

## **Appendix**

This file is a summary version of the Radiation Risk and Protection Research Platform Preparatory Committee's report (Japanese, 2016)

### **A plan of new network for low dose radiation research in Japan: PLANE**

#### **Abstract**

In Japan, researchers, academic societies, the former Nuclear Safety Commission and others engaging in research on radiation effects and protection have considered constructing a research platform that would autonomously provide the capacity to compile and assess information pertaining to radiation effects and protection, deduce issues to be addressed and then work out solutions. Regulatory policies on radiation protection need to be implemented rationally based upon accurate information. There is also a renewed awareness of the importance that such a research platform has for sufficient and effective risk communication with the public about the health effects of low-dose and low-dose rate radiation, and the need for such platform is expected to further increase in the future.

With the aim of constructing such research platform, National Institute of Radiological Sciences, National Institutes for Quantum and Radiological Sciences and Technology (NIRS-QST) set up the Radiation Risk and Protection Research Platform Preparatory Committee in 2016, and the committee summarized that results on the report about the network; tentative name is Planning and Acting Network for Low Dose Radiation Research (PLANET). The Preparatory Committee took into consideration previous conceptions of research platforms in discussing such matters, specifically, reviewed a) research issues to be resolved and examples of roadmaps for their resolution, b) functions required of a research platform including considering research strategies and the prioritization of key topics, and c) the framework necessary for construction of a research platform.

Keywords: low dose, low dose rate, radiation risk, research network

#### **1. Introduction**

National Institutes for Quantum and Radiological Science and Technology (QST) is a

new national corporation and mission of National Institute of Radiological Sciences (NIRS) includes medical application of radiation, radiation effects, radiation protection and radiation emergency medicine. There are important issues for radiation effects, especially decreasing uncertainty of risk estimation of low dose/low dose-rate radiation exposures. Desirable approach is to establish mechanistic and numerical model based on stem cell biology and radiation biology at high dose rate, and then to underpin the selection of appropriate risk model of chronic exposures.

In order to carry out these researches steadily and continuously, it is necessary to promote collaboration among stakeholders and establish all-Japan network among regulators, academia and research institutes. QST-NIRS set up the Radiation Risk and Protection Research Platform Preparatory Committee in 2016, and the committee summarized that results on the report about the network; tentative name is Planning and Acting Network for Low Dose Radiation Research (PLANET). The PLANET will identify priorities of research needs, and propose strategies to improve quantitative estimation of low dose/low dose-rate radiation risk. In addition, this network will propose support system for cooperation and collaboration researches among related researchers and institutes in Japan.

With a view toward establishing a platform of radiation risk and protection research (hereinafter collectively referred to as “research platform”), the preparatory committee deliberated the functions, framework and other elements comprising such a research platform as well as the research issues to be given priority within the research platform. A synopsis of these deliberations has been compiled and is presented here.

## **2. Necessity for a Research Platform**

Risk assessments, the current foundation for radiation protection, are based upon epidemiological investigations conducted of survivors of the Hiroshima and Nagasaki atomic bombings. With only epidemiological study results, it is difficult to quantitatively assess risks inherent at low-dose levels of 100mGy and below because of statistical limitations. Although substantial results have been obtained in basic research in the field of radiation biology to supplement epidemiological studies, these have not been sufficient enough to allow a direct link to be established with risk assessments based upon low-dose or low-dose rate radiation exposure to humans (exposures of approximately 100 mSv or less or 20 mSv/year or less). In our present age when low-dose or low-dose rate radiation

exposure has emerged as a real social issue since the accident at Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Station, there is an even greater need for risk assessments that will serve as the basis for how regulations governing low-dose and low-dose rate radiation exposure should be structured as well as the accompanying social consensus (Figure 1).

