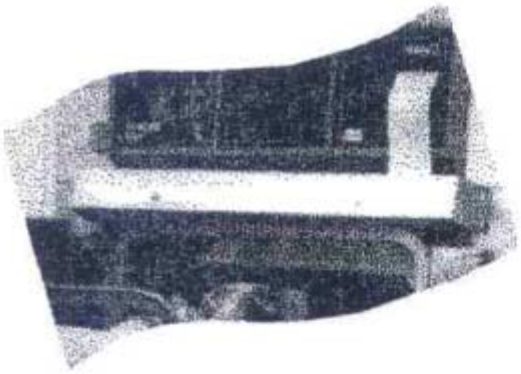
Ethylene Oxide in Hospitals in Québec



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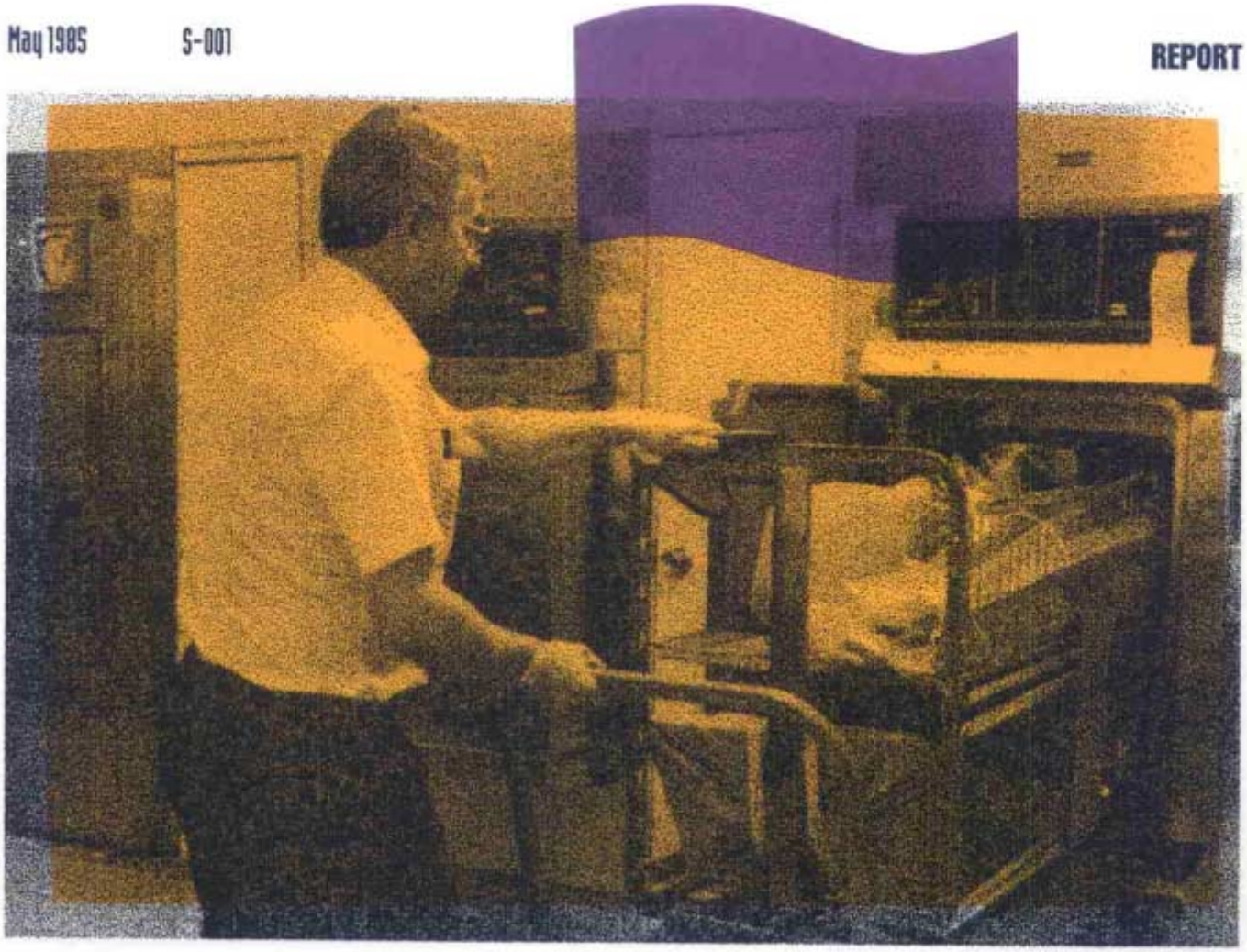

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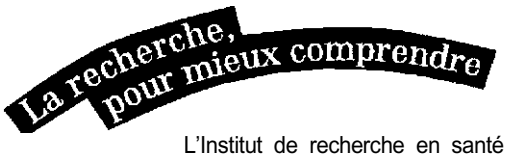

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Ethylene Oxide in Hospitals in Québec

ÉTUDES ET RECHERCHES

Institut de recherche en santé et en sécurité du travail du Québec.
Association paritaire pour la santé et la sécurité au travail -
secteur affaires sociales

REPORT

This study was financed by IRSST. The conclusions et recommendations are those of the authors.

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We wish to thank all the hospitals that allowed us to carry out the industrial hygiene study and to thank as well all those who took part in producing this document.

We would also like to thank all those who participated in carrying out this project, particularly Jocelyne Marion, Brigitte Roberge and Louis Gendreau for analytical support in the field, Daniel Drolet for analytical support in the laboratory, Helen Shaver for translation and Caroline Proulx for typing the text.

* IRSST is the Institut de recherche en santé et en sécurité du travail du Québec (which means the Quebec Research Institute for Occupational Health and Safety).

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1. Introduction

Ethylene oxide (EtO) is used mainly as a starting material in chemical industry to make various industrial and commercial products.

A small proportion of the ethylene oxide produced is used as a sterilant. However, this use causes the greatest number of workers to be exposed to concentrations higher than those found in chemical industry (1).

Hospitals and medical or dental clinics that use ethylene oxide sterilizers are therefore especially concerned by the present debate about this substance.

Until recently, the worker exposure standards for ethylene oxide were based on knowledge of acute or chronic nonmalignant effects. In the last few years, some research has led to this substance being considered a potential carcinogen. This caused some organizations and countries to make a series of recommendations with a view to drastically reducing the existing exposure standards.

Quebec cannot remain indifferent to this issue and disregard this new aspect of ethylene oxide toxicity, especially since it has adopted previous American exposure standards which have just been reevaluated in this particular case.

Health and Welfare Canada (2), OSHA (Occupational Safety and Health Administration) (3) which has reevaluated the exposure threshold limit values, NIOSH (National Institute for Occupational Safety and Health) (4) and others have proposed stringent guidelines concerning the use of ethylene oxide. OSHA has just issued a final standard reducing the exposure limit for ethylene oxide from 50 to 1 ppm as an 8-hour time-weighted average and set an action level of 0.5 ppm. However, up until now the exposure limit in Quebec has remained unchanged.

In this general context, a task force involving the Institut de recherche en santé et en sécurité du travail and the Association pour la santé et la sécurité du travail, secteur affaires sociales, was mandated to better document the ethylene oxide sources to which hospital workers may be exposed and to thus make it easier for hospitals to take charge as planned by the law relating to occupational health and safety.

This study tries to answer a certain number of questions relating to:
— the number of hospitals involved;
— the number of exposed workers;
— the types of sterilizers used;
— the users' work practices;
— the environmental measuring methods available for different concentrations;
— the sources of ambient air contamination;
— the types of worker exposure;
— the various means of eliminating these sources of exposure;
— ambient ethylene oxide levels once all emission sources have been controlled.

The data were collected by means of a questionnaire sent to all hospitals and by a detailed evaluation of the exposure sources and the control measures in 14 hospitals.

The collected data should allow the hospitals to determine where they stand in relation to the current exposure standards, to understand the significance of certain recommendations, and to plan for the eventual reduction of exposure standards. The data should also suggest to the various hospitals the most effective ways to reduce exposure levels through better identification of the sources of contamination. However, the aim of the study is not to determine the actual exposure level for 8 hours for workers assigned to the sterilization procedure. In a larger sense, the study should provide the Association sectorielle with the knowledge necessary to formulate all information or intervention policies dealing with this subject.

This document begins by presenting a brief summary of the principal toxic effects of ethylene oxide, the current discussions concerning exposure standards, and a description of the processes using ethylene oxide. A description of the methodology and of the data collected by means of a questionnaire and by means of the industrial hygiene study are then presented. After a short discussion of the results, the publication concludes with several recommendations.

2. Properties and Uses of Ethylene Oxide

Ethylene oxide (C_2H_4O) is a gas at ordinary temperature and pressure, is soluble in water, has a higher density than air, and is easily liquified at room temperature.

Because of its boiling point, 10.4°C, ethylene oxide is a gas at room temperature. The chemical reactivity of the epoxide nucleus of this gas makes it electrophilic, allowing it to react with nucleophilic groups of biologic molecules such as enzymes and proteins, making them unable to carry out their metabolic functions. Therefore, ethylene oxide acts as a biocide on any organisms having such molecules, be they bacterial, fungal, or animal.

This property of ethylene oxide is used to advantage in the pharmaceutical, food or cosmetic industry to sterilize packing material. Ethylene oxide is also used as a sterilant for any material which is sensitive to heat and humidity. As a result, it is used for all materials which cannot be sterilized by steam. The CSA standard Z314.2M-1977 (12) specifies in clause 3.4 that: "A product which can be sterilized by either a steam or ethylene oxide process should always be sterilized using steam"

The use of this gas as a sterilant presents indisputable advantages because:
— its chemical reactivity makes it possible to kill all microorganisms including the most resistant spores;
— the material to be sterilized can be wrapped and sterilized in the same packaging which will keep it sterile until it is used;
— this gas will not affect any of the following materials: rubber, metal, glass, plastic, cloth, paper;
— it completely penetrates articles of irregular shape, thus ensuring complete sterilization.

Among other sterilant uses of ethylene oxide, the fumigation of airplanes, boats, museum artifacts and furs must be mentioned.

Ethylene oxide is widely used in chemical industry in the synthesis of ethylene glycol, surfactants, and also in the preparation of starch for the paper and textile industries.

However, the reactivity of its epoxide ring has certain disadvantages. In fact, the chemical reactions of ethylene oxide are extremely exothermic and potentially explosive when it is heated or comes into contact with alkali metal hydroxides or highly reactive catalytic surfaces.

Bases, acids and the anhydrous chlorides of iron, tin and aluminum can act as catalysts and cause ethylene oxide to polymerize. In the presence of such catalysts, polymerization may be so rapid that an explosion may occur.

Therefore, the handling, storing and use of ethylene oxide must be the subject of stringent precautions, because even though ethylene oxide in the liquid form is relatively stable, vapor concentrations from 3 to 100% are extremely flammable and may explode when exposed to heat or to an open flame.

3. Effects on Health

The acute and chronic effects of ethylene oxide were recently the subject of several scientific reviews: the report by Berthelette and Abenhaim (5), a review of the literature by Gennart et al. (6), a report on the subject by Holliday et al. (7) and a special bulletin by NIOSH (4).

The aim of this document is not to show the toxic effects of ethylene oxide, but to assess the impact of recent discoveries about its use. Therefore, only a brief account of these effects is presented, leaving it to the interested reader to consult the references mentioned.

References in the literature to acute poisoning by ethylene oxide are rare. Nevertheless, it is known that several minutes exposure to ethylene oxide concentrations of 500 ppm or more affects the lungs and to a lesser extent the nervous system. With the appropriate medical care, these lesions heal in a few days. Moreover, contact with ethylene oxide can cause burns to the skin and irritation to the eyes. These lesions also will heal.

