

An Integrated Occupational Health Consultation Model for the Medical Supply Manufacturing Industry

Yi-Kuei LIN^{1*}, Lien-Hsiung LEE¹ and Shey-Huei SHEU¹

¹Department of Industrial Management, National Taiwan University of Science and Technology, No.43, Sec.4, Keelung Rd., Taipei, 106, Taiwan, R.O.C.

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Abstract: In this research, we designed a three-stage consultation procedure and eight major consultation items in order to construct an integrated occupational health consultation model that emphasizes both inspection and consultation. The main characteristics of the proposed model include cooperation among governmental departments, combining non-governmental professional consulting organizations, and establishing partnerships with industrial associations. This model has clear active and passive performance indicators and includes technical guidance during consultation as well as the exit mechanism after consultation. This consultation model enables small- and medium-sized enterprises to achieve environmental improvements with minimum investment. Companies that improved after consultation have a mean ethylene oxide exposure concentration, for the time weighted average, that dropped from 7.36 ± 16.88 ppm to 0.76 ± 1.35 ppm ($p < 0.01$). In addition, the overall company compliant item ratio for regulations increased from 34.1% to 89.7%. The above results demonstrate the integrated occupational health consultation model assists small- and medium-sized enterprises in reducing exposure concentrations at operational sites. Our results further demonstrate the feasibility of successfully implementing the proposed consultation model within Taiwan's medical supply manufacturing industry.

Key words: Environmental monitoring, Consultation team, Industry association, Ethylene oxide, Manufacturing industry

Introduction

Ethylene oxide (EO) is commonly utilized in sterilizing medical devices and instruments (especially plastic materials) that are sensitive to high temperatures and high humidity levels¹. Sterilization with EO is used mainly in large-scale medical organizations and the disposable medical supply manufacturing industry. During low temperature gas sterilization, operating staff must open the sterilizer and remove the medical products in order to perform subsequent aeration or storage. Consequently, technicians and storage personnel have a high probability of contacting residual EO emis-

sions from the sterilized products, causing occupational exposure². The International Agency for Research on Cancer (IARC) has classified EO as a human carcinogen. The Institute of Occupational Safety and Health (IOSH) conducted an EO exposure survey on employees at eleven large-scale medical supply manufacturers in 2000³. Measurements were taken after medical instruments were removed from the sterilization chamber, after being sterilized. The average concentration for short time exposure to EO among personnel was 31.79 ± 50.88 ppm, while the highest concentration reached 136 ppm, i.e., 15–65 times higher than the 2 ppm permissible exposure limit-short term exposure limit (PEL-STEL). Additionally, 76.6% of the area samples exceeded the 1 ppm permissible exposure limit-time weighted average (PEL-TWA), with the highest

*To whom correspondence should be addressed.
E-mail: yklin@mail.ntust.edu.tw

concentration for EO time weighted average exposure in the air found to exceeded 42 ppm. In that study, the average number of workers in a medical supply manufacturing firm was 46. Thus, most companies in this field can be characterized as small- and medium-sized enterprises (SMEs), which have neither adequate technical staff nor budget to improve their working environments. These findings underscore the necessity for the medical supply manufacturing industry to reduce EO exposure concentration in the workplace.

