Annex 1

Overview of the Report of the Research on Thyroid Gland Examinations, etc. of Workers at the TEPCO Fukushima Daiichi Nuclear Power Plant

FY2013 Health and Labour Science Research Grants

Health and Labour Science Special Research Program

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Purpose and Methods

Purposes: To epidemiologically analyze radiation effects on the thyroid gland by setting an exposed group (emergency workers exposed to radiation exceeding a thyroid equivalent dose of 100 mSv) and a control group (thyroid equivalent dose of 100 mSv or less), performing an ultrasonic examination for both groups and comparing the results; and to evaluate the analysis results from the viewpoint of clinical medicine in terms of radiation effects on the thyroid gland

Exposed group
(thyroid equivalent dose: over 100mSv)
1,972 people

Control group
(thyroid equivalent dose: 100mSv or less)
Approx. 2,000 people

Collect information on confounding factors, etc.

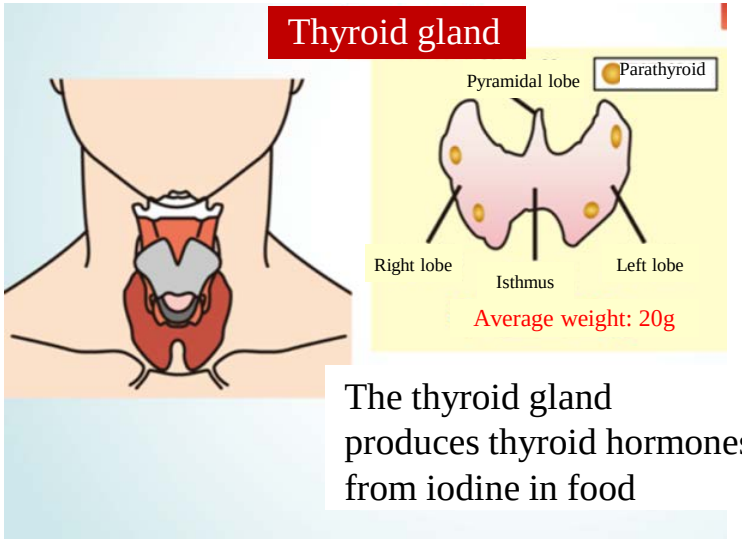
Evaluate thyroid equivalent doses for epidemiological studies

Perform an ultrasonic examination and evaluate the results based on judgment criteria

Compare and examine exposure doses and examination results

Thyroid gland

Thyroid hormones improve the metabolism of the whole body and promote synthesis of proteins, etc.



The thyroid gland produces thyroid hormones from iodine in food

Thyroid gland ultrasonic examination

Methods (Ultrasonic Examination/Survey of Confounding Factors)

Judgment Criteria for Thyroid Gland Ultrasonic Examination (Adopted by the Research Team)

Classification		Criteria	Judgment
A	A1 (Normal)	No abnormal finding was detected	・Normal ・You do not need to receive a secondary examination.
	A2 (Secondary examination unnecessary)	A nodule (lump) of 5.0mm or smaller, or a cyst of 20.0mm or smaller	・You do not need to receive a secondary examination although a small nodule (lump) or cyst was detected.
B (Secondary examination recommended)		A nodule (lump) of 5.1mm or larger, or a cyst of 20.1mm or larger	・You are encouraged to receive a secondary examination.
C (Secondary examination required)		A secondary examination is required immediately in light of the state of the thyroid gland, etc.	・You need to receive a secondary examination immediately, judging from the state of the thyroid gland, etc.

- **Cysts themselves do not need to be treated**. However, as a large cyst may cause symptoms in the neck, a cyst of 20.1mm or larger was judged as level B.
- According to the "Draft Criteria for Handling Nodal Pathology in Thyroid Gland Ultrasonic Examinations(Note)" compiled by the Japan Association of Breast and Thyroid Sonology, **a detailed examination is not required for nodules of 5mm or smaller** but it **is required for nodules of 5mm to 20mm that are judged malignant**. In this research, in order to increase the detection rate, **nodal pathology larger than 5mm was judged as level B (secondary examination recommended) irrespective of whether nodules were judged malignant or not**. **Even if a detected nodule was 5mm or smaller, when a detailed examination was considered to be necessary based on image data**, the relevant examinee was **classified into level B**.