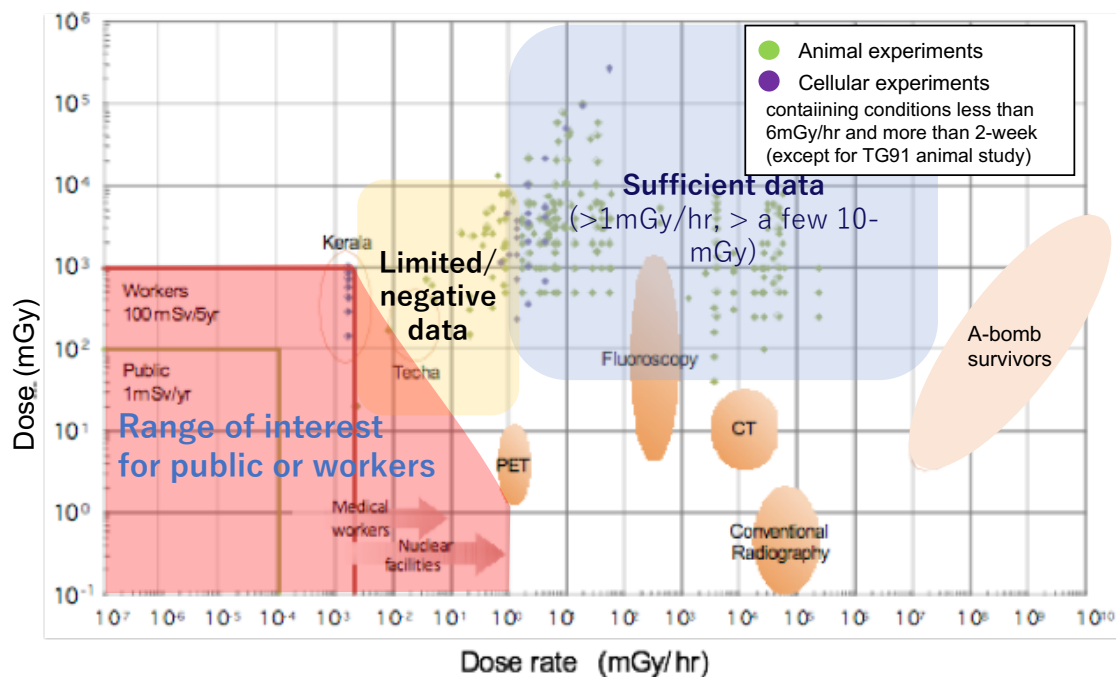


Figure 1. Current status of low dose/low dose-rate biological research

In Japan, researchers, academic societies, the former Nuclear Safety Commission and others engaging in research on radiation effects and protection have considered constructing a research platform that would autonomously provide the capacity to compile and assess information pertaining to radiation effects and protection, deduce issues to be addressed and then work out solutions. While that effort was underway, the accident occurred at Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Station. Anxiety over the lack of accurate information about the effect of low-dose and low-dose rate radiation on health as well as confusing risk communication turned into a social issue engulfing the general public. It is an important issue that a correct understanding be held of the risks posed by low-dose and low-dose rate radiation exposure, which the general public and radiation workers have a high likelihood of experiencing, and that this understanding be put to use in radiation protection regulations.

Therefore, it is essential that a (radiation risk and protection research platform) framework be constructed so that information pertaining to the risks posed by low-dose and low-dose rate radiation exposure may be collected, analyzed, and such research conducted to enhance scientific knowledge in a strategic manner to an extent greater than before, that this knowledge be reflected in Japan's regulations governing radiation protection, and that a social consensus be secured on how such regulations should be structured.

### **3. Research Platform Purposes**

The research platform will have the following two purposes.

- 1) To bring relevant domestic organizations, researchers, and experts together to collect and analyze information about radiation effects, risks, and protection, which will provide a basis for radiation regulations, to communicate these results broadly throughout Japan and the world, and to provide such information and assist the activities of the Nuclear Regulation Authority and other relevant entities.
- 2) To consolidate specific research issues to quantitatively assess low-dose and low-dose rate radiation risks, and to incorporate a top-down approach to clarifying the issues for achieving these purposes and proposing specific strategies.

### **4. Research Platform Functions**

The research platform will have the following three functions.

- 1) To consolidate information available in Japan and throughout the world about radiation risks, compile ideas about risks and protection, and publish reports to communicate these ideas.
- 2) Consider research issues and roadmaps to be pursued and update them.
- 3) Support joint research and assistance for utilization and training of human resources as a long-term approach.

### **5. Synopsis of Priority Research Issues for the Research Platform**

Below are five research issues to be given priority.

