付属資料 1-3

Advisory Opinions for Improving Radiation Protection Measures in Japan

March 2022

Japan Health Physics Society

Japanese Association for Radiation Accident/Disaster Medicine

Japanese Society of Radiation Safety Management

The Japanese Radiation Research Society

The Representatives' Council of the Japanese Umbrella-structured Platform for Radiation Protection

These advisory opinions are based on surveys and studies conducted by the Japanese Society of Radiation Safety Management, Japanese Radiation Research Society, and a working group on the effective doses and operational quantities of radiation established by the Representatives' Council of the Japanese Umbrella-structured Platform for Radiation Protection. Some measures required for the promotion of radiation safety measures in Japan were compiled by the Representatives' Council of the Japanese Umbrella-structured Platform and are published jointly by the academic societies participating in the *Radiation Protection Academia.*

Contents

1 Introduction

In recent years, two events that had a social impact have occurred; these provided opportunities to review Japan's preparedness for accidents at radiation facilities and radiation disasters.

The first event, an accident resulting in radiation exposure, occurred on May 29, 2021 during the inspection of a measuring device that uses X-rays (Ministry of Health, Labour and Welfare, MHLW, 2021). According to media reports, the workers inspecting the device may have been exposed to anywhere from several times to several tens of times the annual radiation dose limit for workers; however, many aspects of this accident remain unknown. For example, normally, the power switch on such devices is turned off during inspection, but in this case, for some reasons, the device continued to emit X-rays. Although the Labor Standards Inspection Office investigated this accident, the details have not been disclosed, partially because the authority might consider the privacy of the individuals who were exposed to radiation.

The second event was the 32nd Summer Olympic and Paralympic Games held in Tokyo from July 23, 2021 to August 8, 2021 and August 24, 2021 to September 5, 2021. These games were held when the Japanese medical system was under intense pressure owing to the novel coronavirus disease 2019 pandemic. If a major terrorist attack were to occur under such circumstances, the difficulty in securing medical facilities that can admit large numbers of injured and exposed patients would have been expected to greatly surpass current hypothetical scenarios. In such a case, it is necessary to triage the victims according to their injuries and health conditions and allocate them to appropriate medical facilities while simultaneously starting the collection of information and samples for dosimetry. However, there are numerous problems associated with these activities that need to be solved. These problems include the small number of experts/specialists who are able to perform radiation dose assessments, the need to develop technologies for radiation dose assessments, and the need for cooperation between various relevant organizations.

In *Radiation Protection Academia*[1], academic societies with various interests and specialties have cooperated to propose the priority topics for radiation safety and regulation studies and discussed the problems related to securing and training human

[1] One member body of the Radiation Protection Research Network formed by the Radiation Safety Regulation Research Strategic Advancement Project of the Nuclear Regulatory Authority, Japan. Four academic societies related to radiation protection participate in *Radiation Protection Academia*. A representatives' council composed of representatives from the participating organizations of the Japanese Umbrella-structured Platform for Radiation Protection makes decisions on the activities of this network.

resources in the field of radiation protection. In fiscal year 2020, academic societies selected themes related to radiation accidents and disasters in response to each concern, collated new knowledge from countries other than Japan, and conducted surveys on domestic circumstances regarding each selected theme. These surveys and studies conducted by the academic societies resulted in two important conclusions detailed below. Thus, we decided to propose urgent advisory opinions requiring specific roles to be played by the national government, local government, private industries, and specialized organizations (described in this paper).

1) It is of vital importance that organizations establish detailed regulations and manuals for preventing accidents and incidents from occurring and for handling the aftermath in case they occur.
2) Dose assessment is an essential part of dealing with accidents, and therefore there is a need for Advanced Radiation Emergency Medical Support Centers (AREMSCs) and related institutions to rapidly develop technologies that improve and link their systems, particularly for performing dose estimates during large-scale radiation disasters.

In addition, the *Radiological Protection Academia* has proposed urgent measures for the national government, local government, private industries, and specialized institutions to solve various related problems.

With an eye toward global trends, the International Commission on Radiological Protection (ICRP) began conducting reviews for revising its 2007 recommendations, and in July 2021, it released "Keeping the ICRP Recommendations Fit for Purpose" (Clement et al., 2021). Beginning with this and continuing over the next several years, experts from around the world will conduct discussions to improve the radiation protection system and bring it in line with scientific advancements and societal changes. The abovementioned document specifies the adoption of changes in operational and protection quantities, which were proposed by the International Commission on Radiation Units and Measurements (ICRU) in its 2007 recommendations (ICRU, 2020). The changes in operational and protection quantities are expected to have a major influence on radiation regulations worldwide. Thus, in 2020 a working group (WG) consisting of members recommended by five academic societies[2] related to radiation protection was formed.

[2] The five are the Japan Health Physics Society, Japanese Association for Radiation Accident/Disaster Medicine, Japanese Radiation Research Society, Japanese Society of Radiation Safety Management, and the subcommittee of Health Physics and Environmental Science of the Atomic Energy Society of Japan.

This WG examined the preparations necessary to adopt new concepts of operational and protection quantities into Japanese regulations. Based on these surveys and studies, mid- and long-term advisory opinions were to be made to radiation-related ministries, radiation-related academic societies/associations, and those engaged in radiation-related research and development (R&D), management, and medicine.

For the *Radiation Protection Academia*, summarizing these advisory opinions is the first step toward activities that will contribute to future radiation regulations. For experts in this field, contributing to the improvement and appropriate application of radiation regulations and protection is part of their raison d'être. Nevertheless, the involvement of academic societies/associations in the field of radiation protection is less than in the fields of nuclear power and medical use of radiation. This may be attributable to the fact that radiation protection covers a wide range of areas such that academic societies/associations are generally segmented by the field of expertise and specific issues[3]. This shows that, as a practical matter, it is difficult to consolidate the various views of experts and specialists. Therefore, the Japan Health Physics Society, Japanese Association for Radiation Accident/Disaster Medicine, Japanese Radiation Research Society, and Japanese Society of Radiation Safety Management have been working toward solving problems related to radiation protection and have shared their information and awareness of the issues with the Atomic Energy Society of Japan, Society for Risk Analysis Japan, and Japan Network for Research and Information on Medical Exposure (J-RIME).

Some major challenges remain for the continuation of these activities. The activities of the academic societies/associations are primarily based on the voluntary activities of its members, and their contributions to regulation and protection are no exception. Unless each individual member of the academic societies/associations is aware of their contribution to radiation regulation and protection, it will be difficult to continue these activities as part of their contributions. For raising awareness among experts that one of the goals of his/her researches is contribution to the improvement of regulations, it is important to satisfy the need to strengthen the collaboration among regulators, private industries, and experts while simultaneously experiencing repeated successes.

As the first step in this direction, the academic societies/associations involved in radiation protection will collaborate in the future to exchange opinions with regulators,

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[3] The Atomic Energy Society of Japan has approximately 6,500 individual members and approximately 200 groups that are supporting members. The Japan Radiological Society has approximately 10,000 individual members. The member body of the *Radiation Protection Academia* with the highest number of members is the Japan Health Physics Society, with approximately 800 members.

business operators, and even concerned international organizations in order to realize these advisory opinions. Through these regulatory activities, research activities, and global cooperative activities, experts will solidify the roles to be played in improving radiation protection measures in Japan.