The literature on the chronic toxicity of ethylene oxide reveals properties that call for caution: it reports cases of sensitization, effects on blood cells, effects on chromosomes, etc. Several authors of epidemiological studies observed that the number of deaths from leukemia seemed to be higher in workers exposed to mixtures of contaminants, some of which included ethylene oxide. In certain cases, experiments with animals have attributed carcinogenic properties to ethylene oxide.

These observations taken together cause ethylene oxide to be considered as a potential carcinogen for man.

Since the dose-effect relationship in the case of exposure to carcinogenic substances is not evident, the different organizations involved in the setting of standards tend to minimize and to carefully control their use. In concrete terms, this is expressed in a marked reduction in the exposure thresholds.

4. Exposure Thresholds

Before it became evident that ethylene oxide was a potential carcinogen and mutagen, its toxicity had been considered only in relation to its acute and chronic nonmalignant effects on health.

The exposure thresholds in effect in the past and even today are a reflection of our knowledge. Recent revisions of the exposure thresholds considered as being safe (particularly the OSHA revisions (3)) have developed exposure criteria which take into account present knowledge of the toxicity of ethylene oxide.

4.1 United States

4.1.1 American Conference of Governmental Industrial Hygienists (ACGIH)

This organization is made up of a group of industrial hygienists from government and education. The organization is devoted to the development of the administrative and technical aspects of the protection of workers' health. It is not a governmental organization.

Before 1979, ACGIH recommended limiting occupational exposure to ethylene oxide to 50 ppm as a time-weighted average. In 1979, it recommended reducing this threshold to 10 ppm. In 1981, this recommendation was adopted and the time-weighted average was reduced to 10 ppm. At that time, ACGIH recommended reducing it again, to 5 ppm, taking into consideration the latest toxicological studies. Today, ACGIH considers the substance as a potential carcinogen, and as a result, recommends limiting exposure to 1 ppm (8).

4.1.2 National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA)

NIOSH is an American government organization whose mandate is applied research in the area of occupational health and safety.

OSHA is an American government agency responsible for administration and legislation in matters of health and safety.

In 1977, NIOSH (1) recommended that the daily occupational exposure to ethylene oxide be limited to 50 ppm as a time-weighted average for 8 hours and that short-term exposure be limited to 75 ppm as a time-weighted average for 15 minutes (OSHA adopted this recommendation in 1979). In 1981, NIOSH recommended that ethylene oxide be considered as an occupational carcinogen and that the threshold of 50 ppm be revised (4). In April 1983, OSHA proposed that the existing threshold (50 ppm) be reduced by 50 times in order to minimize an increased risk of cancer and to prevent disastrous reproductive effects. Following this proposal, OSHA, in July 1983, proceeded to hold public meetings in order to decide on a new threshold limit value. The presentations of various involved groups (industry, hospitals, employee associations, and industrial hygienists) were heard.

A final decision was issued by OSHA following these hearings. It reduced the exposure limit to 1 ppm as an 8-hour time-weighted average and set an action level of 0.5 ppm.

4.2 Canada

In 1982, the Canada Safety Council in its publication "Signal de danger" V-1501-22 (9) recommended that ethylene oxide be considered a potential carcinogen. The Council recommended that the users of this gas voluntarily evaluate worker exposure to ethylene oxide and reduce this exposure so as not to exceed a 5 ppm time-weighted average.

In 1981, Ontario proposed that the time-weighted average be set at 10 ppm (10). In Quebec, the exposure threshold presently in effect is 50 ppm as a time-weighted average for 8 hours and 95 ppm for 15 minutes (11).

5. Description of the Ethylene Oxide Sterilization Methods Used in the Hospital Environment

After a brief discussion of the concentrations of ethylene oxide used for sterilization, this chapter will describe the two available sterilization methods, the sources of contamination and the different control measures offered by the manufacturers.

5.1 Commercial Forms Used

In Quebec hospitals, 3 commercial forms of ethylene oxide are used:

a) Oxyfume 12®

This is a mixture of ethylene oxide and Freon 12® in a ratio of 12:88, that is, 12% ethylene oxide and 88% Freon 12®. This mixture has the advantage of being nonflammable and nonexplosive. It should be noted that Freon 12® is a simple asphyxiant whose toxicity is negligible when compared to that of ethylene oxide.

At present, this mixture is the one used most for sterilization.

b) Steri-Gas®

This is 100% ethylene oxide and has the disadvantage of being explosive and flammable.

c) Anprolene®

This is a mixture of ethylene oxide and inert gas in a ratio of 84:16 or 97:3. These two mixtures have the same disadvantage as 100% ethylene oxide, that of being explosive and flammable.

5.2 Sterilization Method Using Oxyfume 12® or Steri-Gas®

This ethylene oxide sterilization method requires that the material to be sterilized be exposed to a precise concentration for a given amount of time, as well as at a precise temperature, pressure, and humidity. If any one of these parameters is changed, the others must also be changed.

In general, these parameters are preset by the sterilizer manufacturer or distributor. Figures 1 and 2 illustrate the exposure cycles when Oxyfume 12® or Steri-Gas® is used.

5.2.1 Method

a) Preparation of the articles to be sterilized

The contaminated articles must first be washed with soap and water, rinsed well with distilled water and dried before sterilization. If necessary, the articles will be packed in a material meeting the CSA standard Z314.2-M1977 (12), and then put inside the sterilizer.

b) Sterilization cycle

Once the sterilizer door is closed, the sterilization cycle begins with the heating cycle in which the sterilization chamber reaches a temperature between 29 and 63°C (85 and 145°F).

When the desired temperature is reached, a pump creates a partial vacuum inside the chamber, thus preventing dilution of the gas with air. This also reduces the danger of ignition when Steri-Gas® is used.

Subsequently, steam is introduced into the chamber so that a humidity between 30 and 60% is reached.

This operation is generally followed by a short waiting period in order to allow the humidification of all the articles to be sterilized. This is a very important step because the microorganisms thus humidified are more vulnerable to the action of ethylene oxide.

Finally, ethylene oxide is introduced under pressure to the sterilization chamber. The pressure necessary for sterilization is between 5 and 30 psig*, the gas concentration being proportional to the pressure of this gas in the sterilization chamber. It should be noted that sterilizers requiring the use of Steri-Gas® operate at negative pressure.

The introduction of ethylene oxide into the sterilizer is the beginning of the exposure period to the sterilant gas. The length of this cycle depends on the other factors previously mentioned: temperature, humidity, pressure, the gas mixture used, and the material to be sterilized. This exposure period usually lasts from 2 to 6 hours.

After a sufficient exposure time, the gas is exhausted from the chamber by one of the following means, depending on the make of sterilizer and its year of manufacture:
— oil-sealed vacuum pump;
— water-sealed vacuum pump;
— compressed air ejector.

The sterilization cycle has now been completed and as soon as atmospheric pressure is restored inside the chamber, the sterilizer door can be opened.

c) Aeration

Once sterilization has been completed, the material sterilized by ethylene oxide must be aerated so as to allow the off-gassing of the residual gas absorbed by the material.

In general, the aeration takes place in cabinets designed for this purpose, called aerators. These cabinets consist of a closed chamber in which heated air circulates at a minimum temperature of 49°C (120°F). The freshly sterilized material is placed in the aerator and left for an aeration period varying from 6 to 48 hours depending on the material and on the temperature maintained inside the aerator.

* 5 and 30 psig = 35 and 207 kPa

Figure 1
Sterilization Cycle Using Oxyfume 12®

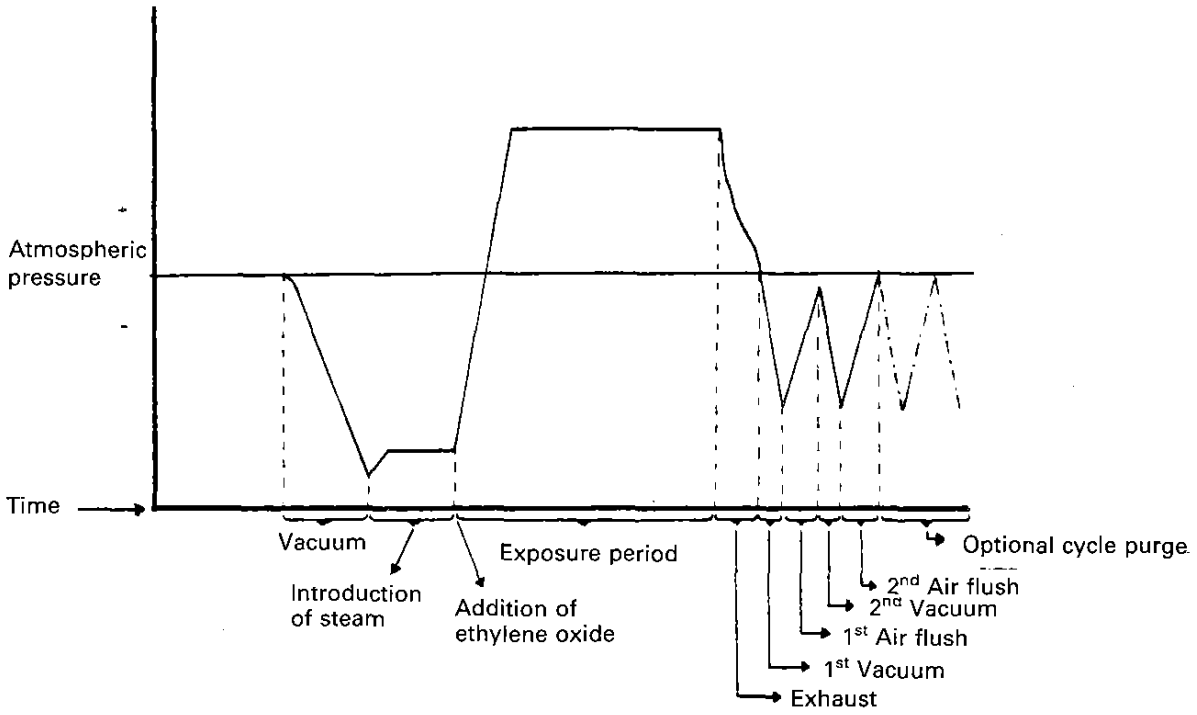
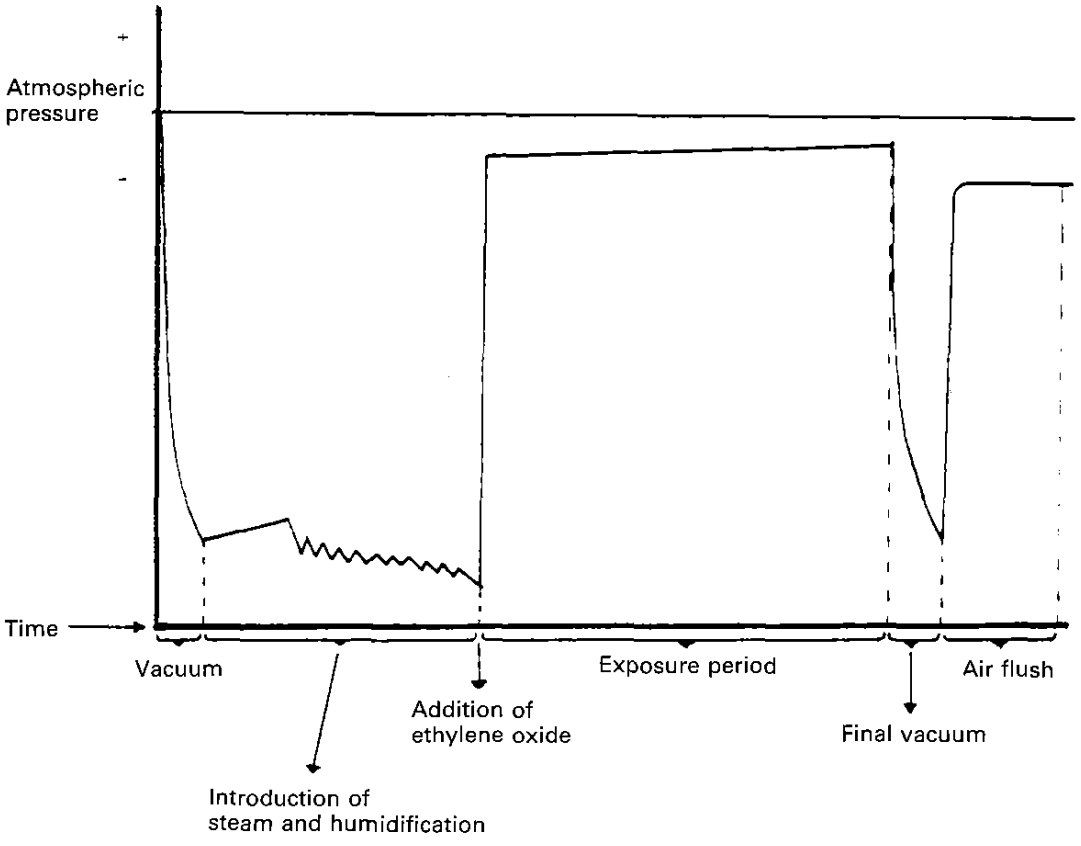


Figure 2
Sterilization Cycle Using Steri-Gas®



5.2.2 Sources of Ethylene Oxide Emission during the Sterilization Procedure

It is interesting to note that certain authors (13) point out that the ethylene oxide in the sterilization chamber is released at the end of the cycle in the following way:

— 95% of the ethylene oxide is evacuated by the vacuum pump during the final vacuum;

— 5% remains in the sterilization chamber. Part of this 5% is absorbed by the sterilized material; the rest escapes when the door is opened at the end of the cycle.

