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Basic Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources

电离辐射防护与辐射源安全基本标准

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Basic Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources

1 Scope

This standard specifies the basic requirements of ionizing radiation protection and radiation source safety (hereinafter referred to as “protection and safety”).

This standard is applicable to the protection of ionizing radiation exposure received by personnel in practice and intervention as well as source safety in practice.

This standard is not applicable to the protection for detriment to personnel possibly caused by nonionizing radiation (such as microwave, ultraviolet, visible light and infrared radiation).

2 Definitions

See Appendix J (Normative) for the terms and definitions adopted by this standard.

3 General Requirements

3.1 Application

3.1.1 Practice

The practice applicable to this standard shall include:

a) Source production and radiation or radioactive substance application in medical, industry, agriculture or teaching and research, including various activities related to application involved or possibly involved in radiation or radioactive substance exposure;

b) Generation of nuclear energy, including various activities involved or possibly involved in radiation or radioactive substance exposure in nuclear fuel cycle;

c) Practice involved in natural source exposure and controlled according to regulatory authority specification;

d) Other practices specified by regulatory authority.

3.1.2 Source

3.1.2.1 The source applicable to the requirements of this standard for practice shall include:

a) Radioactive substance and component containing radioactive substance or generating radiation, including consumer product, sealed source, unsealed source and radiation generator;

b) Device and facility with radioactive substance and equipment generating radiation, including irradiation installations, mine or mill processing radioactive ores, installation processing radioactive substances, nuclear installation and radioactive waste management facility;

c) Other sources specified by regulatory authority.

3.1.2.2 The requirements of this standard shall be applied to each radiation source in device or

facility; if necessary, the requirements of this standard shall be applied to whole device or facility considered as single source according to regulatory authority specification.

3.1.3 Exposure

3.1.3.1 It shall be the exposure applicable to the requirements of this standard for practice, and shall refer to occupational exposure, medical exposure or public exposure caused by relevant practice or source in practice, including normal exposure and potential exposure.

3.1.3.2 Under general condition, the natural source exposure shall be considered as a kind of prolonged exposure; if necessary, the requirements for intervention of this standard shall be followed. Under the following various conditions, the requirements for intervention of this standard shall be followed if it is not eliminated or the relevant practice or source is not exempted:

a) Public exposure caused by discharge of effluent generated by practice of natural sources or radioactive waste disposal;

b) Occupational exposure of worker caused by exposure of natural sources under the following conditions:

1) Radon exposure of worker owing to working demand or direct relation with working, regardless if the exposure is higher or lower than the action level of remedial action under prolonged exposure condition of radon in working space [see Appendix H (Informative)];

2) Though the radon exposure of worker during working is not regular, the exposure size is higher than the action level of remedial action under prolonged exposure condition of radon in working space [see Appendix H (Informative)];

3) Exposure of natural sources received by operating personnel during jet airplane flight process;

c) Exposure of other natural sources specified by regulatory authority and needed to follow the requirements of this standard for practice.

3.1.4 Intervention

3.1.4.1 The intervention conditions applicable to this standard shall be:

a) Emergency exposure condition requiring adopting protective action, including:

1) Accident conditions and emergency circumstances have implemented emergency plan or emergence program;

2) Other any emergency exposure condition having the justifiable reason to carry out intervention confirmed by regulatory authority or intervening organization;

b) Prolonged exposure condition requiring adopting remedial action, including:

1) Exposure of natural sources, such as radon exposure in building and working space;

2) Exposure of radioactive survivor caused by departed incident and exposure of radioactive survivor caused by departed practice and source utilization without notification and approval system control (see 4.2.1 and 4.2.2);

3) Other any prolonged exposure condition having the justifiable reason to carry out intervention confirmed by regulatory authority or intervening organization.

3.2 Excluding

Any exposure condition essentially incapable control for size or possibility of exposure through this standard requirement implementation, such as the exposure caused by ^{40}K in human body and cosmic ray reaching earth surface shall not be applicable this standard, and shall be excluded in the application scope of this standard.

3.3 Responsible Party of Implementation and Responsibility

3.3.1 Responsible party

3.3.1.1 The responsible party (hereinafter referred to as "main responsible party) undertaking main responsibility for the implementation of this standard shall be:

a) Registrant and licensee;

b) Employer.

