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by [Yasui S](#)

The fact that OECD countries have a wide range of emergency dose criteria means that an establishment of emergency dose limits requires social consensus-building, not just a scientific basis. The Japanese case can provide useful guidance for the setting and operation of emergency dose control in other countries. Necessity of further case studies in other countries are warranted.

Affiliation: Ministry of Health, Labor and Welfare, 1-2-2 Kasumigaseki Chiyoda-ku Tokyo, Japan, 100-8988. sysui@st.rim.or.jp

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Re-establishment of post-accident procedures for setting emergency dose limits based on the lessons learned in the 2011 Fukushima nuclear accident

By Shojiro Yasui, DSc

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In response to the accident at the Fukushima Daiichi atomic power plant in 2011, the Ministry of Health, Labor and Welfare issued an exemption ordinance to increase the dose limits for emergency workers temporarily from 100 mSv to 250 mSv from 14 March to 16 December 2011. However, there were many problems with setting and applying the dose limits as well as radiation protection. Based on the lessons learned, in 2015, the Government of Japan deliberated setting emergency radiation protection standards to ensure preparedness for future nuclear emergencies. This paper aims to describe and share the experience gained in that decision-making and social consensus-building process of setting emergency dose limits. It outlines issues relating to the setting and application of emergency dose limits, restricting these to emergency workers and training them accordingly, and mid-to-long-term dose control. When deliberating on emergency dose criteria, the Government of Japan had to harmonize its efforts with international guidance documents and find a way to balance the protection of emergency workers with the prompt implementation of a crisis management plan to maintain control over the nuclear accident. The fact that leading countries have a wide range of emergency dose criteria means that the establishment of emergency dose limits requires not just a scientific basis as prescribed in international documents but also social consensus-building. Further case studies on the decision-making process for setting radiation protection standards in other countries are thus warranted.

Key terms atomic power plant; emergency response; Fukushima Daiichi accident; nuclear emergency; radiation protection.

In response to the accident at the Fukushima Daiichi atomic power plant of Tokyo Electric Company triggered by the "Great East Japan Earthquake" of 11 March 2011, the Ministry of Health, Labour and Welfare (MHLW) issued an exemption ordinance to increase the dose limits for emergency workers temporarily from 100 mSv to 250 mSv from 14 March to 16 December 2011 (1). There were many problems with setting and applying the dose limits and radiation protection (2). The decision-making process to increase the dose limits took a couple of days and slowed down the emergency response, while the decision itself was reached without adequate consensus among key stakeholders. Newly recruited emergency workers neither received sufficient training nor formally confirmed their consent to engage in emergency work (3). Moreover, there was controversy in government over the combined control of the emergency and normal dose, which took a month to resolve

(1). Finally, emergency workers exposed to >100 mSv were excluded thereafter from normal radiation work because the government had not determined long-term radiation control methods for workers exposed to >100 mSv over five years (4).

Based on these lessons learned, in 2015 the MHLW discussed the establishment of emergency radiation protection standards and healthcare methods in the event of future nuclear incidents. The MHLW organized a meeting (hereafter the Expert Meeting), which brought together eight experts from disparate but relevant fields (ie, radiation protection, epidemiology, nuclear medicine, and occupational health) to examine the problematic issues that had arisen in the Fukushima accident. Starting in December 2014, the group convened over five sessions, which were open to the public, and provided its report to the MHLW in May 2015 (5). Based on the recommendations of the report,

¹ Ministry of Health, Labour and Welfare, Tokyo, Japan..

Correspondence to Mr Shojiro Yasui, Ministry of Health, Labour and Welfare, 1-2-2 Kasumigaseki Chiyoda-ku Tokyo, Japan, 100-8988. [E-mail: syasui@st.rim.or.jp]

the MHLW drafted the amendment of the ordinance and collected and evaluated opinions from the general public through a public comment scheme (6). Furthermore, the MHLW consulted with and got the endorsement of the Labor Policy Council, comprised of the representatives of trade unions and employers' organizations, and the Radiation Council, which consists of experts in radiation protection and nuclear medicine. Finally, the MHLW publicized its conclusions, responding to the public comments, on the government website (6). Following this lengthy process, the MHLW promulgated the amended ordinance in August 2015 and enacted it in April 2016 (7).

