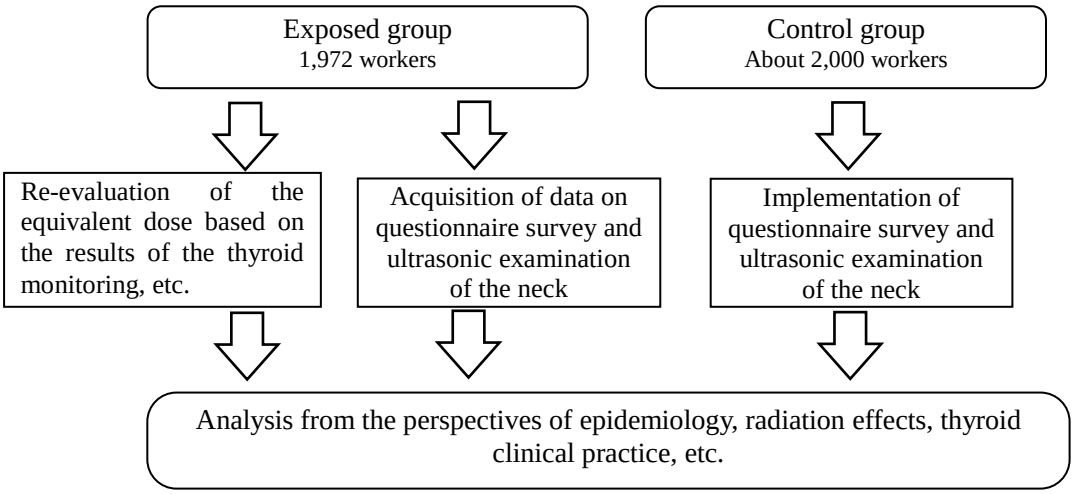
Reference 6

Research on Thyroid Gland Examinations, etc. of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant (Research Design)

1. Research outline

The ultrasonic examination of the neck will be performed for a control group (thyroid equivalent dose of 100 mSv or less; that is, workers with as low an exposure dose as possible), based on the thyroid nodule (mass) ultrasonic diagnostic standard of the Japan Society of Ultrasonics in Medicine. Meanwhile, the examination will also be performed for an exposed group (emergency workers exposed to radiation exceeding a thyroid equivalent dose of 100 mSv [equivalent to an effective dose of 5 mSv]) based on the same diagnostic standard. The difference in the detection rate of thyroid nodules (masses) between the exposed group and the control group will be analyzed and evaluated from the perspectives of epidemiology, radiation effects, thyroid clinical practice, etc.

Outline of research on surveys, etc. of thyroid monitoring of workers at the TEPCO Fukushima Daiichi Nuclear Power Plant



2. Purpose

The detection rate of thyroid nodules (masses) is compared between the exposed group and the control group.

3. Study subjects

(1) Exposed group

- Emergency workers exposed to radiation exceeding a thyroid equivalent dose of 100 mSv (equivalent to an effective dose of 5 mSv) (about 2,000 workers)

- In order to increase the participation rate of contractor employees in this research, cooperation of contractors will be promoted.

(2) Control group

- Workers with as low an exposure dose as possible will be selected with a thyroid equivalent dose of less than 50 mSv, in principle.
- The control group will be set taking into account the number of targets per age group of the exposed group.
- The target size of the control group will be 2,000 workers.

4. Examination method of the control group

(1) Questionnaire survey

1) A questionnaire survey will be conducted upon implementation of an ultrasonic examination, in principle.

2) The questions to be asked will be the following: (i) height and weight; (ii) medical history; (iii) family medical history (occurrence of any thyroid diseases); (iv) history of medical exposure (experience of CT scanning of the head and neck or the chest; if any, the number of times scanned, etc.); (v) lifestyle habits (alcohol/tobacco consumption); (vi) experience receiving ultrasonic examinations of the neck. Also, as basic attributes, the name, address, and age will be confirmed.

(2) Identification of the exposure dose

1) While the control group should not have been exposed to radiation insofar as possible, information on the effective exposure dose accumulated during work (cumulative exposure dose) will be acquired.

