Review (Invited)

Current Issues in Protection from Medical Radiation in Japan —The Situation after the Fukushima Nuclear Disaster—

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This paper provides a broad overview of the regulatory framework on medical radiation safety and current medical radiation protection issues such as diagnostic reference levels, shielding calculations for X-ray facilities, accidental excessive emissions of gaseous ^{18}F , security of radioactive sources, and induced radioactivity in Japan, and discusses the impact from the 2011 Fukushima nuclear disaster regarding risk communication issues. The Fukushima nuclear disaster has had an inevitable impact on issues related to protection from medical radiation. However by taking this situation, communication activations on radiation are being accelerated in certain initiatives utilizing quantitative risk expression on the premise of seeking fairness for risk allocation to the society.

KEY WORDS: medical radiation, radiation safety, radiation accident, shielding calculation, releasing nuclear medicine patients, risk communication.

I INTRODUCTION

This paper provides a broad overview of the regulatory framework on medical radiation safety and current medical radiation protection issues in Japan, and discusses the impact from the 2011 Fukushima nuclear disaster. Basically, Japan's regulatory framework on medical radiation safety is based on international standards provided by the IAEA (International Atomic Energy Agency) such as exemption levels of radionuclide and recommendations of ICRP (International Commission on Radiological Protection) such as dose limits for radiation workers. However, some parts are unique, such as those dealing with shielding calculations for X-ray CT room, linear accelerator facilities, and nuclear medicine facilities including an assessment of radioactive concentration of wastewater. Japan's policies on radioactive waste and induced radioactivity are also unique. These parts are based not only on international standards such as the basic safety standard and the other technical documents of the IAEA, recommendations of ICRP, and standards of IEC (International Electrotechnical Commission) but also on research activities in Japan reflecting the historical aspects of its medical radiation protection culture and are reforming to adapt international standards.

II METHODS

A literature review of the current radiation safety issues focused on medical radiation was performed. The official governmental websites and related websites including a website for medical radiation safety management case study¹⁾ were used to assess the regulations and the officially announced notifications as of January 2016. Furthermore related examples presented or discussed at domestic academic society conferences were analyzed regarding the impact from the Fukushima nuclear disaster to medical radiation safety.

III RESULTS

1. Regulatory framework on medical radiation safety

In Japan, there are several laws concerning medical radiation safety, such as the Medical Care Act, Pharmaceutical and Medical Device Act, Prevention of Radiation Hazards due to Radioisotopes Act, and Industrial Safety and Health Act. Each ministry has a role in medical radiation protection (**Table 1**). The Radiation Council was organized to unify and harmonize technical standards for radiation protection in various regulations in Japan.

Each act provides the basic principles and Ministerial ordinance provides the actual safety procedures. More detailed procedures are indicated in official notifications issued by each ministry. According to the decentralization act, a part of medical radiation safety is in charge of local governments, so that each local government proves local ordinance on medical radiation safety. National institute of Public Health provides a training course for medical inspectors to learn about radiation safety in medicine.

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Table 1 Laws concerning medical radiation safety.

Ministry	Law
MHLW (Ministry of Health, Labour and Welfare)	Medical radiation devices; radiopharmaceuticals; and medical radiation protection for patients, medical workers, and the public.
NRA (Nuclear Regulation Authority)	General radiation and radioactive materials, X-ray generators over 1 MeV since 2012 (before that Ministry).
MLIT (Ministry of Land, Infrastructure, Transport and Tourism)	Transportation of radioactive materials.
NPA (National Personnel Authority)	Radiation protection for governmental workers.

2. Basic statistics

2.1 Radiation dose to medical workers

The distribution of effective doses among medical workers in Japan in fiscal year 2014 was indicated in **Table 2**. The total monitored medical workers were 333,930. Among them, 235,988 (71%) workers were below detection limit, 312 (0.1%) were above 20 mSv and 11 (0.003%) workers were above 50 mSv. Note that this data was provided from the council on

Table 2 Effective doses among medical personnel ($n = 333,930$) in Japan.