This paper aims to (i) describe the decision-making and social consensus-building process for setting emergency dose criteria; (ii) share lessons learned for scholars, experts, nuclear operators, and government officials who are responsible for radiation protection; and (iii) provide guidance for similar kinds of decision making.

Methodology

The MHLW summarized and issued a press release of the Expert Meeting report in May 2015 (5). The factual information described in this article is based on this report, official meeting transcripts, and official transcripts of national councils, unless other references are specified. As an MHLW officer responsible for drafting the amendment of the regulation, the author's observations were also enriched by his personal communication with members of the Expert Meeting and the representatives of relevant stakeholders.

Setting emergency dose limits

The General Safety Requirements of the International Atomic Energy Agency (IAEA) prescribes occupational dose criteria in emergency situations in three levels, as follows: (i) lifesaving actions: <500 mSv (this value may be exceeded under circumstances in which the expected benefits to others clearly outweigh the emergency worker's health risks, and the emergency worker volunteers to take action); (ii) actions to prevent severe deterministic effects or the development of catastrophic conditions: <500 mSv; (iii) actions to avert a large collective dose: <100 mSv [(8) p373].

A survey of emergency dose criteria in the Nuclear Energy Agency of the Organization for Economic Cooperation and Development (NEA of the OECD) revealed that each nation has a different criterion, and no uniform criteria are accepted internationally (9). Looking at only

the highest dose criteria for life saving, the criteria were 500 mSv in Australia, Canada, and South Korea, 500 mGy to the whole body in the UK, 300 mSv in France, 250 mSv in the USA, and 200 mSv in Russia. Furthermore, Australia, France, South Korea, and the USA have exemption prescriptions such as "this dose can be exceeded if justified, but every effort shall be made to keep the dose below this level" (table 1).

In opinions collected from public comments in Japan, some argued that 250 mSv should not be employed as the emergency dose limit because 150 mGy of radiation temporarily decreases the number of sperm, and acute radiation syndromes were observed in atomic bomb victims in Hiroshima who were exposed to <250 mSv. In contrast, some argued that 500 mSv should be adopted in accordance with ICRP recommendations (10). For deliberation of emergency dose criteria, the MHLW decided to review the academic literature concerning acute deterministic health effects of radiation exposure. For the indicator of acute radiation syndrome, hematopoietic functions are employed because they are sensitive to radiation.

Literature review on acute radiation syndrome: recommendations of the ICRP

The 2007 recommendations of the International Commission of Radiological Protection (ICRP) shows 0.5 Gy (total dose in a single short-time exposure) is the threshold that presents a reduction of hematopoietic function [(11) table A.3.1, p164].

The detailed reasoning thereof is given in ICRP Publication 41, mainly based on Bond et al (12) and Lamerton (13), and says that the threshold of occupational irradiation for detectable depression of hemopoiesis probably exceeds 0.4 Sv per year and that the threshold for fatal marrow aplasia probably exceeds 1 Sv per year (14).

ICRP Publication 118 states that healthy young men exposed to external gamma radiation at dose rates of <0.25 Gy/year and cumulative doses of 1.0–1.5 Gy showed no evidence of reduced hematopoiesis and that higher annual doses of 0.25–0.5 Gy and total doses of 1.5–2.0 Gy led to cases of thrombocytopenia and unstable leukopenia [(15) paragraph 66, p61].

In conclusion, ICRP Publication 118 states that acute threshold doses of approximately 0.5 Gy and chronic dose rates of 0.4 Gy/year remain the recommended values for preventing depression of hematopoiesis [(15) paragraph 668, p287].