(Note) Thyroid Gland Ultrasonic Examination Guidebook, ver. 2

< Quality control of ultrasonic examinations>

- We used ultrasonic examination equipment and probes with higher resolution that are suitable for thyroid examinations as detection of, and judgment on, thyroid tumors of 10mm or smaller are often significant.
- Examiners were limited to technicians who are medical sonographers (in the field of body surface or health checkups) certified by the Japan Society of Ultrasonics in Medicine or who have experience and capability equivalent thereto, and who obtained a certain score in a test on ultrasonic imaging prepared by the quality control committee of the research team.
- We held a judgment meeting of experienced physicians, where all image data were scrutinized and some judgments were revised.

Collection of information concerning confounding factors, etc.*: The following information was collected upon performing the ultrasonic examination

(i) Height and weight; (ii) Medical history; (iii) Family medical history (experience 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 of receiving ultrasonic examinations

* Factors relating to both exposure factors and health effects

Results (Ultrasonic Examination)

- The number of workers who agreed to the research and received the examination was **627** in the exposed group (**31.8%**) and **1,437** in the control group, totaling **2,064**.
- In the comprehensive judgment, **percentages of those to whom a secondary examination was recommended (level B) and those for whom a secondary examination was judged necessary (level C) were almost the same for both groups, but the percentage of those for whom a secondary examination was judged unnecessary (level A2) was high for the exposed group**.
- **A clear correlation** was observed between **age and the percentage of those to whom a secondary examination was recommended (level B)**.

Table 1 Number and Percentage of Examinees by Entity
(percentage: only for the exposed group)

	Exposed group			Control group	Examinees Total (workers)
	All subjects (workers)	Examinees (workers)	Percentage (%)	Examinees (workers)	
Contractors	996	22	2.2%	137	159
TEPCO	976	605	62.0%	1,300	1,905
Total	1,972	627	31.8%	1,437	2,064

Table 5-a Comprehensive Judgment (percentage)

	Exposed group		Control group		Total
	Number (workers)	**Percentage (%)**	Number (workers)	**Percentage (%)**	
Level A1	320	**51.0%**	907	**63.1%**	1,227
Level A2	239	**38.1%**	392	**27.3%**	631
Level B	67	**10.7%**	136	**9.5%**	203
Level C	1	**0.2%**	2	**0.1%**	3
Total	627	**100.0%**	1,437	**100.0%**	2,064

Table 5-c1 to 5-c2 Comprehensive Judgment by Age Bracket

	Comprehensive judgment (workers)									
Age	Level A1		Level A2		Level B		Level C		Total	
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
20-24	84	66.7%	39	31.0%	3	2.4%	-	-	126	100.0%
25-30	132	65.0%	63	31.0%	7	3.4%	1	0.5%	203	100.0%
30-34	141	65.9%	61	28.5%	11	5.1%	1	0.5%	214	100.0%
35-39	196	64.7%	86	28.4%	21	6.9%	-	-	303	100.0%
40-44	203	62.1%	97	29.7%	27	8.3%	-	-	327	100.0%
45-49	190	58.6%	100	30.9%	33	10.2%	1	0.3%	324	100.0%
50-54	188	53.4%	111	31.5%	53	15.1%	-	-	352	100.0%
55-59	87	46.0%	61	32.3%	41	21.7%	-	-	189	100.0%
60-64	6	24.0%	13	52.0%	6	24.0%	-	-	25	100.0%
65-69	-	-	-	-	1	100.0%	-	-	1	100.0%
70-74	-	-	-	-	-	-	-	-	-	-
Total	1,227	59.4%	631	30.6%	203	9.8%	3	0.1%	2,064	100.0%

A1: Normal
A2: Secondary examination unnecessary
B: Secondary examination recommended
C: Secondary examination required

Results (Reliability Distribution of Exposure Evaluation)

- We **estimated more realistic thyroid equivalent doses** from **conservative evaluation of internal exposure**, which are mainly for health management, but the parameters at calculation were re-evaluated as more reliable values based on mean values.