Annual effective dose (mSv)	Number of medical personnel
Not detected	235,988
0.10–1.00	64,829
1.01–5.00	27,709
5.01–10.00	3,768
10.01–15.00	978
15.01–20.00	346
20.01–25.00	147
25.01–50.00	154
50.00–	11

Table 3 Medical radiation devices in general hospital ($n = 7,426$) in Japan.

	Number of equipped hospitals	Number of equipment	Examination per hospital during Sep. 2014
Mammography	2,512	2,709	85.9
Scintigraphy including SPECT	1,137	1,459	74.2
PET	61	72	38.5
PET-CT	273	346	136.2
Multi slice CT	5,437	6,702	419.2
The other CT	980	1,014	53.3
Linear accelerator/Microtron	728	922	284.2
Gamma knife/Cyber knife	85	90	22.9
RALS	163	169	4.4

SPECT, Single photon emission tomography.

RALS, Remote after loading system.

As of Sep. 2014, Survey of Medical Institutions, MHLW.

Note: The Japanese hospitals have at least 20 beds. That is a difference between hospitals and clinics in Japan.

Gamma knife is a registered trademark of Elekta instruments.

Cyber knife is a registered trademark of Accuray Incorporated.

personal dosimetry service and was not the official statistics confirmed by the Governmental organizations. That means it might include incorrect data.

2.2 Medical radiation equipment

In Japan, a medical institution has to carry out a proper procedure for usage of a medical radiation device. A medical institution has to notify to a public health center when an institution installs or changes a medical radiation device including an X-ray device according to Medical Care act so that all medical radiation devices are registered officially. On the other hand, a medical institution has to obtain permission from the Nuclear Regulatory Authority (NRA) in advance when an institution installs or changes a linear accelerator or sealed sources according to Prevention of Radiation Hazards due to Radioisotopes Act. Adding this all medical radiation device should be produced properly according to Pharmaceutical and Medical Device Act and basically examined in advance of usage in medical institution according to Medical Device Act. Although there is no official database system of medical radiation devices, a survey of medical institutions is conducted every year by the Ministry of Health, Labour and Welfare (MHLW) in Japan. The number of medical radiation devices in general hospital ($n = 7,426$) was shown in **Table 3** and in medical and dental office ($n = 10,461$) in **Table 4**. Medical institutes are divided to hospital and clinic in Japan. According to the definition described in Medical Care Act, hospitals have at least 20 beds.

One of the characteristics of medical radiation devices in

Table 4 Medical radiation devices in medical and dental office ($n = 10,461$) in Japan.

	Number of equipped hospitals	Number of equipment	Examination per hospital during Sep. 2014
Mammography	1,315	1,495	194.7
Scintigraphy including SPECT	28	30	35.0
PET	24	29	20.3
PET-CT	63	100	214.9
Multi slice CT	3,042	3,075	67.2
The other CT	2,318	2,325	30.4
Linear accelerator/Microtron	728	922	284.2
Gamma knife/Cyber knife	9	9	23.7

As of Sep. 2014, Survey of Medical Institutions, MHLW.

Fig. 1 Number of X-ray CT per 1M inhabitants among countries.

Japan is high prevalence of X-ray computed tomography (CT) scanners. According to OECD, Japan is the most prevalent country of X-ray CT showing 107.12 per million population (total number is 13,636) in 2014 (**Fig. 1**).²⁾

