Report of the Expert Meeting on Epidemiological Studies Targeting Emergency Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant

4 June 2014

Contents

I. Overview of the Meeting and Members

1. Purpose

At the TEPCO Fukushima Daiichi NPP, the emergency exposure limit was raised from 100 mSv to 250 mSv during the period from March 14 to 16 December in 2011. During this period, approximately 20,000 workers engaged in emergency work, out of which 174 workers were exposed to radiation exceeding 100 mSv, which is the upper limit for five years for workers engaging in work under normal conditions.

As there is a concern that these emergency workers may suffer health problems due to radiation in the future, the Ministry of Health, Labour and Welfare (MHLW) has built a database for long-term health care, which accumulates exposure doses and other data, and has been managing such workers' health on a long-term basis, including after their retirement, based on the MHLW Ministerial guidelines.(Note 1)

The report of the Expert Meeting on the Long-term Health Care of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant(Note 2) suggests that the utilization of the information in the database for epidemiological studies should be supposed under certain conditions and any such information should be utilized based on a proper study plan.

Therefore, the Director of Occupational Safety and Health Department, Labour Standards Bureau, MHLW, invited experts to hold a meeting to discuss how to make plans for epidemiological studies targeting emergency workers, including means to utilize the information in the database.

(Note 1) Guidelines on Maintaining and Improving the Health of Emergency Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Guidelines Public Notice No. 5, dated 16 October 2011)

(Note 2) Report of the Expert Meeting on the Long-term Health Care of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (September 2011)

2. Agenda

(1) Selection of the study population and examination methods
(2) Items required to be checked in medical tests and biological inspections, etc. and frequencies of the tests and inspections
(3) Examination methods for cumulative doses, etc.
(4) Confounding factors and other items and examination methods
(5) System for the studies and medium to long-term schedules
(6) Others

3. Composition

(1) This Meeting is to be held with the members shown in the attachment who were invited by the Director of the Occupational Safety and Health Department, Labour Standards Bureau, MHLW.

(2) This Meeting has a chairperson, who organizes the business of the Meeting.
(3) New members may be added to this Meeting as necessary.
(4) This Meeting may request persons other than its members to attend the meeting.

4. Others

(1) This Meeting is open to the public, in principle. However, when any personal information or business proprietary information is handled, the Meeting may be not open to the public.
(2) Affairs of this Meeting shall be administered by the Industrial Health Division, Occupational Safety and Health Department, Labour Standards Bureau, MHLW.

Members (Family name order)

Makoto Akashi	Executive Director, National Institute of Radiological Sciences
○Toshiteru Okubo	Chairman, Radiation Effects Research Foundation
Fumiyoshi Kasagi	Director, Radiation Epidemiologic Study Center, Radiation Effects Association
Kazunori Kodama	Chief Scientist, Radiation Effects Research Foundation
Yumiko Suto	Team leader, Biological Dosimetry Research Team, Research Center for Radiation Emergency Medicine, National Institute of Radiological Sciences
Tomotaka Sobue	Professor, Environmental Medicine and Population Sciences, Graduate School of Medicine, Osaka University
Noboru Takamura	Professor, Atomic Bomb Disease Institute, Nagasaki University

○ Chairperson

II. Development of the Meetings

- First Meeting: Friday, 14 February 2014
  - Ascertaining the current state and presentation of issues
  - Free discussion on how to proceed with epidemiological studies

- Second Meeting: Thursday, 27 February 2014
  - Answers to questions raised at the first meeting
  - Discussion on each issue

- Third Meeting: Wednesday, 26 March 2014
  - Presentation of a draft outline of the meeting report
  - Discussion on the draft outline

- Fourth Meeting: Monday, 21 April 2014
  - Presentation of a draft report based on discussions on the draft outline
  - Discussion on the draft report

- Fifth Meeting: Friday, 16 May 2014
  - Final coordination of the draft report

III. Basic Concept for Conducting Epidemiological Studies

Section 1. Purpose

At the TEPCO Fukushima Daiichi NPP, the emergency exposure limit was raised from 100 mSv to 250 mSv during the period from March 14 to 16 December in 2011. During this period, approximately 20,000 workers engaged in emergency work, out of which 174 workers were exposed to radiation exceeding 100 mSv, which is the upper limit for five years for workers engaging in normal work.

