INTRODUCTION

Although a known human carcinogen with various health effects, ethylene oxide (EO) is used extensively in hospitals to sterilize re-usable medical devices such as endotracheal tubes, and in the medical-supply industry to sterilize disposable products such as plastic syringes that are heat or radiation sensitive [1–12].

Workers at factories manufacturing medical supplies, and particularly sterilization system operators and stock workers, are exposed to high levels of EO [13]. Sterilization operators, who are considered to have the highest exposure, had mean short-term (~15 min) exposure of 20–30 ppm when opening the sterilizer door during un-loading, while their mean time-weighted average work-shift (8 hr) exposure level was nearly 10 ppm. Furthermore, area monitoring revealed high EO concentrations throughout the facilities. Specifically, mean EO concentrations in the aeration area, near the sterilizer and in the warehouse were approximately 10, 6 and 9 ppm, respectively. Each value markedly exceeds the current Taiwan work-shift permissible exposure limit (PEL-TWA) of 1 ppm or short-term exposure limit (PEL-STEL) of 2 ppm [14]. Consequently effective methods must be found to reduce worker exposure.

Previous studies have demonstrated that plastics absorb EO during sterilization and release it during subsequent aeration [15–21] and considerable time is required for sterilized products to fully release the EO residual [22]. Residual EO off-gassed both in the sterilizer and during subsequent aeration/storage were the two main exposure sources for workers [13]. Control measures should thus focus on minimizing residual EO emissions. Increasing the number of post-sterilization purge cycles offers a simple means of reducing residual EO levels and eliminating extremely high short-term exposure while unloading sterilized goods. However, cycle-purging is not adequately implemented since it is relatively time consuming. Moreover, respiratory protection such as airline respirator is rarely adopted. Consequently, other control measures, particularly engineering modifications, should be considered.

This study, which was part of an on-site consulting program aiming to minimize EO-related health risks, attempted to provide practical engineering designs and parameters for reducing air EO concentrations and worker exposures in sterilization operations. The effectiveness of these control measures was evaluated.
through comparing worker EO exposure concentrations before and after control implementation.

METHODS

Overview of the Sterilization Process

The sterilization process is described in detail elsewhere [13]. Briefly, products are typically manufactured on-site, packaged individually in special paper-backed polyethylene bags, then packed in cardboard cartons. After logging the products were loaded into the sterilizer. Sterilization takes 3–8 hr, including chamber pre-conditioning, filling with EO, sterilization and in-chamber purge cycles (to reduce residual EO). Three types of EO gases—100% EO (single-use cartridge), 90% EO with 10% CO2 in a cylinder, and 20% EO with 80% CO2 in a cylinder—were used depending on sterilizer type. Sterilization frequency varied, from one load every few days in small factories with one sterilizer to ~10 loads daily in factories with multiple sterilizers.

Following sterilization, some operators unloaded the sterilized products shortly after the completion of the process, whereas others left the loads in the sterilizers overnight for convenience and unloaded the next morning. Before unloading, some operators fully opened the sterilizer door and ventilated the chamber with large floor fans for ~10 min. The sterilized loads were then transferred, by cart or by hand, to temporary storage areas (usually next to the sterilizers), where they were aerated and the biological indicators (BI) removed for additional quality assurance testing. When the results of BI met the quality criteria, the sterilized products were sent to warehouses or shipped.

Principles of Control

Residual EO emitted during un-loading and subsequent storage was the main exposure source for workers [13]. Therefore three designs that potentially reduce exposures in these operations were proposed.

1. Improvement of sterilizer venting function—to reduce EO off-gassing inside sterilizer before unloading. This could be achieved by adding a set of venting duct/pump to the sterilizer that is independent of the normal sterilizer operations. Sterilizers in most factories generally have small-sized vacuum ducts (for after-sterilization purging cycles) and cannot promptly remove EO off-gassed within the sterilizer chamber, potentially leading to high worker exposure during unloading.