Case studies of radiation accidents

Chapter 6 of Bond et al (12) was a principal reference concerning human effects of radiation exposure in ICRP Publication 41 (14).

Table 1. Dose criteria for emergency workers in OECD countries. [L=dose limit; R=reference level.]

Country	L/R	Highest level dose criteria	Conditions	Exemptions
Australia	R	500 mSv in effective dose	Lifes-saving actions.	This dose can be exceeded if justified, but every effort should be made to keep the dose below this level. ^a
Canada	L	500 mSv in effective dose 5000 mSv in skin equivalent dose	During control of an emergency.	
France	R	300 mSv in effective dose	Group 1: special teams of technical, health or medical intervention. Intervention is intended to protect people.	Reference level may be exceeded exceptionally for saving people. ^a In any case, the effective dose integrated over the life-time must not exceed 1 Sv.
Korea	L	0.5 Sv in effective dose 5 Sv in skin equivalent dose	Emergency work or inevitably taking part in such works as dealing with accidents to prevent the spread of damage	Dose limits should not apply to lifesaving emergency works.
Russia	L	200 mSv/year	In case of lifesaving actions towards the people and/or prevention of their exposure. ^a	
UK	R	500 mGy in whole-body dose 5000 mSv in dose to skin	For life saving, upper values of dose should normally not be exceeded.	
USA	R	25 mSv in sum of external effective dose equivalent and committed effective dose equivalent	Life saving or protection of large population, if a lower dose is not practicable.	Above 250 mSv, only on a voluntary basis to persons fully aware of the risks involved.

^a Only for emergency workers who are volunteers and well informed of the risk of their intervention.

This chapter reported on ten radiation accident cases in which the physical dose estimation was <1000 mSv. The cases included (i) Los Alamos I – one case (202 mGy); (ii) Los Alamos II – four cases (550, 360, 270 and 220 mGy; and (iii) Argonne 1952 – three cases (680, 680, and 220 mGy) [(12) p154]. Furthermore, information was available on a large group of Marshallese exposed in the Pacific testing ground fallout accident.

Bond et al concluded that “the data presented indicated that whole-body exposure with <1000 mGy would not cause clinical symptomatology that would require medical attention.” However, “laboratory examinations, in general, provide evidence for the preceding exposure, particularly at dose level 500–1000 mGy. Those consist of a mild lymphocyte count drop initially, which may be detectable for many weeks” [(12) p156].

For the accident in the Y-12 plant in Oak Ridge, Andrews et al (16) and Andrew & Sitterson (17) presented a detailed report, the conclusion of which was almost the same as that of Bond et al.

Case studies of medical irradiations

Nickson reported five cases of whole-body medical irradiations of 270–600 mGy and concluded that the lymphocytes showed the only uniform response of any of the blood elements that were studied in this group.

In every instance but one (270 mGy), there was a drop in the number of the lymphocytes in the peripheral blood during the first four days [(18) p335].

The subjects who were exposed to 600 mGy showed a 69.2–27.8% drop in lymphocytes count and a 22–6-point decrease in the proportion of lymphocytes in all white blood cells [(18) table 2.1–2.5].

Animal studies

Regarding rats, Suter indicates “the lymphocytes are extremely sensitive to radiation, and unquestionable falls are seen with as little as 25 r (250 mGy) when counts are taken at 24 hours after radiation” (19).

Specifically, Suter reported, “the lymphocyte values remain extremely low and counts taken 25 days after radiation still show less than normal values in groups exposed to 50 r (500 mGy) or greater”. Approximately 30% lymphocyte depletion was observed after irradiation with 250 mGy, but the lymphocyte count recovered to the normal level in about one week.

On the other hand, immediately after 500 mGy irradiation, an approximately 60% drop in lymphocyte count was observed, and it took nearly one month to return to the normal level [(19) figure 10, p3].

Furthermore, Suter found no difference in the sensitivity of blood testing between species such as rats, monkeys, and dogs [(19) figure 3, p1].