- 1) Epidemiological research on low-dose and low-dose rate radiation that is appropriately designed for risk assessment
- 2) Clarification of mechanisms for assessing risks posed by low-dose and low-dose rate

radiation

- 3) Intermediation with the purpose that data from animal experiments be used in interpretation in epidemiological research
- 4) Relationship between radiation and the factors of age, sex, genetic factors and lifestyle
- 5) Collection of data, including negative data, and database creation (archiving)

An ICRP Task Group (TG) studied key dose and dose rate effective factors (DDREF) in assessments of risks associated with low-dose and low-dose rate radiation and produced a report recommending a DDREF value of 2 rather than 1, which was based on research results from epidemiological and animal experiments. However, experts on living organisms believe that a DDREF of 2 is small and have pointed out the need for more careful analysis as there are possible effects resulting from the validity of meta-analysis, differences in photon energy as well as dose rate effect, age effect, and other variables.

In addition, although the problem remains of how to marshal the results of animal experiments for humans in a convincing manner, animal experiments have merit because the modifying effects on radiation impact, in other words radiation quality, dose rate and epigenetic items, may be controlled. If there are similarities in terms of organs and diseases, these may also be correlated in the animal model and human being model. The utility of applying the animal model to the human being model has been debated.

Based on the above, the Committee's conclusion was to set as research issues the questions of how to link animal experiments to risk estimation and incorporate such methodology, of which one research challenge is to use DDREF as the subject matter and present a new method that analyzes these from a biological perspective.

## **6. Consideration of Pressing Research Issues for the Research Platform**

Comments were made about the usefulness of knowledge regarding living organisms when forming epidemiological hypotheses, knowledge relating to dose rate affects attributable to stem cells and commonalities in carcinogenesis in humans and mice supporting the formation of such hypotheses, and finding methodologies, rather than extrapolations, for establishing consistency with epidemiology. The importance of making use of knowledge about living organisms in the formation of epidemiological hypotheses was confirmed.

There are close similarities between human beings and animals embryologically, and even

more similarities have been further found at the tissue level than the individual level. In addition, it is known that there are times corresponding to periods of development in mice and human beings that are dependent upon organs and tissue. In addition, certain cancers in human beings have a similar type also in mice, and experiments have already begun that are looking at age dependence and carcinogenesis as well as the chronological process leading up to carcinogenesis. Risks may correspond to such embryological mechanisms, and there have been proposals suggesting schemes for applying the results of animal analyses to human beings.

Based on the aforementioned, a decision was made to select issues for the purpose of rationally and coherently interpreting the results of animal experiment data analyses and the results of epidemiological studies with respect to points about which there is high regulatory interest and insufficient epidemiological knowledge, including biological effects in low-dose areas, age dependency, and dose rate affects about which there is significant epidemiological uncertainty. In other words, from the perspective of “how to link animal experiments to risk estimation and incorporate such methodology, of which one research challenge would be to use DDREF as the case studies analyzed from a biological perspective to present a new method,” it was decided that top priority issue would be placed on making use of knowledge gained from animal models relating to age dependency, dose rate affects and other variables in regulations, and taking into account the most recent developments in biology and to discuss, through deliberations among different fields, the practical application (validation) of animal experiment data in order to and to synthesize such knowledge with epidemiology.

## **7. Research Platform Framework**

The framework for the research structure will be as described below.

- 1) A steering committee will be established, and an open and all-Japan framework constructed that allows research institutions, universities, scholarly associations, government and regulatory institutions, general public, and a variety of stakeholders concerned with radiation effects, risks, epidemiology and protection to participate. This framework will include not only experts in fields related to radiation but also other fields and make it possible for interdisciplinary and multi-faceted issues to be considered.
- 2) Working groups will be established under the auspices of the steering committee to consider specific issues.

3) The National Institutes for Quantum and Radiological Science and Technology's National Institute of Radiological Sciences will serve as the secretariat, which will be the point of contact for business activities relating to the research platform.

4) This cross-sectoral network should also aim to work together with international organizations and cooperation both in Japan and abroad will be promoted. We are committed to promote research on low-dose radiation and deepen collaboration with MELODI.