In November, 1994, Taiwan implemented the Occupational Safety and Health Management System, which was based on the Voluntary Protection Program (VPP) from the Occupational Safety and Health Administration (OSHA), in the United States. To enable companies to become self-regulating, the government implemented an occupational health consultation model. As of 2005, 936 companies had been consulted and obtained the self-regulation entity label, with large businesses accounting for 77.9% and SMEs accounting for 22.1%. SMEs had a relatively lower passing rate owing to the following reasons: (1) insufficient funding to purchase equipment and the inability to improve the working environment in a timely manner; (2) lack of engineering improvement methods, fear of failure after attempted improvements, and the inability to comply with regulatory standards; (3) a dependency on part-time staff to manage efforts, most companies outsourced environmental monitoring and physical examinations to non-governmental consulting firms, which prevents internal learning and mentoring of occupational health management experiences; and (4) absence of a plan-do-check-action (P-D-C-A) management cycle, making it impossible to fulfill self-regulation requirements. Within the occupational health sector, SMEs generally lack human resources and/or equipment to comply with regulations⁴⁾, explaining why many industrialized countries are striving to assist SMEs to prioritize health-related problems. For instance, in 1998, OSHA⁵⁾, in the United States, implemented the Strategic Partnership Program (OSPP) consultation model for SMEs whose occupational health performances did not reach acceptable standards. Additionally, OSHA formed partnerships with SMEs to improve occupational health conditions collaboratively. Governmental departments and consulting firms were largely in charge of stipulating performance indicators and inspection results. SMEs seeking various improvements contacted occupational health professional consulting firms. The Japanese government established the Dandelion consultation model⁶⁾ in 1999 as a supporting tool to assist safety and health activities of SMEs. Under the auspices of the Japanese Ministry of Health, Labor and Welfare, such a model offers guid-

ance to SMEs registered as manufacturers. Consultation content included the items that SMEs specifically applied for. Additionally, a consulting team was established for each SME, in order to carry out professional guidance and suggestions.

In Taiwan, a small- and medium-sized enterprise refers to a legal entity with capital revenues less than NT\$80 million and fewer than 200 employees. According to the Small and Medium Enterprise Administration of the Taiwan Ministry of Economic Affairs, SMEs accounted for 97.6% of all Taiwan businesses in 2007 and for 77.1% of all employed workers. The 2007 Annual Statistical Labor Report indicated that 284,000 enterprises and 5,160,000 workers fell under the Labor Safety and Health Laws. However, the Labor Inspection Offices (LIO) employed only 309 labor inspectors to handle all business safety and health inspections. Given a limited expansion of labor inspection personnel, the annual inspection rate of business was only around 10%⁷⁾, i.e., ineffective in improving occupational health. To resolve this problem, the government attempted to modify the implementation model to include occupational health consultation through third-party non-governmental sources. Under such an approach, selected non-government professional consulting organizations would perform inspections and make improvements. Moreover, the government collaborated with the human resources divisions of industrial associations to follow up on inspections and offer network platform services to affiliated members. Based on observations of this approach, the current study presents an innovative integrated occupational health consultation model that emphasizes inspection and consultation. Validity of the proposed model is demonstrated by using the Taiwan medical supply manufacturing industry as an illustrative example.

Methods

Consultation model

The integrated occupational health consultation team (Fig. 1) comprises the following three governmental departments and two other institutions. First, IOSH is the only governmental organization charged with occupational safety and health research. Using scientific techniques, hazardous factors in working environments are investigated and analyzed, and strategies for protecting the safety and health of workers are recommended. Second, LIO helps enterprises establish an occupational safety and health management mechanism to supervise the implementation of labor safety and health inspections and to prevent occupational injuries and disease. Third, the Industrial Development Bureau (IDB) is