As there is a concern that these emergency workers may suffer health problems due to radiation in the future, the Ministry of Health, Labour and Welfare (MHLW) has built a database for long-term health care, which records and preserves exposure doses and other data, and has been managing such workers' health on a long-term basis, including after their retirement, based on the MHLW Ministerial guidelines.(Note 1)

The report of the Expert Meeting on the Long-term Health Care of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant(Note 2) suggests that the utilization of the information in the database for epidemiological studies should be supposed under certain conditions and any such information should be utilized based on a proper study plan.

This Meeting compiled the basic ideas, as shown in Section 2 to Section 8 below, to be noted in making plans for epidemiological studies, which are to be conducted for the purpose of examining health effects of radiation exposure of emergency workers.

(Note 1) Guidelines on Maintaining and Improving the Health of Emergency Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Guidelines Public Notice No. 5, dated 11 October 2011)

(Note 2) Report of the Expert Meeting on the Long-term Health Care of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (September 2011)

Section 2. Study Population and Methods, etc.

1. Study population and period

(1) Emergency workers comprise a special group exposed to radiation under circumstances where the emergency exposure limit was raised temporarily, with some having received effective doses as high as around 680 mSv. They are covered as subjects for long-term health care in the database managed by the MHLW for long-term health care of emergency workers. Therefore, epidemiological studies should cover all of these emergency workers (approx. 20,000) as study subjects.

(2) The study period should last throughout the respective workers' lifetimes, in principle.

2. Survey of the current state, etc. for following up on and maintaining the study population

(1) Exposure doses and other information on emergency workers, which are submitted under laws and regulations, are registered in the database managed by the MHLW for long-term health care of emergency workers. Additionally, the MHLW conducts the survey of the current state(Note 1) regularly (once a year in principle).

(2) Entities conducting studies shall obtain updated information on addresses, etc. from the aforementioned MHLW's database,(Note 2) follow up on and maintain the study population by using such information, and conduct epidemiological studies.

(Note 1) The survey covers such items as each worker's address, telephone number, and employer, as well as whether the individual engages in radiation work. For targeted workers who do not respond to this survey, their information shall be obtained by requesting their residence certificate as necessary.

(Note 2) At the request of R&D-oriented incorporated administrative agencies or MHLW-funded entities, the MHLW provides them with information on study subjects' addresses, etc. after checking whether they will take sufficient measures for protecting personal information.

3. Health effects and radiation exposure factors to be examined

(1) Health effects to be examined (endpoints) should cover solid cancers, leukemia and non-cancerous diseases, for which effects of radiation have been suspected in previous studies, as broadly as possible, and psychological effects should also be examined.

(2) The cumulative dose(Note 1)(Note 2) should be set as an exposure factor. Basically, dose-response relationships with various health effects (endpoints) are to be examined, and classification by exposure conditions(Note 3)(Note 4) should be made

possible as well.

(3) When targeted exposure factors are classified into multiple categories, multiple small groups (sub-cohorts) may be set up(Note 5) among the entirety of the study subjects.

(4) As exposure factors for psychological effects, it is also necessary to examine the details of the work that relevant workers engaged in, the time when they engaged in said work, and what damage due to the accident they have personally sustained, etc.(Note 6)

(Note 1) The cumulative dose shall be the total sum of (i) normal exposure dose before the emergency exposure limit was applied; (ii) exposure dose during the period when the emergency exposure limit was applied; and (iii) normal exposure dose after the emergency exposure limit ceased to be applied up to the time of the examination of the endpoints.

(Note 2) Ingestion dates necessary for evaluating doses of internal exposure are not always clear, and amounts of radioactive iodine, which had been undetected due to the delay in measurement, were estimated by using certain methods. Therefore, when such data are used as the cumulative dose, the reliability of the measurement results needs to be assessed.

