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Short Communication

# The Quality Control Program for Industrial Hygiene Laboratories in Korea

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ABSTRACT

In 1992, the quality control program was introduced in Republic of Korea to improve the reliability of the work environment monitoring, which was introduced in the 1980s. The commission entrusted by the Ministry of Employment and Labor, the Occupational Safety and Health Research Institute has conducted the program for industrial hygiene laboratories including designated monitoring institutions and spontaneously participating agencies. The number of institutions that participated in the program has increased from 30 to 161. The initial conformance ratio in the participants was 43% (organic solvents) and 52% (metals). Thereafter, the conformance ratio increased rapidly and it has remained in a stable state at more than 89% since 1996. As subject materials, 13 kinds of organic solvents and 7 kinds of metals were used. To improve the capability of measurement and analysis of private institutions, educational courses were conducted annually. An assessment at the actual sites of participants was additionally introduced into the program in 2013. Thus, the program turned into a system that administrates the overall process of participants. For the future, the scope of target materials will be extended through additional items. Thus, the reliability of the results of the work environment monitoring is expected to increase accordingly.



## 1. Introduction

The concept of work environment monitoring (WEM) in Republic of Korea was initiated on the basis of the investigation of occupational diseases among coal miners in 1959, and thereafter, this measurement has been used spontaneously by private institutions [1]. Since then, along with the enactment of the Occupational Safety and Health Act in 1981, the enforcement decree (1982) and enforcement regulations (1983) were established. Thus, the measurement for the work environment found its legal ground [2–4]. In 1990, the Occupational Safety and Health Act was enacted wherein the provision specifying mandatory reporting of the results of the WEM to the Minister for Ministry of Employment and Labor (MoEL) was included. Furthermore, there were detailed stipulations that specified the number and method of measurements, the requirement to designate institutions dedicated for the measurement, and the procedure of designation (or cancellation) of such institutions [5].

However, during the mid and late 1980s, the incidents of intoxication by mercury and carbon disulfide and exposure to carcinogenic cokes oven emission occurred, and consequently, the reliability of the WEM became a social concern. To cope up with such problems, the quality control (QC) program was introduced in 1992, and thus, the institutions designated as those dedicated for the measurement of the work environment had to participate. From 1995, the institutions that intended to apply for an inclusion as a new one beyond existing institutions designated for WEM were obliged to make these applications with certified qualifications of QC program [6]. Thus, the QC program is the minimum legal ground to ensure the reliability and accuracy of the results of WEM.

The QC program was introduced in Republic of Korea by modifying the model of Industrial Hygiene Proficiency Analytical Testing Program developed in the United States of America. Since 2000, Occupational Safety and Health Research Institute (OSHRI) has been continuously conducting studies delving into the legal and institutional administration and technologies for technical application of the QC program [7–9].

Thus, this article was designed to introduce the QC program for industrial hygiene laboratories in Republic of Korea by reviewing

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the following. The data of past 25 years included the topics on the background of introduction, operation system, consequences of the implementation, and educational courses and directions for the future QC program.

## 2. Introduction and stages of development of the QC program

In 1987, the workers of Wonjin Rayon factory were intoxicated with carbon disulfide, and this triggered the introduction of the QC program for work environment measurement in Republic of Korea in 1992. For introduction of the program in Republic of Korea, the OSHRI started bibliographic examinations of overseas cases and conducted basic preliminary studies since October 1991 to develop detailed plans. Based on the plans, the guidelines and regulations for QC over working environment measurement were notified to the public. Thereafter, through analyses of samples and reviews of the Operational Committee, final assessment result of the first QC program was officially announced on July 25, 1992 [10,11].

When the first QC program was introduced, the degree of conformance was 43% and 52% for organic solvents and metals, respectively. With the introduction of QC, the conformance ratios for organic solvents and metals started improving gradually year by year and reached a level of approximately 90% commonly from 1996; it subsequently entered into the stage of stable consolidation. At the initial stage of the QC program, it focused on the competence of analysts. By accomplishing the analytical competence of analysts, it was found that the existing standards of QC program needed further modifications. The site assessment system was introduced in 2013 and was thus integrated into the QC program located in the stage of further improvement.

## 3. Operation of the QC program for WEM

### 3.1. Administrative Organization

The OSHRI was designated as an agency responsible for the QC program for WEM by the official notification of MoEL. There are two committees for the operation and practical execution of the program that run under the institute. The committee for practical execution consists of experienced analysts who are responsible for the establishment and detailed scheduling for the implementation, preparation of reference specimens, evaluation of the results, and actual implementation of decisions made by the operational committee. The committee for operation consists of the head of the OSHRI, four mandatory members, and six specialists; additionally, it is accountable for final determination of the concentration of sample, methods of preparation and evaluation of reference materials, providing feedback on final results, and education on QC.