Setting of emergency dose criteria

The literature review revealed that the experimental studies regarding the deterioration of human hematopoietic function due to acute exposure to doses <1 Sv are only supported by the data from limited cases of accidents and nuclear bomb tests or the cases of medical exposure. Most of these reports were published in the 1940s and 1950s. Regarding human data, no apparent decrease in the number of lymphocytes can be recognized with an exposure dose of approximately 250 mGy (12, 20). On the other hand, with an exposure dose of approximately 600 mGy or higher, some reports demonstrate a substantial decrease in the number of

lymphocytes (18) or a smaller reduction (12, 20). Some of the experimental data obtained using rats demonstrate an approximately 30% decrease in the number of lymphocytes immediately after irradiation with 250 mGy and a nearly 60% decrease shortly after irradiation with 500 mGy (19).

According to the above literature, the Expert Meeting recognized that the threshold value for causing a significant decrease in the number of lymphocytes is between approximately 250 mGy and 500–600 mGy. However, because few data are available on exposure between these values, it is hard to define the definite value of the threshold.

Taking all these considerations into account, the Expert Meeting concluded that it was conservative yet appropriate to have adopted 250 mSv as the emergency dose criterion of effective dose, which certainly falls below the threshold value from the standpoint of ensuring prevention of immune function depression due to a decrease in the number of lymphocytes (5). The decision considered that there are some other factors that could increase the risk of infection such as the fact that many workers may have to stay in a small space for an extended period with insufficient shower facilities and inadequate food supplies (3). Furthermore, the Expert Meeting recommended that at this point, it is hard to foresee tasks that will necessitate exposure to >250 mSv in a nuclear emergency. Tokyo Electric Company could have managed the emergency response under the limits of 250 mSv even in the core meltdown of multiple reactor units but for several internal-exposure cases caused by inappropriate respiratory protection (3).

Furthermore, the Expert Meeting recommended that the existing equivalent dose limits for emergency situations for the lens of the eye (300 mSv) and the skin (1 Sv) should remain unchanged. The equivalent dose of the lens of eye and the skin is unlikely to exceed the limit if the effective dose is controlled by the dose limit of 250 mSv and workers wear appropriate protective equipment, such as full face masks to protect the lens of the eye, and HAZMAT (hazardous materials) liquid-proof coveralls and long protective boots to protect the skin (5).

Framework of application of emergency dose limits

Based on the recommendation of the Expert Meeting report, the MHLW amended the ordinance and prescribed the dose control during emergency situations, as follows (21): (i) The Minister of the MHLW, at his/her own discretion, can designate the exceptional emergency dose limit within the range not >250 mSv when he/she considers that it is difficult to comply with the dose limit of 100 mSv for proper implementation of emergency

work; (ii) The Minister shall immediately define 250 mSv as the exceptional emergency dose limit when a nuclear emergency, such as a situation of loss of coolant of a nuclear reactor or site blackout, or an accident that is highly likely to lead to such emergency, should occur; (iii) The Minister shall abolish the exceptional emergency dose limit as early as possible by taking into consideration the situation of the accident; (iv) Nuclear operators shall provide sufficient training to assigned emergency workers to make sure the workers understand the health risk of radiation exposure (22) and they shall make every effort to minimize the radiation exposure.

As the limits are designated by the notice of the Minister of the MHLW, members in the Radiation Council worried that setting exceptional emergency dose limits may be delayed by a failure of timely publication of the Minister's notice. For optimization of the limits, however, the MHLW needs a meticulous alteration of the limits, such as phased reduction of the limits or limitation of workers applied. Such alterations will be done by amendment of the notice. To avoid disrupting the immediate response in an emergency situation, the MHLW made a prescription that "the Minister shall immediately designate the exceptional emergency dose limit as 250 mSv." (21) A legal act on the designation of the limits shall be enacted immediately and the notice shall apply retroactively to the date of the event.