The abovementioned bodies will continue to cooperate and study various issues such as (i) the creation and collection of scientific knowledge on low-dose exposure (public and occupational exposure) and emergency exposure, (ii) proposals for the formulation of protection systems and safety standards, and (iii) human resource development for radiation protection.

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2 Urgent advisory opinions for improving radiation protection measures in Japan

(1) Measures for preventing accidents and adverse events from occurring at radiation facilities and for handling the aftermath

1) Background of the advisory opinions

Numerous incidents of mishandling of radiation and radioactive materials or accidents at facilities that handle them have been reported in Japan and abroad. Among these, cases of unplanned exposure to radiation have also been reported. In May 2021, an accident involving radiation exposure occurred during the inspection of a measuring device that uses X-rays in Japan. To prevent such accidents and incidents from occurring and to deal with them swiftly when they do occur, it is important to elucidate the causes of such accidents and incidents both in Japan and abroad, identify problems with the way they were handled, and share the results of such analyses widely.

Therefore, the Japanese Society of Radiation Safety Management (2021) conducted a survey on radiation exposure accidents[4] that occurred in countries other than Japan since 2000 (International Nuclear and Radiological Event Scale [INES] level 2 and above). To use the results of the survey as reference material for responses to accidents involving radiation exposure in Japan, these accidents and incidents were classified into the following three categories: I) radiation exposure due to the dispersal of unsealed radioisotopes (RI) during work-related tasks, II) exposure of those engaged in interventional radiology (IVR) to radiation doses exceeding dose limits for workers, and III) underestimation of the dose and/or risk. The cases of errors resulting in the accidents and exposure were analyzed and the lessons learned were extracted.

The Japanese Society of Radiation Safety Management (2021) also categorized incidents that occurred in Japan since 2013 that were required to be reported by law. Typical cases of the following four categories were analyzed to identify the causes of the incidents and problems: 1) missing unsealed RI, 2) missing "Approved Device with Certification Label," i.e., design-certified RI instrument, 3) leakage of RI due to damage, and 4) fire. A questionnaire survey was also conducted on the state of preparation of manuals on how to handle eight problems that were identified based on these incidents. The results showed that approximately 20%–50% of the facilities in Japan had inadequate manuals for dealing with similar problems (Japanese Society of Radiation Safety Management, 2021).

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[4] The term "accident" refers to an event of level 4 and above according to the International Nuclear and Radiological Event Scale (INES) that has a local impact such as the nuclear accident that occurred at Tokai-mura, Japan, in 1999. However, in this document, the term "radiation exposure accident" refers to serious incident of INES 3 or higher that is associated with unusual radiation exposure.

The Radiation Protection Academia verified the aforementioned report provided by the Japanese Society of Radiation Safety Management and determined that in order to prevent the occurrence of accidents involving radiation exposure and handle the aftermath in the event that they do occur, the following are important and thus required: a) an independent and continuous review of radiation management methods and systems in place at workplaces throughout Japan, and b) guaranteeing the effectiveness of these methods and systems. Thus, it was decided that specific advisory opinions would be issued for improving the radiation hazard prevention regulations and measures provided in emergency response manuals followed at workplaces. In addition, advisory opinions would be made to the regulatory authority to enforce the Plan-Do-Check-Act (PDCA) cycle throughout Japan to prevent recurrences of accidents that occurred in the past.

2) Current situation and problems

<u>The current situation and problems related to accidents involving radiation exposure that occurred in countries other than Japan</u>

The Japanese Society of Radiation Safety Management extracted comprehensive data pertaining to accidents that occurred since 2000 across countries other than Japan from public databases of the Landelijk Kernenergie Archief Foundation (LAKA) in the Netherlands[5]. There were 473 cases of accidents/incidents related to radiation safety management, graded as INES level 2 and above, reported between January 1, 2000 and December 4, 2020. Many of them occurred in Europe and North America and were graded as INES level 2.

In addition, there have been numerous reports of “unusual exposure” worldwide. Among all accidents/incidents graded as INES level 2 or above that occurred in RI facilities, the history, cause, and handling of the aftermath of 203 accidents/incidents were surveyed. Based on the survey results, the Japanese Society of Radiation Safety Management judged that the countermeasures for the following three cases might be insufficient in many facilities in Japan and consequently further examined each domestic countermeasure.

I. Measures to prevent the dispersion of unsealed RI during work

Accidents have occasionally occurred around the world in which workers have been exposed to splashed RI solution due to unsafe operation, resulting in the contamination of eyes and hands. In 2019, the following happened in a hospital in Switzerland. When a worker handling a radiopharmaceutical inserted a syringe into the mouth of a vial containing Ga-68 solution to draw out a sample, droplets of the solution scattered and

5 https://www.laka.org/docu/ines/

contaminated the worker's right eye (INES 2). The worker was not wearing protective eyeglasses at the time, and although the worker followed measures such as eye washing, the lens of the eye was judged to have been exposed to an equivalent dose of 27 mSv.

In 2017, a worker at an organization affiliated with the Australian Nuclear Science and Technology Organisation (ANSTO) accidentally dropped a vial of a solution containing Mo-99. The solution dispersed and contaminated the worker's hands. Although the worker was wearing double gloves at the time, erythema and blisters appeared on the worker's hands. This indicates that the skin of the hands had been exposed to a radiation dose equivalent to 10–20 Sv, meaning that the accident was graded as INES level 3, i.e., a serious incident. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) analyzed the causes behind the incident and pointed out i) the lack of organizational systems that would have allowed the learning of effective lessons from minor and near-miss incidents, ii) the insufficient recognition of the risk of accidents among the workers, iii) the insufficient notations alerting the workers about hazards during work-related tasks in workplace manuals and so on, and iv) the shortcomings in the training related to the safe performance of work-related tasks (ARPANSA, 2018). ARPANSA provided guidance to ANSTO regarding its preparations to reduce radiation exposure and the training of its workers.

Similar accidents might occur in Japan as well; therefore, there is a need for workers and workplaces to ensure that the measures shown below in Table 1 are fully implemented.

Table 1. Measures to prevent and reduce radiation exposure due to the dispersion of unsealed RI during work-related tasks

Target	Measure
Individual workers	Ensure to wear protective eyeglasses and other protective gear
Business operators	Prepare an organizational system that facilitates effective learning from near-miss accidents Provide appropriate training to workers Review workplaces and work procedures for reducing radiation risk e.g., ･Adjust lead shields in drafts based on ergonomics ･Automate tasks that are currently performed manually by workers ･Reduce the concentration of RI in quality control samples Establish systems that facilitate the early implementation of decontamination and other emergency medical measures for radiation exposure e.g., ･Educate occupational health physicians and health nurses ･Conduct prior consultation with the organization implementing the medical treatment for radiation exposure

II. Countermeasures for IVR physicians and others who are at high risk of being exposed to doses exceeding the dose limits for workers

During IVR procedures, physicians are exposed to radiation from X-rays that scatter from patients. Thus, physicians who perform higher numbers of IVR procedures are likely to be exposed to doses that exceed the dose limits for workers even if no particular accidents have occurred.

There have been reports from outside Japan of medical practitioners being exposed to unusual doses of radiation during IVR procedures when classified using INES. An incident that occurred in the UK in 2019 reported that the estimated equivalent doses to the lens of the eye were 25.8 mSv.[6] This dose was considered a realistic assumption based on the worker's recollection of their use of personal protective equipment (PPE).