This 5% residual gas constitutes the principal source of worker exposure when the door is opened.

The emission of ethylene oxide can occur in three ways. Chronologically they are:

a) Before sterilization:

— from the cylinder valve or from the gas-lines between the cylinder and the sterilizer, due to possible leaks.

b) During sterilization:

— from the ethylene oxide gas-lines between the cylinders and the sterilizer, due to possible leaks;

— from the sterilizer door seal, due to possible leaks;

— from the exhaust outlet from the pump through which ethylene oxide is exhausted at the end of the sterilization cycle;

— from the safety valve in case of overpressure in the sterilization chamber.

c) After sterilization:

— when the sterilizer door is opened, due to residual ethylene oxide inside the sterilization chamber;

— from the material just sterilized, due to residual ethylene oxide absorbed by the packages;

— from the seal of the aerator door, due to possible leaks;

— from the exhaust outlet of the aerator, if it is not connected to the building's exhaust system;

— from the ethylene oxide gas-lines that allow residual ethylene oxide under pressure to escape when cylinders are changed;

— from the filter located on the ethylene oxide gas-lines which allows residual gas to escape when it is changed.

5.2.3 Control Measures Available from Sterilizer Manufacturers

Manufacturers offer six different control measures applicable to three emission sources:

a) Exposure at negative pressure

In some recent models of sterilizers using 100% ethylene oxide, the exposure period occurs at negative pressure*, thus preventing leaks through the seal of the sterilizer door. A safety mechanism aborts the exposure cycle if the pressure inside the sterilizer exceeds 0.92 Bars**. However, only the 3M Company offers this option.

* 3M model 400C
** 0.92 Bars = 92 kPa

b) Cycle purge

This modification of the sterilization method allows the inclusion of successive vacuums at the end of the sterilization cycle for a period of about 30 minutes. These vacuum cycles allow an aeration period before the sterilizer is opened. This control measure reduces the residual concentration in the sterilizer, thus reducing the contamination when the door is opened.

c) Post vacuum

This modification of the sterilization method allows the addition of another vacuum cycle to the initial vacuum cycle after sterilization. This second vacuum is followed by an aeration period carried out at a negative pressure of −2 psi*** with air flushing for twenty minutes. This control measure reduces contamination when the door is opened by reducing the residual ethylene oxide concentration in the sterilizer in the same way as does the cycle purge.

d) Local exhaust

An exhaust hood just above the sterilizer door allows the leaks through the door during sterilization to be controlled and also allows the residual ethylene oxide to be exhausted from the chamber when the sterilizer door is opened. This exhaust hood must be connected to a ventilation system which vents the air directly outdoors.

e) Water/gas separator

When the gas is exhausted by means of a water-sealed vacuum pump, the gas is carried by the water through the pump, the water being discharged into a drain connected to the sewer. Since this system is open and only a small amount of gas is absorbed by the water, almost all the exhausted ethylene oxide escapes into the ambient air. In fact, several authors (13) point out that of the 95% of the ethylene oxide released during the exhaust cycle, only 10% is absorbed by the water; therefore 85% is released into the ambient air behind the sterilizer.

To control this emission source, manufacturers offer a water/gas separator which is connected to the vacuum pump outlet. The water is discharged into the drain while the residual ethylene oxide is vented outdoors by means of a vent or a fan.

f) Valve

This control measure is an automatic or manual valve which is installed in the ethylene oxide gas-lines as close as possible to the cylinder. This valve prevents the pressurized gas-lines from emptying when cylinders are changed.

5.3 Sterilization Method Using Anprolene®

The sterilization method using Anprolene® does not require the same conditions of temperature and pressure as those described in the preceding section. This sterilization procedure is carried out at room temperature and pressure. Only the humidity must be controlled in order to ensure the sterilant actien of ethylene oxide.

Sterilization with Anprolene® is carried out in a covered cylindrical or rectangular metal container.

*** −2 psi = −14 kPa

5.3.1 Method

a) Preparation of the articles to be sterilized

The contaminated articles must first be washed with soap and water, rinsed well with distilled water and dried before sterilization. If the articles cannot be washed with water, they must be humidified by keeping them for an hour in a closed space which is saturated with water vapor.

b) Sterilization

Before sterilization with Anprolene® can be carried out, the ambient relative humidity must be at least 30%.

The articles previously prepared and packed are placed in a large bag which is partially permeable to ethylene oxide. Inside this bag is placed an ampule of Anprolene®, which itself has been placed in a small bag which is permeable to ethylene oxide. The air in the larger bag is evacuated and the bag is sealed with the tie supplied or by a heat seal. Once the bag is sealed, the ampule is broken from outside the larger bag. The gas expands in the small bag containing the ampule and diffuses into the larger bag. The large bag is then put into the metal container which is kept closed for 24 hours. Some facilities use only the large bag without the metal container.

After the sterilization period, the larger bag is opened and the sterilized material is removed. This material must then be aerated for at least 24 hours. The aeration is usually carried out in the open air since facilities using this method of sterilization do not have an aerator.

5.3.2 Sources of Ethylene Oxide Emission during the Sterilization Procedure

a) During sterilization:

— if the ampule is broken outside the larger bag, there is a risk of contamination because the small bag containing the ampule is very permeable to ethylene oxide;

— during the ethylene oxide exposure period, because the larger bag is partially permeable and allows the gas to be diffused, and because the metal container is not airtight and often is not even used.

b) After sterilization:

— when the bag is opened, due to residual ethylene oxide inside the bag;

— during aeration of the freshly sterilized material, due to residual ethylene oxide absorbed by the packages.

5.3.3 Control Measures Available from the Manufacturer of Sterilizers Using Anprolene®

The manufacturer of these sterilizers offers no control measures for the reduction of possible contamination during their use. An effective method of controlling contamination from these sterilizers is by placing them under an exhaust hood similar to those used in a laboratory. The aeration of the material should also be carried out inside this hood.

6. Identification of Exposed Workers

6.1 Data Collection

The data necessary for identifying exposed workers in the hospital environment was collected by a questionnaire (Appendix I) sent to the hospitals likely to use ethylene oxide sterilization, which are short-term medical care hospitals and psychiatric hospitals.

The aim of the questionnaire was to collect data relating to:

— the number and models of sterilizers used;
— the manufacturers of sterilizers;
— the sources of supply of ethylene oxide;
— the annual consumption of ethylene oxide;
— the existence of a preventive maintenance and environmental monitoring program;
— the facility design and the location of sterilizers;
— the number of exposed workers;
— work practices;
— the workers' perception of the risks associated with ethylene oxide;
— the information available;
— health problems already reported.

This questionnaire was addressed to those in charge of the sterilization service of each hospital. The accompanying letter asked that copies of the questionnaire be distributed to the other related departments, if necessary (surgical unit, out-patient clinic, inhalation therapy, etc.). A total of 182 questionnaires were sent out.

6.2 Validation of the Questionnaire Data

The answers to the questionnaire were validated through interviews with the person in charge of the service, with the employee representative and with the person in charge of facility design in each of the 14 hospitals.

The results of the interviews corroborate the data collected by the questionnaire.

6.3 Criteria for Answer Selection

The questionnaire was made up of 17 questions. Three were rejected for the following reasons:

— Question number 12 concerning the number of hours the sterilizer is in operation is not covered in the tabulation of data because it was included in the questionnaire only to validate the answer to the question involving the annual consumption of ethylene oxide;

— Question number 16 concerning the information available about the risks associated with ethylene oxide. This question made it possible to validate the previous question concerning the recognition of risks associated with ethylene oxide exposure;

— Question number 17 concerning health problems reported by workers. Since these problems can be connected to ethylene oxide exposure, the question seemed too subjective to be used.

The answers to questions 3 and 4 allowed us to identify the suppliers of sterilizers and of ethylene oxide. We met with them in order to obtain technical data on ethylene oxide sterilization and on users. Appendix IV gives the addresses of the four manufacturers of the sterilizers in use in Quebec.

6.4 Compilation of Answers

We received 140 of the 182 questionnaires sent out. Only nine of them came from services other than sterilization. By visiting certain hospitals we learned that the questionnaire had not always been distributed as requested.

It was also noticed during the study that three types of hospitals which had not received the questionnaire were likely to use ethylene oxide sterilization. They are extended-care hospitals, and medical and dental clinics. The data can therefore not be considered complete, because it reflects only the situation in short-term medical care hospitals and psychiatric hospitals.

Of the 140 hospitals that answered, 85 use ethylene oxide and 55 use other sterilization methods (heat and steam).

6.4.1 Exposed Workers

In these 85 hospitals, 1004 employees are assigned to two aspects of the sterilization procedure as demonstrated in Table 1.

Table 1

Employees Assigned to the Sterilization Procedure

Employees	Number
Assigned to the sterilization service	785
Assigned to the changing of cylinders	219
Total	1 004

6.4.2 Method

Ethylene oxide sterilizers are supplied by four manufacturers and are distributed in 85 hospitals as presented in Table 2.

Table 2

Sterilizer Models

Sterilizer	Number in use
Amsco	57
Castle	33
3M	10
Bard	14
Total	114

These 114 sterilizers are distributed among 89 different sterilization services in the 85 hospitals.

The average annual consumption of ethylene oxide for the different methods was determined and is presented in Table 3.

Table 3

Ethylene Oxide Consumption

Commercial form of ethylene oxide used	Container	Average annual consumption of the 85 sterilization services
Oxyfume 12®: EtO: 12% Freon 12®: 88%	Cylinder (135 lbs)	28 cylinders/ sterilizer
Steri-Gas®: EtO: 100%	Cartridges (67 or 134 g)	371 cartridges/ sterilizer
Anprolene®: EtO: 84 or 97% Inert gas: 16 or 3%	Ampules	116 ampules/ sterilizer

6.4.3 Facility Design

The data relating to the design of sterilization rooms and mechanical ventilation are presented in Tables 4 and 5 respectively.

Table 4

Sterilizer Location

Hospitals	Number
Having sterilizers located in the sterilization services area	81
Having sterilizers located in a closed room	8
Total	89

Table 5

Mechanical Ventilation

Sterilization services	Number
With mechanical ventilation system	65
Without mechanical ventilation system	24
Total	89

6.4.4 Work Practices

Answers to questions connected with work practices and with awareness of ethylene oxide toxicity are presented in Tables 6 to 10.