(Note 3) When evaluating the effects of "having been exposed to high doses in a short term", instead of the effects of cumulative doses, one option is to first check data depending on cumulative doses and then classify emergency workers into a "group having been exposed to high doses during the emergency" and a "group not having been exposed to high doses during the emergency" to make comparisons.

(Note 4) When adopting the "internal exposure dose by organ" as an exposure factor, grouping based on internal exposure by organ (such as the thyroid gland in particular) may be possible.

(Note 5) In order to examine psychological effects due to emergency work as an exposure factor, an exposed group and a comparative group may be set depending on when they engaged in emergency work (e.g., workers engaged in work in March and April 2011 and others)

(Note 6) With regard to exposure factors relating to psychological effects, exploratory factor analysis needs to be made for the effects of other various factors, while taking into account those of radiation exposure.

4. Study methods

(1) The prospective cohort study method should be employed in principle, but nested case-control study should also be considered.

(2) Information on study results should be provided to each study subject (target)to the extent possible.(Note 1) Distribution of newsletters, etc. would contribute to improving and maintaining their participation rate.

(3) When compiling study results, both the analysis results with statistically significant differences and the analysis results that show no significant difference as a result of a sufficiently capable statistical test should be clearly indicated.(Note 2)

(4) Based on the government's ethical guidelines, etc.(Note 3) studies should be commenced after consulting with the ethics committee of the respective entities, obtaining consent from study subjects, and properly ensuring the protection of

personal information.

(Note 1) Information provision may include the introduction of medical institutions for detailed examination and the provision of health guidance and health consultations.

(Note 2) Research hypotheses, exposure factors and statistical tools, etc. need to be considered and determined in an exploratory manner, while conducting studies. However, in order to ensure objectivity, it should be noted researchers should not publicize only analysis results with statistically significant differences or vice versa arbitrarily.

(Note 3) Ethical Guidelines for Clinical Studies, Ethical Guidelines for Epidemiological Studies, etc.

Section 3. Health Effects to be Examined and Points to be Noted in Ascertaining Them

1. Basic ideas concerning health effects to be examined (endpoints)

(1) Solid cancers, leukemia and non-cancerous diseases listed in Table 1, for which effects of radiation have been suspected in previous studies, should be covered as broadly as possible as health effects to be examined.

(2) As it is difficult to ascertain the occurrence of all of these diseases only through health checkups, the cancer registry system, vital statistics and other data should also be referred to.

2. Items requiring examination

(1) Items to be examined should be determined based on those for legal health checkups or as provided for in the MHLW Ministerial guidelines (Table 2), while referring to those actually adopted for examinations targeting atomic bomb survivors in Hiroshima and Nagasaki.

(2) Items listed in Table 3 should also be examined for the time being. However, as test methods and analysis methods advance quickly, due consideration is required for long-term studies like these epidemiological studies so that items may be changed or new items may be added, while paying attention to ensuring the ongoing utilization of accumulated data.

3. Frequencies of examinations

(1) Items to be examined in legal health checkups are required to be examined once a year under laws and regulations. Therefore, these items should be examined every year also in the epidemiological studies.

(2) Out of the items defined by the MHLW Ministerial guidelines, the items annually examined in cancer screening for the general population(Note 1) should be examined every year also in the epidemiological studies. Examinations of other items should be considered to be conducted around once every three to five years.(Note 2)

(3) Based on study results concerning survivors of the atomic bombings, it would be appropriate to conduct kidney function tests and inflammation-related tests around once every three to five years.(Note 3)

(4) It would also be appropriate to conduct infectious disease tests around once every three to five years.(Note 4)

(5) Biological samples (blood) collected at the time of the initial examination should be divided into those to be examined immediately and those to be stored for a long period. Those to be stored for a long period should be refrigerated. From

the second examination onward, part of the biological samples (blood) should be refrigerated basically once every five years.[Note 5]

(Note 1) Cancer screening conducted by municipalities based on Article 19-2 of the Health Promotion Act

(Note 2) In the case of indolent cancer, the discovery rate is high at the time of the initial examination. There is no advantage in repeating examinations, or, rather, false positive results may increase. Therefore, examinations should be conducted at proper frequencies.