  (If exposure doses are evaluated higher than in reality, this will result in underestimation of health effects due to exposure.)

- We **classified the reliability** of evaluation of internal exposure into levels from **A to D**, and they **varied** significantly.

- With regard to **cases classified into reliability level C or D**, **quantitative evaluation should be conducted carefully**.

  (Thyroid equivalent doses obtained through reliable measurements (those classified into reliability level A or B) account for only about 31% of the total (levels A to D).)

A: Iodine-131 **measured** by using a thyroid monitor (Ge semiconductor detector)
B: Iodine-131 **measured** by using an NaI scintillation survey meter or an NaI scintillation WBC (able to identify nuclides)
C: Iodine-131 **estimated** based on the detection limit by an NaI scintillation WBC or **estimated** using the ratio of iodine/cesium based on measured values of cesium-137
D: Iodine-131 **estimated** using the ratio of iodine/cesium based on values of cesium measured by using a plastic scintillation WBC (unable to identify nuclides)
#N/A: Internal exposure was not measured as the person was free from the possibility of internal exposure for such reasons as not having engaged in emergency work

Table 10-a1 to 10-a2 Number (Percentage) of Examinees by Reliability Level of Exposure Evaluation and Thyroid Equivalent Dose

		Reliability of evaluation of internal exposure										Total (workers)	
		A		B		C		D		#N/A			
Thyroid equivalent dose[(Note)] (mSv)	> 1000	21	32.3%	5	2.1%	5	1.1%	3	1.3%	-	-	34	1.6%
	501 to 1000	21	32.3%	15	6.3%	30	6.7%	2	0.9%	-	-	68	3.3%
	201 to 500	19	29.2%	65	27.3%	153	34.4%	5	2.1%	-	-	242	11.7%
	101 to 100	4	6.2%	79	33.2%	151	33.9%	16	6.8%	1	0.1%	251	12.2%
	51 to 100	-	-	45	18.9%	60	13.5%	41	17.5%	28	2.6%	174	8.4%
	≤ 50	-	-	29	12.2%	46	10.3%	167	71.4%	1053	97.3%	1,295	62.7%
	Total	65	100.0%	238	100.0%	445	100.0%	234	100.0%	1082	100.0%	2,064	100.0%

(Note) Thyroid equivalent dose: Dose only focusing on thyroid exposure, which is calculated as a total of internal exposure and external exposure (including exposure prior to the accident); Thyroid equivalent dose is 1/20 in the case that it is converted to the whole-body exposure dose (effective dose)

Results (Correlation between Findings and Doses)

- In order to eliminate bias in selection of study subjects to the extent possible, examinees were chosen who had no experience of receiving ultrasonic examinations, excluding those classified into reliability of evaluation of internal exposure level C or D, and the correlation was analyzed between exposure doses (six groups) and comprehensive judgment after age adjustment.

- As a result, the percentage of those **for whom a secondary examination was judged unnecessary (level A2)** was **relatively high in workers whose doses were high**, **showing a statistically significant correlation between doses and the percentage of people judged as level A2** (p=0.0161).

- However, **no statistically significant correlation was found between doses and the percentage of those to whom a secondary examination was recommended (level B) or for whom a secondary examination was judged necessary (level C)** (p=0.3714 or 0.4063).

Supplement Table 10-h19 to 10-h27 Comprehensive Judgment Seen by Thyroid Equivalent Dose
(limited to examinees without the experience of receiving ultrasonic examinations, excluding those classified into reliability level C or D ((n=1,189))

	Thyroid equivalent dose (mSv)						
	50 or less	50-	100-	200-	500-	1000 or more	Total
Number (percentage) of examinees judged as level A1	658 (64.5%)	37 (57.8%)	22 (52.4%)	22 (62.9%)	7 (33.3%)	6 (85.7%)	752 (63.2%)
Number (percentage) of examinees judged as level A2	271 (26.6%)	16 (25.0%)	18 (42.9%)	12 (34.3%)	11 (52.4%)	1 (14.3%)	329 (27.7%)
Number (percentage) of examinees judged as level B	91 (8.9%)	10 (15.6%)	2 (4.8%)	1 (2.9%)	3 (14.3%)	0 (0.0%)	107 (9.0%)
Number (percentage) of examinees judged as level C	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Total	1,020 (100%)	64 (100%)	42 (100%)	35 (100%)	21 (100%)	7 (100%)	1,189 (100%)