In 2017 in a hospital in Saint-Denis, France, an incident occurred in which the equivalent dose of radiation that the hand of a radiologist was exposed to in one quarter exceeded the annual limit (500 mSv). This occurred due to the fact that the physician's hand entered the irradiation field when performing IVR under computed tomography fluoroscopy. The Autorité de sûreté nucléaire (ASN) in France surveyed this incident on January 24, 2018 and reported the results of its assessment of the cause, measures to make improvements, and assessment of INES on its website.[7] Prior to this incident, ASN announced that they cooperated with related professional associations, industries, and regulatory authorities for improving training provided to operators when installing new equipment.[8]

One frequent problem in medical settings in Japan is the failure to use personal dosimeters or wear PPE (Kunugita, 2019; Hosono et al., 2021). In addition, it is estimated that many of the cases in which occupational radiation exposure exceeds the dose limits are in the medical field.[9] Most of them, however, are discovered only when the Labor Standards Inspection Office conducts on-site inspections to investigate reports of occupational accidents and problems in work schedule management. Therefore, there are limited number of cases in which exposure exceeding the dose limits is found as a violation of the established laws and regulations.

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6 In the European Union, member nations are required to legislate directives for Basic Safety Standards (BSS). In the United Kingdom, an analysis of the effects of regulations for the development of laws was conducted in 2017. In accordance with the demands in the EU directive, national regulations that reflect the equivalent dose limitation (100 mSv/5 years) for the lenses of the eyes that are stipulated in Part 3 of the General Safety Requirements (GSR) of the IAEA were to come into effect by February 6, 2018.

7 http://www.french-nuclear-safety.fr/Information/News-releases/A-radiologist-suffers-radiation-overexposure-of-the-hands

8 https://www.asn.fr/espace-professionnels/activites-medicales/radiologie-et-scanographie/guides-de-l-asn/recommandations-relatives-a-la-formation-a-l-utilisation-des-dispositifs-medicaux-emetteurs-de-rayonnements-ionisants

9 http://www.kosenkyo.jp/siryou/gyousyu31.PDF

Medical facilities that use radiation must comply with Article 44 of the Regulation on Prevention of Ionizing Radiation Hazards. The MHLW has implemented the Subsidy Project for the Renovation of Facilities to Reduce Radiation Exposure (MHLW, 2020) and the Project to Support the Adoption of Occupational Safety and Health Management Systems Related to the Management of Radiation Exposure (Nuclear Safety Technology Center, 2020).

Thus, a wide range of support programs for workplaces have been implemented for reducing the exposure of medical practitioners to radiation. Along with the continuation of these programs, it is hoped that workplaces will actively work toward this goal. In the future, increased cooperation between regulators and experts to ensure strict adherence to radiation dose limits is necessary (Table 2).

Table 2. Measures for handling exposure to medical radiation that is of particularly high likelihood to exceed dose limits

Target	Improvements, etc.
Individual workers (medical practitioners)	Ensure that personal dosimeters and PPE are used
Business operators	Conduct trainings on radiation protection for medical practitioners handling radiation and RI Ensure that protective measures and training information is updated particularly when new devices are introduced
Regulators	Provide continuous assistance to workplaces for reducing medical practitioners' radiation exposure Classify the INES level, report to the International Atomic Energy Agency (IAEA), and release reports on the website regarding incidents in accordance with Article 44 of the Regulation on Prevention of Ionizing Radiation Hazards Provide educational information to help prevent the recurrence of accidents/incidents throughout the nation
Experts	Establish a system in which academic societies/associations that have expert opinions on the reported cases can cooperate to provide assistance for problem solving based on the background conditions of the workplace in question

III. Dealing with underestimated doses and risk assessments

In many cases of radiation exposure accidents that occurred overseas, the exposure dose and risks were initially underestimated. In addition, there have been cases in which the doctors who conducted the medical examinations initially diagnosed the symptoms as allergies or insect bites, resulting in serious illnesses due to the lack of appropriate treatments.

The event in which the hand of a worker was contaminated (mentioned in Section I above; Australia, 2017) was also a case in which the exposed dose was underestimated. At first, ANSTO estimated an equivalent dose to the hand of 0.85 Sv; however, as erythema and blisters appeared on the worker's hand > 2 weeks after the accident, the estimate was revised to between 10 and 20 Sv, which was considered more valid under the circumstances (ARPANSA, 2018). ARPANSA identified the following problems and provided guidance to ensure that they would not occur again: the scene of the radiation exposure was not appropriately preserved, which made it impossible to collect data that were important to estimate the dose, and preparations for the dose assessment system, among other things, were not appropriately handled.

Table 3. Roles of those who estimate the dose and risks in the occurrence of radiation exposure accidents/incidents

Target	Role
Experts (radiation dose assessment)	In cases of local exposure, the experts ascertain the dose and distribution of the exposed part on the body as accurately as possible and estimate the severity of damage (the degree of tissue reaction, such as inflammation or necrosis, that may occur within several weeks to several months of exposure).
Experts (radiation emergency medicine)	In some cases of local exposure, symptoms such as pain, erythema, and blisters do not appear immediately after exposure. Thus, experts collect a wide range of information regarding the patient's positions, behaviors, and surrounding circumstances, confirm the possibility of radiation exposure, and determine medical treatment based on this information.
Business operators (management)	Provides education to occupational health physicians regarding the aspects of radiation exposure.
Business operators (e.g., radiation protection supervisors and occupational health physicians)	When an event occurs, experts collect and preserve data useful for dose estimation (photos of the site of exposure, monitoring data, descriptions/records of behaviors, and available samples that could be useful in retrospective dosimetry, such as clothing, nail clippings, etc.) in as much detail as possible so that the regulatory authorities and specialized organizations are able to easily perform retrospective verification.

In May 2021, a radiation exposure accident occurred in Japan during an inspection of a measuring device that used X-rays. The workers were believed to have been exposed to a dose that vastly exceeded the established limits, but the final result of the estimated dose was not disclosed. Instead, based on the lessons learned from the ANSTO incident, the roles of those involved in estimating doses and risks have been summarized as shown in Table 3.

<u>Current status of and problems related to accidents/incidents that occur at radiation facilities in Japan</u>

The Nuclear Regulation Authority publishes information on accidents and notifications of measures to be taken in case of danger on its website, which correspond to legal reporting events reported by business operators. Among 29 cases that occurred between April 2013 and November 2020, the Japanese Society of Radiation Safety Management categorized and surveyed four cases in detail and summarized the following four incidents that could potentially occur at many radiation facilities. They identified eight problems (for details, see Japanese Society of Radiation Safety Management, 2021).

- Missing unsealed RI (occurred on December 21, 2017, corporation)
  Summary: In the time between sterilization and proper disposal, animal carcasses in storage that had been administered C-14 were lost.
  Problem i. Records on the use of the RI-administered animals were inadequate.
- Missing "Approved Device with Certification Label" (occurred on December 16, 2019, corporation)
  Summary: The location of a Cesium-137 gamma ray source for standardizing exposure rate was unknown.
  Problem ii: Records on the use of "Approved Device with Certification Label" were inadequate.
- Leakage of RI due to damage (degradation over time) (occurred on October 29, 2013, university)
  Summary: The contamination spread from a sealed source of tritium in storage.
  Problem iii: Insufficient awareness regarding the management of sealed radioactive sources, including tritium and electroplated radiation sources; i.e., insufficient awareness regarding degradation over time, sealed radiation source equipment, and the criteria for urgent reporting as well as insufficient details on the code of conduct in terms of responding to unusual events.
- Fire (occurred on July 1, 2016, university hospital)

Problem iv: Inaccurate radiation rate estimates. In this case, measurements taken using an ion chamber survey meter[10] indicated a radiation rate of 0.5 μSv/h, which appeared to be 10 times the usual radiation rate; however, this measured value was insignificant and inaccurate.