(Note 3) The results of studies on survivors of atomic bombing show correlations between exposure doses and decline in kidney functions, increase in inflammatory reaction (CRP), and increase in rheumatoid factor.

(Note 4) Infectious disease tests need to be conducted at certain intervals as vaccination may be carried out for helicobacter pylori and hepatitis or other infectious diseases may be cured through interferon administration.

(Note 5) Specific frequencies for refrigerating biological samples are to be determined by the respective entities based on their available systems, etc.

4. Utilization of the cancer registry system and vital statistics

(1) Cancer registry system

a. A cancer registry will be mandated by law from 2016 onward and a nationwide database on cancer patients[Note 1] is expected to be developed.

b. As patients' consent is necessary for utilizing this database in epidemiological studies, a consent document for epidemiological studies needs to include wording concerning consent to the use of the cancer registry system (including existing local cancer registry systems) in the studies.

(2) Vital statistics

a. The death form data of the vital statistics may be utilized to ascertain the cause of death.[Note 2] This fact also needs to be included in a consent document for epidemiological studies.

b. As the date of death, registered address and other information need to be ascertained for utilizing the death form data, it is necessary to receive the provision of such information obtained through the survey of the current state included in the MHLW's database.

(Note 1) Data are matched based on the name, gender and date of birth.

(Note 2) Data are matched based on the registered address (competent local health center), date of death, gender and date of birth.

5. Examination on psychological effects

(1) Questionnaires by which endpoints of psychological effects can be properly ascertained[Note] should be prepared and used.

(2) Depending on examination results, mental health care institutions may be introduced to the study subjects as necessary.

(Note) As exploratory analysis is required for exposure factors of psychological effects, it is necessary to prepare and use questionnaires by which wide-ranging factors, including those other than exposure doses, may be examined.

Section 4. Points to be Noted in Ascertaining Cumulative Doses

1. Points to be noted in ascertaining emergency exposure doses

(1) With regard to both the external exposure and the internal exposure, such data as types of measuring instruments, measurement conditions and measurement results,[(Note 1)] should be preserved in the form of the original document to the extent possible so that these data may be verified in the future. These primary source materials should be preserved by TEPCO and primary contractors, but entities conducting studies should also preserve copies thereof after obtaining consent from the study subjects.

(2) Internal exposure doses (committed doses) have been evaluated on the safer side (meaning to adopt higher doses in estimations) to the extent possible from the perspective of long-term health care, and these figures are appropriate as indicators for health care. However, from the viewpoint of epidemiological studies, such an approach may reduce the credibility of dose-response relationships. Therefore, it is preferable to evaluate exposure doses, adopted from the perspective of epidemiological studies,[(Note 2)] including external exposure doses, from different aspects. It is also effective to evaluate the credibility of the measurement results of internal exposure and classify them by estimation method.

(3) Exposure doses (equivalent doses) by organ[(Note 3)] should also be evaluated.

(Note 1) For the measurement of internal exposure, primary records, such as copies of a WBC test sheet containing the details of the work done by the relevant worker that prove the ingestion date (date on which he/she started to engage in said work), results of a behavioral survey (including the administration of stable iodine tablets), shift rosters, attendance records and a radiation passbook, need to be preserved, in addition to detailed measurements including detection limits. Additionally, the calculation process of internal exposure doses (committed doses) also needs to be recorded.

(Note 2) For example, when estimating undetected radioactive iodine, not the largest estimated value but the median value with the highest probability may be adopted.

(Note 3) For example, the equivalent dose in bone marrow may be used in an examination concerning leukemia.