Table 6

Waiting Period after Sterilization

Inclusion of a waiting period once the door is opened and before the sterilized materials are transferred to the aerator	Number
Always	65
Often	13
Sometimes	1
Never	10
Total	89

Table 7

Preventive Maintenance Program

Effective preventive maintenance program	Number
Yes	49
No	37
Does not apply (sterilization with Anprolene®)	3
Total	89

Table 8

Environmental Monitoring Program

Environmental monitoring program	Number
Yes	10
No	76
Leak detection program	3
Total	89

Table 9

Ethylene Oxide as a Risk

Do workers consider ethylene oxide a risk	Number
Yes	43
No	46
Total	89

Table 10

Odor of Ethylene Oxide

Odor of ethylene oxide detected*	Number
Yes	34
No	55
Total	89

* The mean olfactory threshold is approximately 700 ppm.

7. Industrial Hygiene Study in the Hospital Environment

It is important to specify that this is a study to define methods and not a study of worker exposure to ethylene oxide.

The study allowed the detection of ethylene oxide emission sources (leaks and other sources), the evaluation of their significance and the comparison of control measures pertaining to the method, to the facility design and to work practices.

7.1 Criteria for Hospital Selection

Of the 85 hospitals using ethylene oxide, 14 were considered in the comparative study. Five criteria were used in selecting these hospitals. These criteria, formulated from the answers to the questionnaire and from information relating to control measures supplied by the sterilizer manufacturers, are presented below.

a) Control measures used:

— cycle purge;
— post vacuum;
— local exhaust;
— water/gas separator;
— valve.

The hospitals were chosen in such a way as to allow a comparison of the effectiveness of each of the control measures. Only the use of a valve was not evaluated because its usefulness is evident.

b) The make, model and year of manufacture of the sterilizer

The control measures differ from one manufacturer to another, and by comparing several models from each company, the relative advantages can be determined. In addition, the modifications in sterilizer design and production by the manufacturers from one year to the next demand comparison. The choice of hospitals reflects the variation between makes and between models of the same make.

c) Number of potentially exposed workers

Knowledge of the number of potentially exposed workers made it possible to select different sized hospitals so that possible differences in work methods and practices could be taken into consideration.

d) Hospital request

Hospitals which had already requested it were included in the industrial hygiene study.

e) Geographical location of the hospital

The choice of hospitals was made in such a way as to reflect their distribution in the various regions of Quebec.

Table 11 presents the criteria used in hospital selection.

Table 11

List of Criteria Used in the Selection of the Fourteen Hospitals

Hospital	Cycle purge	Post vacuum	Local exhaust ventilation	Separator	Valve	Sterilizer make	Model	Year	Number of workers	Hospital request	Location
A		X			X	Amsco Cryotherm	N65G	1972	45	X	06A
		X	X	X	X	Amsco Eagle	2045	1981			
B					X	Castle	3045	1975	16	X	06B
C	X		X			Castle Sentry	400	1970	14		06B
D	X		X	X	X	Amsco Eagle	2025	1981	8	X	06C
	X		X	X	X	Amsco Eagle	2025	1981			
E	X		X		X	Castle	3045	1974	11		06A
F	X			X	X	Castle	3145	1983	2		06B
					N/A	Bard					
G	X				N/A	3M Sterivac	202B	1982	2		06B
H					N/A	3M Sterivac	200AA	1975	5		03
	X		X		N/A	3M Sterivac	400	1979			
I						Amsco Cryotherm		1971	10		03
						Castle Sentry	400	1971			
J		X				Amsco Cryotherm		1981	7	X	09
K						Castle Steroxo.	1630B	1958	20		03
						Castle Steroxo.	2020	1963			
L			X		X	Amsco Cryotherm	656	1968	10	X	08
M	X				X	Castle Steroxo.		1972	38	X	06
		X	X	X	X	Amsco Eagle	2055	1983			
N					N/A	Bard			2	X	04
Totals	8	4	8	5	10	21 sterilizers	N/A	N/A	190	7	N/A

N/A: Not applicable
Note: Geographical locations are presented in Appendix V.

7.2 Factors Considered in the Industrial Hygiene Study

The hygiene study involved the evaluation of 19 factors. Tables 12, 13 and 14 present these factors with regard to their relation to the three following categories: method, facility design and work practices. These tables also specify the reasons for choosing these factors and the methods used for their evaluation.

Table 12

Factors Considered in Evaluating the Method

Factor	Justification	Evaluation method used
Water/gas separator	A water/gas separator should reduce the ethylene oxide concentrations released into the mechanical room air.	Analysis of gas concentrations at the drain during the exhaust cycle
Cycle purge: repeated vacuum or air flush cycles at the end of the sterilization cycle	This option should reduce residual concentrations of ethylene oxide absorbed by the sterilized articles as well as reduce the concentration of ethylene oxide present in the sterilizer chamber when the door is opened.	Analysis of gas concentrations inside the sterilizer immediately after the door is opened
Exhaust hood above the door: installed by the manufacturer or by the hospital	An exhaust hood should capture the ethylene oxide that escapes when the sterilizer door is opened at the end of the cycle and should capture the fugitive emissions.	Analysis of gas concentrations 15 cm above the exhaust hood and 50 cm in front of the door
Valve	This prevents the escape of gas when the ethylene oxide cylinders are changed	Noting the number of cylinders having this control measure

Table 13

Factors Considered in Evaluating the Facility Design

Factor	Justification	Evaluation method used
Mechanical room at negative pressure	Having a mechanical room at negative pressure ensures that ethylene oxide emissions at the drain and leaks in the gas-lines between the cylinder and the sterilizer are confined to the mechanical room.	Analysis of airflow by smoke tubes
Enclosed sterilizer	Enclosing a sterilizer in a mechanical room or elsewhere ensures the control of emissions at the drain and from the sterilizer gas-lines.	Noting the number of hospitals having enclosed sterilizers
Location of ethylene oxide cylinders	Placing cylinders in the mechanical room ensures a control of the leaks from gas-lines and from the cylinder. The contamination of other areas when cylinders are changed is minimized.	Noting the number of hospitals having gas cylinders located in places other than the mechanical room
Aerator connected to an air exhaust system	Connecting the aerator exhaust to an exhaust system eliminates a source of ethylene oxide emission in the mechanical room.	Noting the number of hospitals having the aerator exhaust connected to an air exhaust system
General ventilation system with air recirculation: sterilization services area	A general ventilation system that recirculates some of the contaminated air from the sterilization services area could recirculate ethylene oxide not only in the sterilization services area, but also in other parts of the hospital.	Consulting the person in charge of facility design and if necessary the plans of the ventilation system

(continued next page)

General ventilation system having air recirculation: mechanical room	The same justification applies.	Same
Continuous use of the mechanical room ventilation system	Certain hospitals have ventilation systems that are turned on manually by a sterilization services worker. This situation leaves the possibility that the mechanical room is not always at negative pressure during sterilizer exhaust or at other times.	Noting the number of hospitals having a switch for the ventilation system

Table 14

Factors Considered in Evaluating the Work Practices

Factor	Justification	Evaluation method used
Leaks around the sterilizer door	Detection of ethylene oxide leaks around the door during the sterilization cycle is an indication of the effectiveness of the door seals.	Analysis of gas concentrations around the door during the exposure cycle
Leaks from the sterilizer and cylinder gas-lines	Detection of ethylene oxide leaks from the sterilizer and cylinder gas-lines is an indication of the effectiveness of an inspection program for these leaks	Analysis of gas concentrations in the air of the mechanical room
Mechanical room, door closed and locked	The mechanical room door being closed and locked is an indication of the inaccessibility to unauthorized persons (the room being a source of exposure to ethylene oxide).	Noting the number of hospitals having a locked mechanical room
Continuous or interrupted operation of the exhaust hood located above the sterilizer door	The use of an exhaust hood during only part of the sterilization cycle jeopardizes the effectiveness of the control of ethylene oxide exposure. Note: When an exhaust hood is installed by the manufacturer, the user decides when to operate it.	Noting the length of time the exhaust hood is in operation during sterilization
15-minute waiting period after the door is opened before the sterilizer is unloaded	The 15-minute waiting period allows a large amount of residual ethylene oxide to be diffused outside the sterilizer once the cycle is finished. The waiting period should reduce worker exposure during unloading of the sterilizer.	Consultation with the person in charge of the sterilization service and observation of work practices
The wearing of gloves while unloading the sterilizer	Wearing gloves designed specifically for this procedure should reduce the possibility of skin contact during transfer to the aerator.	Consultation with the person in charge of the sterilization service
Transfer to the aerator immediately after the 15-minute waiting period after the door is opened	The immediate transfer to the aerator prevents ethylene oxide off-gassing from the sterilized material into the air of the sterilization services.	Consultation with the person in charge of the sterilization service
Material not aerated	Certain hospitals do not aerate the material immediately after sterilization. Depending on where it is stored, it may present an exposure problem for personnel.	Consultation with the person in charge of the sterilization service

7.3 Data Collection

The factors presented were compared and evaluated using a questionnaire (Appendix II) that was filled out during the visit, by observing the facility design and work practices, and by quantitative analysis of ethylene oxide concentrations.

The results of the quantitative analyses make it possible to draw conclusions after comparing different methods, equipment, and certain work practices. The results of the questionnaire and observations make it possible to qualify these comparisons with respect to the distinctive features of each facility.

a) The questionnaire filled out during the visits

This questionnaire was filled out during the visits to the hospitals and its aim was to validate the data obtained by the questionnaire (Appendix I) relating to the identification of worker exposure, and to complete the data.

b) Quantitative analysis

The aim of the quantitative analysis was to characterize environmentally the ethylene oxide sterilization process.

This characterization was carried out using three sampling and analytical techniques. These techniques had been previously perfected in the laboratory and validated in the workplace. These methods followed a sampling and analysis strategy which was developed taking into consideration the method used, and was validated by preliminary visits to the sterilization services (14, 15, 16).

The explanation for the choice of sampling and analytical techniques as well as a description of the particular features of the instruments used are given in Appendix III.

The three sampling and analytical methods used during this study are summarized below:

— Detection by infrared spectroscopy (IR)

A MIRAN 80 manufactured by FOXBORO was used. It is a direct reading instrument with an infrared detector. Using this instrument made it possible to have instantaneous readings of ethylene oxide concentrations from 3 to 800 ppm. The instrument was used to measure concentrations which may fluctuate rapidly (e.g. during the sterilizer exhaust cycle and upon opening the door). The instrument must be calibrated before use, and possible interference in the choice of wavelength must be taken into consideration.

— Detection by photoionization (GC)

The instrument used was a Model 10A10 manufactured by PHOTOVAC. It is a portable chromatograph with photoionization detector. Using this instrument makes it possible to have instantaneous readings of ethylene oxide concentrations from 0.1 to approximately 20 ppm. This instrument was used mainly to measure concentrations below the lower detection limit of the MIRAN 80 (3 ppm). The instrument must be calibrated in the laboratory before use and periodically checked in the field, due to its sensitivity to fluctuations in temperature.

— Activated charcoal tubes (AC)

The sampling method used was absorption on Qazi-Ketcham charcoal tubes, followed by laboratory analysis using gas chromatography with flame ionization detection. This technique makes it possible to measure very low concentrations (approximately 1 ppm) and very high concentrations (approximately 500 ppm). The detection limits for this method depend on the sample volume.

The results of the sampling carried out using this method represent a weighted average over the sampling time.

7.4 Sampling Strategy

A sampling strategy was developed to evaluate the factors presented in Tables 12, 13 and 14. This strategy was developed following some preliminary visits to the sterilization services.

The strategy is shown in Tables 15, 16, 17, 18 and 19. Each table lists in chronological order the gas emission sources before, during, and after sterilization. For each emission source, the appropriate control measure requiring evaluation is indicated, as well as the specific sampling to be carried out. Finally, the sampling methods are identified.