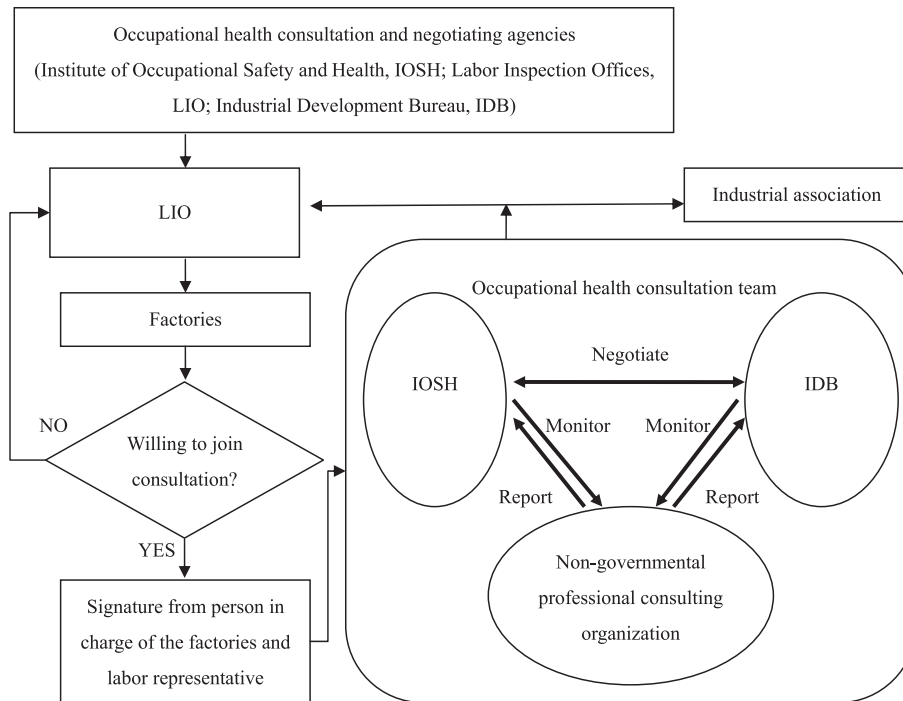


Fig. 1. Members of the integrative occupational health consultation team.

charged with the general industrial development of the nation, assisting industries to improve their work environments. Additional participants include non-governmental professional consultants from non-profit occupational health organizations. Industrial associations establish partnerships with the government and become the communication platforms of governmental departments and their affiliated members. Within governmental departments, the integrated occupational health consultation model emphasizes cross-departmental cooperation; IOSH holds one working group meeting per quarter in every fiscal year. On the other hand, LIO performs a medical supply manufacturing industry inspection while IDB provides low interest rate loans to companies who require large funds for necessary improvements. Non-governmental professional consulting organizations, whose members consist of retired occupational health inspectors, scholars from universities' occupational health departments, and professionals who possess engineering backgrounds, coach businesses to establish self-regulation systems and provide concrete and feasible improvement tactics. In Taiwan, the president of an industrial association is normally head of the leading enterprise of the industry. Therefore, the leading enterprise combined with the medical supply manufacturing industry and its members hold a demonstration workshop to increase firms' technical application skills through demonstrations and exercises. The current research's integrated occupational health consultation

model used SMEs as the consultation objects to assist SMEs in improving on-site occupational health standards.

The integrated occupational health consultation model adopted SMEs as the consultation objects to assist SMEs in resolving on-site occupational health problems. Based on the data from LIO and IDB, the register of Taiwan's medical supply manufacturing sector contained 345 companies. Among them, 117 joined the industrial association. The sterilization operations medical-supply manufacturing sector was selected to demonstrate the feasibility of this model. Owing to the large number of companies, this work presents a novel three-stage consultation procedure, utilizing consultation resources efficiently (Fig. 2). The first stage focuses mainly on the integrated occupational health consultation team. The focus is on establishing appropriate improvement strategies to deal with harmful characteristics of the medical supply manufacturing industry, within the relevant occupational health area. Firms are also coached in how to comply with regulatory standards. The second stage exposes companies to established methods while specifying proper adjustments and modifications for improvement strategies, producing various instruments, methods, and concrete knowledge content output from all results. Meanwhile, an effective partnership with the industry association is established. The third stage includes two major tasks. The first task is effective tracking, checking and following up periodically on the