2. Points to be noted in ascertaining normal exposure doses and medical exposure doses

(1) In order to ascertain normal exposure doses prior to the accident and exposure doses in the case where workers engage in radiation work under normal conditions at other nuclear power plants in the future, it is indispensable to secure cooperation in the provision of data preserved by the Radiation Dose Registration Center for Workers that the Radiation Effects Association manages.[(Note 1)]

(2) It is important to ascertain high-dose medical exposure[(Note 2)] upon conducting

epidemiological studies. Utilization of a health calendar(Note 3) or other measures is required for ascertaining histories of medical exposure because merely counting on individuals' memory would cause bias depending on their health consciousness.

(Note 1) Before commencing studies, the respective entities need to consult with the Radiation Effects Association and obtain consent from the study subjects also with regard to the utilization of the data preserved by said Center, and then take such measures as concluding an agreement or agreements with the Radiation Effects Association.

(Note 2) As a thoraco-abdominal CT scan causes high-dose exposure, in particular, the credibility of cumulative doses becomes doubtful without ascertaining this.

(Note 3) Records of CT scans, etc. may be ascertained objectively through medical receipts. Entities conducting studies should consult with the respective health insurance societies of TEPCO and other companies and should endeavor to utilize data contained in medical receipts after obtaining consent from study subjects.

3. Chromosome assays

(1) Chromosome assays enable biological measurement of exposure doses (effective doses). Refrigeration of biological samples would make it possible, when any health effects emerge in the future, to retrospectively check the effects on chromosomes exerted by the radiation at the time of collecting said biological samples. Such an approach is expected to bring about useful information for identifying biological effects by radiation exposure.

(2) A chromosome assay should be conducted with regard to workers whose effective doses exceed 100 mSv,(Note 1) in principle.

(3) In principle, the fluorescence in situ hybridization (FISH) method(Note 2) targeting specific chromosomes should be adopted to detect stable-type chromosome aberrations.

(4) Biological samples (blood) should be collected at the time of the initial examination. Collected samples should be cultured and refrigerated in the state of a fixative solution and with the use of slide cover glasses.(Note 3)

(Note 1) There is clearly an advantage to conduct a chromosome assay with regard to workers who were exposed to radiation exceeding 100 mSv, which is the upper limit for five years for workers engaging in normal work, to check their exposure doses (effective doses) and clarify the effects of radiation on living bodies.

(Note 2) The FISH method is also applicable at a stage long after the exposure. Chromosomes to be used for a test should be limited to the minimum necessary for identifying doses. However, the respective entities should decide the optimal method in accordance with the future advancement of technologies.

(Note 3) A chromosome assay should be conducted immediately after collecting a biological sample. However, the timing of subsequent tests should be determined by the respective entities, including the possibility that a test is required when a disease emerges several decades later. An efficient method of storage should also be determined by the respective entities in accordance with the future advancement of technologies.

Section 5. Points to be Noted in Ascertaining Confounding Factors

1. Basic ideas

(1) As the epidemiological studies will continue for a long time and cover cancers and other diseases caused by various factors, it is very important to properly ascertain confounding factors for analyzing the results of the studies.

2. Items of confounding factors

(1) Questionnaires used for large-scale cohort surveys in Japan are being standardized, while referring to confounding factors examined in epidemiological studies, etc. targeting survivors of atomic bombings (Table 4). Confounding factors(Note 1) for epidemiological studies need to be set based on such questionnaires.

(2) Workers' history of exposure to toxic substances needs to be examined characteristically according to their occupational field. It is also significant to examine their educational background, job title and assigned duties, which are closely related to their physical and mental burdens.

(3) When examining psychological effects, relevant psychological factors other than radiation exposure(Note 2) need to be examined separately.

(Note 1) Height, weight, past medical history (both that of the study subject and that of his/her family members), current diseases (including administration), past history, smoking habits, drinking habits, etc.

(Note 2) Job-related stresses (caused by the hydrogen explosion, need to evacuate because of the tsunami, etc.), experience of grief (bereavement, etc.), stresses as an accident victim and a natural disaster (earthquake and tsunami) victim (loss of property, refugee life, etc.), experiences of discrimination or defamation

3. Examination method and frequencies

(1) At the time of the initial examination, the respective entities should obtain consent in writing and use a questionnaire for ascertaining confounding factors.