The OSHRI joined the Proficiency Analytical Testing (PAT) program directed by the American Industrial Hygiene Association in 1992. Through this, the reliability of QC with respect to the agency is verified and its proficiency is maintained by participating in the quarterly PAT program over the four materials, such as organic solvents, metals, silica, and asbestos, every year.

### 3.2. Subjects of QC

Institutions that are responsible for the measurement of work environment are obliged to participate in the QC program. Otherwise, the institutions will be deemed as institutions showing inconformity. Non-profit-oriented university laboratories or other industrial hygiene research institutions are not obliged but are encouraged to participate in the QC program spontaneously.

### 3.3. Procedure

Types of QC program are divided into regular, occasional, spontaneous, and temporary types. Regular and spontaneous QC programs are carried out twice a year; therefore, the plans for each type of QC are notified 30 days in advance to receive respective applications during the period of 30 days. On completion of the period of application for the programs, the prepared samples are sent to each applicant within 2 weeks and the applicants are given an average period of 20 days to complete the analyses of the samples sent. The results of analyses reported by applicants are then aggregated and put into statistical analyses to determine the range of conformance. Thereafter, the results are forwarded to the two committees for operation and practical execution to finalize the conformance of the statistically analyzed results to be reported to the applicants who participated.

In the case of applicants who participated for the first time, a member of the committee of operation and one of the staff members of the OSHRI visited the new applicants and checked analyst responsible for participation and equipment used for the analyses. The occasional QC program was introduced from the site assessment system, and it is usually conducted on the occasion of expiry of the certified period due to unavoidable reasons such as the absence or retirement of analysts qualified in each institution. The temporary QC program is realized in the case of occurrence of civil petitions that resulted from or are related to inappropriate measurement of the work environment of respective institutions or in case where the need for temporary QC is determined by the operational committee.

### 3.4. Samples and range of conformance

The materials to be subjected are selected by considering materials frequently used in Republic of Korea and the subject materials in overseas countries. The materials for each session are determined by the operational committee. For the sample of organic solvents, a fixed amount of 1–3 kinds of organic solvents is injected into a charcoal tube and sealed. For the metal sample, a fixed amount of standard solution of 1–3 metals is injected on the mixed cellulose ester filter and dried thereafter. The samples are made in the concentrations of 10 stages. And 10% of samples selected randomly were analyzed. When the coefficient of variation thereof is less than 5%, the samples are used as QC samples. Among the samples, four samples are randomly selected in each field and are distributed to each institution.

At the initial implementation stage of the QC program, the reference values were mean values obtained by solely using the values analyzed in the standard laboratories. Thereafter, all of the values obtained from the standard laboratories and respective institutions were used to determine the reference values through the statistical test (Grubbs' test) conducted to exclude values of the outliers. For the range of conformance, the range of the reference value $\pm$ 3 times of the value of standard deviation thereof is normally taken. When the coefficient of variation of standard deviation is less than 3%, the value is adjusted to 3% to determine the range of conformance.

### 3.5. Judgment on conformance

When more than 75% of the analyzed values of samples fell in the range of conformance, it was judged to be commonly suitable for two kinds of subject materials, namely organic solvents and metals. The criterion was set in such a way so as to allow for non-hierarchical errors as far as possible within the extent avoiding the deviation from the range of conformance of samples due to