2. Improvement of local ventilation near the sterilizer door—to promptly reduce EO off-gassed from product cartons and thus minimize worker exposure during un-loading. Such improvement represents an alternative means of reducing worker short-term exposure for factories that are unable to modify their sterilizers.

3. Enclosure and venting of the aeration area—to provide sufficient ventilation and limit fugitive EO emissions during aeration. It is known that sterilized products continue to emit EO for days, even after purge cycles, causing contamination in the air. Such contamination is particularly severe in storage areas with stagnant ventilation, a common phenomenon in this industry.

Assessment of Worker Exposure and Effectiveness of Controls

The sampling and analysis protocol was detailed previously [13]. In short, two types of air sample, including personal and area, were taken to assess worker exposure to EO, and to assess the effectiveness of the control measures. Personal samples were collected, usually over 15-min periods, near the breathing zones of sterilizer operators, who potentially had high EO exposure while unloading sterilized products. Area samples were collected at locations potentially contaminated with EO, at heights of ~150 cm.

Airborne EO was collected with an HBr-coated charcoal tube connected to a portable sampling pump. Sampling rates varied, from 50 to 200ml/min, based on a pre-determined sampling time of ~15min to 6hr, to optimize analytical sensitivity. Samples were desorbed with 10% dichloromethane in methanol, and analyzed with GC/MS by a certified laboratory. The lowest quantifiable levels used by the current method ranged from approximately 0.05 ppm (for a typical 6 hr sampling time and 50ml/min sampling rate) to 0.56 ppm (for a typical 15 min sampling time and 200ml/min sampling rate). Concentrations of EO were investigated before and after the implementation of each specific control measure.

RESULTS AND DISCUSSION

Plastics absorb EO during sterilization and release it
during subsequent handling, potentially leading to worker exposure. EO remaining in the sterilization chamber was the main source of high-level, short-term worker EO exposure. However, EO emitted from sterilized products during aeration/storage should not be overlooked as certain workers stay in these areas for long periods [13]. Accordingly, this study proposed and evaluated three engineering designs controlling off-gassed EO:

**Improvement of Venting Function of the Sterilizer**

Figure 1 presents a design that improves the post-sterilization venting function of the sterilizer. The model sterilizer had a volume of ~20m³ and was used primarily to sterilize hemodialysis-tube. Four openings, each with a diameter of ~5cm, were installed on one side of the sterilizer and connected to a venting duct and blower. The system had a venting rate of 14.4 m³/min, corresponding to a theoretical air change rate of 42.2 hr⁻¹. Airflow pattern evaluation, assessed via smoke visualization, indicated that venting system performance was satisfactory since all released smoke was sucked into the sterilizer chamber.

Following sterilization, including 20 purge cycles, the sterilizer door was opened slightly and the venting pump was operated for 30min before un-loading the sterilized goods. Worker short-term (15 min) exposure levels during un-loading were 6.3 ppm (n = 2) when the venting system was off, whereas the concentration reduced to 2.0 ppm (n = 2) when the venting system was in use. These figures corresponded to a 68% improvement in exposure concentration, and met the PEL-STEL of 2 ppm.

Sterilizer workers experienced high EO exposure during unloading as a result of residual EO off-gassed and retained in the sterilizer chamber [13]. Cycle purges after sterilization reduced residual EO in hospital and medical-supply sterilization. When sufficient purging is infeasible, as in some factories, it is useful to draw the off-gassed EO out of the sterilizer chamber via an additional ventilation system. Venting a sterilization chamber not only removes residual EO from the chamber but also eliminates heat associated with sterilization, thereby further reducing the emission potential of sterilized goods.