(2) Around once every five years, changes in the situation should be ascertained through a questionnaire.

Section 6. System for the Studies

1. Framework of the system (see the Chart)

(1) As survey subjects are dispersed nationwide, it is difficult for a sole research institute to cover all of them. However, it is indispensable to stably maintain a body that controls the studies in their entirety on a long-term basis in order to properly preserve biological samples, keep the accuracy of the analyses thereof, manage letters of consent, and undergo examinations by ethics committees.

(2) Therefore, a "controlling research institute", which controls the studies in their entirety, should be first designated, and "cooperative research institutions" that offer cooperation in the respective sectors should be selected thereunder.

(3) Furthermore, "consigned health check organizations", etc.,(Note 1) such as those obtaining consent for studies from study subjects, those collecting biological samples, and those conducting examinations other than biological sample examinations, may be selected(Note 2) under the consignment of the controlling research institute.(Note 3)

(Note 1) It would be effective for multiple study coordinators to be selected and fostered in "consigned health check organizations", etc. and have them carry out studies.
(Note 2) At least one organization needs to be selected generally for each prefecture.
(Note 3) Consigned organizations that undertake collection and transport of biological samples from "consigned health check organizations", etc. as well as dispensing and refrigeration thereof would also be necessary.

2. Roles of the MHLW

(1) In order to ensure the objectivity of the studies to the extent possible, the MHLW should only take budgetary measures, carry out research activities and evaluate the outcomes thereof. However, in order to facilitate the studies, the ministry will assist the controlling research institute with regard to the following:

a. Consultation concerning cooperation in the studies with TEPCO and primary contractors

b. Consultation concerning provision of data from the Radiation Dose Registration Center for Workers and the respective health insurance societies

(2) Provision of information in the MHLW's database

a. Provision of information, such as the affiliations, addresses and telephone numbers of targeted workers and their exposure doses, registered in the MHLW's database is indispensable for the studies.

b. At the request of R&D-oriented incorporated administrative agencies or MHLW-funded entities, the MHLW provides them with information after checking whether they will take sufficient measures for protecting personal information.

3. Roles of the controlling research institute

(1) Management of the planning as a whole

a. The institute shall establish a steering committee that controls the studies in their entirety, and set up working sessions and working groups thereunder. In this framework, the institute makes study plans, decides examination methods and statistical tools, prepares consent documents and questionnaires for confounding factors, and discusses technical matters, such as items for biochemical examinations and detailed methods for control of analysis accuracy.

b. Division of roles with cooperative research institutions

(2) Standardization of test methods and control of analysis accuracy

a. Control of analysis accuracy of biochemical examinations

b. Standardization of examination methods, including interviews

(3) Consultation concerning cooperation in the studies with relevant organizations

a. Cooperation in the studies with TEPCO and primary contractors

b. Provision of data from the Radiation Dose Registration Center for Workers and respective health insurance societies

(4) Recruitment of and guidance for relevant organizations

a. Recruitment of consigned health check organizations, etc., guidance thereof and cost sharing thereof

b. Recruitment of organizations collecting biological samples, and training and guidance for study coordinators who carry out examinations

c. Recruitment of analytical bodies and guidance for control of analysis accuracy

(5) Preservation of collected data of exposure doses, and examination results and storage of biological samples, etc.

a. Building and maintenance of an epidemiological database

b. Preservation of epidemiological raw data

c. Securing and control of refrigerators suitable for storing biological samples

d. Preservation of copies of detailed measurement data necessary for evaluating exposure doses

(6) Administrative work, such as accounting management and document management

4. Control of analysis accuracy and its relation with legal health checkups

(1) The accuracy of the studies should be maintained from the perspective of ensuring a certain level of reliability in conducting examinations for all of the 20,000 study subjects, and from the perspective of ensuring comparability

among the results of ongoing examinations to be conducted multiple times over several decades from now on.

a. The controlling research institute consigns the analysis of biological samples to a small number of reliable analytical bodies.
b. With regard to examinations other than biological sample examinations, the controlling research institute compiles standardized methods and provides guidance to entities conducting examinations.