3.3.1.2 Other related parties shall undertake the respective corresponding responsibility for the implementation of this standard, and other related parties may include:

a) Supplier;

b) Worker;

c) Radiation protection officer;

d) Medical practitioner;

e) Health professional;

f) Qualified expert;

g) Any other parties entrusted with specific responsibility by main responsible party.

3.3.2 Responsibility

3.3.2.1 Each responsible party shall undertake general responsibility and specific responsibility specified in the relevant chapters and articles of this standard.

3.3.2.2 The general responsibility undertaken by main responsible party shall be:

a) Establishing protection and safety target meeting relevant requirements of this standard;

b) Establishing and implementing written protection and safety outline, and this outline shall be corresponding with risk property and degree of responsible practice and intervention, and sufficiently guarantee to meet the relevant requirements of this standard. This outline shall:

1) Determine measures and resources required by realizing protection and safety target, and guarantee to correctly implement these measures and provide these resources;

2) Maintain the regular examination for these measures and resources, and periodically check the realization of protection and safety target;

3) Identify any invalidity or defect of protection and safety measures and resources, and take steps to rectify and prevent secondary occurrence;

4) Work out various arrangements convenient for consultation and cooperation of related parties according to protection and safety demand;

5) Preserve relevant records of responsibility fulfillment.

3.4 Supervision and Administration of Implementation

3.4.1 The implementation of this standard and supervision and administration implemented by this standard shall be charged by regulatory authority; for intervention condition, the intervening organization shall be in charge of main responsibility for relevant requirements of this standard.

3.4.2 The main responsible party shall receive the supervision for protection and safety with approved practice of personnel formally authorized by regulatory authority, including inspection of protection and safety record.

3.4.3 When the condition against relevant requirements this standard happens, the main responsible party shall:

a) Investigate the reason and of violation behavior;

b) Adopt corresponding action to rectify and prevent secondary occurrence of similar violation incident;

c) Report the violation reason, adopted or preparing to be adopted rectification action or protective action to regulatory authority;

d) Adopt other necessary actions according to the requirements of this standard.

3.4.4 The main responsible party shall timely report violation incident. If the standard violation has performed or is about to be performed to emergency exposure condition, it shall be reported timely.

3.4.5 After standard violation incident occurrence, if the main responsible party is incapable of adopting rectification or improvement action within the stipulated time limit according to national relevant regulations, the regulatory authority shall revise, suspend or cancel issued registration certificate, license or other approval documents.

4 Major Requirement for Practice

4.1 Basic Principles

4.1.1 Introduction, implementation, interruption or stopping of any practice and exploitation, mill, processing, design, manufacture, construction, assembling, procurement, import, export, sales, sell out, lending, lease, receiving, installation, positioning, debugging, holding, use, operation, maintenance, repair, transfer, decommission, disassembly, transportation, storage or disposal of any source in practice shall be carried out according to relevant requirements of this standard; unless the exposure generated by relevant practice or source is excluded or the relevant practice or source is exempted by the requirements of this standard.

4.1.2 For any practice applicable to this standard, any source in practice or any activity specified in 4.1.1, the implementation of each relevant requirement of this standard shall be corresponding with

characteristic of this practice or source and size and possibility of its caused exposure, and shall meet specified relevant requirements by regulatory authority.

4.1.3 The transportation of radioactive material shall follow the requirements of national relevant safety transportation laws and regulations of radioactive substance.

4.2 Management Requirements

4.2.1 Notification

4.2.1.1 Any legal person intended to carry out some item practice or any activity specified in 4.1.l of this standard shall submit notification to regulatory authority to explain the purpose and plan, and shall only explain the plan in such aspects as manufacture, assembling, import and sales for consumer product.

4.2.1.2 If the practice or activity meets the following conditions and is confirmed by regulatory authority, only the notification procedure shall be fulfilled, if not, the corresponding approval procedure shall be fulfilled according to the requirements of 4.2.2:

a) The caused normal exposure unlikely exceeds a certain small share of specified relevant limit by regulatory authority;

b) The possibility and size of accompanied potential exposure may be neglected.

c) Any other accompanied possible detriment consequence may also be neglected.

4.2.2 Approval: registration or licensing

4.2.2.1 Any legal person responsible for any sealed source, unsealed source or radiation generator shall propose application to regulatory authority to obtain approval unless the responsible source is exempt. Whether adopt registration mode or licensing mode for this approval shall be determined by regulatory authority according to source or practice property utilizing this source and size and possibility of caused exposure. The practice suitable for approval with registration mode shall be provided with the following characteristics:

a) Guarantee safety to a great extent through the design of installation and equipment;

b) Simple and easy working procedure;

c) Extremely low requirements for safety training;

d) Hardly any safety problem in history run.