Problem v: Incomplete records on the quantity and species of the radionuclides.

Problem vi: Delays in urgent reporting to the Nuclear Regulation Authority and releasing information to neighboring residents. In this case, the quantity and species of the radionuclides could not be ascertained (cf. Problem v), which delayed the public release of information.

Problem vii: Insufficient cooperation between multiple management departments. In this case, the departments involved in building management, RI room management, and radiation handling were different, which delayed information sharing and systemic response to emergencies.

Problem viii: Insufficient response to the absence of personnel in charge of radiation handling.

Sixteen individuals affiliated with private companies, medical, and educational facilities that use radiation conducted a survey on emergency response manuals and regulations for the prevention of radiation damage at the facilities of their affiliation in response to problems i through viii extracted from the abovementioned four incidents. They assessed whether measures designed to prevent “preventable incidents,” i.e., incidents whose occurrence can be controlled in the course of normal management tasks, were sufficient, and whether “nonpreventable incidents,” i.e., incidents whose occurrence cannot be controlled in the course of normal management tasks, could be responded to without any problems (Table 4).

As a result, it was found that the percentages of facilities that had established regulations for the prevention of radiation and emergency response manuals describing responses to deal with some of the eight abovementioned problems were low. They lacked in the following aspects (in the given order from the lowest): Problem i: completeness of the records on animals administered radioactive substances, problem iii: appropriate awareness and management of sealed radioactive sources, problem ii: completeness of the records on the use of “Approved Device with Certification Label,” and problem vi: appropriate release of information. It is hoped that facilities that do not have established regulations covering problems i through viii will check their regulations and make the necessary improvements.

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[10] If an ion chamber survey meter is used assuming a high dose rate but the actual dose rate is low (<1 μSv/h), an accurate value may not be obtained.

Table 4. State of preparing emergency response manuals and regulations for the prevention of radiation hazards at the respective facilities (responses from 16 facilities)

Incident	Category	Problems assessed	Assessment perspective	%*
Missing unsealed RI	Preventable incidents	i: Completeness of the records on animals administered radioactive substances	Do the radioactivity hazard prevention regulations at your facility include sufficient response instructions for the cases listed on the left?	50%
Missing “Approved Device with Certification Label”		ii: Completeness of the records on the use of “Approved Device with Certification Label”		58%
Leakage of RI due to damage (degradation over time)		iii: Appropriate awareness and management of sealed radioactive sources		50%
Fire	Nonpreventable incidents	iv: Accurate measurements of dose rate	Does the emergency response manual at your facility include instructions for a smooth response to fire?	73%
		v: Records on the use of nuclides and their quantities		73%
		vi: Appropriate release of information		60%
		vii: Cooperation between management systems		79%
		viii: Selecting a representative for the responsible individuals		73%

*Percentage of facilities that have implemented the regulations

3) Advisory opinions

Analysis of the accidents/incidents involving radiation exposure that occurred outside Japan since 2000 and events in Japan that were legally required to be reported since 2013 revealed the following: continuous and independent reviews of a facility's own systems and management methods are more important in workplaces than tightening regulations to prevent the occurrence of such accidents/incidents and respond to them in the event that they do occur. In particular, the following actions are recommended for establishing regulations and manuals that cover specific measures that should be implemented and for confirming and improving the continued efficacy of these measures:

1. When devices that emit radiation are newly adopted or when “near-miss” incidents occur, the effectiveness and validity of reviewing protective measures and the details of training should be examined on an organizational level and appropriate changes

should be made as soon as possible. These changes should then be included in regulations and manuals. When a worker makes a proposal to a workplace to make improvements to their working sites and work processes for reducing the risk of radiation exposure, the workplace should consider the effectiveness and validity of such proposals as an organization and establish a system to facilitate their implementation.

2. To ensure a swift response to any incidents involving radiation exposure, information/education should be provided to ensure that everyone at the workplace is aware of how important dose and risk assessments are. Further, manuals should be prepared/updated and training must be held for collecting and storing samples as well as various necessary data.
3. When creating a ledger for radioactive waste, checks should be continuously made to determine any potential blind spots, such as whether appropriate records are being kept for tracking all uses or whether records are being stored with regard to animals (carcasses) administered radioactive substances. When necessary, revisions should be made to the regulations and manual. The regulations and manual should also include entries ensuring that all users who create records are aware of all updates and revisions, and mechanisms to ensure the same must be established.
4. To prevent contamination due to the loss of integrity of sealed radiation sources, it is necessary to periodically check for leakages or comply with the working life as stipulated by the International Organization for Standardization (ISO).
5. The legal regulations for "Approved Device with Certification Label" are not particularly strict. Hence, management practices tend to be insufficient. Therefore, regular checks should be performed to ensure "Approved Device with Certification Label" are stored in appropriate and dedicated containers and that those containers are kept stored in locked safes.
6. In cases in which fire or other accidents occur, a system should be established that allows the necessary data to be compiled, enables prompt reporting to the Nuclear Regulation Authority, local governments, and related organizations, and facilitates announcements to the residents of local communities.

To ensure that the aforementioned advisory opinions are followed, the rules and regulations will be reviewed and the implementation system will be improved as necessary. Rules and systems will be periodically reviewed for improvement.

In cases in which radiation exposure following an accident/incident occurs at a radiation-related facility, it is essential for analysis and verification to be conducted by the regulatory authority and a third-party organization. The regulatory authority will particularly encourage the workplace to release information regarding the accident/incident and ensure that analysis and verification is performed by a specialized organization as well as that the PDCA cycle is carefully followed to provide feedback about the results of the analysis and verification process to all employees. In cases in which an examination on reinforcing regulations is performed following the implementation of the PDCA cycle after an accident/incident involving radiation, it is desirable to ensure cooperation among various stakeholders, such as policy makers, researchers, and those in the industry in order to ensure risk-based management for optimizing resource distribution by introducing the graded approach of radiation management into regulations recommended in IAEA GSR part 3 (IAEA, 2014) and GSG-7 (IAEA, 2018). Alternatively, more reasonable regulations should be established based on an analysis of the effects of the regulations.

(2) Measures for improving the estimation of radiation doses in cases of large-scale radiation disasters

1) Background of the advisory opinions

In response to the Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Plant accident (Fukushima Nuclear Accident), the air radiation dose rates were measured based on the release of radionuclides into the environment and the external exposure dose was estimated using those measured values. These estimates were far beyond what was in place at the time of the Chernobyl Nuclear Power Plant accident (the Japanese Radiation Research Society, 2021). There was also greater awareness on the importance of measuring and assessing individual doses. Prior to the Fukushima Nuclear Accident, actual measurements using personal dosimeters for estimating external exposure and direct measurements for estimating internal exposure had been thought to be necessary mainly for validating the results of dose assessment using models. Hence, they had been assumed to be conducted in a limited number of cases. However, from the perspective of health management and risk communication, these measurements were performed on a large number of residents during the Fukushima Nuclear Accident, although there were no individuals who required medical treatment for acute injury or internal radiation exposure.