Furthermore, some members of the Radiation Council urged the MHLW to treat emergency dose criteria as "reference levels" rather than "dose limits". ICRP recommended that emergency dose criteria be reference levels [(11) p31]. Some opinions stated in the public comments argued the same thing (10). However, the survey in NEA/OECD countries revealed that there is a clear division between four countries (Australia, France, UK, and the USA) that employ reference levels and three countries (Canada, Korea, and Russia) that use dose limits (9) (table 1).

The Radiation Council stated its concern that if the government established an emergency dose standard as a dose limit, nuclear operators may control the emergency dose at a value lower than the limit because they fear that they will be punished for violating dose limits. As a response, the MHLW clarified that the law should not be enforced in such a way that the Ministry will automatically punish the operators without sufficiently taking into consideration the circumstances because the Occupational Safety and Health Act is a law for protecting workers, not for punishing operators.

Limiting dose limits to emergency workers and providing adequate training

The meeting recommended that the application of such emergency dose limits should be limited to the workers who have sufficient knowledge and skills for preventing the development of catastrophic conditions, and they should receive special training accordingly. Taking into consideration that the normal dose limit for five years is 100 mSv, setting emergency dose limits >100 mSv needs specific justification. Based on the IAEA guidance documents, the meeting determined that “actions to prevent the development of catastrophic conditions” are those that most justify raising the dose limits to >100 mSv.

In the Labour Policy Council, a representative of trade unions expressed concern about the assignment of emergency workers. Most of the preassigned and pre-trained workers are assumed to be employees of nuclear operators. However, in case of an accident, untrained contracted workers may be additionally assigned to emergency work gradually due to a shortage of pre-assigned workers.

In response, the MHLW requested that nuclear operators assign an adequate number of emergency workers in accordance with necessary tasks in emergency operations (23). There should be a clear division of roles between emergency workers, who are subjected to emergency dose limits, and ordinary radiation workers, who are subjected to normal limits. The emergency workers should concentrate their operations on preventing catastrophic conditions, which need advanced knowledge and expertise. The ordinary radiation workers should cover other technical work, such as operation of construction vehicles for cleaning up contaminated debris. Nuclear operators can reduce the radiation exposure of each ordinary worker by rotating workers as much as possible.

Furthermore, the representative of the Federation of Trade Unions of Nuclear Workers demanded the operators obtain explicit consent when assigning workers to emergency work. He argued, “We cannot tolerate that unassigned and untrained workers engage in emergency work.” Furthermore, he argued, “Any adverse change in working conditions is unacceptable if workers refuse to engage in emergency operations due to their health risk.”

The MHLW requested nuclear operators make a proper labor agreement with each emergency worker on an equal footing between employers and workers in the signing and modifying of labor contracts. (24) The MHLW requested the operators propose a labor contract to worker with a clear explanation of tasks of emergency operations and that both parties sign or confirm the deal on equal footing (23). MHLW also asked operators to consider workers’ wishes about being dispatched to emergency operations. In addition, the Nuclear Reactor

Regulation Law obligates the operators to collect written consent from all workers before assigning them to emergency work (25).

Mid- to long-term dose control

ICRP recommendations rarely cover the issues of lifetime dose control of emergency workers exposed beyond normal dose limits (11) (8). ICRP Publication 75 only describes the response to severe accidents with high-dose exposure in a short time, such as the critical accident in the Y-12 plant in Oak Ridge (26). In public comments, some people stated strong opposition to accepting a lifetime exposure of 1 Sv for former emergency workers undertaking normal radiation work.

After thorough deliberation, the Expert Meeting recommended not to exceed 1 Sv in a lifetime, and that operators set a dose limit individually in proportion to the remaining work period of each worker. The ICRP 1990 Recommendation stated that a radiation protection system should be established to control the accumulated effective dose/person during the period of his/her employment under approximately 1 Sv (27). Furthermore, the ICRP Publication 75 states that “implementing a temporary dose restriction-based pro-rata on the remaining period to which the dose limit relates might be appropriate” [(26) paragraph 61].