(3) Ultrasonic examination

The examiner will determine the level from A to C based on the presence/absence and the size of nodules or cysts by using the thyroid nodule (mass) ultrasonic diagnostic standard of the Japan Society of Ultrasonics in Medicine.

5. Collection of data pertaining to the examination of the exposed group

(1) Questionnaire survey

1) A questionnaire survey will be conducted upon implementation of an ultrasonic examination, in principle. The contents of the questionnaire will be the same as those of the questionnaire for the control group.

(2) Identification of the exposure dose

1) The data that will serve as the basis for the actual measurement or estimation of the thyroid equivalent dose will be acquired from the data of the exposure dose

accumulated during work to deal with the accident at the Fukushima Daiichi Nuclear Power Plant.

(3) Ultrasonic examination

1) TEPCO has a framework to implement the ultrasonic examination of the neck for workers with a thyroid equivalent dose exceeding 100 mSv. The examination data obtained in that framework will be acquired with the consent of the examinees.

2) The research team will analyze the provided image data after determining the level from A to C based on the presence/absence and the size of nodules or cysts by using the thyroid nodule (mass) ultrasonic diagnostic standard.

7. Dose re-evaluation for the exposed group

(1) The data of thyroid equivalent dose includes data of actual measurements using a thyroid monitor and data of estimates based on the neck measurement using a survey meter and estimates based on the Cs-137 measurement using a whole body counter. Therefore, while consideration will be made to optimize the estimation methods, consideration will also be made to separately evaluate people whose dose was actually measured using a monitor and those whose dose was estimated, upon epidemiologic evaluation.

(2) As the exposure dose, the cumulative thyroid equivalent dose including any dose before the accident will be identified. In addition, the experience of receiving CT scanning of the head and neck or the chest will be confirmed so as to take it into consideration upon analysis.

8. Statistical analysis

(1) Preparation of analysis data

A dataset for analysis will be prepared for each of the two groups, the exposed group and the control group, including the age, thyroid examination result, thyroid equivalent dose, cumulative effective dose, lifestyle habits, the occurrence of any thyroid diseases in the medical history, history of medical exposure, and experience of receiving ultrasonic examinations of the neck.

(2) Comparison of the detection rate of thyroid nodules, etc. between the exposed group and the control group

The difference in the prevalence of thyroid nodules, etc. between the exposed group and the control group will be tested by such methods as the χ^2 test and the Mantel-Haenszel test (potential confounding factors such as the age and lifestyle habits will be adjusted). The test will be a one-sided test with a significance level of 0.05.

(3) Analysis of the dose-response relationship of the detection rate of thyroid nodules, etc.

The probability of occurrence of thyroid nodules, etc. in the exposed group and the control group will be analyzed by a multivariable logistic model. Then, the relative risk and the 95% confidence interval will be calculated for each dose group that has been classified based on the thyroid equivalent dose, and the influence of the exposure on risks of thyroid nodules, etc. as well as the influence of the age, lifestyle habits, medical history, history of medical exposure, etc. on such risks will be evaluated.

Furthermore, after adjusting potential confounding factors, the shape of the dose-response relationship will be studied by using a linear model or a quadratic curve model.

9. Evaluation of the examination results and analysis results

(1) Evaluation of the examination results

With regard to targets who were determined to be level B or C of the diagnostic standard, information on the free T4, TSH, antithyroglobulin antibody, antithyroid microsomal antibody, antithyroid peroxidase antibody, etc. will be acquired insofar as possible, and the relationship between those indicators and thyroid nodules, etc. will be evaluated from a clinical perspective.

(2) Evaluation of the analysis results

The results of the comparison of prevalence between the exposed group and the control group, and the results of the dose-response analysis, will be taken into consideration, along with epidemiologic literature and other information related to atomic bomb survivors and groups subject to occupational exposure concerning radiation exposure and its influence on the thyroid and the above-mentioned evaluation of the examination results, to comprehensively evaluate the possibility that the exposure from the accident has had any influence on the thyroid.