**Improvement of Local Ventilation Near the Sterilizer Door**

Figure 2 illustrates an engineering design that improves ventilation around the sterilizer door. In the model presented, a canopy-type hood was installed adjacent to and above the sterilizer door. Meanwhile, baffles (retractable, sliding plastic film) were positioned on both sides and in the front to minimize air shortcut. The dimensions of the hood opening were 2.53 m (W) × 1.77 m (L), sufficient to cover the size of the pallet used to hold goods during sterilization. A perforated plate (with uniformly distributed round slots representing ~19% of its total area) was applied inside the hood for air current stabilization. The venting rate was 159 m³/min. Subjective airflow pattern evaluation indicated that the hood performed satisfactorily and no smoke escaped.

After sterilization, including five purge cycles, a pallet load of sterilized goods (comprising hemodialysis-and infusion-tube, syringe etc.) was automatically re-

![Figure 1](image1.png)  
*Figure 1. Schematic representation of an engineering design that improves the post-sterilization venting function of the sterilizer.*

![Figure 2](image2.png)  
*Figure 2. Schematic representation of an engineering design that improves ventilation around the sterilizer door.*
moved from the sterilizer and placed underneath the hood, where the goods remained for 15 min for venting before being moved elsewhere for further aeration/storage. Subsequent pallet loads were treated similarly until all three were ventilated. Worker short-term exposure levels during un-loading were 10.2 ppm (n = 2) before control, but reduced to 2.0 ppm (n = 2) after the hood was utilized. This reduction represented an 80.4% improvement in worker exposure level and met the PEL-STEI of 2 ppm.

Although EO is heavier than air, it generally follows natural warm air currents and flows upward from a sterilizer after normal sterilization. Thus an exhaust hood immediately above the sterilizer door efficiently reduces peak EO levels. Numerous investigations have recommended using local exhaust ventilation near hospital sterilizer doors to reduce worker exposure to EO during sterilizer door opening [23–27]. For example, Samuel proposed a side-draft hood with a baffle above the door of a table-top sterilizer and demonstrated that this design effectively reduced worker exposure to well below the permissible level [24]. Although some medical-supply manufacturers utilized exhaust hoods immediately above/around the sterilizer door, such arrangement did not effectively limit worker exposure [13]. This insufficiency was likely because the sterilizers used in medical-supply factories were generally much larger than those used in hospitals, meaning an exhaust hood outside the sterilizer was insufficient to draw the EO out of the sterilizer chamber.

Enclosure and Venting of the Aeration Area

Figure 3 shows a typical enclosure design for the aeration area that improves dilution ventilation and limits fugitive emission. Enclosure is necessary since EO is a known carcinogen.

In one model factory, a room [4.3 m (W) × 6.1 m (L) × 2.6 m (H)], next to the sterilizer, was dedicated to this application. Sliding plastic doors were installed at the entrance to minimize EO runaway, while two window-mounted axial fans were installed on the opposite side of the room for venting. This layout generated an overall flow rate of ~3000 m³/hr, equaling a theoretical air change rate of 44 hr⁻¹. After sterilization (including six purge cycles), sterilized products (comprising a mixture of infusion, respiratory and urinary supplies) were transferred to the room for 24–48 hr aeration before being moved to a warehouse for further storage.

Air measurement from the area samples indicated that EO concentrations before and after the utilization of the control were 5.67 and 0.58 ppm, respectively. This improvement represented an 89.8% reduction, and the concentration met the PEL-TWA of 1 ppm for an 8-hr work shift.

In the second factory, a room [4.1 m (W) × 4.2 m (L) × 4.4 cm (H)], next to the sterilizer, was used for this application (enclosure and venting). Plastic film (multi-piece type) was placed at the entrance of the room to minimize EO runaway. A tube-type axial fan, venting at 60 m³/min, was installed at the inner bottom corner since the room was windowless and EO at room temperature is heavier than air. The fan was operated at a frequency of 5 min per 15 mins, creating a theoretical air change rate of 16 hr⁻¹. Following sterilization (comprising nine purge cycles), sterilized products (mainly urological and anesthetic supplies etc.) were transferred into the room for aeration for 48 hr before further handling. Area sample results indicated that EO concentrations after design implementation were 0.68 ppm (n = 2), meeting the PEL-TWA. Since the establishment was new there were no pre-control data. Notably, the factory sterilized and aerated loads using plastic baskets (with products individually packaged) while in other factories products were typically sterilized/aerated in partially sealed cardboard boxes.