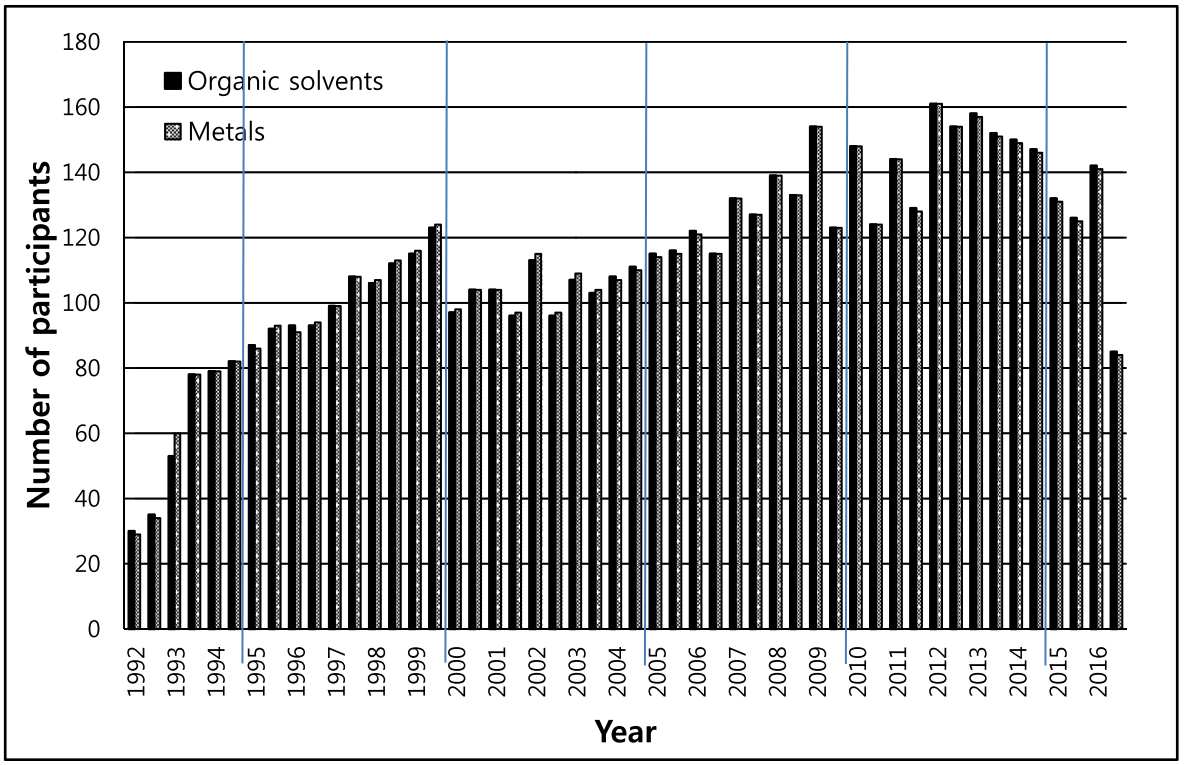


**Fig. 1.** Number of participants by enrolled field and year.

hierarchical errors, such as errors in preparation of standard solutions or errors ascribable to miscalculation of concentration [10].

At the initial implementation stage, the cases of Pass that satisfied the two fields were determined to be suitable in the comprehensive judgment. From 1994, the results of all QC program were collected annually. Among them, more than one judgment of conformance from each of the two fields was judged as a case of Pass. From the year 1995, more than one judgment of conformance from each of the two fields among recent consecutive participation in the QC program was considered as a case of Pass. In the case of new participants, joint conformance of the two fields at the session of QC program was mandatory to attain the judgment of Pass. When the institutions previously designated as institutions of the measurement of work environment failed from the comprehensive assessment, the institutions were obliged to take administrative measures, including business suspension up to 6 months.

In 1999, the provisions that specified exemption from participation in the QC program were newly stipulated based on which the institutions that attained consecutive judgment of conformance to standards for more than four times commonly from these two fields were allowed to avoid mandatory participation in the QC program. This enabled the subject institutions to participate in the program once a year generally [12].

### 3.6. Site assessment system

By improved modification of the QC program, the institutions of WEM were allowed to participate in the program once at an interval of 3 years since 2013. Thereby, the OSHRI and the operational committee visited the subject institutions to evaluate the state of existing equipment and devices used for analyses, the state of preparation for each analysis, and the competence of analysts therein. By which, the cases of institutions that attained a score of $>$ 75 points from a total of 100 points from the site evaluation were judged as the cases showing conformance.

The assessment item of the “competence of analysts” included the analysis of samples for which a score of 26 points was allocated thereto, and thus, failure to attain a score of 26 points in this category indicated failure to attain overall conformance of each institution irrespective of attainment of other score points. The institutions and analysts who participated and were approved by the judgment of conformance were authorized with certifications effective for 3 years. In case of expiry of each certificate owing to the absence or retirement of certified analysts, the corresponding institutions were obliged to participate in occasional QC program.

### 3.7. Results of implementation of QC program

From the first QC program initiated in 1992, the annual QC program has been maintained up to the 50$^{th}$ round carried out in 2016. In the first round, 30 institutions had participated. The number of participants increased rapidly to 78 in the round of the second half in 1993, and it continued to increase to 124 in the second half of 1999. With the introduction of exemption of institutions from mandatory participation, the number of institutions participating temporarily reduced to 98 in 2000; however, the number of institutions of WEM that participated in the QC program has been increasing gradually thereafter, and it reached up to 161 in 2012 (Fig. 1). As the site assessment system was applied from 2013 to 2016, the number of participants decreased.