Assessments of individual doses are more important in the early treatment of acute radiation syndrome and internal radiation exposure or for the screening of subjects who should undergo detailed dosimetry. In such cases, biodosimetry is likely to be an effective method of assessment. After the 9/11 terrorist attack in the United States in 2001, the development of a biodosimetry system for use in large-scale radiation disasters became a global issue, and as a result, the United States began the development of a high-throughput system that would allow biodosimetry assessments to be performed on tens of thousands of people (Grace et al.、2011,　Wang et al., 2020).

Using the lessons learned from past accidents and disasters (including terrorist attacks) that have occurred both in Japan and overseas, efforts to develop a variety of technologies and improve systems related to dosimetry in Japan are currently in progress. However, efficient improvement and guarantees of effectiveness require cooperation between a wide range of organizations and individuals, including national and local governments, specialized organizations, experts/specialists, private industries, and medical facilities. The AREMSCs, which were designated by the Nuclear Regulation Authority in 2015, play important roles in establishing cooperation among various organizations and individuals by acting as a liaison with academic organizations. Thus, the Japanese Radiation Research Society conducted surveys both in Japan and overseas pertaining to dosimetry methods during large-scale radiation-related disasters, surveyed all AREMSCs, and performed analyses of their current status (Japanese Radiation Research Society, 2021).

The *Radiation Protection Academia* reviewed the results of the surveys conducted by the Japanese Radiation Research Society. As a result, it was concluded that the biodosimetry systems in place in Japan (e.g., dicentric chromosome frequency, premature chromosome condensation [PCC], and cytokinesis-block micronucleus [CBMN] assay) are insufficient to assess the doses of 100–1,000 individuals for the purpose of triaging highly exposed patients or screening residents who may have been exposed to high doses; thus, it was determined that measures should be implemented as soon as possible. Thus, the *Radiation Protection Academia* decided that specific advisory opinions would be provided to the national government, local governments, and AREMSCs.

2) Current situation and problems

According to a survey conducted by the Japanese Radiation Research Society (2021), the state of preparedness of the AREMSCs for large-scale disasters is as follows:

<u>Dose assessment methods for use during large-scale radiation-related disasters</u>

AREMSCs are able to conduct physical dose assessments in Japan using methods whose implementation is based on technical standards that conform to global standards. These methods include dosimetry for measuring external exposure among exposed persons using individual dosimeters and remotely gathering information (such as data of environmental radiation monitoring/measurement, data of surface contamination surveys using GM survey meters, and data of internal exposure examination performed by thyroid dose monitoring using NaI survey meters and whole-body counters). Regarding thyroid dose monitoring, which was a problem during the Fukushima Nuclear Accident, the Nuclear Regulation Authority has taken the lead in designing a system that will link with the development of dedicated measuring devices and is cooperating with relevant organizations (Nuclear Regulation Authority, 2021). It plans to intensify these efforts in the near future.

Regarding biodosimetry, there has been a history of discussion focused on handling up to 10 patients considering high-dose exposure dosimetry. For this, the AREMSCs can conduct biodosimetry using the dicentric chromosome method (triage method). The disadvantage of dosimetry using chromosome analysis is that it is time-consuming to culture blood cells (up to 48 hours) and analyze chromosome aberrations. Thus, both in Japan and overseas, efforts are being made to automate the process and develop high-throughput analysis methods using artificial intelligence and other technologies. In Japan, there is a tendency to focus on the development of methods that can be easily automated and made high-throughput and can consequently be applied to dosimetry. The cytokinesis-block micronucleus (CBMN) assay is a triage method that has been verified globally and for which efforts toward automating its analysis are being made extremely rapidly. Although the accuracy of the dose assessments made by CBMN is lower than that of those made using the dicentric chromosome method, its merit is the fact that it is possible to use it as a dosimetry method within several months. Considering that the changes in blood cell count vary greatly among individuals, methods using blood cell count are considered to be inferior in terms of their accuracy in dose estimation. However, it is now possible to conduct analysis on smaller amounts of blood than previously, and even if there is a shortage of physicians who are knowledgeable in the field of radiation emergency medicine, it is now possible to perform screening of those who require dose assessments in a short duration. As a result, more consideration can be paid to the usefulness of this technology as a triage method for between 100 and 1,000 individuals.

Looking back on the JCO accident[11] and Fukushima Nuclear Accident, we see that there is a need to standardize the chromosome imaging system and establish an image sharing system to ensure that dose assessments during large-scale radiation-related disasters can be performed through cooperation by all AREMSCs. However, at present, the necessary equipment will be provided by each AREMSC. No specific plans beyond this have been formulated.

Prior to the Fukushima Nuclear Accident in 2011, the National Institute of Radiological Sciences (currently known as the National Institutes for Quantum Science and Technology), a regional tertiary radiation emergency hospital, took the lead in establishing the Chromosome Network, which is composed of domestic experts in the field of chromosome analysis for biodosimetry. Currently, the AREMSCs are collaborating in activities such as personnel training via workshops and the establishment of dose effect standard curves. However, they do not fully function as a network that can perform dosimetry accurately and promptly during emergencies through cooperation with experts from around the country. Thus, the cooperative system needs to be improved.

<u>Requesting dose assessments during large-scale radiation-related disasters</u>

The AREMSCs assume that they will be asked to perform dose assessments under the following three circumstances: i) requests in parallel with medical procedures for saving life, ii) requests after lifesaving procedures have been completed, and iii) cases in which

[11] Chromosome analysis was performed on 43 individuals, including JCO employees and firefighters who were exposed to low doses of radiation during the JCO criticality accident in 1999 and residents who were found to have low lymphocyte counts in their blood after this accident.

lifesaving procedures are unnecessary but dose assessments are necessary.

In physical dosimetry, it is possible to provide dose assessment data for any of the abovementioned circumstances: i) through iii). However, the time taken until the data is provided and the accuracy of the data is largely dependent upon the information available at the time when dosimetry is requested.

On the other hand, requests for and acceptance of biodosimetry are dependent upon the determination of the exposure status of patients performed by physicians in charge of making data-related decisions on site and the ability to process the analyses performed by the laboratories of the AREMSCs. Nevertheless, at the moment, there is no system in place for specific requests and acceptance, such as who makes the request (the examining physician, a medical facility, or a workplace) and who receives it (laboratories, the AREMSCs, or other specialized organizations). Hence, all laboratories are independently accepting requests.

All AREMSCs individually examine requests for dose assessments, methods for the delivery of samples, and the format for dose assessment information. If multiple laboratories are to cooperate in analyzing and reporting the results obtained from samples sent from multiple patients, there is a need to establish common guidelines for all to follow regarding methods and formats. In addition, assessments of internal doses via analysis of human excrement or other samples, i.e., bioassays, involve the same problem; however, currently, as several days are required to quantify radioactivity using bioassays after the samples are obtained and chemical separation is performed, such assessments are not believed to be useful in triage and screening.

<u>Involvement of dosimetry in nuclear disaster prevention drills</u>

Each year, nuclear power-related facilities and nearly all the 24 prefectures in Japan within a 30 km radius (UPZ) of these facilities conduct nuclear accident prevention drills, assuming an accident with the same amount of RI release as the Fukushima Nuclear Accident. This drill includes i) training on emergency reporting for pertinent individuals, ii) training on evacuating residents within the UPZ, iii) on-site medical training for the treatment of multiple people suffering from contamination illness, and iv) other training such as environment monitoring and assembly training. However, this drill does not include little related to performing individual dose assessments.

