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Country Report

“Purchase survey” of respiratory protective equipment as a follow-up on the national certification system in Japan

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Abstract: Since respiratory protective equipment (RPE) are essential for the workers who are occupationally exposed to harmful airborne substances, it is necessary to complete a strict certification test on RPE. In Japan, Technology Institution of Industrial Safety (TIIS) is responsible for the RPE certification and examines the RPE submitted by the manufactures to make an admission decision with the national standards. However, the certification system cannot ensure the quality of the RPE after the shipping because some RPE may deteriorate during the distribution process or the storage period at retail stores. In this article, the author aimed to introduce the follow-up system on national RPE certification in Japan and the role of the follow-up survey committee established by TIIS.

Key words: Follow-up, National certification system, Occupational Safety and Health Law, Purchase survey, Respiratory protective equipment

Background

Since respiratory protective equipment (RPE) are essential for the workers who are occupationally exposed to harmful airborne substances in industrial environments, it is necessary to complete a strict certification test on RPE by a non-interest public agency. According to the Occupational Safety and Health Law in Japan, commercial RPE for industrial use (dust masks, gas masks and powered air-purifying respirators (PAPRs)) are administratively certified by Technology Institution of Industrial Safety (TIIS) which is a non-governmental, non-profit and self-sustaining organization founded in 1965. TIIS examines the RPE submitted by the manufactures and makes an admission decision with the national standards for RPE prescribed by Ministry of Health, Labor and Welfare, Japan (MHLW). Owing to the certification system, all the commercial RPE models in Japanese market are to be guaranteed in quality before factory shipment. However, it will inevitably take a certain period of time from the shipment of RPE to the purchase of it by the user, and the certification system cannot ensure the quality of RPE after the shipping because some RPE may deteriorate during the distribution process or the storage period at retail stores. In order to fill in this “blank” and to ensure the quality and performance of RPE on the market, a follow-up survey (namely, purchase survey) for the RPE has been conducted every year by TIIS since 2000. The follow-up survey is a competition plan which MHLW calls for public offering, and TIIS makes a successful bid for the offering every year. Therefore, the survey has been implemented by the national budget. Probably this follow-up for RPE quality assurance is unique to Japan.

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Table 1. Breakdown of the sampled RPE models for the follow-up survey

	Dust musk	Gas musk	PAPR
2018	35	35	14
2017	35	35	14
2016	30	30	14
2015	30	30	10
2014	30	25	10

RPE: respiratory protective equipment; PAPR: powered air-purifying respirators.

Survey Outline

The follow-up survey is conducted by TIIS according to the implementation criteria provided by MHLW. Originally, this survey has been conducted for dust masks and gas masks, the criteria have added PAPRs to the survey subjects since 2013. As a premise of the follow-up, the commercial RPE certified under national standards are sampled by unannounced purchasing at retail stores or online shopping. Among the many models of the RPE on the market, the specimens to be tested are sampled by TIIS staff in consideration of following requirements.

·The productive volume and the sales volume of the sampled RPE models are estimated to be large.
·The sampled RPE are the models for the worker who are occupationally exposed to highly toxic substances.
·The sampled RPE models are related to actual industrial accidents.
·If any, defective product information of the sampled RPE model have been reported.
·The sampling is performed for each RPE model once in about 5 yr.
·The RPE to be tested should be sampled without regional bias of procurement area.
·The expired REP are excluded from the sampling.

While considering these requirements, several dozen models of RPE are sampled from the market every year. The breakdown of the number of RPE models sampled in the last five years is shown in Table 1. For each model, four to nine products are procured and subjected to the same test as the national certification test for RPE in addition to visual inspections for the product body and the packaging. Further follow-up survey will be conducted for the model that failed the first follow-up test. Note that the survey on the shipment status of each model and its optional parts by means of questionnaire to the manufactures has been conducted along with the follow-up survey since 2018.

Results of the Survey

Results of the follow-up survey for the last five years are shown in Table 2. In the latest 2018 survey, one model of dust mask and four models of gas mask did not meet the national standards, and a pass certificate ravel of the test was missing in one dust musk model. (Thus, two dust mask models failed the follow-up survey test in 2018.) The RPE to be tested in 2018 were procured at Chiba, Yamanashi, Aichi and Mie Prefecture. Details of reasons for failing the follow-up survey test in the last five years were shown in Table 3.

Every year, the results of the follow-up survey have been fed back to RPE manufacturers so as to help quality control in the manufacturing process and in the retail market. Probably owing to the feedbacks, serious defects of RPE on the market have been decreasing in Japan.

The results of the follow-up survey are then summarized in an annual draft report by TIIS.

Evaluation Committee for the Follow-up Survey

In order to confirm the annual draft report which presents the results of the follow-up survey, TIIS established an evaluation committee for the follow-up. The committee consisting of external experts has been held twice a year since its establishment. As a secretariat, TIIS asks the committee for review and approval of the draft report, and the approved report will be submitted to MHLW by TIIS. The current member of the committee (as of 2018) is shown in Table 4.

Conflicts of Interest

The author declares that there are no conflicts of interest.

Table 2. Breakdown of the number of the RPE models that failed the test of the follow-up survey in the past five years

	Dust musk	Gas musk	PAPR
2018	2/(35)	4/(35)	0/(14)
2017	3/(35)	0/(35)	1/(14)
2016	2/(30)	0/(30)	2/(14)
2015	2/(30)	1/(30)	−/(10)*
2014	4/(30)	1/(25)	−/(10)*

*Since the Japanese Industrial Standard for PAPR (JIS T 8157-2009) had been substituted for the national standard before 2015, the value is not listed in the source data and this table. RPE: respiratory protective equipment; PAPR: powered air-purifying respirators.

Table 3. Details of reasons for failing the follow-up survey test in the last five years

	RPE category	Failure reason
2018	Dust mask	·Insufficient tensile strength of the strap
		·Missing of the pass certificate ravel
	Gas mask	·Failing to meet the exhaust resistance criteria
		·Failing to meet the intake resistance criteria
		·Failing to meet the air tightness criteria
2017	Dust mask	·Failing to meet the capture efficiency criteria
		·Incorrect description of the manual and/or attached documents
	PAPR	·Incorrect description of the manual and/or attached documents
2016	Dust mask	·Incorrect description of the manual and/or attached documents
	PAPR	·Incorrect description of the manual and/or attached documents
2015	Dust mask	·Insufficient tensile strength of the strap
		·Missing of the manual
	Gas mask	·Insufficient decontamination performance of the canister
2014	Dust mask	·Insufficient tensile strength of the strap
		·Failing to meet the air tightness criteria
	Gas mask	·Incorrect description of the manual and/or attached documents

RPE: respiratory protective equipment; PAPR: powered air-purifying respirators.

Table 4. Member of evaluation committee for the follow-up survey (2018)

Name*	Affrication
Shin-ichi ABUKU	Nippon Steel Corporation, Human Resources Department
Isamu KABE	Kubota Corporation. Occupational Physician
Jun OJIMA (chairperson)	National Institute of Occupational Safety and Health, JAPAN
Juji YABUTA	Kitasato University, Department of Health Science

*Listed in alphabet order.