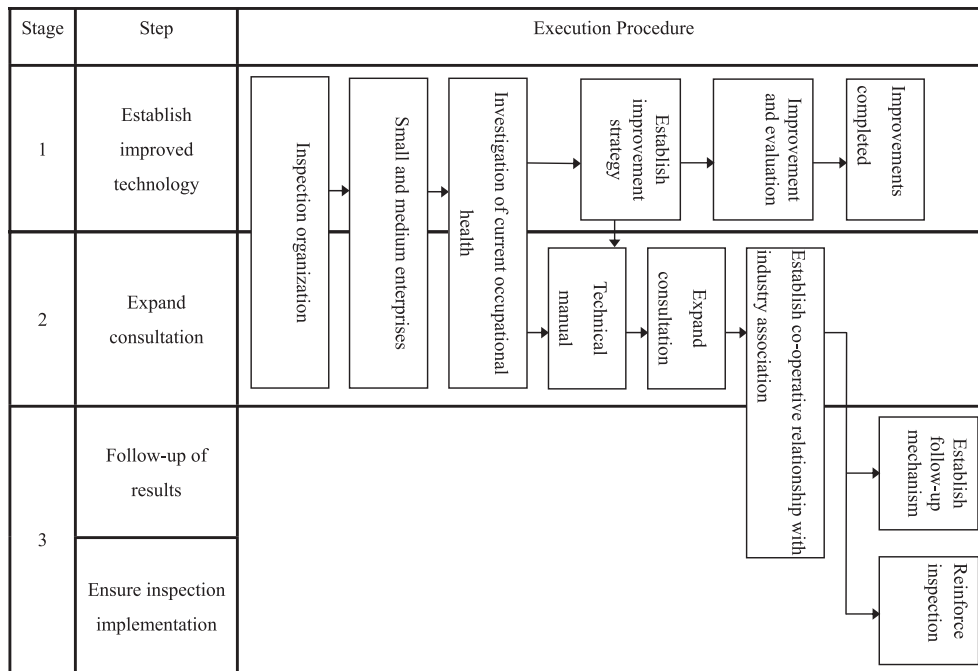


Fig. 2. The three stages of the occupational health consultation process.

companies who receive consultation and make improvements. The goal is to help companies become self-regulated and perform sound occupational health practices. The second task is inspection fulfillment; LIO reinforces inspection for companies who have not sought consultations or are unwilling to improve their practices and can not reach regulatory standards. In addition to providing specific and feasible improvement tactics, based on each company's circumstance, the consultation team establishes core procedures to enhance engineering and administrative management practices. This approach ultimately enables SMEs to improve their working environments with minimum investment, free of consultation fees. Moreover, implementing the integrated occupational health consultation model improves the ability to agglomerate professional skills for employees within the firms.

To comply with Taiwan's Labor Safety and Health Law regulations, occupational health consultations include the following eight major items: setup and operation of a ventilation system, execution of a work environmental monitoring system, management of personal protective equipment, improvement of a factory's overall hygiene, implementation of worker education and training, management of physical examinations, a general hazard communication program, and establishment of a self-regulation system. In line with the current occupational health standards, from the medical supply manufacturing industry's EO sterilization specifications, this study stipulated active and passive performance indica-

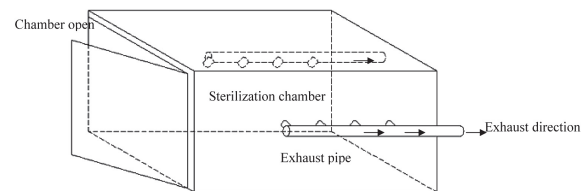


Fig. 3. Sterilization chamber's additional exhaust.