To prepare systems that are designed to effectively assess radiation doses when large-scale nuclear disasters occur at Nuclear Emergency Core Hospitals and AREMSCs that accept patients exposed to radiation, there is a need to conduct training including dosimetry such as thyroid monitoring and dose assessments for local residents during future nuclear accident prevention drills. These initiatives would allow the establishment of common guidelines for issues such as procedures for requesting dose assessments, methods of delivering samples, and dose assessment report formats, as mentioned above.

3) Advisory opinions

As indicated above, the Fukushima Nuclear Accident was an opportunity to review the importance of assessing the individual dose. There appeared to be no major technical problems involved in monitoring and triaging between 100 and 1,000 patients using physical dosimetry for external exposure. Regarding chromosome analysis for biodosimetry, it would be desirable for government agencies involved in the prevention of nuclear disasters to initially take the lead in the field of nuclear accident prevention to determine the categories of victims and workers who would be subjected to chromosome analysis during large-scale nuclear disasters, identify the speed and scale at which these should be performed, and improve the functions of the AREMSCs. In particular, in addition to the technical aspects of dosimetry methods, there is a need to strategically prepare soft and hard infrastructures for the purpose of collaboration among AREMSCs and information sharing and collaboration between the disaster site, medical facilities, and the analysis laboratories of AREMSCs.

Thus, the *Nuclear Protection Academia* provides the advisory opinions listed below for biodosimetry functions at AREMSCs and requests the cooperation of experts in all related fields in following these opinions.

1. The AREMSCs should strengthen existing systems to allow cooperation between different centers in the event that biodosimetry is to be performed on multiple injured individuals during large-scale disasters.
   - Standardize the dicentric chromosome analysis techniques through efforts such as the introduction of new equipment, personnel exchange, and technical training.
   - Prepare a system for sharing images that allow remote analysis
   - Determine the number of specimens that can be received by each laboratory and examine the division of roles (division of labor)
   - Establish common guidelines for tasks, such as requesting dose assessments, delivering samples, and formats used to report the results of dose assessment
2. If there is a shortage of equipment or personnel when implementing the abovementioned cooperation system in AREMSCs, human resource development and exchange should be enhanced. Other measures, such as entering into contracts with organizations other than ARMSCs and establishing processes for accepting organizational support in emergency situations (including cooperation with private industries), should also be implemented.

3. As dicentric chromosome analysis, a method that is able to provide an accurate dose assessment, requires both time and labor, AREMSCs should continually engage in discussions with each other regarding methods that are appropriate for triaging large numbers of victims. When gathering information regarding standardized methods, expert/specialist networks both in Japan and overseas[12] should be consulted.
4. It is necessary to be prepared to perform biodosimetry for various types of exposures, such as using the PCC method for exposures exceeding 5 Gy and using techniques to detect chromosomal translocations and CBMN for chronic exposures.
5. Networks that allow experts/specialists in chromosome analysis throughout Japan to cooperate in performing timely and accurate dose assessments during emergencies should be re-established.

Many experts/specialists in dosimetry are assigned under the assumption that they will work in laboratories. Thus, they are not considered personnel who can handle a triage (i.e., screening of patients who require dose assessments) of victims on site during disasters. Therefore, there is a need to examine the cooperation among on-site responders and experts/specialists in dosimetry who work in laboratories. The *Radiation Protection Academia* recommends that training in performing dose assessments is introduced in nuclear disaster prevention training programs that are implemented by national and local governments.

Additionally, as human-derived specimens are used in biodosimetry, there is a need to establish agreements to exchange personal information, obtain consent, and provide and share blood, specimens, and microscopic images when exchanging information between institutions and requesting testing. It is desirable that these agreements are conducted based on discussions held between each AREMSC and the local governments regarding support with biodosimetry provided by the AREMSCs. As AREMSCs are designated based on the Nuclear Emergency Response Guidelines, they will not be burdened with tasks requiring them to respond to incidents other than nuclear disasters, such as terrorist attacks, other types of accidents, or natural disasters. With regard to a framework for performing dose assessments during emergencies other than nuclear disasters, a decision on response guidelines for the national and local governments is still pending. However, as the number of facilities that are able to systematically perform dose assessments is

[12] The International Biodosimetry Network (BioDoseNet) operated by WHO is currently conducting the 3rd BioDoseNet Survey of the systems and state of preparation of biodosimetry laboratories worldwide. The results of this survey are scheduled to be announced at EPR-BioDose 2022 (Okayama University of Science). The current status of laboratories and experts in Japan is expected to be among the data announced.

limited, in any case of radiation-related accident, there is a high probability that organizations designated as AREMSCs will have to perform this task. Therefore, in addition to clarifying the roles of AREMSCs during emergencies other than nuclear disasters, there is also a need for regional or local governments to establish agreements with AREMSCs, as necessary, if responses are to be undertaken with different chains of command and radiation medicine systems than those at the location of the nuclear disaster.

3 Mid- and long-term advisory opinions for globalizing the Japanese radiation protection measures in Japan

(1) Measures for the adoption of new concepts regarding effective dose and operational quantity in Japan

1) Background of the advisory opinions

It is needless to say that dose estimation is important for radiation protection and establishment of radiation regulations. Nevertheless, the unit system of radiation dose used in radiation protection is not always easy to understand. In particular, when the media reports on accidents/incidents involving radiation exposure, academic communities must be aware of and provide information regarding the concept behind absorbed and effective doses used in emergencies and the relationship between the "Sievert" (Sv) and cancer risk so as to avoid misunderstandings among the public. As indicated above in the introduction section, in the new recommendations to be published by ICRP, the adoption of changes in effective dose and protection quantities proposed by ICRU in 2020 will be mentioned (Clement et al., 2021). These changes are expected to have a major impact on the radiation regulations worldwide.

Thus, as part of the fiscal year 2020 Umbrella Project commissioned by the Nuclear Regulatory Authority, a WG on the effective doses and operational quantities of radiation (Dose WG) was established under the direct control of the Representatives' Council of the Japanese Umbrella-structured Platform for Radiation Protection. The Dose WG was entrusted with activities to promote the accurate understanding of radiation doses and examine proposals for linking specific future actions. Through planning and holding webinars related to the effective dose and operational quantities (total of five in a series), the Dose WG gathered a variety of information on several topics, including the history of the concept of doses, risk assessment, overseas trends, biological effects, and communications, and shared this information within the *Radiation Protection Academia*. The information was summarized into the three below-mentioned points to conduct an analysis of the current status:

(1) Necessary investigations and preparations when a new concept of operational quantities is introduced in Japan
(2) Responses to problems faced by sites that use the effective dose
(3) Limitations of risk assessments using the effective dose

The proposals regarding (1) are consolidated for regulatory authorities, facilities involved in R&D, experts, and academic associations as well as those who perform radiation management; those regarding (2) are consolidated for academic societies/associations related to radiation protection and radiation-related ministries; and those regarding (3) are consolidated for academic societies/associations related to radiation medicine and those performing medical procedures in medical care settings (Dose WG, 2022). The Representatives Council checks the validity of the contents of their proposals and the status of the analyses performed by the Dose WG and summarizes and lists the key points.