This strategy is also presented for the benefit of anyone involved in occupational health and safety wishing to determine the exposure problems connected with ethylene oxide sterilization.

During this study, ethylene oxide concentrations were at first measured as near the emission source as possible, in order to eliminate variations caused by differences in ventilation (air currents, direction, speed) from one hospital to the next. Once this concentration had been measured, the contribution of these sources of contamination to personnel exposure could be determined by placing the sample collecting device farther and farther from these same sources. In fact, this last type of sampling represents part of the possible exposure of workers if these samples were taken in the breathing zone of these workers.

Table 15

Evaluation of Ethylene Oxide Emission Sources and the Appropriate Control Measures, before the Exposure Period

Ethylene oxide emission source	Control measure to be evaluated	Samples to be taken	Sampling and analytical methods (depending on concentrations)
Leaks from the door of the aerator, when in operation	Effectiveness of the door seal	Detection of leaks around the door	GC, IR
		EtO concentration in the breathing zone 60 cm in front of the door	AC, GC
EtO off-gassing from the sterilized and stored material		EtO concentration in the breathing zone in the center of the storage area	AC, GC
Residual EtO in the air since the last sterilization (if carried out the evening before)		EtO concentration in the breathing zone near most of the workers	AC, GC
Gas-line leaks in the mechanical room		EtO concentration near the gas-lines above the sterilizer	AC, GC

Note: To avoid contamination of these samples, sampling is completed before the start of the exposure period.

Table 16

Evaluation of the Ethylene Oxide Emission Sources and the Appropriate Control Measures, during the Exposure Period

ETO emission source	Control measure to be evaluated	Samples to be taken	Sampling and analytical methods (depending on concentrations)
Leaks from the sterilizer door	Effectiveness of the door seal	Detection of leaks around the door and in the interstice	GC, IR
		EtO concentration in the breathing zone 60 cm in front of the door	AC, GC, IR
	Effectiveness of an exhaust hood located above the door	EtO concentration 15 cm above the exhaust hood	AC
Gas-line or sterilizer leaks in the mechanical room		EtO concentration near the gas-lines above the sterilizer	AC

Note: To avoid contamination of these samples, sampling is completed before the start of the exhaust cycle.

Table 17

Evaluation of the Ethylene Oxide Emission Sources and the Appropriate Control Measures, during the Exhaust Cycle

EtO emission source	Control measure to be evaluated	Samples to be taken	Sampling and analytical methods (depending on concentrations)
EtO vented from the sterilizer during the first vacuum cycle	Effectiveness of the water/ gas separator located above the drain	The highest EtO concentration at the drain	IR, short-term AC
		Reduction in EtO concentrations at the drain after the start of the first vacuum cycle	IR, short-term AC

* To avoid contamination of these samples, sampling is completed before the sterilizer door is opened.

Table 18

Evaluation of the Ethylene Oxide Emission Sources and the Appropriate Control Measures when the Sterilizer Door Is Opened

EtO emission source	Control measure to be evaluated	Samples to be taken	Sampling and analytical methods (depending on concentrations)
Residual EtO in the sterilizer	Effectiveness of the cycle purge or post vacuum	The highest EtO concentration inside the sterilizer, immediately after opening the door	IR, short-term AC
		Reduction in EtO concentrations at the drain after the start of the first vacuum cycle	IR, short-term AC
	Effectiveness of the exhaust hood located above the door	EtO concentrations 15 cm above the exhaust hood	AC, GC
		Concentration of EtO in the breathing zone in front of the door	AC, GC

Note: To avoid contamination of these samples, sampling is completed before the material is transferred to the aerator.

Table 19

Evaluation of the Ethylene Oxide Emission Sources and the Appropriate Control Measures during Transfer of the Material to the Aerator and while the Aerator Is in Operation

EtO emission source	Control measure to be evaluated	Samples to be taken	Sampling and analytical methods (depending on concentrations)
Diffusion of residual EtO outside the sterilizer during unloading Off-gassing of absorbed EtO during transfer of the material		EtO concentration in the breathing zone of the worker during unloading and during transfer to the aerator	GC, IR
Leaks from the aerator door*	Effectiveness of the door seal	Detection of leaks around the door	GC, IR
		EtO concentration in the breathing zone in front of the door	AC, GC

* This evaluation is an indication of EtO concentrations which may be present at the start of aeration, whereas the evaluation of these leaks, itemized in Table 15, gives information about the EtO concentrations which may be present during aeration.

8. Results and Discussion of the Industrial Hygiene Study

It is important to note that quantitative measurements of ethylene oxide for a process such as sterilization present major difficulties:

— the gas concentrations in the air change rapidly;
— sterilizers are of different makes and sizes;
— the quantity and type of sterilized material varies from one time to the next;
— the facility design varies from one hospital to the next;
— work practices vary;
— heat, humidity and Freon 12® can interfere with the analysis.

Following a very strict experimental protocol under these conditions, one can run into problems which are difficult to control beforehand. The data reflect these problems and thus make certain comparisons more difficult.

However, the emission sources are the same during each sterilization and as a result may lead to rather significant contamination of the workplace air, depending on which control measures are used.

In thirteen hospitals visited, 19 sterilizers using Oxyfume 12® and Steri-Gas® were evaluated. In the 14th hospital, the sterilizer using Anprolene® was evaluated. However, this one example cannot be considered as representative of sterilization with Anprolene® and as a result this data does not appear in this document.

The results of the evaluation in the thirteen hospitals are presented as a function of the evaluation of emission sources and follow the sterilization cycle chronologically: before, during and after the cycle. The significance of each emission source as well as the effectiveness of the appropriate control measures are discussed.

A summary table of the results of the industrial hygiene study is presented in Section 8.4.

8.1 Before the Sterilization Cycle

Before the sterilization cycle, only leaks from the cylinder valve or from the gas-lines between the cylinder and the sterilizer can lead to contamination.

The significance of this exposure source was not determined. It should be minor because the leaks are generally located inside a ventilated mechanical room.

8.2 During Sterilization

The four following sections, 8.2.1 to 8.2.5, describe the emission sources present during sterilization.

8.2.1 Ethylene Oxide Gas-Lines between the Cylinders and the Sterilizer

Leaks were detected in the gas-lines in three of the ten mechanical rooms evaluated. The results are presented in Table 20.

Table 20

Ethylene Oxide Concentrations Measured by AC, near Mechanical Room Gas-Lines during the Exposure Period

Sterilizer	Hospital	Average concentration (ppm)	Sampling time (min)
Amsco Cryotherm	J	0.6	47
Castle Steroxomatic 1630-B	K	0.3	156
Amsco Eagle 656	L	11	104

N.B. It is important to emphasize that the leaks from high-pressure gas-lines produce constant contamination. Because of this, the differences in sampling times must not be taken into consideration.

The low ethylene oxide concentrations detected near the gas-lines in these mechanical rooms confirm that this exposure source seems minor but may contribute to increased exposure of persons having access to this room. Insofar as the room remains at negative pressure with respect to the sterilization service and that access to it is limited, this source should not be a significant exposure source for personnel.

Given the possibility of leaks from the cylinder and from the gas-lines, certain measures are recommended in order to avoid worker exposure.

The present study made it possible to verify whether these measures were applicable. The measures which can be used are the following:

— sterilizers enclosed in a mechanical room;
— ventilation of the mechanical room while maintaining negative pressure;
— mechanical room, door closed and locked;
— cylinder location.

a) Sterilizers enclosed in a mechanical room

Of the 19 sterilizers evaluated, 16 were models designed to be enclosed in a mechanical room (Amsco and Castle). Out of these 16 sterilizers, 13 are effectively enclosed in a mechanical room. Two sterilizers are installed in the sterilization services area, without any control of gas leaks. In addition, these two sterilizers are located approximately 150 cm from a work bench. In the third case, it is a new facility. The sterilizer is located in a closed room away from the sterilization service and access is limited to the sterilization worker. This room has its own ventilation system. The control of leaks is ensured by this ventilation and by closing the door of the room.

b) Ventilation of the mechanical room while maintaining negative pressure

All the mechanical rooms visited are equipped with a ventilation system. An analysis of airflow between the mechanical room and the sterilization services area made it possible to observe that all these rooms are kept at negative pressure.

Since it is possible to detect ethylene oxide contamination in the mechanical room, it is important that the air not be recirculated. Only one of the mechanical rooms visited has a ventilation system using recirculated air. One of the hospitals uses a mechanical room ventilation system which can be turned on manually. This procedure allows the possi-

bility that the ventilation system is not always in operation during sterilization, either due to forgetfulness or due to a malfunction.

c) Mechanical room, door closed and locked

Only eleven of the fourteen hospitals used sterilizer models requiring a mechanical room. Nine of the eleven hospitals kept their mechanical room door closed. Only two kept it locked, thus preventing access to unauthorized persons. In several cases, these rooms are used as cloakrooms or as storage rooms for various equipment or supplies.

d) Location of ethylene oxide cylinders

In eight out of the eleven hospitals using ethylene oxide cylinders, these cylinders are located in the mechanical room. In two hospitals they are located in the sterilization services area. In another hospital, the ethylene oxide cylinder is located in a storage room which is maintained at negative pressure and is vented to the outdoors.

The fact that these cylinders are kept in the sterilization services area suggests a possibility of contamination either by leaks or during the changing of cylinders (see Section 8.3.5).

8.2.2 Sterilizer Door Seal

Out of 19 sterilizers evaluated during the study, 14 had leaks in the door seal. Tables 21 and 22 give the concentrations measured around the door and as close as possible to the seal.

Table 21

Ethylene Oxide Concentrations Measured by IR or GC around Sterilizer Doors during the Exposure Period (Sterilizers with or without Exhaust Hood)

Sterilizer	Hospital	Concentrations (ppm)		Method used
Amsco Cryotherm	A	7	18 *	IR
Castle Sentry 400	C	4	6 *	IR
Amsco Eagle 2025	D	0.7		GC
Amsco Eagle 2025	D	0.3	0.6*	GC
Amsco 2025	M	0.3	1.6*	GC
Amsco Cryotherm	J	1.3	3.5*	GC
Amsco Cryotherm	I	0.3		GC
Castle Steroxomatic 2020	R	0.1	1.8*	GC

* Leaks were detected at different points around the door. These results give the lowest and the highest readings.

Table 22

Ethylene Oxide Concentrations Measured by AC around Sterilizer Doors during the Exposure Period (Sterilizers with or without Exhaust Hood)

Sterilizer	Hospital	Average concentration (ppm)	Sampling time (min)
3M Sterivac 202B	G	111	27
3M Sterivac 202B	G	344	17
3M Sterivac 400	H	28	33
3M Sterivac 200AA	H	22	57
Amsco Cryotherm	I	0.2	80
Castle Sentry 400	I	1.1	197
Castle Steroxomatic	M	0.2	275
Amsco Cryotherm 656	L	2.2	118

* Since the gas pressure remains the same inside the sterilizer during the exposure cycle, the gas leaks from the door should produce constant contamination. Because of this, the difference between the sampling times should not be taken into consideration.

As is shown in Tables 21 and 22, these leaks can be minimal (0.1 ppm) but may also be significant (111 and 344 ppm). They are an indication of the condition of the sterilizer door seal. The high number of sterilizers showing such leaks shows a significant problem with the reliability of door seals.

Moreover, it seems that certain models of 3M sterilizers would be more likely to have significant leaks (see hospitals G and H, Table 22).

The effect that these leaks can have on concentrations in the ambient air was also checked. To do this, concentrations were measured by AC and GC in the worker breathing zones. These measurements are presented in Table 23.

They show that the leaks can cause breathing zone contamination. In certain cases, when the leak is significant and the workplace is poorly ventilated, the concentration can be higher than 1 ppm during the exposure cycle (see hospitals A, G and H).