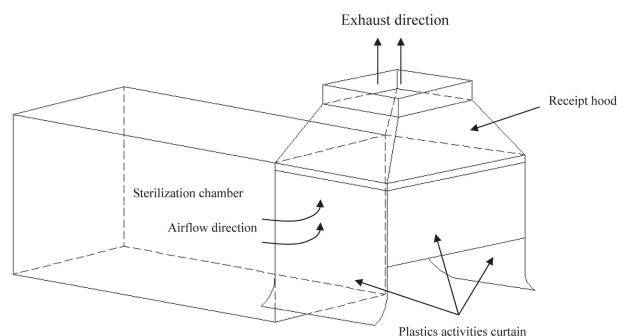


Fig. 4. Sterilization chamber's additional external local exhaust device.

tors. For ventilation schemes, this study added exhaust pipes to the sterilization chamber (Fig. 3), added a local exhaust device to the outside of the sterilization chamber (Fig. 4), and strengthened the airtight/ventilation design of the temporary storage area (Fig. 5). Relevant consultation aspects of administrative management include the following: (1) environmental monitoring, i.e., drafting the environmental monitoring plan and analyz-

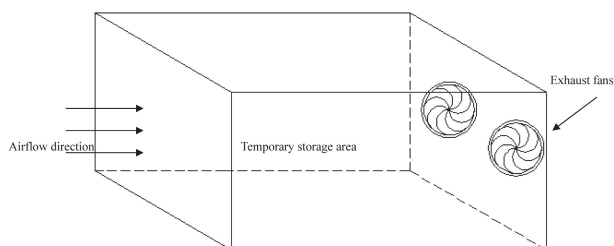


Fig. 5. Temporary storage area's strengthened airtight/ventilation design.

ing and resulting reports, (2) protective equipment, i.e., planning personal protective equipment management and correct usage of protective equipment, (3) overall factory hygiene, i.e., promoting 5S activities—“seiri (arrangement)”, “seiton (orderliness)”, “seiketsu (standardization)”, “seiso (cleanliness)”, “shitsuke (discipline)”, (4) education and training, i.e., compiling interactive digital teaching materials and performing worker training, (5) physical examinations, i.e., indicating government designated physical examination hospitals, and analyzing and retaining physical examination results, (6) hazard communication, i.e., promoting the Globally Harmonized System (GHS) of classification and labeling of chemicals to ensure that chemical management conforms to international standards, and (7) self-regulation, i.e., establishing all available self checking forms and specifying a standard operation procedure.

Assessment indicators

One of the major goals of the consultation was to decrease exposure concentrations within the working environment. Thus, the reduction of exposure concentration was set as the passive indicator for the program. Environmental sampling was performed both prior to and after consultation. The data was then analyzed. The EO's analysis method adopted OSHA No. 5020 and NIOSH No. 16146⁸⁾ standard methods. The data was first input into Excel 4.0 and then transferred to SPSS 12.0 for further statistical analysis. An independent *t*-test was then performed to determine if the differences were statistically significant.

Active indicators included the percentage of compliance with the Labor Safety and Health Laws, labeling rate of hazardous materials, conforming rate of hazard perceptions, rate of correct usage of personal protective equipment, rate of proper maintenance of personal protective equipment, number of companies with improvement tactics, number of factories establishing a self-regulation system, number of workers receiving training, and number of companies who implement monitoring.

Environmental monitoring

When consultation was initiated, workers' EO exposure concentration in related working areas was monitored. Environmental monitoring included personal sampling and area sampling. Personal samples were collected around the worker's breathing zone while area sampling was collected at different positions, which were 150 cm above the possible exposure range. Two personal samples were collected from operational staff who worked in sterilization chambers: short term time (around 15 min) and time weighted average (6 h or more). EO in the air was collected through a sampling pump (Model LFS 133DC, Gilian Corp., USA) combined with a hydrogen bromide coated (HBr) active carbon tube (No. 226-38-03, SKC, USA). The sampling rate was 50–200 ml/min. Sampling time was set from 15 min to 6 h, depending on the specific sampling method, to achieve an optimum analytical sensitivity. Following sampling, all samples were sent to accredited laboratories for analysis to ensure data accuracy. Finally, samples were analyzed using a Gas Chromatography/Mass Spectrometer (GC/MS).