* A generalized Mantel-Haenszel test to ascertain the correlation between thyroid equivalent doses and the percentage of workers judged as a specific level after adjusting age (four age brackets: 20-34; 35-44; 45-54; and 55 or over)

Results (Correlation between Examination Results and Doses)

● In order to eliminate bias in selection of study subjects to the extent possible, thyroid equivalent doses were classed into six groups and the correlation was analyzed between exposure doses and the presence/absence and size of cysts and nodules for examinees excluding those classified into reliability of evaluation of internal exposure level C or D, after age adjustment. The analysis results suggest that **the incidence of relatively larger cysts* was high for people with high doses**, although **no correlation was found between nodule size and thyroid equivalent dose**.

* **Cysts themselves do not need to be treated**. However, as a large cyst may cause symptoms in the neck, a cyst of 20.1mm or larger was judged as level B (only one case).

Supplement Table 12-9, 12-11 Presence/Absence and Maximum Diameter of Cysts Classified by Thyroid Equivalent Dose
(limited to examinees with no experience of receiving ultrasonic examinations, excluding those classified into reliability level C or D)

		Presence/absence and size of cysts																Total		Average age
		None		- 3.0mm		3.1mm - 5.0mm		5.1mm - 10.0mm		10.1mm - 15.0mm		15.1mm - 20.0mm		20.1mm - 25.0mm		25.1mm -				
Thyroid equivalent dose (mSv)	> 1000	6	85.7%	-	-	-	-	1	14.3%	-	-	-	-	-	-	-	-	7	100%	42.1
	501 to 1000	7	33.3%	4	19.0%	7	33.3%	1	4.8%	2	9.5%	-	-	-	-	-	-	21	100%	41.7
	201 to 500	23	65.7%	3	8.6%	6	17.1%	2	5.7%	1	2.9%	-	-	-	-	-	-	35	100%	43.5
	101 to 100	24	57.1%	6	14.3%	11	26.2%	1	2.4%	-	-	-	-	-	-	-	-	42	100%	39.6
	51 to 100	42	65.6%	3	4.7%	7	10.9%	9	14.1%	2	3.1%	-	-	1	1.6%	-	-	64	100%	46.4
	≤ 50	720	70.6%	92	9.0%	107	10.5%	80	7.8%	16	1.6%	5	0.5%	-	-	-	-	1,020	100%	40.5
	Total	822	69.1%	108	9.1%	138	11.6%	94	7.9%	21	1.8%	5	0.4%	1	0.1%	-	-	1,189	100%	40.9

Supplement Table 12-10, 12-12 Presence/Absence and Maximum Diameter of Nodules (or Nodules within Cysts) Classified by Thyroid Equivalent Dose
(limited to examinees with no experience of receiving ultrasonic examinations, excluding those classified into reliability level C or D)

		Presence/absence and size of nodules (or nodules within cysts)																Total		Average age
		None		- 3.0mm		3.1mm - 5.0mm		5.1mm - 10.0mm		10.1mm - 15.0mm		15.1mm - 20.0mm		20.1mm - 25.0mm		25.1mm -				
Thyroid equivalent dose (mSv)	> 1000	7	100%	-	-	-	-	-	-	-	-	-	-	-	-	-	-	7	100%	42.1
	501 to 1000	18	85.7%	-	-	-	-	2	9.5%	-	-	1	4.8%	-	-	-	-	21	100%	41.7
	201 to 500	33	94.3%	1	2.9%	-	-	1	2.9%	-	-	-	-	-	-	-	-	35	100%	43.5
	101 to 100	36	85.7%	-	-	4	9.5%	2	4.8%	-	-	-	-	-	-	-	-	42	100%	39.6
	51 to 100	53	82.8%	1	1.6%	1	1.6%	4	6.3%	3	4.7%	-	-	2	3.1%	-	-	64	100%	46.4
	≤ 50	887	87.0%	16	1.6%	30	2.9%	60	5.9%	17	1.7%	4	0.4%	4	0.4%	2	0.2%	1,020	100%	40.5
	Total	1,034	87.0%	18	1.5%	35	2.9%	69	5.8%	20	1.7%	5	0.4%	6	0.5%	2	0.2%	1,189	100%	40.9

Consideration (Interpretation 1)

● This is **an interim report** based only on the ultrasonic examination, prepared before definite diagnoses based on the detailed examination have become available. It would be dangerous to draw a conclusion based only on the results of this research due to **bias in selection of study subjects** and **uncertainties resulting from estimation of their exposure doses**.