Sterilized products continue to emit EO for days, contaminating the aerating zone. Previous investigations have demonstrated that environmental factors such as temperature, relative humidity, air change rate and the amount of plastic in a product carton significantly impacted and interactively affected EO emission kinetics [22]. Air change rate is a simple and achievable
means of controlling air EO concentrations. However, enclosure design should be incorporated into the system to minimize fugitive emissions and ensure that desired ventilation is achieved. Additionally, since the plastic content (types and amounts) in a product carton significantly influences EO emission characteristics, different aeration schedules should be utilized. Accordingly, multiple aeration systems may be necessary for manufacturers that handle large loads or sterilized products with various plastic compositions.

**Significance of Findings**

Sterilization characteristics (e.g. EO concentration and dwell time) and product characteristics (e.g. composition of sterilized materials, load density, and packaging type) [15–21, 28–30] are the main determinant of residual EO. Thus the design parameters presented in this study, despite having been proven effective, should be considered factory-specific. Time, venting rate and system integrity are just three of the determinants of the actual performance of these control measures. Although plastics are known to absorb EO during sterilization and release it during the subsequent aeration, other medical materials should also be applicable to current findings. Notably, this study focused on controlling of worker exposures resulting from EO residue, other EO-related operations such as maintenance and production that also had exposure potential were not addressed [31].

In hospitals, the use of combined sterilizer-aerator eliminated the need to transfer sterilized loads for aeration, thus significantly reducing worker exposure to EO [25]. However, such practice is rarely implemented in this industry because the sterilizers generally lack an additional venting function for removing residual EO, and sterilization generally faces time constraints.

Although multiple aeration systems are recommended to accommodate large quantities of sterilized products for sufficient aerating time, these facilities may not be achievable owing to space limitations typically encountered in this industry. Furthermore, tight manufacturing schedules prevent sterilized goods from being retained for the time required for sufficient aeration. Given these unfavorable conditions, aerating sterilized stocks in an independent aeration area/system for at least 1–2 days offers a practical alternative since the mean EO emission rate from sterilized products on the first day following sterilization was twice that after the second day [22].

**CONCLUSIONS**

EO emitted from sterilized goods has been identified as the major source of worker exposure in hospital and medical-supply sterilization. Although increasing post-sterilization purge cycles offers a simple means of reducing residual EO levels and eliminating extreme worker exposure while unloading, it is time-consuming and may not completely eliminate EO residue. Consequently, promptly removing the off-gassed EO from the sterilization chamber through enhancing the sterilizer venting function may be desirable. Alternatively, placing newly-sterilized stocks within a well-designed local exhaust system for some time also partially withdraws emitted EO and reduces worker short-term exposure during unloading. Moreover, uncontrolled aeration/storage of sterilized stocks results in high EO concentrations in the relevant areas and associated worker exposure. Such conditions can be resolved by enclosure and venting. However, sterilized products should stay in the aeration system for sufficient periods of time as they continue emitting EO for many days.

This work has explored feasible engineering controls for reducing worker EO exposure in medical-supply sterilization, both during unloading and aeration. The designs and parameters presented herein effectively reduced the worker short-term exposure during unloading below the PEL-STEL, and reduced mean air EO concentrations in the aeration/storage areas below the PEL-TWA.

Finally, as residual EO in sterilized products is influenced by numerous factors such as product types, the parameters used in engineering control for each factory should be adjusted accordingly for optimal performance.

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**REFERENCES**


