration of radionuclides for exemption level** given in Table I.1, Schedule I of Radiation Protection and Safety of Radiation Sources: IAEA BSS.

#### Specific radioisotope (Ordinance, Article 39)

This term as used in the Ordinance for Enforcement of the Act means sealed radioisotope that is likely to cause a serious influence on human health. Sealed radioisotopes are categorized in accordance with the categorization scheme set out in Schedule II of Radiation Protection and Safety of Radiation Sources: IAEA BSS.

### Notification user (Act, Article 3 – 2 para. 2, dealer or lessor (Act, Article 4 para. 2.)

The term "notification business operator", such as notification user, dealer or lessor, as used in the Act and relevant Ordinances, means the user of radioactive substances other than radioisotopes exceeding the quantity specified by laws and regulations or an approved device with certification label, or a business operator dealing or leasing radioisotopes as a business only, who are not required to be granted permission or license for the activities, but are required notification only to the regulatory body. The term is, therefore, deemed to correspond to **registrant** as used in the IAEA BSS.

#### Permission user (Act, Article 10.) and permission waste management operator (Act, Article 11)

The term "permission business operator", such as permission user or permission waste management operator, as used in the Act and relevant Ordinances, means the user of radioisotopes exceeding the quantity specified by laws and regulations, (excluding the user of a specified approved or an approved device with certification label), and a radiation generating apparatus who are required to be granted permission or license for the activities. The term is, therefore, deemed to correspond to **licensee** as used in the IAEA BSS.

#### Management and Disposal of radioactive wastes

In the Radiation Hazards Prevention Act and its relevant Ordinances, **disposal** (Act, Article 4 - 2 para. 2 (7)) of radioactive wastes is not provided for, except for the shallower underground burial of wastes with very low radioactivity concentration. The term "radioactive waste management" includes in general both the disposal and predisposal of radioactive wastes. In the Act, however, the term "waste management" is used as to mean all activities pertaining to radioactive wastes, including transfer, processing, storage and transport, but excluding disposal operation.

#### 1-cm dose equivalent (rate) (Cabinet Order, Article 12(3)), (Notice, Article 2)

This term is applied to the control of effective dose. In cases where this term is used as an operational quantity for area monitoring, this term should be understood to identical to the "**ambient dose equivalent (rate)** (Cabinet Order, Article 12(3)) " at the depth of 10 mm, defined by ICRU. In cases where used for individual monitoring, this term should be understood to identical to the "**personal dose equivalent (rate)** (Ordinance, Article 20.2(1)(a)) " at the depth of 10 mm, defined by ICRU.

#### **70-µm dose equivalent (rate) (**Notice, Article 20 para.2)

This term is applied to the control of skin dose. In cases where this term is used as an operational quantity for area monitoring, this should be understood to identical to the "**directional dose equivalent (rate)** (Ordinance, Article 20.(1)) " at the depth of 0.07 mm, defined by ICRU. In cases where used for individual monitoring, this term should be understood to identical to the "**personal dose equivalent (rate)** (Ordinance, Article 20.2(1)(a)) " at the depth of 0.07 mm, defined by ICRU.

#### Terms pertaining to Radioactivity Concentration Confirmation

Mass unit for evaluation (Ordinance, Article 24.(5)(b))

In cases where, dividing the object for radioactivity concentration confirmation into two or more assemblies, the measurement and evaluation of radioactivity concentration are conducted on each assembly, the term corresponds the concerned assembly, and in cases where the measurement and evaluation are conducted on the whole object deemed to be one assembly, the term corresponds to the whole object concerned.

**Object for radioactivity concentration confirmation** (Ordinance, Article 24.(5) (b)), (Notice, Article 27 para.1 Item 1)

This term as is used in the Ordinances of the Act means the contaminated object of which radioactivity concentration is intended to be confirmed pursuant to the provisions of Article 33-2 Paragraph 1 of the Act.

#### Radioisotope evaluated of radioactivity concentration (Notice, Article 27 para.1 Item 1)

Radioisotope in one mass unit for evaluation which is measured and evaluated according to the method for measurement and evaluation of radioactivity concentration granted approval referred to Article 33-2 Paragraph 2 of the Act.