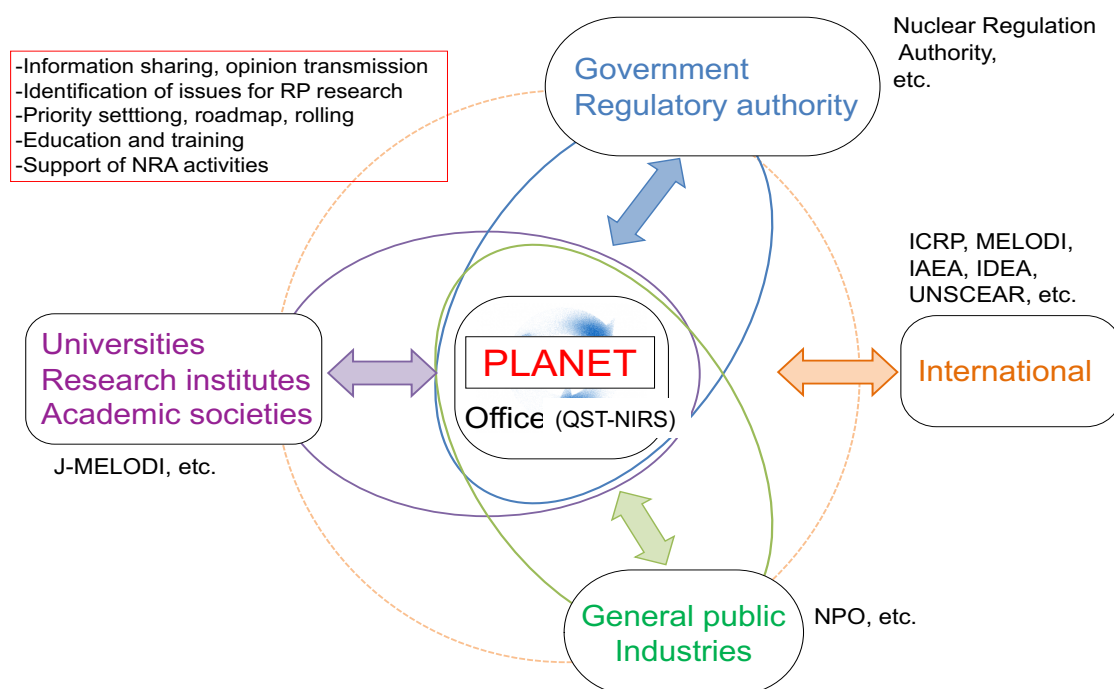


Figure 2. Framework of PLANET

## 8. Effects of Research Platform Activities

1) Implementation of radiation regulations and policies as well as administrative policies by regulatory and other organizations that are more rational and scientific.

2) Efficient progress in research and the creation of new knowledge about health effects of low-dose and low-dose rate radiation.

3) Enhancing the general public's understanding of radiation and contributing to risk communication that is free of misunderstandings, biases, and confusion.

4) Strengthening cooperation among regulatory organizations, research institutions and the general public in Japan, and the improvement of cooperation with regulatory agencies and research institutions outside of Japan to facilitate efforts to address issues that are

unable to be solved only by Japan.

5) Facilitation of the development of human resources in the field of radiation risk and protection through joint research and research collaboration.

## **9. Conclusion**

It is expected that the results gained from administration of this sort of research platform will enable regulatory institutions and other organizations to implement regulatory policies and administrative policies that are more rational and scientific as they will be based upon accurate information about radiation effects and risks and the analysis of such data. In addition, consolidating research challenges that need to be resolved and presenting policies for solving these issues will aid in effectively advancing research related to health effects posed by low-dose and low-dose rate radiation as well as the creation of new knowledge. Furthermore, the presentation and dissemination to the general public of accurate and current information about radiation risks as well as decision-making criteria will contribute to enhancing the understanding of radiation and foster risk communication that is free of misunderstandings, biases and confusion. The strengthening of liaisons among domestic regulatory agencies, research institutions and the general public through the research platform activities as well as the enhancement of liaisons with regulatory agencies and research institutions around the world will also promote efforts to address issues that Japan alone is unable to resolve. In a long-term, assistance provided through the research platform will develop joint research and research cooperation as well as facilitate the development of human resources specializing in the fields of radiation risks and radiation protection. The results produced through the research platform activities will ultimately be utilized for promoting the welfare, safety, and health of the Japanese people.



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