4.2.2.2 The legal person responsible for any following source shall submit application to regulatory authority to obtain approval, and the approval for this source shall be adopted with licensing mode:

a) Irradiation installations;

b) Mine or mill processing radioactive ores;

c) Installation processing radioactive substances;

d) Nuclear installation;

e) Radioactive waste management facility;

f) Other any source that is non-exempt and the regulatory authority has not designated approval suitable for registration mode.

4.2.2.3 Any applicant shall:

a) Submit relevant data for supporting the application to regulatory authority;

b) Explain the analysis on property, size and possibility of caused exposure by responsible source in submitted application information, and explain various measures used to plan to adopt for protecting worker, public and environment.

c) If the exposure may be larger than some level specified by regulatory authority, the corresponding safety assessment and environmental impact assessment shall be carried out, and shall be taken as one part of application form to submit to regulatory authority;

d) Any activity specified in 4.1.1 of this standard shall not be carried out before regulatory authority issuing registration certificate or license.

4.2.2.4 The medical exposure practice and source applicant shall include the following contents in the application form:

a) Explain the qualification of medical practitioner in radiation protection; or

b) Promise that only the medical practitioner with professional qualification of radiation protection specified in relevant regulations or written in license can allow issuing source inspection application form or treatment prescription.

4.2.3 Authorized legal person: registrant and licensee

4.2.3.1 The registrant and licensee shall be responsible for establishing and implementing each necessary technique and organization measure to ensure the protection and safety of authorized source; they can entrust other parties to complete certain relevant activities or tasks, but they still undertake the main responsibility for these activities or tasks. The registrant and licensee shall employ qualified personnel according to demand and ensure to meet this standard.

4.2.3.2 If the registrant and licensee are intended to revise the authorized practice or source, and the proposed revision may have important impact for protection or safety, the revision plan shall be noticed to regulatory authority, and this revision shall not be carried out before obtaining regulatory authority recognition.

4.2.4 Exemptions

4.2.4.1 If the source meets one of the following conditions and is confirmed and agreed by regulatory authority, this source or practice utilizing this source may be exempted by the requirements of this standard:

a) Meeting the exemption requirements specified in Appendix A (Normative) of this standard;

b) Meeting the exemption level determined by regulatory authority according to exemption criteria specified in Appendix A (Normative) of this standard.

4.2.4.2 The practice has not been proved as justifiable practice shall not be exempted.

4.2.5 Clearance

4.2.5.1 If the source (including substances, materials and articles) in noticed or approved practice meets the clearance levels specified by regulatory authority, it may be carried out with clearance without following the requirements of this standard after regulatory authority recognition.

4.2.5.2 Unless otherwise stated by regulatory authority, the determination of clearance levels shall be considered with exemption criteria specified in Appendix A (Normative) of this standard, and the clearance levels shall not be higher than the exemption level specified in Appendix A (Normative) of this standard or established by regulatory authority according to specified criteria of this Appendix.

4.3 Radiation Protection Requirements

4.3.1 Justifiability of practice

4.3.1.1 If the interest for radiated individual or social brought by one practice can sufficiently make up possibly caused radiation hazard after considering social, economy and other relevant factors, this practice is justifiable. The practice without justifiability and the source in this practice shall not be approved.

4.3.1.2 The justifiability judgment related to practice of medical exposure shall follow the detail requirements specified in Chapter 7.

4.3.1.3 In addition to the practice judged as justifiable and related to medical exposure, it is not justifiable by addition of radioactive substance or increasing radioactivity in relevant daily commodities or products through activation in the following practices:

a) Practice involved in food, drink, cosmetics or other any goods or product for eating, suction, skin intake or skin application;

b) Practice involved in insignificant application of radiation or radioactive substance in daily commodities or products (such as toys).

4.3.2 Dose limit and potential exposure risk limit

4.3.2.1 The normal exposure received by individual shall be limited to guarantee individual total effective dose and total equivalent dose of relevant organs or tissues caused by comprehensive exposure of each approved practice not exceeding corresponding dose limit specified in Appendix B (Normative) except the particular case specified in 6.2.2 of this standard. The dose limit shall not be applied to medical exposure in approved practice.