The conformance ratios of organic solvents and metals were 43% and 52%, respectively, in the first half of 1992. However, in the second half of the year, the ratios increased rapidly to 77% and 82%, respectively. Also, during the interval from 1996 to 2016, the level of conformance of the two fields increased; currently, it is in the range of 89–99% (Fig. 2).

The compound and frequency of use of the materials to be subjected to the QC program are presented in Table 1. The subject materials of 10 kinds of organic solvents and 6 kinds of metals were used alternately until 2000. Along with the emerging social

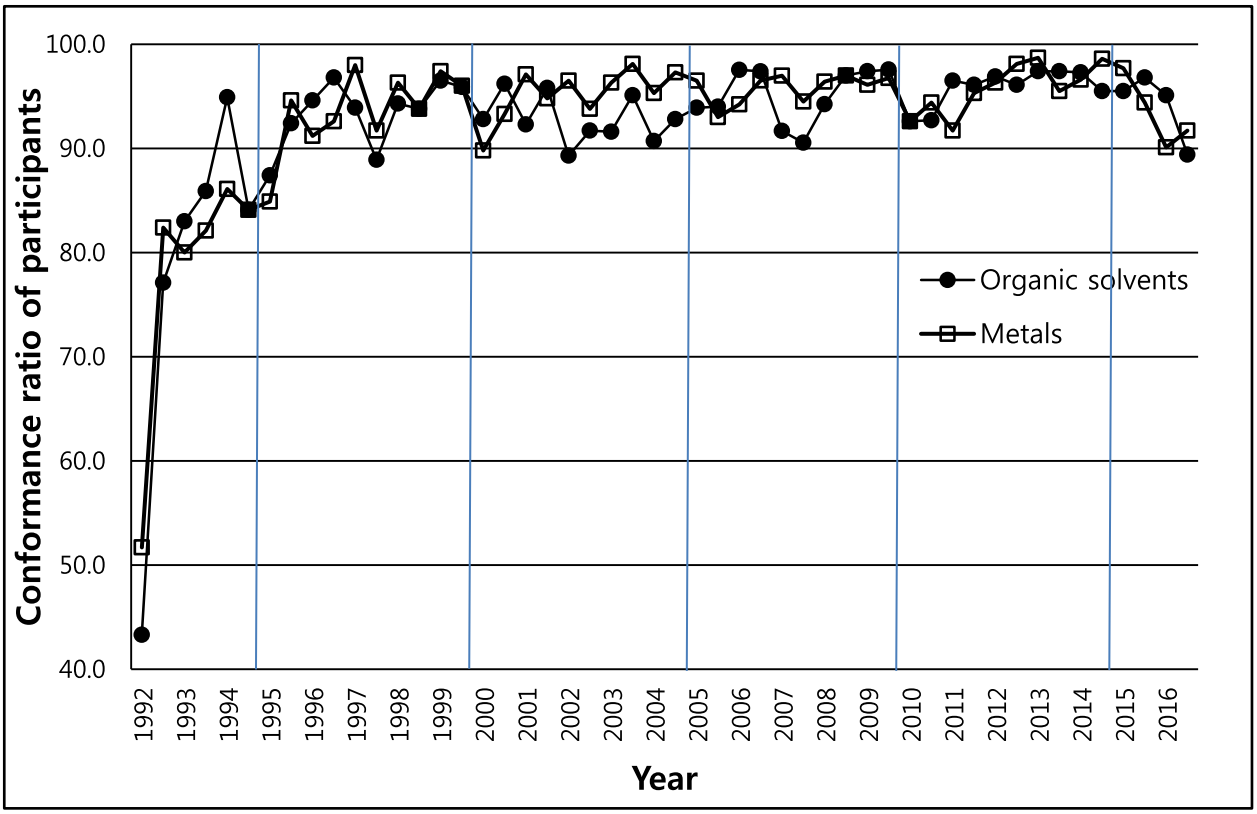


**Fig. 2.** Ratio of conformance by enrolled field and year.

requests, 2-methoxyethylacetate (2003), chloroform (2003), methyl ethyl ketone (2011), and nickel (2016) were added thereto, and thus, 13 kinds of organic solvents and 7 kinds of metals are currently used for the QC program (Table 1). In the initial stage of implementation of QC, 1–2 materials were employed for each field. Since 2005, three materials are being used for the samples. Among the materials of organic solvents, benzene (24 times) and toluene (24 times) were used most frequently, whereas cadmium (38 times) and lead (36 times) occupied the dominance of usage. 2-Methoxyethylacetate, which was introduced into the set of subject materials for the QC program by the socially emerged concern over cellusolves used in the ship building industry, was used once but became obsolete thereafter.