3. Diagnostic reference level

An important issue in recent medical radiation protection is diagnostic reference levels (DRLs). To establish DRLs in Japan, the Japan Network for Research and Information on Medical Exposure: J-RIME³⁾ was launched in 2010. J-RIME is consisted from Japan Association on Radiological Protection in Medicine, Japanese Society for Pediatric Radiology, Japanese Association of Medical Physics, Japan Association of Radiological Technologists, Japan Radiological Society, Japan Radiation Research Society, Japanese Society of Nuclear Medicine, Japanese Society of Radiological Technology, Japanese Society of Nuclear Medicine Technology, Japanese Society for Radiation Oncology, Japan Medical Imaging and Radiological Systems Industries Association, Japan Health Physics Society, Japanese Society for Oral and Maxillofacial Radiology and it was established by suggesting and encouraging by Dr. Maria PEREZ of WHO. Through tremendous efforts spanning the country, the J-RIME released the first version of DRLs (*Japan DRLs 2015*) based on the latest surveys carried out by many relevant academic societies in Japan. These activities of J-RIME have been reported as a good practice by international organizations such as Radiation Protection of Patients (RPOP), IAEA, International Organization for Medical Physics, and Quality News (July 2015) of the International Society of Radiology. These levels will be updated in future. One of the motivations on optimizing administrative activities of radiopharmaceutical to patients was the unfortunate over-dose cases of pediatric patients in Yamanashi prefecture reported in May 2011.

4. Shielding calculations for X-ray facilities

The official guidelines for shielding calculations for X-ray facilities in Japan are a notification from MHLW. It was based on National Council on Radiation Protection and Measurements (NCRP) Report No. 49 (1976) and Report No. 102 (1989) and the other documents including the recommendations of ICRP as mentioned in the introduction section. This notification was revised in 2014 based on NCRP Report No. 147. However, shielding calculations for

X-ray CT rooms using dose-length product (DLP) were not implemented in this notification since there was a concern about underestimation of scattered radiation of newly developed X-ray CT.⁴⁾ The Japanese Society of Radiological Technology and Japan Medical Imaging and Radiological Systems Industries Association are developing a new shielding calculation model.

One of the characteristics of medical radiation equipment in Japan is that many medical offices are equipped with X-ray CT scanner.⁴⁻⁶⁾ In some case, a doctor's office is in a compound building and residential areas are quite close. In such cases, to ensure dose constraints those are indicated as dose limits in Japanese laws, shielding should be added for a high throughput X-ray CT scanner.

5. Hand-held dental X-ray equipment

In recent years, regulations for hand-held dental X-ray equipment have been disputed in various countries. The US Department of Health and Human Services and American Dental Association established new guidelines on hand-held dental X-ray equipment.⁷⁾ The Japanese Society for Oral and Maxillofacial Radiology is revising its radiation protection guidelines by optimizing the usage of hand-held dental X-ray equipment and will provide a guideline in accordance with MHWL.

6. Releasing patients to the public

Based on the safety report of IAEA⁸⁾ wherein some national maximum activity levels for release of patients (e.g., for ¹³¹I, ⁸⁹Sr, and ⁹⁰Y) were compared across countries and on an additional fundamental study,⁹⁾ the radiation safety guidelines and notification from the MHLW were established for outpatient-based remnant thyroid ablation with ¹³¹I performed after total thyroidectomy in patients with differentiated thyroid cancer. The national maximum activity remaining in the patient at the time of discharge from a hospital was set as 1.1 GBq in accordance with appropriate supervision and guidance from qualified experts. The national maximum activity for release of patients was set as 200 MBq for ⁸⁹Sr and 1,184 MBq for ⁹⁰Y. For ¹³¹I, dose rate from the surface of the patient body is also applicable (below 30 μ Sv/h). These standards were induced to ensure dose constraints such as 1 mSv/year for public and 5 mSv/episode for caregivers and relatives. In actual situation individual basis approach is employed considering the specific situation of each patient. Regarding the situation in Japan such as relevant radiation monitoring after the Fukushima nuclear accident and the spread of flame detector those are sensitive to ultraviolet radiation, the Japanese Society of Nuclear Medicine provides a leaflet for patients.

Following these guidelines, the guidelines on ²²³Ra and ¹⁷⁷Lu were established¹⁰⁾ based on a national survey.¹¹⁾ For ²²³Ra, issues on the establishment of radioactivity standard¹²⁾ and radioactive equilibrium between progeny nuclides for calculation of external radiation to caregivers were considered. Inflow ratio of used or administrated radionuclides to transfer to wastewater tank or drainage of controlled area is assumed to be 1% for the radiation safety design of radioactive wastewater

tank according to the Japanese traditional assumption procedure.