Results

Table 1 summarizes the assessment results, indicating that workers were exposed to a high level EO concentration when engaging in medical-supply sterilization before control (2005/07). Specifically, the mean time weighted average exposure concentration was 6.38 ± 9.10 ppm, i.e., six times higher than the 1 ppm PEL-TWA. As is generally observed, sterilization chamber operational staff and workers near the aeration area were potentially exposed to a high level concentration of EO. During the opening of the sterilization chamber, or unloading after sterilization, the average short time exposure concentration was 21.00 ± 28.44 ppm, ten times higher than the 2 ppm PEL-STEL. Additionally, area sampling results revealed a high concentration of EO exposure. EO concentration in the aeration area and around the sterilization chamber was 12.07 ± 12.75 and 10.86 ± 25.56 ppm, respectively. All measures significantly exceeded the current 1 ppm PEL-TWA.

During the consultation period, companies adopted ventilation engineering methods and administrative management practices to improve the workplace environment. Consequently, according to the assessment results (Table 1), average reductions of 81 to 91% occurred in each area after the improvement. EO concentration in the sterilizer area decreased 91.2% (from 10.86 ± 25.56 down to 0.96 ± 1.36 ppm), exhibiting the largest reduction. The second largest reduction was in the finished goods storage area with a 91.1% (from

Table 1. EO exposure before and after implementation of control measures

Exposure sampling	2000/07 (ppm) before control	2005/07 (ppm) before control	2005/11 (ppm) after control	2006/09 (ppm) after control	2007/07 (ppm) after control	Concentration improvement ^a (reduction%) ^b
Personal sampling						
Short term	31.79 ± 50.88 ^c (n=23)	21.00 ± 28.44 (n=12)	15.09 ± 24.33 (n=13)	7.95 ± 13.50 (n=18)	4.11 ± 6.37 (n=27)	16.89 (80.4%)
Time weighted average	12.99 ± 23.11 (n=23)	6.38 ± 9.10 (n=12)	3.05 ± 2.89 (n=9)	3.08 ± 5.85 (n=12)	0.87 ± 1.20 (n=11)	5.51 (86.4%)
Area sampling						
Sterilizer area	7.65 ± 12.07 (n=94)	7.36 ± 16.88 (n=77)	2.18 ± 3.07 (n=79)	2.22 ± 5.96 (n=77)	0.76 ± 1.35 (n=86)	6.60 (89.7%)
Aeration area	3.20 ± 3.18 (n=11)	10.86 ± 25.56 (n=25)	2.77 ± 3.65 (n=28)	2.51 ± 6.19 (n=24)	0.96 ± 1.36 (n=33)	9.90 (91.2%)
Storage area	8.44 ± 12.07 (n=81)	12.07 ± 12.75 (n=14)	4.14 ± 3.55 (n=11)	5.19 ± 9.17 (n=17)	2.05 ± 2.19 (n=10)	10.02 (83.0%)
Office area	–	3.92 ± 6.63 (n=31)	1.39 ± 2.18 (n=32)	0.86 ± 3.00 (n=26)	0.35 ± 0.88 (n=35)	3.57 (91.1%)
	0.14 ± 0.04 (n=2)	0.64 ± 1.14 (n=7)	0.54 ± 1.06 (n=8)	0.04 ± 0.07 (n=10)	0.12 ± 0.17 (n=8)	0.52 (81.3%)

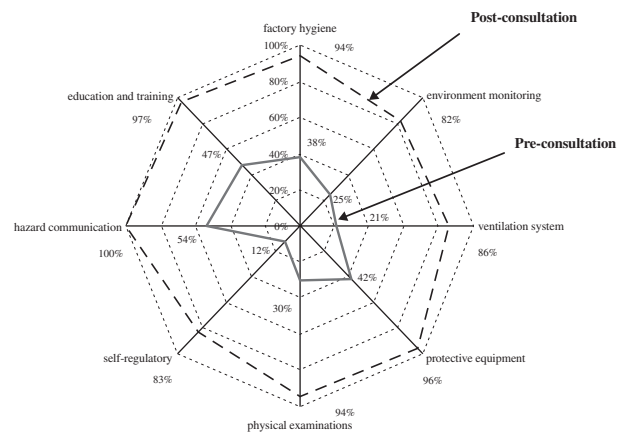
^aConcentration improvement = average concentration in July 2007 after improvement – average concentration in July 2005 before improvement.