## 4. Education of QC program over WEM

The OSHRI provided education to the people who were in charge of measurement and analysis of work environment to raise the level of reliability of WEM.

Since 1992, institutions which newly participated in the QC program had to undergo an initial educational course within 6 months from participation, together with continuing subsequent supplementary education programs more than once every year. From the year 1998, the education programs prepared for three classes of institutions were provided wherein the A-class (satisfied 100% of the qualification standards of both fields) were exempted from the supplementary education programs for 1 year. The B-class (satisfied $>$ 75% but $<$ 100%) were supposed to take the annual supplementary education program, whereas the C-class (satisfied any of the two fields by $<$ 75%) had to take special practical training courses as well as the annual supplementary education program. For institutions that newly participated in the QC program, basic educational courses were provided. Since then, the institutions were obliged to participate in the education on QC program until 2000, and thereafter, education was changed to the spontaneously selected courses. The educational courses of spontaneous participation of institutions have been continued once or twice every year from 2001 to 2016, wherein the courses on the directions of industrial hygiene policies, measurement methods, and improvement of working environment are included.

Besides, the OSHRI had provided the institutions, which were judged to be incompatible, or the 4–8 institutions, which requested for help regarding the education on pretreatment of samples prepared for QC program and analytic methods thereof, with the actual appropriate site-support by visiting each site. The OSHRI had provided the institutions with the Basic Courses for Analysts from 2007 to 2009, and thus, 76 new analysts took the courses configured with 12 sessions that lasted for 3 years. The curricula were prepared for the basic courses for practical analyses.

## 5. Suggestions on the development of the QC program

The MoEL in Republic of Korea has established and implemented diverse policies to raise the reliability of WEM by introducing the Assessment of Reliability of WEM (2007) and System of Assessment of the Designated Monitoring Institutions (2012) as well as by regular supervision over the institutions designated for WEM. The QC program over WEM is the basic institutional system relevant to working environment measurement that has been stably maintained for a long time.

As shown by the conformance ratio of institutions for WEM that participated in the initial QC program thereon during the stage of its introduction, the program has contributed to the enhancement of analytic competence of analysts working in respective

**Table 1**
Compound and frequency of used subject materials (1992–2016)

| Organic solvents | Metals |
|---|---|
| Benzene(24), Toluene(24), o-Xylene(18), Trichloroethylene(15), n-Hexane(12), Perchloroethylene(8), Isopropylalcohol(7), Chloroform(6), Ethylacetate(6), Methylisobutylketone(6), n-Butylacetate(5), Methylethylketone(2), 2-Methoxyethylacetate(1) | Cadmium(38), Lead(36), Chromium(25), Zinc(15), Manganese(14), Copper(2), Nickel(2) |

institutions. The Site Assessment System which was introduced in 2013 also contributed to the improvement in systematic administration of overall systems for work environment measurement of the designated institutions as well as to enhancement of analytic competence of analysts by checking and examination of working environment measurement systems comprising the analytic facilities and equipment, procedures, and maintenance practices. In Republic of Korea, currently there are about 170 institutions designated for WEM, and recently, the number of institutions has increased by 5–10 annually. Contrary to cases of the institutions in overseas countries, the institutions designated for WEM in Republic of Korea are obliged to participate in the QC program.

There are opinions suggesting that the scope of QC program should be expanded to the sampling process in workplaces. However, expansion of the scope of QC program needs to fulfill the prerequisites. The point of necessity of introduction of a certification system to authorize the institutions has been raised continuously, and thus, the request is partially reflected in the current site assessment system.

As the current work environment measurement systems in institutions are seemingly stabilized, efforts of the OSHRI will focus on the assessment and enhancement of analytical competence of analysts. Further, the fields of spontaneous control which are to be introduced will accompany additional designations of measurement equipment beyond the existing ones designated by the current requirements that were established for the designation of existing institutions for working environment measurement systems.

There are suggestions for the introduction of commercial entrusted institutions to perform professional analyses of samples for respective working environment measurement. These suggestions also show that the QC program for the entrusted institution shall be administered more strictly than the existing QC program. Therefore, additional discussions on the introduction of a commercial entrusted institution seem necessary to reach a consensus based on social agreement.

Nevertheless, the OSHRI needs to devote its efforts to the enhancement of reliability of WEM, accuracy and precision of analyses thereon, and improvement of the program as an institution dedicated for the QC program of WEM in Republic of Korea.

## Conflicts of interest

All authors have no conflicts of interest to declare.

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