The control measure for this emission source consists of using an exhaust hood located above the sterilizer door.

a) Exhaust hood above the sterilizer door

Seven hospitals out of thirteen have exhaust hoods above the door (manufacturer's model or in-house installation). Six of them have the exhaust hoods operating during the entire sterilization cycle. The other hospital has it operating only when the door is opened.

Having the exhaust hood operating during the entire sterilization cycle is desirable because it ensures the control of leaks through the door seal. This practice is all the more important since the majority of the sterilizers evaluated have this kind of leak.

Table 23

Ethylene Oxide Concentrations Measured by GC or AC in the Breathing Zone in front of Sterilizer Doors during the Exposure Period

Sterilizer	Hospital	Average concentration (ppm)	Method	Sampling time (min)
Amsco Cryotherm	A	1.7	AC	4
3M Sterivac 202B	G	4.5	AC	175
3M Sterivac 200AA	H	7*	GC	40
Amsco Cryotherm	I	0.6	AC	60
Amsco Cryotherm	J	0.1	AC	243
Castle Steroxomatic 2020	K	0.6	AC	113
Castle Steroxomatic 1630-B	K	0.6	AC	113
Castle Steroxomatic	M	N.D.	AC	342

N.B. This sampling was carried out only for those sterilizers not equipped with an exhaust hood, which explains the smaller number of results presented with respect to those in Tables 21 and 22.
N.D. Not detected
* Average of the recorded concentrations by GC in 40 minutes

8.2.3 Outlet from the Vacuum Pump

While the contamination produced by the vacuum pump outlet was being determined, the effect of the water/gas separator could be noted. This separator reduces the ethylene oxide emissions at the drain during the exhaust cycle.

Tables 24 and 25 compare gas concentrations at the drain, with and without a separator.

Table 24

Ethylene Oxide Concentrations Measured at the Drain by IR during Exhaust of Sterilizers Equipped with a Water/Gas Separator

Sterilizer	Hospital	Concentrations (ppm)	Sampling time (min)
Castle 3145	F	191[a], 7[b]	11
Amsco Eagle 2025	D	220[a], 7[b]	10

a: Concentration at time 0
b: Concentration at the end of the sampling period

Table 25

Ethylene Oxide Concentrations Measured at the Drain by IR during Exhaust of Sterilizers Not Equipped with a Water/Gas Separator

Sterilizer	Hospital	Concentrations (ppm)	Sampling time (min)
Amsco Cryotherm	A	400[a], 7[b]	9
Amsco Eagle 2025	A	>800[ac], 3[b]	9
Amsco Cryotherm	I	700[a], 28[b]	5
Amsco Cryotherm	J	114[a], 26[b]	5
Castle Steroxomatic	K	136[a], 26[b]	3
Amsco Cryotherm 656	L	298[a], 16[b]	8

a: Concentration at time 0
b: Concentration at the end of the sampling period
c: Linear upper limit of the calibration curve of the spectrophotometer

Tables 24 and 25 show that the vacuum pump outlet at the drain is a source of significant contamination which it is necessary to control. The concentrations at time 0, presented in Tables 24 and 25, show variations from 114 to more than 800 ppm. However, these concentrations decrease quite rapidly.

Several authors recommend using a water/gas separator (13). However, our data does not confirm its effectiveness. It turns out that even if a separator is used, the source of contamination remains significant (Table 24). As a supplementary preventive measure, it would be desirable to have a ventilated mechanical room (such as is described in Section 8.2). In the absence of such a room, an airtight capture box connected to an outside vent should be installed. This modification is described in Section 10.2.

It must be emphasized that Amsco and Castle separators operate on two different principles. The Castle separator is completely enclosed and vented directly to the outdoors by means of a vent. The Amsco separator operates on a principle similar to that of an exhaust hood. It is connected to a fan which draws the air from the room through openings on the side of the separator. The fan exhaust is connected directly to the outdoors. The relative effectiveness of these two types of separators has not been determined during this study. However, determining the effectiveness of the Amsco separator would be significant because this separator is not completely enclosed and thus allows ethylene oxide to escape. This could occur if the air capture velocity were not high enough, taking into consideration the conditions under which it is being used: heat, humidity, and significant release of gas.

8.2.4 Safety Valve

The number of sterilizers having a safety valve connected to an outside vent was not noted. However, it seems evident that such a measure would prevent significant contamination should this valve open. The emptying of the sterilization chamber by means of the emergency valve could release a significant amount of ethylene oxide into the workplace.

8.3 After Sterilization

The six following sections (8.3.1 to 8.3.6) describe the emission sources present after sterilization.

8.3.1 Opening the Sterilizer Door

Ethylene oxide concentrations in the sterilizer were measured by infrared spectrophotometry and by adsorption on activated charcoal tubes immediately after the door was opened. In cases where it was impossible to put the detector of the instrument and the charcoal tubes inside the sterilizer, the concentrations were measured above the door.

These samples made it possible to determine the significance of this contamination source and to check the effectiveness of the different means for exhausting ethylene oxide which are used after the sterilization cycle. The following tables compare residual ethylene oxide concentrations measured in sterilizers having only one vacuum cycle and those having a vacuum and a post vacuum cycle or else a vacuum and cycle purge.

Table 26

Ethylene Oxide Concentrations Measured by IR when the Door Is Opened, inside Sterilizers Having a Post Vacuum or a Cycle Purge

Sterilizer	Hospital	Concentrations (ppm)	Sampling time (min)
Amsco Cryotherm	J	454[a], 23[b]	8
Amsco Eagle 2025	D	400[a], 63[b]	12
3M Sterivac 400	H	309[a], 97[b]	9

a: Concentration at time 0
b: Concentration at the end of the sampling period

Table 27

Ethylene Oxide Concentrations Measured by AC when the Door Is Opened, inside Sterilizers Having a Post Vacuum or a Cycle Purge

Sterilizer	Hospital	Average concentration (ppm)	Sampling time (min)
Amsco Cryotherm	J	78	15
Amsco Eagle 2025	C	62	20
3M Sterivac 202-B	G	230	20
Amsco Eagle 2025	D	128	10

Table 28

Ethylene Oxide Concentrations Measured by IR when the Door Is Opened, inside Sterilizers Having a First Vacuum Cycle Only

Sterilizer	Hospital	Concentrations (ppm)	Sampling time (min)
Amsco Cryotherm 656	L	>800[ac], 105[b]	9
Amsco Cryotherm	I	>800[ac], 9[b]	6
Castle Sentry 400	I	80[a], 6[b]	2
Castle Steroxomatic 1630	K	>800[ac], 102[b]	15
Castle Steroxomatic 2020	K	>800[ac], 170[b]	16

a: Concentration at time 0
b: Concentration at the end of the sampling period
c: Linear upper limit of the calibration curve of the spectrophotometer

Table 29

Ethylene Oxide Concentrations Measured by AC, when the Door Is Opened, inside Sterilizers Having a First Vacuum Cycle Only

Sterilizer	Hospital	Average Concentration (ppm)	Sampling time (min)*
Amsco Cryotherm 656	L	352	10
Amsco Cryotherm	I	2400	3
Castle Sentry 400	I	122	30
Castle Steroxomatic 1630-B	K	1256	5
3M Sterivac 200AA	H	278	39
Castle Steroxomatic 2020	K	217	13
Castle Steroxomatic	M	3900	5

* When high ethylene oxide concentrations were present, the sampling times were shortened to avoid saturation of the activated charcoal tubes.

The results in Tables 26 to 29 show that opening the sterilizer door is a significant source of exposure. In fact, Tables 26 to 28 show that immediately upon opening the door (at time 0), the concentrations vary from 309 to more that 800 ppm. However, there is a value of 80 ppm for hospital I (Table 28). This can be explained by the small quantity of material being sterilized when the evaluation was carried out, which is not representative of normal operation. In fact, the concentrations inside the sterilizers are affected by several factors, such as the size of the sterilizer, and the amount and the absorption properties of the material sterilized. The significance of these factors was not determined during this study. For these reasons, comparisons between sterilizers should be avoided.

Table 29 confirms that opening the door is a significant source of exposure. In fact, short-term samples (3 and 5 minutes) give values between 1256 and 3900 ppm.

The control measures which can minimize this source of exposure are:

— cycle purge or post vacuum;
— 15- to 20-minute waiting period;
— exhaust hood above the door.

a) Cycle purge or post vacuum

The addition of a cycle purge or a post vacuum makes it possible to reduce the concentrations of ethylene oxide present when the door is opened. Tables 26 and 27 show lower concentrations than those in Tables 28 and 29, which confirms the effectiveness of a cycle purge or a post vacuum.

When Tables 26 and 28 are compared, the concentrations at time 0 for sterilizers having a first vacuum cycle only can be seen to be at least two times greater than those measured when there is a cycle purge or a post vacuum. Since the sampling times are different in Tables 27 and 29, it is impossible to make a direct comparison between sterilizers.

b) 15- to 20-minute waiting period once the sterilizer door is opened

Eleven of the thirteen hospitals include a 15- to 20-minute waiting period once the sterilizer door is opened to allow the gas to be diluted. Two hospitals transfer the material immediately to the aerator without this waiting period.

Tables 26 and 28 show that ethylene oxide concentrations decrease rather rapidly once the door is opened. However, even if the sampling period changes, it appears that after several minutes the measured concentrations are much lower than at the beginning of sampling.

The manufacturers' instructions for leaving the door ajar for a 15- to 20-minute period are therefore justified. This waiting period considerably reduces the risk of worker exposure.

c) Local exhaust, exhaust hood located above the door: exhaust hood installed by the manufacturer or by the hospital

The effectiveness of an exhaust hood to remove the residual ethylene oxide in the sterilizer after the door is opened was determined by the method described in the sampling strategy (see Section 7.3).

Tables 30 and 31 show the maximum concentrations measured in front of the door in the breathing zone. These measurements were taken during the 15 minutes following the opening of the door.

Table 30

Maximum Ethylene Oxide Concentrations Measured by GC, during the Waiting Period after the Door Is Opened, 60 cm in front of Sterilizers Equipped with an Exhaust Hood

Sterilizer	Hospital	Concentration (ppm)
Amsco Eagle 2025 (#2)	D	0.1
3M Sterivac 400	H	0.4
Amsco 2055	M	N.D.
Castle Sentry 400	C	1.0
Castle 3045	E	0.5
Amsco Cryotherm 656	L	0.4

N.D.: Not detected

Table 31

Maximum Ethylene Oxide Concentrations Measured by GC or IR during the Waiting Period after the Door Is Opened, 60 cm or more in front of Sterilizers Having no Exhaust Hood

Sterilizer	Hospital	Concentration (ppm)	Sampling method
Amsco Cryotherm	I	16	IR
Castle 3045	B	6	IR
Castle 3145	F	>13*	GC
Castle Steroxomatic 2020	K	3**	GC
Castle Steroxomatic	M	5	GC

* Linear upper limit of the calibration curve depending on the technique used during this sampling
** Measurement carried out 150 cm in front of the door

In Table 31, maximum concentrations measured in the absence of an exhaust hood can be seen to vary from 5 ppm to 16 ppm, 60 cm in front of the door. Table 30 shows that the maximum concentrations measured when there is an exhaust hood vary from 0.1 ppm to 1 ppm, 60 cm in front of the door. The installation of an exhaust hood can thus contribute to reducing exposure to a lower value of approximately 1 ppm.

It can be seen in Table 31 that sampling in hospital K was carried out 150 cm in front of the sterilizer door, giving a value of 3 ppm. Even at this distance from the sterilizer, this value is higher than those measured when an exhaust hood is used.

8.3.2 Freshly Sterilized Material

The transfer of the freshly sterilized material is a source of contamination of the ambient air. Table 32 shows concentratons that vary between 0.6 and 70 ppm during transfer. Here again the range in concentrations measured is explained by the differences in sterilizer size and in the amount of material sterilized.