^bPercentage reduction = [(average concentration in July 2007 after improvement – average concentration in July 2005 before improvement) / average concentration in July 2005 before improvement] × 100%.

^cMean ± SD (ppm), SD: standard deviation.

3.92 ± 6.63 to 0.35 ± 0.88 ppm) reduction on the average. Enhancement tactics, increasing the number of air washing procedures after sterilization and improving ventilation at the product temporary storage area and finished goods storage area, were proved to be a highly effective tactic for reducing concentrations.

Occupational health consultation teams provided the medical supply manufacturing industry the following consultations: In relation to cognition, the model gave common sense training related to risk and compiled interactive digital teaching materials. In the context of assessment, we developed software that analyzed the combined database related to workplace environmental monitoring and physical examinations; through the software's statistics and analysis, we can gain a better understanding of workplace exposure and labor health trends. Related to control, the model developed a technical handbook for engineering improvement of the ventilation systems and also created self-assessment software for occupational health management, within the medical supply manufacturing industry, which company managers can utilize in the form of a checklist. The list, generated by the software, can be used to diagnose the extent of legal compliance, and understand the current occupational health of the company. In order to achieve SMEs self-regulation, the model actually coached enterprises to perform P-D-C-A management cycles, which improved the overall yearly workplace EO time weighted average exposure concentration average to: 6.38 ± 9.10, 3.08 ± 5.85 and 0.87 ± 1.20 ppm,

**Fig. 6.** Pre and post consultation occupational health regulation conformance.

respectively, ultimately displaying an annual downward trend. These results support the overall effectiveness of the consultation approach.

The consultation team operated from the base of established active and passive indicators and adopted standards that were in line with or exceeded regulatory standards. This approach improved compliance with regulations from 34.1% in 2005 to 89.7% in 2007. Most of companies that received consultation conformed to the occupational health regulations (Fig. 6). According to radar graph analysis, eight major consultation items complied with regulatory standards, with an average above 80%. Among them, effects of hazard

communication (compliance rate of 100%), education and training (compliance rate of 97%), and personal protective equipment (compliance rate of 96%) were significant.

In addition to helping the staff of every enterprise implement occupational health education and training, the consultation model designed digital teaching materials. The model used lively and vivid content to compile a hazard prevention handbook. Tests were administered before and after the training classes for risk recognition; test samples totaled 206. Results indicated that risk recognition scores increased from 62 ± 23.2 (full score was 100), before the training class, to 84 ± 8.0 . A paired *t*-test revealed a statistically significant difference ($p < 0.05$).

Discussion

Improvement of administrative controls

Following on from the consultations, an effort was made to increase visibility of the process and the results. Results of consultations were announced at the annual meeting of the industrial association. A "Hazard Protection against Ethylene Oxide" section was set up on the industrial association's website to provide occupational health information on EO sterilization and strategies for improvement. Expanding the consultation work, the model was introduced to industrial associations, which involved inviting employers, the industrial association's staff, academic groups and other interested parties. Additionally, the consultation team invited example company representatives to share their experiences, serving as a valuable reference for other companies.

Occupational health is a long-term effort. The consultation schedule normally lasts three years. To maintain positive results and avoid a reoccurrence of workplace exposure, e.g., a relapse, this consultation model established a partnership with the industrial association during the second stage. The partnership jointly assists companies in improving workplace practices in order to comply with regulations. The proposed model also offered its established knowledgebase, such as consultation tools and technical handbooks, to the staff of the industrial association. During the third stage, the model covered follow-up inspection procedures. Doing so enabled the industrial association to further serve its members through continuously following up. Companies thus were supported in continuously developing and improving their self-regulation practices long after the consultation team had departed.