- According to the research results, the percentage of workers who had the experience of receiving ultrasonic examinations was **high for the exposed group (56.9% against 5.6% for the control group)** while the percentage of workers who received this screening was **low for the exposed group (31.8%; 62.0% for employees of TEPCO and 2.2% for employees of contractors)**. This suggests the possibility of a considerable bias in the incidence of cysts and nodules among workers with high doses.
- In other words, there is a possibility that workers for whom a secondary examination was judged unnecessary (level A2) in their previous ultrasonic examinations selectively participated in this research. Or, workers to whom a secondary examination was recommended (level B) or for whom a secondary examination was judged necessary (level C) in their previous ultrasonic examinations might have selectively dropped out of this research.
- With regard to workers whose internal exposure evaluation results are considered to be less reliable (**those classified into reliability level C or D**), quantitative evaluation of their internal exposure should be conducted carefully.

● Efforts need to be made to **collect and analyze the results of the detailed examinations for study subjects in whom an abnormality was detected in this screening**, and also to **collect and analyze the results of previous thyroid gland ultrasonic examinations for the exposed group**.

- **The results of the ultrasonic examinations** (FY2012 on a voluntary basis) and **the secondary examinations (detailed examinations**; FY2012 and FY2013) **have yet to be collected**.
- A **notice recommending a detailed examination** was sent to study subjects to whom a secondary examination was recommended (level B) or for whom a secondary examination was judged necessary (level C), **with a referral form to medical institutions** where they can receive a detailed examination.

Consideration (Interpretation 2)

●**Based on the previous consideration** and the comprehensive judgment, it was found that **there is no difference** in the percentage of those **to whom a secondary examination was recommended (level B)** or **for whom a secondary examination was judged necessary (level C) between the exposed group and the control group, without any correlation with thyroid equivalent doses**.

●On the other hand, the percentage of those **for whom a secondary examination was judged unnecessary (level A2)** was **relatively high for workers with high doses**, and **the same tendency was observed in the analysis using re-evaluated thyroid equivalent doses**.

・For those **for whom a secondary examination was judged unnecessary (level A2)**, **a notice to that effect was sent**.

●While **no correlation was found between nodule size and thyroid equivalent dose**, the research suggested that **the incidence of relatively larger cysts* was high for workers with high doses**.

* **Cysts themselves do not need to be treated.** However, as a large cyst may cause symptoms in the neck, a cyst of 20.1mm or larger was judged as level B (only one case).

Long-term Health Management, etc. by the MHLW

Reference

● With regard to workers engaged in emergency work at TEPCO Fukushima Daiichi NPP, the Ministry of Health, Labour and Welfare requests their employers to have them receive **cancer screening, etc.(Note 1) depending on their exposure doses**, based on **the MHLW Minister's Guidelines.(Note 2)** After such workers leave their jobs, Japanese government implements these measures.

(Note 1) Workers whose effective doses (whole-body exposure doses) due to emergency work exceed 50mSv are to receive a cataract examination, and those whose effective doses exceed 100mSv are to receive cancer screening (including a thyroid gland examination).

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

●As a result of this research, there was **no significant difference** in the percentage of **those to whom a secondary examination is recommended (level B) or for whom a secondary examination is judged necessary (level C) between the exposed group and the control group**, **without any significant correlation with thyroid equivalent doses**. However, the MHLW will continue their health management based on the MHLW Minister's Guidelines.

● In the **epidemiological studies on emergency workers, which are scheduled to be commenced in the second half of this fiscal year**, the MHLW will also **continue examining** radiation effects on the thyroid gland.