7. Clinical research and regulation

One of the complex problems regarding development of nuclear medicine in Japan is compliance with regulations for clinical trials, wherein an IND (Investigational New Drug) application must be submitted as per PMDA (Pharmaceutical and Medical Devices Agency) requirements, and for import of radioactive pharmaceuticals. The Medical Act is followed in case of clinical trials with INDs, whereas the Prevention of Radiation Hazards due to Radioisotopes Act is followed for other types of clinical trials.

Although research volunteer exposure has not been regulated in Japan, following the survey on radiation exposure to research volunteers in institutes with nuclear medicine,¹³⁾ the Japanese Society of Nuclear Medicine proposed the principle on radiation protection for research volunteer in biomedical field.

8. Accidental excessive emissions of gaseous ^{18}F

^{18}F gaseous releases during the production of ^{18}F -fluorodeoxyglucose should be below the concentration limit for routine operations.¹⁴⁾ However, in 2007, there were at least three incident reports on excessive radioactive waste gas emissions from medical facilities due to inadequate maintenance of automated radio-synthesis modules.^{15–17)} The Ministry of Education, Culture, Sports, Science and Technology (MEXT) issued a notification to prevent these accidents by increasing medical institutions' awareness.¹⁸⁾ This issue was discussed at a scientific congress¹⁹⁾ and a newly developed method for reducing medical workers' radiation exposure was announced.²⁰⁾

9. Security of radioactive sources

9.1 Regulatory framework on security of radioactive sources

In accordance with the IAEA's Code of Conduct on the Safety and Security of Radioactive Sources and guidelines for safety and security of radioactive sources, the NRA has imposed legal restrictions to ensure that the licensee hands over high-activity sealed radioactive sources to only authorized license holders. Furthermore, business operators must report to the NRA details of the specification, receipt, and issue of any sealed radioactive isotopes above a set amount that have pose significant risks to human health. In addition, they must provide the NRA with a report on any such radioactive sources in their possession at the end of each fiscal year. There is a well-established mechanism for the handover of disused radioactive sources to licensees with the requisite expertise by using an online recording system. Licensees are obliged to submit a notification of a decommissioning plan to the regulatory authority when they terminate the use of the sources, and to report the outcome of the handover. All licensees are required to conduct an annual inventory check of both sealed and unsealed radioactive sources in their possession and report the results to the

regulatory authority, to prevent the occurrence of orphan sources. The Radiation Hazards Prevention Act prescribes penalties for misconduct of radioactive sources lies with the licensee. Most sources in Japan are imported from overseas. It would be desired that sources with a long half-life and high activity are returned to the original foreign manufacturers. However, as described below, it is not easy to do so in case of the radioactive source for blood irradiation because of the high cost. The entire process of distribution of radioisotopes and sealed sources in Japan is organized by a single supplier (the Japan Radioisotope Association (JRIA), from distribution and delivery of almost all radioactive sources to the recovery of disused radioactive sources. However, used radioactive sources for blood irradiation are known to have been sold to other hospitals. Although there have been no serious radiation hazard incidents involving radioactive sources or orphan sources to date, several incidents of stolen sources have been reported. Accordingly, the NRA is preparing a revised version of the Act in order to strengthen the security of sealed radioactive sources. The NRA committee provided the outline of regulatory reform regarding the security of radioactive sources in November 2015,²¹⁾ and issued the report for the reforming the regulation in September 2016.²²⁾

9.2 Long-term management of sealed radioactive sources unreturnable to the manufacturers

As previously described, most sealed radioactive sources used in Japan are manufactured abroad, imported, and then expected to be returned to foreign manufacturers after use. However, most radioactive sources are becoming unused, since irradiated blood is provided from the blood centers of the Japan Red Cross Society. Therefore, Japan has around hundred sealed radioactive sources that are not able to return to the manufacturers. The storage and management of these sources are becoming the main issue pertaining to security of sealed sources since radiation issues become social controversy after the nuclear accident and it is widely believed that it should be extremely difficult to build a central storage or disposal facility for radioactive substances.