(2) Relation with legal health checkups

a. Legal health checkups are conducted by various medical institutions and health checkup institutions but they may not necessarily use the same test materials. Therefore, these data are not sufficiently reliable in terms of comparability. However, a very high percentage of people receive legal health checkups and the percentage of the study subjects who receive examinations may be increased by taking advantage of the opportunities for legal health checkups.
b. Possible options include to additionally collect blood samples for epidemiological studies or to conduct cancer screening additionally at the time of legal health checkups. Biological samples thus collected should be sent to analytical bodies consigned by the controlling research institute.
c. In such case, the results of tests other than the blood test(Note) need to be obtained from employers, and entities conducting studies and employees must have sufficient discussion, including discussing who will bear the cost.

(Note) As image data need to be obtained with regard to the results of an X-ray exam, ultrasonic exam or electrocardiogram exam, etc., sufficient discussions with health checkup institutions that conduct legal health checkups are required.

5. Consent to participation in epidemiological studies

(1) Acquisition of consent to participation in epidemiological studies

a. As it is very troublesome to obtain consent separately for each item (confirmation of death, cause of death, whether or not cancer develops, follow-up using the results of health checkups), consent as comprehensive as possible needs to be obtained at the time of commencing the studies.
b. Consent should be obtained through an interview, in principle, but if it is difficult to have an interview, other means should also be considered, such as obtaining consent by post or via an employer.
c. When intending to store blood samples for a long period, comprehensive consent should be sought, including that to allow the use of samples for newly developed examinations in the future.
d. Consent also needs to be obtained for utilizing personal information, such as

addresses, registered in the MHLW's database and for requesting the relevant person's residence certificate based thereon.

(2) Means to obtain cooperation in the studies

a. As many of the subject emergency workers are presently engaged in other jobs, it is necessary to develop means to ask them to be absent from their jobs and cooperate in the studies.(Note)

b. Additionally, measures helpful for participants need to be taken as much as possible, such as providing health consultations and health guidance and issuing newsletters.

(Note) After examining cases of other epidemiological studies, the possibility of offering rewards for participation should also be discussed.

6. Other matters to be noted

(1) Requirements for the controlling research institute

a. The institute must have sufficient personnel and the organizational and financial basis for implementing the matters set forth in items 1 to 5 of Section 6 stably on an ongoing basis.

b. The institute must have the personnel and organizational system for undergoing examinations, etc. by international organizations and have the capacity to transmit the outcomes of the studies internationally.

c. The institute must have the capacity to evaluate exposure doses, including internal exposure doses (committed doses), independently.

(2) Ethics committees

a. A central ethics committee that examines the studies in their entirety needs to be established at the center of the whole system. It would be efficient for cooperative research institutions to conduct ethical reviews as necessary thereunder.

b. The most efficient option is to utilize the ethics committee established in the controlling research institute as the central ethics committee.

(3) Securing of necessary funds, etc.

a. It is necessary to secure the necessary funds stably over years.

b. The mechanism should be such that a single institute continues to be designated as the controlling research institute stably over the long-term.

Section 7. Study Period, Evaluation and Publication of Study Results

1. Study period, etc.

(1) Many of the emergency workers are in their early 20s. It is indispensable to follow up on all study subjects throughout their lifetimes in order to achieve the purpose of the studies. Therefore, the study period may be over 60 years.

(2) In order to ensure the quality of the studies over the years, a mechanism is required to undergo evaluation by an international third-party panel at intervals, such as once every five years, in addition to normal evaluation of the studies.

(3) It is not necessarily required to divide the study period into multiple terms, but if terms need to be set for the allocation of funds or on any other grounds, respective entities should review their studies in relation to the opportunities to undergo evaluation by an international third-party panel.