This exposure source can sometimes be significant (see hospitals A, G, and K). However, it must be emphasized that the exposure lasts only a few minutes.

Table 32

Ethylene Oxide Concentrations Measured in the Breathing Zone during Transfer of Material to the Aerator

Sterilizer	Hospital	Concentration (ppm)	Sampling method	Sampling time (min)
Amsco Eagle 2045	A	70	IR	2
Castle 3045	B	3	AC	4
Amsco Eagle 2025	D	0.4	GC	2
Castle 3045	E	1.1	AC	22
3M-Sterivac 202B	G	8.3	IR	2
3M-Sterivac 400	H	1.3	GC	2
Castle Sentry 400	I	0.8	GC	2
Amsco Cryotherm	J	0.6	GC	2
Castle Steroxomatic 1630B	K	3.6	IR	2
Castle Steroxomatic 2020	K	20	IR	2
Amsco Cryotherm 656	L	0.9	GC	2
Amsco Eagle 2055	M	0.8	GC	2

Certain measures can reduce this source of contamination and are presented in the four following sections.

a) Transfer of all the material to the aerator

All the material sterilized by ethylene oxide must be transferred to the aerator immediately after the waiting period following the opening of the door.

By this study we were able to see that eleven out of thirteen hospitals transfer the material to the aerator after the 15-minute waiting period when the door is ajar.

In two of the thirteen hospitals, the aerator is not sufficiently large with respect to the sterilizers. Therefore, the material must wait to be aerated. Two hospitals have no aerator. In one case the material is directly sent to the surgical unit after sterilization; in the other, the material is aerated in the sterilization services area.

b) Use of carts or baskets for the transfer of material

Eight out of thirteen hospitals include this procedure which makes it possible to reduce the transfer time of the material to the aerator. This also eliminates any skin contact with the freshly sterilized material. In addition, the unloading of deep sterilizers is made easier because the worker no longer has to put his head inside the sterilizer.

c) The wearing of personal protective equipment

The wearing of gloves was observed in nine out of thirteen hospitals. In nine hospitals, most of the employees wore surgical gloves, the others wore mitts. It must however be pointed out that the effectiveness of this protective equipment was not determined.

During the study, it was noticed that several workers were wearing surgical masks during the unloading. This type of mask is completely ineffective in preventing ethylene oxide inhalation. The wearing of respiratory protective equipment brings up a great number of questions concerning its necessity and its relevance.

d) Other measures having an effect on contamination during transfer

The 15- to 20-minute waiting period before the material is transferred to the aerator allows for considerable dilution of the ethylene oxide concentrations (see Tables 26 and 28). In addition, having a cycle purge or a post vacuum also reduces exposure during transfer by reducing the amount of ethylene oxide in the sterilizer when the door is opened (see Section 8.3.1).

8.3.3 Aerator Door Seal

The evaluation of this source of contamination could not be systematically carried out in all the hospitals. However, in all those hospitals where it was carried out, leaks were detected. Table 33 shows concentrations measured at the aerator door seal at the start of aeration.

The detected leaks are rather significant and vary from 6.2 to 45 ppm (Table 33). These leaks lead to contamination between 0.3 and 8 ppm in the worker breathing zone (Table 34). It must also be emphasized that this source becomes more significant when the aeration cycle lasts several hours (up to 48 hours in certain cases).

Table 33

Ethylene Oxide Concentrations Measured at the Aerator Door Seal at the Start of Aeration

Aerator	Hospital	Concentration (ppm)	Sampling method
3M Sterivac 33B	G	6.2	GC
Castle	K	34	IR
Amsco	L	45	IR
Amsco	M	22.5	GC

Table 34

Ethylene Oxide Concentrations Measured in front of the Aerator in the Worker Breathing Zone at the Start of Aeration

Aerator	Hospital	Concentration (ppm)	Sampling method and time
Castle	C	1	GC
3M Sterivac 33B	E	1.1	AC average for 21 min
Castle	F	0.3	GC
3M Sterivac 33B	G	1.7	GC
Castle	K	8	IR
Amsco	L	2.3	GC

N.B. The precise location where each of the samples was taken is not given because it varies from one hospital to another. These samples were taken in the employee working areas.

A periodic check of the door seal is a control measure for reducing or eliminating this source of contamination.

By visual inspection of the aerator door seals, the obvious deterioration can be detected (hardened or flattened seals). These seals should be replaced when their effectiveness becomes questionable.

In addition, it is suggested that manufacturers improve the door locking system as well as the effectiveness of the door seal.

8.3.4 Aerator Exhaust Outlet

In eleven of the thirteen sterilization services equipped with an aerator, the warm air exhaust outlet of the aerator is connected to an exhaust system in order to avoid contamination of the area. One of the other two hospitals whose aerator exhaust outlet was not connected to the exhaust system modified its set-up after the sampling visit. It goes without saying that connecting the warm air exhaust outlet to the exhaust system completely eliminates this source of contamination.

In the case of aerators which are not enclosed in a mechanical room, this source of contamination becomes all the more significant when there is a long aeration cycle.

8.3.5 Changing Cylinders and Filters

During the changing of cylinders and filters, contamination is due to the emptying of gas-lines containing ethylene oxide under pressure.

This contamination could be checked in only one hospital. In this one case it was possible to determine the exposure of workers assigned to this task.

The average concentration recorded in the worker breathing zone during the 20 minutes that it took to carry out this procedure was approximately 78 ppm. The maximum and minimum concentrations are 526 ppm and 5 ppm respectively. These concentrations were measured using infrared spectrophotometry. Valves would prevent this leaking of gas into the ambient air.

a) Valve

Through observation of facility design during the sampling visit to the hospitals, it was seen that out of a total of sixteen sterilizers in which the gas supply is from cylinders, only ten were equipped with a valve between the cylinder and the sterilizer. This control measure was not evaluated. Its usefulness is evident because it prevents the emptying of the ethylene oxide gas supply line into the ambient air during the changing of cylinders.

8.3.6 General Ventilation System

The lack of a general ventilation system or having a deficient one can magnify the effect of the various sources of contamination evaluated. An efficient general nonrecirculating ventilation system is an additional safeguard for reducing exposure levels.

The study showed that ten hospitals out of fourteen have a general ventilation system in the sterilization services area. In these ten hospitals, some of the services area air is recirculated. One of the hospitals recirculates 100% of the services area air by using an air conditioner. No dilution with fresh air is possible in such a case. In that service, a concentration of 20 ppm was measured by IR, 60 minutes after opening the door. This concentration was measured in the center of the room, in the worker breathing zone.

The four other hospitals do not have a general ventilation system but have only a manually operated fresh air supply system.

It seems therefore that none of the hospitals evaluated had a totally adequate general ventilation system. In addition, the results of the identification of exposed workers show that approximately 30% of the sterilization services are not equipped with mechanical ventilation (see Table 5). One can foresee that this corrective measure will be the most difficult to implement, especially because of the cost of installation or modification as well as the cost of operation.

8.4 Summary of the Results of the Industrial Hygiene Study

This section presents a table relating the factors considered in the study to the different sterilizers evaluated.

Table 35: Summary Table of the Industrial Hygiene Results

Hospitals	A		B		C		D		E		F		G		H		I		J		K		L		M		N	Totals
Sterilizers	AMSCO CRYOTHERM 30"	AMSCO EAGLE 2045 60"	CASTLE 3045	——	CASTLE SENTRY 400	——	AMSCO EAGLE 2025	AMSCO EAGLE 2025	CASTLE 3045	——	CASTLE 3145	BARD ANPROLENE	3 M STERIVAC 202 B	——	3 M STERIVAC 400	3 M STERIVAC 200 AA	AMSCO CRYOTHERM	CASTLE SENTRY 400	AMSCO CRYOTHERM	——	CASTLE STEROXOMATIC 2020	CASTLE STEROXOMATIC 1630 B	AMSCO CRYOTHERM 656	——	AMSCO EAGLE 2055	CASTLE STEROXOMATIC	BARD ANPROLENE	
Factors considered: Procedure																												
First vacuum only			X									N/A				X	X	X			X	X	X			X	N/A	8/19
First vacuum and post vacuum	X	X										N/A							X								N/A	3/19
First vacuum and cycle purge					X		X	X	X		X	N/A	X		X										X		N/A	8/19
Exhaust hood (manufacturer)		X					X	X				N/A			X										X		N/A	5/19
Exhaust hood (hospital)					X				X														X					3/19
Water/gas separator			1				X	X			X	N/A	N/A		N/A	N/A									X		N/A	4/16
Valve	X	X	X				X	X	X		X	N/A	N/A		N/A	N/A							X		X	X	N/A	10/16
Factors considered: Facility design																												
Mechanical room: negative pressure	X		X		X		X		X		X		N/A		N/A		X		X		X		X		X		N/A	11/11
Mechanical room: continuous ventilation	X		X		X		X		X		X		N/A		N/A		X		X		X		X		X		N/A	11/11
Mechanical room: air recirculation													N/A		N/A								X				N/A	1/11
Enclosed sterilizer	X	X	X		X		X	X	X		X	N/A	N/A		N/A	N/A			X		X	X	X		X	X	N/A	14/16
Cylinders in the mechanical room	X		X				X				X		N/A		N/A		X		X		X				X		N/A	8/11
Aerator connected to exhaust system	X				X		X		X		X		X		X		X		X				X		X		N/A	11/14
Sterilization service having air recirculation	X		X		X		X		X						X		X				X		X		X		X	14/16
Factors considered: Work practices																												
Leaks from the sterilizer door	X				X		X	X				N/A	X		X	X	X	X	X		X	X	X		X		N/A	14/19
Leaks from the gas-lines													N/A		N/A		N/A		X		X		X				N/A	3/10
Mechanical room: door closed	X		X		X				X		X		N/A		N/A				X		X		X		X		N/A	9/11
Mechanical room: door locked	X								X																X			3/11
Exhaust hood: continuous operation	2				X		X		X														X		X			6/19
Exhaust hood: interrupted operation															X												N/A	1/19
15-minute waiting period before transfer	X		X				X		X			N/A	X		X		X		X		X		X		X		N/A	11/13
Immediate transfer					X						X																N/A	2/13
Gloves worn during transfer	X		X				X				X		X				X		X		X		X				N/A	9/13
Material not aerated	X																										N/A	0/13
Use of basket: loading, unloading	X	X	X		X		X	X			X	N/A	X					X							X	X	N/A	11/19

Notes

1. A water/gas separator is not used in this hospital because the drain is sealed.
2. The exhaust hood located above the door was not in operation during our visit.

N/A - not applicable to this type of sterilizer

9. Conclusions

The study and the collected data made it possible to answer the questions asked in the introduction.

9.1 Identification of Exposed Workers

The collected data allowed us to determine the number of hospitals involved and the number of exposed workers. This data gives information on the types of sterilizers used in Quebec. It was therefore possible to observe that:

— the collected data show the situation in short-term care hospitals and psychiatric hospitals. However, extended-care hospitals and medical and dental clinics are just as likely to use ethylene oxide;

— 85 hospitals in Quebec use ethylene oxide;

— in these hospitals there are approximately 1000 workers exposed to ethylene oxide;

— the 85 hospitals referred to have 114 sterilizers of which approximately 80% are Amsco or Castle.

9.2 Exposure Sources

The principal exposure sources identified are the following:

— the residual ethylene oxide in the sterilizer when the door is opened and the material unloaded;

— the ethylene oxide released at the drain during the exhaust cycle of the sterilizer;

— the sterilized material, during transfer from the sterilizer to the aerator;

— the ethylene oxide leaks from the sterilizer door;

— the ethylene oxide leaks from the aerator door;

— the aerator exhaust if not connected to the outdoors;

— the ethylene oxide released during the changing of cylinders;

— the ethylene oxide released during the changing of filters;

— the leaks from the ethylene oxide gas-lines.