4.3.2.2 The potential exposure risk received by individual shall be limited to make individual risk caused by all potential exposure in each approved practice and health risk corresponding to normal exposure dose limit in the same quantity level.

4.3.3 Optimization of protection and safety

4.3.3.1 For the exposure of any specific source in one item practice, the protection and safety shall be optimized to keep individual exposure dose size, exposed people number and exposed possibility in reasonably reached low level after considering economy and social factors; this optimization shall take the personal dose caused by this source and potential exposure risk respectively less than dose constraint and potential exposure risk constraint as the prior condition (except medical exposure of treatment).

4.3.3.2 The process of protection and safety optimization may range from visualized qualitative analysis to quantitative analysis using aid decision making technique, but all relevant factors shall be considered with some proper methods to realize the following targets:

a) Determine optimized protection and safety measures for leading condition, and the protection and safety selection for utilization, property, size and possibility of exposure shall be considered during determining these measures;

b) Establish corresponding criteria according to optimization result, and limit the size and possibility of exposure according to the measures adopting accident prevention and relieving accident consequence.

4.3.4 Dose constraint and potential exposure risk constraint

4.3.4.1 In addition to medical exposure, for any specific source in one item practice, the dose constraint and potential exposure risk constraint shall not be larger than specified or approved value for this source by regulatory authority, and shall not be larger than the value possibly causing to exceed dose limit and potential exposure risk limit;

4.3.4.2 For any source possibly releasing radioactive substance to environment, the dose constraint shall still limit the released cumulative effect of this source in pass years to make the received effective dose of any member of the public (including progeny) in any one year not exceeding the corresponding dose limit after considering all release accumulation and exposure possibly caused by other relevant practices and sources.

4.3.5 Guidance level of medical exposure

The guidance level for medical exposure used for medical practitioner shall be established. This guidance level shall:

a) Be established according to detail requirements of Chapter 7 and referring to Appendix G (Informative);

b) Be a kind of reasonable dose indication for medium-size body;

c) Provide guide for medical practice may be accomplished by currently good medical skill (instead of optimal medical skill);

d) May flexibly apply in need of reliable clinical judgment indication, namely allow implementing higher exposure;

e) Be revised with improvement of technology and technique.

4.4 Operating Management Requirements

4.4.1 Sense of safety culture

Cultivate and maintain good sense of safety culture, encourage adopting thinking, research and modesty learning attitude for protection and safety matters and oppose complacency, and guarantee:

a) Establish the policy and procedure regarding protection and safety as higher than all;

b) Timely investigate and rectify the problems impacting protection and safety, and make adopted method corresponding with problem significance;

c) Define the responsibility of each relevant personnel (including higher management) for protection and safety, and each relevant personnel shall be provided with proper training and corresponding qualifications;

d) Define authority and responsibility relation for protection and safety decision;

e) Work out organization arrangement and establish effective communication channel, maintain smooth protection and safety information in all-level departments of registrant or licensee and between departments.

4.4.2 Quality assurance

Establish and implement quality assurance program, and this outline shall:

a) Provide adequate assurance for meeting each specific requirement involved in protection and safety;

b) Provide quality control mechanism and procedure for comprehensive effectiveness of examination and assessment measures for protection and safety.

4.4.3 Human factors

The measures shall be adopted to meet the following requirements to reduce the possibility of human error resulting in accident and incident as much as possible:

a) All relevant personnel of protection and safety shall be provided with proper training and corresponding qualifications to understand their own responsibility and can correctly judge and fulfill responsibility according to established procedure;

b) Design equipment and establish operation procedure according to tried and true human engineering principle to make equipment operation or application as simple as possible and minimize accident probability owing to operation mistake, and reduce misunderstanding possibility of indication signal under normal and abnormal operation condition;

c) Install proper equipment, safety system and controlling procedure, and work out other necessary specifications to:

1) Reduce the possibility of personnel accident exposure owing to human error as much as possible;

2) Provide the means of discovering and rectifying or making up human error;

3) Be convenient for intervention during invalidity of safety system or other protective measures.

4.4.4 Qualified expert

4.4.4.1 The registrant and licensee shall employ qualified expert to provide consultation for implementing this standard as required.

4.4.4.2 The registrant and licensee shall inform the arrangement for qualified expert employment to regulatory authority. The provided information during notification shall include occupation or profession range of employed expert.

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