2. Evaluation by an international third-party panel

(1) Entities conducting studies should establish an independent panel (third-party panel),(Note) which includes researchers who have been acknowledged internationally for their research, and should undergo evaluation of the panel from the international point of view.

(2) The panel should also evaluate whether there is any arbitrary bias, with regard to the selection of research hypotheses, study plans, exposure factors and statistical tools, etc., leading to publicizing analysis results with or without statistically significant differences only.

(3) Evaluation results of the panel should be compiled into a report and be publicized internationally.

(Note) The possibility of including study subjects or other relevant parties as panel members should also be discussed.

3. Publication of study results

(1) As the epidemiological studies are funded by the MHLW, entities conducting studies need to report their activity results to the ministry regularly.

(2) Entities conducting studies should compile the results of follow-up examinations of all study participants regularly and publicize them as descriptive epidemiological reports(Note) in the publications issued by the controlling research institute.

(3) Academic study reports should also be compiled and publicized in relevant international academic journals.

(Note) The controlling research institute should have an organization to examine and select academic study reports to be publicized.

Section 8. Baseline Studies to be Conducted in FY2014

1. Purpose

(1) In preparation for full-scale epidemiological studies from FY2015 onward, the MHLW conducts baseline studies by selecting about 10% of the total number of study subjects,(Note) basically with regard to the matters listed in Section 2 to Section 5 and in the same methods and details explained therein, with the aim of obtaining data, such as the prevalence among emergency workers, necessary for establishing plans for full-scale studies.

(2) Based on the results of the studies mentioned in (1) above, the MHLW discusses specific statistical tools to be adopted in full-scale studies and verifies research hypotheses.

(3) These studies to be conducted on a trial basis at a small scale prior to full-scale studies are also utilized as preliminary studies for obtaining information on the matters listed in Section 6, which is necessary for building the system for full-scale epidemiological studies.

(Note) Consideration should be given to ensure that data for selected targets may be utilized as the baseline for commencing full-fledged studies.

2. Matters to be noted

(1) Continuity between baseline studies and epidemiological studies, which are commenced on a full scale in FY2015, needs to be guaranteed so that study subjects would continue to agree with the participation in epidemiological studies.

(2) Entities conducting studies should particularly prioritize deliberations on the details of test methods, which are left to them, in baseline studies so as to reach certain conclusions.

IV. Reference Materials

Reference 1 Initiatives for Long-term Health Care of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Reference 3 for the first meeting)

Reference 2 Guidelines on Maintaining and Improving the Health of Emergency Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Reference 4 for the first meeting)

Reference 3 Current Status of Long-term Health Care of Emergency Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Reference 5 for the first meeting)

Reference 4 Epidemiologic Survey of Radiation Health Effects (submitted by Mr. Kodama) (Reference 6 for the first meeting)

Reference 5 Cohort Study of Nuclear Industry Workers in Japan (submitted by Mr. Kasagi) (Reference 7 for the first meeting)

Reference 6 Research on Thyroid Gland Examinations, etc. of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (submitted by Mr. Sobue) (Reference 8 for the first meeting)

Reference 7 Biodosimetry of Restoration Workers for the Tokyo Electric Power Company (TEPCO) Fukushima Daiichi Nuclear Power Station Accident (submitted by Ms. Suto) (Reference 9 for the first meeting)

Reference 8 Method of Registration of Workers, Characteristics of Groups, and Past Epidemiological Studies in the Russian Federation (submitted by Mr. Takamura) (Reference 3 for the second meeting)

Reference 9 Medical Check-up Categories Indicating Values to be Increased or Decreased in Relation to Radiation Exposure Doses in the Adult Health Study Conducted by the Radiation Effects Research Foundation (submitted by Mr. Kodama) (Reference 4 for the fourth meeting)

Reference 10 Use of Database Containing Information on Medical Receipts and Special Medical Check-ups (Reference 5 for the second meeting)

Reference 11 Table: Distribution of Radiation Exposure Doses by Age Group (Reference 6 for the second meeting)

Reference 12 Overview of the Report by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (Reference 3 for the fourth meeting)