2) Current situation and problems

In Japan, the ICRP recommendations released in 2007 and the recommendation to lower the lens dose limits have already been introduced into domestic laws. However, workplaces have been preoccupied with following measures; thus, they are not completely accustomed to the new rules. However, worldwide, the next-phase ICRP recommendations are believed to include the adoption of changes to the effective dose and protection quantities (ICRU, 2020; ICRP, 2020).

After ICRP released its recommendations in 2007, it established Task Group 79 in 2010, which started working on solutions to the problems surrounding the issue of doses. One of the problems is that the operational quantities currently in use show significant overestimates of the protection quantities in cases of high-energy photons. Recently, in the fields of medicine, research, and commercial aviation, the types of radiation and energy range requiring protection have increased and these problems have become apparent. A summary of the new concepts jointly determined by ICRU and ICRP is presented below:

i) Change the definition of the effective dose of external exposure

The operational quantities for the estimation of the effective dose will be the measured quantities defined by reference human phantoms replaced with conventional ICRU spheres using the conversion coefficient for fluence that does not underestimate the protection quantities. These changes require the use of a human body phantom for both effective dose and operational quantity as well as some changes to be made to the equipment and methods used.

ii) Change the dose used to assess tissue reaction

The absorbed dose, rather than the equivalent dose, will be used to prevent tissue reactions, such as cataracts and acute skin damage. This means that the equivalent dose is an intermediate quantity in the effective dose calculation and will no longer be meaningful as a protection quantity. In addition, information about the absorbed dose and relative biological effectiveness (RBE) for tissue reactions, which depend on the type of radiation, are required.

International guidelines regarding these new concepts of doses and uses are being drawn up and will be standardized in the future by the IAEA and ISO.

As opposed to when the protection quantity unit and tissue weighting factor were previously changed, it is not appropriate that the introduction of new operational quantities is informed to only those involved in radiation protection and management or that only technical problems associated with this introduction are dealt. Therefore, there is a need to investigate the effect of changes in operational and protection quantities on society as a whole and respond to such changes in ways that minimize confusion.

The response to and problems associated with changes to the protection and operational quantities

The effects of changing the definition of the operational quantities and unit of the dose limit for the prevention of tissue reactions from the equivalent dose to the absorbed dose have already engendered much discussion. For instance, regarding measuring devices and calibration procedures, there seems to be a need to increase the detector response to photons of ≥3 MeV or neutrons of ≥50 MeV and develop detectors that can measure the lens dose more accurately.

The Nuclear Safety Research Association (2020) conducted a survey on the effect of introducing changes in the concept of operational quantities into domestic laws and regulations on the measurements and assessments of operational quantities using a radiation measurement device. The survey it made clear that such changes will result in alterations in the conversion factor for the radiation measurement device as well as the response to standardization by the ISO, the International Electrotechnical Commission (IEC), and the Japanese Industrial Standards (JIS). They will also lead to changes in the terms and symbols used in manuals. Their report summarized that it will be difficult for calibration laboratories, manufacturers of radiation measuring instruments, and radiation management operators to deal with the expected changes in the concept of operational quantities in the future by themselves and that it will be necessary to work in cooperation with each other.

Regarding individual doses, the design of personal dosimeters, the calculation of doses by personal dosimeter service organizations, and the management of radiation exposure by users will all have an impact. Among these changes, the change from equivalent dose (Sv) to absorbed dose (Gy) for the dose limit for the eye lens and skin will require additional calculations that take into account the RBE of neutrons in the neutron–photon mixed field.

There are multiple tissues and organs that are subject to tissue reactions, and the responses vary widely, e.g., in the case of the skin, early transient erythema, main erythema reaction, temporary epilation, and permanent epilation may occur, and depending on the type of radiation and amount of energy, the biological effects may differ (ICRP, 2012). Thus, examination of RBE, quality factor, and radiation weighting factor are global issues, and Japan's contribution, which is at the global forefront of particle beam therapy, is greatly anticipated.

Effective doses, their use, and problems associated with them by age group

Effective dose for radiation protection is based on the average dose to human organs and tissues (ICRP, 2007). Calculations of the equivalent dose to organs and tissues use adult male and female reference computational phantoms. Regarding external radiation exposure, in recent years, the ICRP has set irradiation conditions for whole-body radiation exposure and assessed the dose conversion coefficient. In ICRP publication 144, phantoms and the effective dose (rate) coefficients were provided based on age group (newborn, 1 year of age, 5 years of age, 10 years of age, 15 years of age, and adult; ICRP, 2020). It also provided dose coefficients based on age group for types of internal radiation exposure, such as due to the administration of radiopharmaceuticals. Thus, improvements are in the process of being made to the age-specific effective doses, but these will likely be ready for inclusion in the next recommendations.

In addition, the ways to use effective dose are also being reconsidered. For example, as nearly all medical radiation exposure is local exposure, the use of effective dose tends to be seen as inappropriate, but its use for comparing modalities or imaging technologies and for risk communication is approved (ICRP, 2021). Effective dose will generally be used at doses below 100 mSv, but its use at acute doses in the range up to approximately 1 Sv is reasonable.

Effective dose is the unit that is most widespread in society as it is an approximate indicator of the potential health risks. However, there are a large number of rules regarding its calculation and use. Documents related to radiation created by radiation-related government agencies for lay people include explanations of effective dose and the unit of Sv.[13] However, as they are misused from time to time, it is important for the stakeholders to have a common view of the meaning of effective dose and its intended uses. In particular, it is necessary to prepare for the dissemination of information on

[13] Examples of documents that are currently being created and revised by government authorities and agencies are as follows: Cabinet Office, Consumer Affairs Agency, Reconstruction Agency, Ministry of Foreign Affairs, Ministry of Education, Science, Sports, Culture and Technology, Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Economy, Trade and Industry, Ministry of the Environment, Nuclear Regulation Authority: "Basic Information on the Risks of Radiation." Ministry of Education, Science, Sports, Culture and Technology: "Supplementary Reader on Radiation." Ministry of the Environment: "BOOKLET to Provide Basic Information Regarding Health Effects of Radiation." Consumer Affairs Agency: "Food & Radiation: Q&A."

effective doses by age group as it is likely to attract public attention in the process of being improved and completed.

Explanation of the risks of and problems associated with the use of effective dose

As for the relationship between effective dose and risk, the ICRP 2007 recommendation states that the nominal risk coefficient after detriment adjustment is about 5% per Sv. This implies that exposure to 100 mSv of radiation is assessed as increasing the risk of death due to cancer in the cohort by 0.5%. The calculation of this detriment-adjusted nominal risk coefficient is based on whole-body exposure to low-dose (rate) radiation because dose and dose-rate effectiveness factor (DDREF) and tissue weighting factor (w_T) are used. Therefore, this risk factor was used for risk communication with regard to the Fukushima Nuclear Accident, and it is widely used in Japan.

Previously, DDREF, w_T, and radiation weighting factor (w_R) used the same values regardless of sex or age group. However, more detailed phantoms such as those for fetuses and pregnant women became available, leading to the development of extremely detailed absorbed dose assessment based on age group. Hence, improvements in effective dose by age group are underway, as mentioned above.

On the other hand, looking at the situation in Japan, more than 10 years have passed since the Fukushima Nuclear Accident. Eventually, when the latency period for cancer has passed, the causal relationship between individual exposure dose and the induction of cancer will become an issue. Therefore, there is growing need to explain the contribution of radiation exposure from the Fukushima Nuclear Accident on cancer induction. In addition to risk communication during the response to an emergency, there is also a need to provide an explanation of the risk consistent with a variety of radiation exposures in day-to-day radiation care settings.