9.3 Response to orphan sources

In April 2015, an orphan source of ^{226}Ra (37 MBq) was found in a public playground in Tokyo. The city office immediately took initial action, including setting up an exclusion area, conducting a radiation survey, and immediately assessing the overall situation with help from the NRA and JRIA. The public health center had to answer many questions from parents. To do so, authorities obtained assistance from researchers from the National Institute of Public Health, taking advantage of their expertise in radiation safety and previous experience in risk communication.²³⁾ The dose rate at the surface of the ground above the radioactive source was 0.5 mSv/h and the main concerns of parents were actual dose to their children and predicted health effect.

10. Induced radioactivity

In Japan, an amended law that mandates levels of unintended induced radioactivity has been in effect since April 1, 2012. It specifies a clearance level even in cases where the volume

of radio-activated parts of an accelerator is comparatively small (e.g., below 1 kg such as bolts and nuts). As per this law, if the concentration of induced radioactivity in the affected parts is above the clearance level, the parts must be regarded as radioactive even if they weigh less than 1 kg. A guideline was issued by MEXT, based on scientific investigations, to reduce medical institutions' radiation management efforts. It clearly outlines the criteria for induced radioactivity for each part of 10 MeV linear accelerators. This regulation reform has raised several new issues concerning medical linear accelerators with higher energy, including how to determine the decay period for induced radioactivity before maintenance can be performed and how to identify what parts should be considered radioactive waste. A study found that almost all workers were concerned about radiation risk and about 25% of the maintenance workers felt that insufficient information was provided about the decision making on necessary decay period for safe handling of induced radioactivities. Accordingly, several risk communication activities aimed at improving the understanding of maintenance workers at medical accelerator manufacturers were carried out. The guidelines were also established by the joint working group composed of Japanese Society of Radiation Oncology, Japanese Society of Radiological Technology, Japanese Society of Radiation Safety Management, Japan Society of Medical Physics, Japan Medical Imaging and Radiological Systems Industries Association, The Japan Association of Radiological Technologists. This revealed the important role of risk communication for this issue.²⁴⁾

One of the unique characteristics of medical radiation in Japan is the relatively high prevalence of cyclotron in medical institutions, which leads to safety issues regarding induced radioactivity. Before 2012, radiation safety regulations did not treat any part of the inner concrete wall of a cyclotron vault as radioactive if it was not easy to be detected by routine monitoring, even though certain protective actions were taken for induced radioactivity. However, since 2012, some parts of the inner concrete wall of a cyclotron vault have been treated as radioactive during construction.

IV DISCUSSIONS

The Fukushima nuclear disaster has had an inevitable impact on issues related to protection from medical radiation. Adding the basic and specific characteristics of the previous situation on medical radiation in Japan described in results, risk communication issues make a difference on medical radiation management in Japanese society. These issues are discussed relating with the medical radiation safety management in Japan.

(1) Risk communication issue in relation to the Fukushima nuclear disaster

Regarding the radiation regulation, one of the specific characteristics in Japan is less attention to natural radiation due to lower levels of natural radiation except ingestion. There are any regulations for protection of public on natural radiation in Japan except a guideline for naturally occurring radioactive

material issued by MEXT in 2009. Routine monitoring of natural radioactive substances in the air and drinking water has not been performed except military facilities of United States. It is due to the cultural background of Japan. However, after the Fukushima nuclear disaster, people in Japan, especially those in the comparatively more-affected regions, eventually and inevitably are faced with radiation risk. Individual differences in attention to risk-related messages have been explained by regulatory focus theory: in such a situation, some people wish to avoid radiation risk while others are willing to take the radiation risk and live in the affected area knowing about radiation risk quantitatively expressed such as loss of life expectancy comparing their interested risks and recognizing the difficulties of environmental justice issue.