Based on the recommendation, the Minister’s guidelines have prescribed mid- to long-term dose control for workers who are exposed beyond the normal dose limits (28). The guidelines require nuclear operators to set a specific dose limit per 5-year period individually for each ex-emergency worker. The 5-year dose limit is obtained by calculations as follows:

$$SDL^* = (RD / RW) \times 5$$

$$RD = 1000 - (ED + ND)$$

$$RW = FA - WA$$

$$\text{If } SDL > 100, \text{ then } SDL = 100$$

*SDL shall be recorded in increments of 5 mSv (rounded down to the nearest 5).

where *SDL* (mSv/5 years): specific dose limit per five years

RD (mSv): remaining dose

RW (year): remaining working period

WA (year): worker’s age

ED (mSv): accumulated emergency dose

ND (mSv): accumulated normal dose

FA (year): final age of the working period: 68 (assumed 50-year working period starting from 18 years old).

Furthermore, the meeting deliberated whether the former emergency workers exposed >100 mSv/5 years

should be allowed to engage in normal radiation work. The nuclear operators insisted that the safety of other nuclear power plants may not be maintained due to a shortage of workers if many trained and experienced nuclear workers are exposed beyond the dose limits and become unable to engage in the operation of nuclear power plants.

The Expert Meeting recommended a minimum margin not exceeding 5 mSv/year be adopted for workers who are exposed >100 mSv/5 years only where it is necessary to do so to guarantee the safe operation of the nuclear facility. ICRP Publication 75 recommended that the external dose should be necessarily monitored when the annual effective dose exceeds 5–10 mSv [(26) paragraph 209].

Discussion

For deliberation on emergency dose criteria, harmonization with ICRP recommendations and IAEA guidance documents became an issue to be resolved (8, 11, 26, 27). Additionally, the new criteria should not be much different from the criteria employed in NEA/OECD countries (9).

The ICRP 1990 Recommendation sets out a normal dose limit of 20 mSv/year averaged over five years (100 mSv/5 years). The recommendation states that a radiation protection system should be established to keep the lifetime effective dose no more than approximately 1 Sv, assuming the worker is exposed to radiation almost uniformly every year. On the other hand, ICRP 1990 states that, in case of a severe accident, the dose control for emergency workers could to some degree be mitigated without lowering the long-term protection. However, such mitigated dose limits should not exceed about 0.5 Sv (27). Also, ICRP 2007 recommended that special attention should be paid to prevent serious deterministic effect in an emergency (11).

Based on the ICRP recommendations, as a long-term dose-control method for stochastic health effects, the Ministerial guidelines required that employers should set an individual 5-year dose limit for a worker who exceeded normal dose limits to prevent his/her accumulated dose from exceeding the lifetime dose (1 Sv).

As for preventing serious deterministic effects, the amended ordinance adopted 250 mSv as the emergency dose limit because the expert meeting judged that it was conservative yet appropriate to have adopted 250 mSv, which certainly falls below the threshold value for preventing immune function deterioration by a significant decrease in the number of lymphocytes.

Furthermore, the Expert Meeting recommended that deliberation of a crisis management plan should take

into consideration the lessons learned from the Fukushima accident (3, 4). The government and Tokyo Electric Company were forced into a stopgap measure after the accident because they were insufficiently prepared for the emergency response. The greatest lesson in the internal controversy on emergency radiation protection was how to find a way to keep a balance between the protection of the emergency workers and the prompt implementation of a crisis management plan to prevent the nuclear incident from spiraling out of control (1).

Concluding remarks

The fact that NEA/OECD countries have a wide range of emergency dose criteria means that any effort to establish emergency dose limits requires not just a scientific basis but also social consensus-building. The Japanese case can provide useful guidance for the setting and application of emergency dose control in other countries. Nevertheless, further case studies in other countries are warranted.

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