Worker exposure controls

Many studies have examined the feasibility of using a local exhaust device near the door of the sterilization chamber, capable of reducing worker exposure during unloading⁹⁻¹²). Developing good localized ventilation measures can partially resolve these inadequate conditions. Elliott *et al.*¹³) verified that effective engineering control could reduce the worker's EO time weighted average exposure concentration when performing a sterilization task. The current study found that two factories had installed inappropriate exhaust systems at either top or bottom positions, while many had applied windows' embedded exhaust fans to drive the air outwards in order to achieve better air exchange. The latter has been shown to effectively reduce EO concentration. It is worth noting that the exposure time is too long if the worker must enter the sterilization chamber to move the sterilized products out one by one. Therefore, designing a pallet to load and unload the goods or using an auxiliary tool, e.g., a trolley or a forklift, can significantly reduce worker exposure time.

Major EO exposures occur when opening the sterilization chamber, delivering the newly sterilized products, performing subsequent aeration, and storing. As the aeration/storage area is normally not clearly demarcated from other regions and independent ventilation systems are generally lacking, EO emitted from sterilized goods disseminates to other workplaces. This subsequently exposes other workers to EO. Additionally, owing to production speed demands and operating cost considerations, along with limited space, stand-alone aeration areas can not be set up. This results in another source of exposure to EO, increasing the frequency of workers' EO exposure to an amount significantly higher than PEL-TWA. Therefore, improvement, in such areas must be a priority. Hospitals should carefully implement sterilization control measures¹⁴⁻¹⁷). Differences arise between aerating and transporting operations that cause different exposure traits, necessitating various control requirements.

Other findings

Incentives are indispensable to ensure the smooth implementation of the integrated occupational health consultation model. During consultation, although LIO did not inspect companies for a certain period, those companies were required to devise a drawback improvement strategy and submit it to LIO. The model also assisted companies in applying for waste reduction incentives and low interest rate loans to improve the workplace environment; free consultation was also provided for occupational health issues. Additionally, the model nominated companies that had satisfactory

improvement results for the annual safety and health performance award. Furthermore, in addition to providing free analytical software that integrated an environmental monitoring database and physical examination database, the model also provided self-assessment software to assess occupational health management performance in these firms. In the current study, 60 companies received consultation, 179 companies participated in demonstrations and exhibition workshops, 16 companies applied for IDB low interest rate loans, and two companies received waste reduction rewards.

Characteristics of the integrated occupational health consultation model include the ability to collaborate mutually within governmental departments, interface with non-governmental resources of third parties, and establish partnerships with industrial associations. Moreover, this model established technical guidance during consultation and included an exit mechanism after consultation. Finally, after consultation, the industrial association continuously followed up to help firms with their self-regulation measures. This model is considered more comprehensive than similar models used in Japan and the United States, and can help inspection offices reduce manpower involved in labor inspections, leading to a more flexible inspection workforce.

Conclusion

The integrated occupational health consultation model is based on a concept that is similar to that of the Japanese occupational health service center. Both provide suggestions for improvement to SMEs and achieve improvement in the workplace environment through third-party support. This concept provides a significant contribution to the occupational health of SMEs¹⁸. This study introduces a practical collaboration model for the cooperation between government departments, non-governmental, professional consulting organizations and industrial associations. The consultation model used includes a three-staged consultation process with eight major consultation items. Incentives are indispensable to ensure the smooth implementation of the integrated occupational health consultation model. This approach was applied to the medical supply manufacturing industry that uses EO for sterilization; those results were satisfactory. The proposed model is beneficial to both governmental authorities and business professionals, while also providing a valuable reference for other countries attempting to improve their occupational health practices in the workplace.

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