Even in other countries, radiation risk became a political issue; consequently, almost all countries implemented their own regulations for imports from Japan even though related documents were provided by the Codex Alimentarius and IAEA. Honestly speaking, the Japanese government implemented its own food restriction policy for food imported from East Europe before the Fukushima nuclear accident. In the aftermath of this disaster, local medical practitioners were involved in local radiation issues such as evacuation, food control, and decontamination as a garden physician. These issues were strongly related to local political disputes but these medical practitioners were expected to remain impartial while performing such tasks. Therefore, talking about radiation risk in public was not easy for them. Adding this, medical practitioners don't have enough knowledge on radiation and its risk in general; nevertheless the public realized that these medical practitioners have scientific knowledge. Adding this in daily clinical activities, patients asked about radiation risk including radiological medical examination more frequently than before the nuclear disaster. Local medical practitioners should answer these questions in their clinical situation.

The Fukushima nuclear disaster has had a considerable impact on local communities. We observed good practices in radiation risk communication based on empowerment of residents and establishment of a trust-building approach using local communicators. For these activities loss of life expectancy was recognized as useful tool for daily decision making in existing exposure situation by local residents under the conditions that social justice were treated as important issues.²⁵⁾ This recognition was one of the background factors promoting the establishment of DRLs in Japan, even though determining the size of radiation risk in routine medical activities is difficult.

(2) Radiation safety issues regarding nuclear medicine in relation to the Fukushima nuclear disaster

(i) Detection of patients

In nuclear medicine, radiation from patients is typically detected by using a survey meter. Before the Fukushima accident, it was also known that radiation from a patient who had been administered radiopharmaceuticals was detectable by a survey meter and a radiation monitoring post.²⁶⁾ However, since radiation survey meters became common after the

nuclear disaster, they came to be widely known to the general public.

(ii) Accumulation of radioactive pharmaceuticals in a sewerage plant

Other issues were raised, such as accumulation of radioactive pharmaceuticals in a sewerage plant. Before the nuclear disaster, there were several conflicts between a sludge processing plant and a sludge treatment company partnering a hospital, since decay storage regulations had not yet been implemented in Japan. Meanwhile there is no final disposal facility for radioactive medical waste in Japan, therefore all radioactive medical wastes are kept temporally at the storage facility in Takizawa city, Iwate. The exception was regulations related to short half-life radioisotopes for positron emission tomography since these radioisotopes were thought to be become 0 Bq by decaying for a certain period in each medical institution. These regulations had been implemented in 2004 by revising the Ministerial ordinance of MEXT. Therefore, under the current regulations, dredged sludge from a septic tank in the radiation control area of nuclear medicine in a hospital is considered to be radioactive waste even though the radioisotopes have been decayed sufficiently.

In Japan, the radioactive nuclides used in nuclear medicine in a dehydrated sludge sample could be easily detected through routine monitoring in sewerage plants after the nuclear disaster, since the amount of radioactivity was relatively large (about 15 TBq/y for ^{131}I).²⁷⁾ Sewerage plants had to explain to the public about the safety of exhaust gases from the stacks of their incinerators because the vaporization temperature of iodine is relatively low even though it was classified to be an existing exposure so that it was not responsible for a sewerage plant operator. Moreover, the accumulation coefficient of iodine to seaweed is relatively high, and it is possible to detect ^{131}I in seaweed.²⁸⁾ Furthermore ^{131}I is detectable in routine monitoring of tap water using high concentration method.²⁹⁾ Therefore, in case of detection of radioactive iodine in seaweed and tap water during routine monitoring, the government will have to explain its risk and safety to the public.

V CONCLUSIONS

Current issues in protection from medical radiation in Japan have been discussed, including risk communication issues regarding nuclear medicine in relation to the Fukushima nuclear disaster, shielding calculations for X-ray facilities, accidental excessive emissions of gaseous ^{18}F , security of radioactive sources, and risk communication issues regarding induced radioactivity. The Fukushima nuclear disaster has had an inevitable impact on issues related to protection from medical radiation. However by taking this situation, risk communication activities are being accelerated. Established diagnostic reference levels were precious products brought by voluntary activities based on academic societies and professional bodies with these circumstances. It is a meaningful challenge to ingrain DRL and medical radiation safety culture in Japanese society.

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