The ICRP released Publication 147 to elucidate the use of dose in relation to health risks (ICRP, 2021). Effective dose is used in medicine for a variety of reasons, including comparing doses from different medical procedures, informing judgments on justification, and establishing constraints for carers and volunteers in medical research. When explaining the risk of medical radiation exposure to patients and clinicians, there is a continued need to be careful to avoid creating misunderstandings such as that "the effective dose can be substitute for specific risk analysis for individuals." Thus, the ICRP (2021) recommends the use of general terms such as "can be ignored," "minimum," and "extremely low" and phrases such as "the radiation risk to those aged between 0 and 9 years is approximately double that of those in their thirties."

An effective dose of up to 1 Sv can be used exceptionally in cases of radiation emergencies. However, in the case of the plutonium internal radiation exposure accident that took place in Japan in 2017, the committed effective dose was reported to be 12 Sv.[14] It was confused with "the exposure of the whole body to 12 Sv of radiation" and led to the misunderstanding that it was similar to that in the case of the JCO criticality accident that occurred in 1999.

As effective dose values tend to be perceived as directly linked to risk in medical settings, those involved in medical care need to understand the meaning and limitations of effective dose and provide appropriate explanations regarding this information.

3) Advisory opinions

As mentioned above, because the changes in the protection and operational quantities are so significant internationally, it is important to have a system for understanding international trends and discussing the status of domestic studies in a comprehensive and long-term manner. The *Radiation Protection Academia* proposes that regulatory authorities, R&D organizations, experts/specialists, and those involved in radiation management consider how to deal with issues such as how to best perform the calibration of measuring devices, confirm the validity of measurement methods, and standardize calibration (ISO, IEC, and JIS); how to handle situations in which validity cannot be guaranteed; and the effects of changes made to dose records. When doing this, it is desirable to promote communication between manufacturers, those involved in service tasks and regulations, and stakeholders so that they understand the background to any changes made and sufficiently discuss about the changes made. In addition, relevant academic societies/associations and those involved in radiation management are expected to collect and sort out the data on RBE and ascertain the effects on the various tasks they perform, whereas R&D organizations and experts are expected to provide information on scientific data regarding RBE and the predicted impact on tasks they perform to international organizations.

In addition, in the view of the social background, such as the increase in the use of radiation in medicine and social concern about radiation risks, it is necessary to correctly understand the use of effective doses and effective doses by age group, not only for those involved in radiation protection but also the general public. Therefore, it is recommended that academic societies/associations related to radiation protection work together to prepare a report that structurally organizes information that can act as the basis of providing such information to promote the understanding of such concepts. This can be

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[14] The Japan Atomic Energy Agency (JAEA) published "Contamination at Plutonium Fuel Research Facility of Oarai Research and Development Center (follow-up report)" (June 9) and stated in the table of measurement results of "Nasal smear and lung monitor measurements" that "Inhalation of 2.2 × 104 Bq of Pu-239 is equivalent to a committed effective dose of approximately 12 Sv."

prepared in the form a glossary on the aspects of internal and external exposure, radiation management, and medical exposure, making it possible to establish a common understanding of the meaning of effective doses as defined by the ICRP and the implications of the use of effective doses by age group. To efficiently disseminate this common understanding within the Japanese society, it is proposed that radiation-related ministries reflect the various contents of the report prepared by the academic societies/associations in their own publications for the general public. When academic societies/associations prepare their reports and when government agencies update their publications, it is desirable for them to cooperate in conducting academic conferences, symposia, seminars, and workshops and solicit opinions online via websites so as to revise together with the involved stakeholders and disseminate information throughout society.

Furthermore, there are cases in which effective dose is used to explain the health risks while justifying the application of radiation diagnoses. Therefore, those involved in medical care should have a sufficient understanding of the meaning of effective dose and its limitations in medical use. As a result, the *Radiation Protection Academia* proposes that the academic societies related to radiology sort out the issues concerning the uses of effective dose in medical care settings and the meaning of the risks, inform those involved in medical care, and prepare standard publications that provide patients with appropriate explanations of these issues in cooperation with the academic societies/associations related to radiation protection. In addition, it is expected that academic societies related to radiology will assume the task to continuously update the methods of explanation to patients in accordance with feedback from practitioners in the medical field and advances in diagnostic radiology technology.

4 Conclusion

The basis for ensuring the safe and secure use of radiation is the prevention of unplanned radiation exposure. However, as it is impossible to completely eliminate human errors, and incidents such as the dispersion of unsealed RI during work-related tasks and exposure of operators to radiation during IVR tasks will continue to occur. Workers should wear dosimeters and PPEs during work to take appropriate measures to minimize exposure when such events occur. It is also important for business operators to review work processes, training contents, manuals, etc., when introducing new irradiation equipment or occurrences of near-miss cases, to implement the PDCA cycle, and to constantly share information so that the causes of accidents can be investigated and their effects can be verified. As for the incidents of contamination of sealed sources of tritium that occurred in Japan in 2013 and the loss of animal carcasses administered RI in 2017, the survey found that half of the radiation facilities in Japan still do not include the response to such incidents in their manuals for radiation hazard prevention regulations or emergency response. Therefore, the *Radiation Protection Academia* makes specific advices to business operators regarding accident prevention and the swift handling of the aftermath of accidents. In addition, regulatory authorities are expected to implement a PDCA that will promote the disclosure of information related to accidents and incidents by workplaces, thereby promoting their analysis and verification by specialized organizations, which will eventually provide feedback on the results of these efforts to all related workplaces.

In the events of a large-scale radiation/nuclear accident and nuclear terrorism, there is a possibility that large numbers of people will be exposed to radiation. The Fukushima Nuclear Accident provided an opportunity to reaffirm the importance of individual radiation dose assessment. Consequently, in the field of physical dosimetry, attempts to solve problems associated with the monitoring and triage of 100–1,000 patients are ongoing. As for biodosimetry, several methods are available, each with its own strengths and weaknesses. Thus, there is a need for specialized organizations to cooperate in resolving the weaknesses of the dicentric chromosome method while simultaneously developing dosimetry methods that are suitable for the triage of large numbers of patients. Therefore, the *Radiation Protection Academia* provides specific advices to AREMSCs on the development of infrastructure for cooperation among them and requests experts and specialist to cooperate. It has also proposed that the national and local governments, which plan and implement nuclear power disaster prevention drills, should incorporate training in dosimetry into their drills.

Changes in the effective dose and operational quantities and the adoption of these changes in Japan are issues that will continue to be discussed for several years. Although not urgently relevant to the two abovementioned recommendations, the *Radiation Protection Academia* provides advisory opinions that those involved in R&D and management of radiation cooperate with manufacturers and service organizations in standardizing radiation dose meters and calibration methods. In addition, in Japan, where social interest in radiation has been high since the Fukushima Nuclear Accident, the use of effective doses, especially the appropriate explanation of health risks using effective doses, is an ongoing issue. To ensure that effective doses by age group, which are still in the process of being improved, are not misunderstood as risk indicators for specific individuals, academic societies/associations involved in radiation protection and radiology should cooperate in establishing a common understanding of the meaning and limitations of effective doses. It is also hoped that this information will be shared throughout the society with the cooperation of radiation-related ministries.

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