Sterilizers using Anprolene® are a special case. Since the procedures are different, so are the sources of contamination (see Section 5.3). This method was not the subject of an extensive study. However, the sources can be easily controlled if the sterilizer is used under an exhaust hood.

9.3 Types of Exposure

The aim of the study was not to determine the exact level of worker exposure. However, the collected data allow the observation that:

— the most significant exposures are usually punctual and short-term (unloading the sterilizer, transfer of the freshly sterilized material, ethylene oxide released at the drain);

— leaks from the sterilizer and aerator doors are a continuous source of exposure which can last for several hours;

— the maximum concentrations measured inside the sterilizers upon opening the door show that depending on work practices, short-term exposure (15 minutes) could be higher than the standard presently in effect in Quebec (95 ppm);

— when the principal control measures are not being used, the time-weighted average concentration for 8 hours can be higher than the threshold of 1 ppm proposed by ACGIH.

9.4 Control Measures

The main control measures which can be used are the following:

— cycle purge or post vacuum;
— exhaust hood over the sterilizer door, in operation during the entire sterilization cycle;
— 15- to 20-minute waiting period once the door is opened;
— enclosing the sterilizer in a ventilated mechanical room;
— water/gas separator;
— local exhaust at the drain;
— controlled access to the mechanical room;
— connecting the aerator exhaust outlet to an exhaust system to the outdoors;
— periodic checking and maintenance of the sterilizer and aerator door seals;
— installing valves for cylinder and filter changes;
— sterilizers using Anprolene® must be placed under an exhaust hood.

The evaluations carried out show that these control measures are relatively effective. It must also be emphasized that several of these measures are already in use in hospitals. A good number of the hospitals evaluated use mainly the following measures: a cycle purge or post vacuum, a ventilated mechanical room, a 15- to 20-minute waiting period, and an exhaust hood above the sterilizer door.

9.4.1 General Ventilation

General ventilation is an interesting measure because it is an additional safeguard in the reduction of exposure levels. However, it proves to be the most difficult measure to implement.

9.5 Residual Level in the Ambient Air when the System Is Functioning Optimally

A system which functions optimally will be defined as one which includes the principal control measures presented in Section 9.4.1.

When such a system is used, it is possible for us to conclude that:

— the average concentrations in the ambient air for eight hours of exposure should be lower than 1 ppm;

— the average concentrations in the ambient air for short-term exposure (15 min) could be greater than 1 ppm, especially during unloading of the sterilizer and transfer of the material.

9.6 Use of Sampling and Analytical Methods

There are many problems associated with measuring ethylene oxide concentrations in the ambient air. Due to the nature of the procedure, there is rapid

variation in these concentrations both temporally and spatially. Humidity, temperature and Freon 12® can interfere with sampling or analysis. Finally, measuring concentrations in the order of 1 ppm is in itself a delicate procedure.

The present study made it possible to assess three methods for evaluating the workplace and to define the limitations of these methods. The study allows one to conclude that measuring ethylene oxide concentrations under the aforementioned conditions requires expertise in the use of direct reading instruments and laboratory equipment in order to analyze the samples. No easier solution has yet been found.

The choice of method depends on the following conditions during sampling:

— high concentrations over long and short periods of time can be measured by adsorption on activated charcoal and by IR;

— low concentrations over long periods of time can be measured by two methods, either by adsorption on activated charcoal or by photoionization detection.

— low concentrations over short periods can be measured only by photoionization detection.

10. Recommendations

When the possible effects of ethylene oxide on health are considered, the necessity of reducing worker exposure to the lowest level technically and economically possible is recognized.

The following recommendations are a series of measures aimed at reducing the sources of contamination to the lowest possible level, if not eliminating them altogether. They should provide hospitals with information on the most effective measures to implement.

10.1 Procedure

It is suggested that:

— the sterilizer controls be modified to include an exhaust cycle (purge or post vacuum) at the end of the sterilization cycle. This modification can be easily implemented by the sterilizer manufacturer;

— the locking system and the seals on sterilizer and aerator doors be improved. It is therefore recommended that manufacturers of this equipment develop the appropriate corrective measures and make them available to users.

10.2 Facility Design

In general, it is recommended that a ventilation expert be consulted who will ensure the quality of the ventilation system.

It is suggested:

— that the sterilizer be installed in a ventilated mechanical room maintained at negative pressure with respect to the rest of the sterilization services area;

— that the ventilation system in the mechanical room serve only this area and that the exhaust be connected directly to the outdoors. This will prevent the potential contamination of other areas of the hospital;

— that an exhaust hood be installed above the sterilizer door (see Figure 3). This hood (A) is connected to a fan (B) which is vented directly to the outdoors. It is recommended that the fan exhaust not be connected to an existing ventilation system, so that contamination of other areas of the hospital be avoided.

For some models of sterilizers, the manufacturer can provide an exhaust hood specifically designed for installation above the door. Whenever this is possible, it is preferable to use exhaust hoods recommended by the manufacturer because they are effective.

When an exhaust hood is not available from the manufacturer, one designed by the user must be installed. This exhaust hood must be installed as close as possible to the sterilizer door in order to ensure maximum effectiveness. This hood should be 15 cm deep in order to cover the sterilizer door during the 15- to 20-minute waiting period. The airflow through the hood should be a minimum of 100 cubic feet* per minute per square foot of sterilizer door area.

Another possibility would be to install an exhaust hood equipped with a sliding door which would be lowered during the sterilization cycle and would remain lowered during the waiting period (of 15 to 20 minutes) when the sterilizer door is opened. It is suggested:

— that in the case of 3M sterilizers, the exhaust outlet from the equipment be connected directly to the outdoors. This would prevent contamination of the working area air at the end of the sterilization cycle;

— that the sterilization services area be equipped with a nonrecirculating general ventilation system;

— that the exhaust from the aerator be connected to a nonrecirculating ventilation system vented to the outdoors;

— that the ethylene oxide cylinders be located in the mechanical room or in a ventilated storage room maintained at negative pressure;

— that an air capture system be installed to control ethylene oxide emissions at the drain. This system is offered by the sterilizer manufacturers. It consists of a water/gas separator (J) to which the vacuum pump outlet (K) is connected. The ethylene oxide is exhausted by a vent or by a fan connected to the outdoors, while the water is discharged into the drain in the mechanical room (Figure 3);

— that an airtight capture box (L) be installed above the drain. This box is equipped with a vent connected to the outdoors (Figure 3). This feature makes it possible to exhaust the ethylene oxide that was not captured by the separator (J);

— that the safety valve of the sterilizer (C) be connected to a vent exhausting directly to the outdoors (Figure 3). This prevents significant contamination should the valve open to release overpressure inside the sterilizer;

— that a valve (D) be installed between the sterilizer and the ethylene oxide cylinder (E) (Figure 3). This valve should be installed as close as possible to the cylinder in order to minimize the ethylene oxide leaks during cylinder change;

— that the filter arrangement on the ethylene oxide gas-line be modified in such a way as to reduce exposure when the filter is changed during sterilization. Two valves (F) and (G) will be installed, one before and one after the filter (I). A bypass gas-line equipped with a valve (H) will be installed between the ethylene oxide gas-line and a vent connected to the outdoors (Figure 3);

— that sterilizers using Anprolene® be installed and operated under an exhaust hood so as to minimize exposure.

10.3 Work Practices

The condition of the sterilizer and aerator door seals should be checked regularly. They should be replaced if deteriorating. The frequency of checks depends on sterilizer use. This frequency should be determined by each hospital.

* 100 cubic feet per minute = 2832 litres per minute.

It is also suggested:

— that the exhaust hood above the sterilizer door be in operation during the entire sterilization cycle. This measure prevents exposure due to door leaks;

— that the mechanical room door be kept closed and locked to control access. Only authorized personnel should be allowed to enter;

— that a waiting period of at least fifteen to twenty minutes be included at the end of the sterilization cycle. During this period, the door should be open approximately ten to fifteen centimetres to allow the residual ethylene oxide to be exhausted by the hood. This step makes it possible to minimize exposure during the unloading of the sterilizer;

— that protective mitts be worn during unloading of the sterilizer and during transfer to the aerator, and that they then be put into the aerator and left there for the entire aeration cycle;

— that material which has not been aerated not be left in the working area. The sterilized material should be placed immediately in the aerator when it is unloaded from the sterilizer;

— that valves be used for cylinder and filter changes.

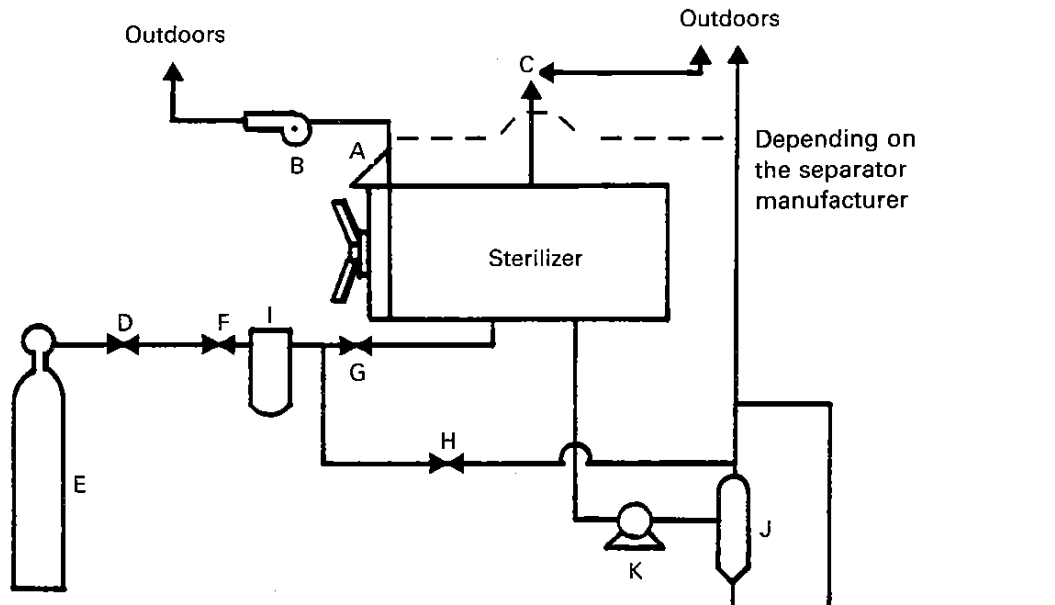
In normal use, valves (F) and (G) placed on both sides of the filter are open and valve (H) is closed. When the filter is changed, valves (F) and (G) are closed and valve (H) is opened in order to release the pressure inside the filter. The ethylene oxide released is exhausted outdoors by means of the vent. The filter can then be removed and a new filter installed. Valves (F), (G) and (H) are then reset at their normal operating position. This procedure minimizes exposure during filter change.

To detect leaks, there are several types of instruments available. These instruments have flammable gas detectors that are used for many substances, one of which is ethylene oxide. Because of their sensitivity of 10 ppm for ethylene oxide, they make it possible to detect leaks at the checkpoints.

Leaks may also be detected by a Freon detector and liquid leak detector.

Figure 3

Recommended Control Measures



Legend

A- Exhaust hood
B- Fan
C- Emergency valve
D- Valve
E- Cylinder
F- Valve
G- Valve
H- Valve
I- Filter
J- Separator
K- Vacuum pump
L- Airtight capture box

Appendix I

Preliminary Questionnaire Sent to the Hospitals

Questionnaire A

Name of the hospital: _____

Address: _____

_____

Telephone: _____

Person in charge of the service: _____

1. How many ethylene oxide sterilizers are used in your service?

   _____

2. What model(s) of sterilizer(s) do you use and in what year was (were) it (they) manufactured?

   Make Model Year

   _____

   _____

   _____

3. Can you give the names and addresses of the manufacturer(s) or supplier(s) of your ethylene oxide sterilizer(s)?

   _____

   _____

   _____

4. From what company do you buy ethylene oxide? _____

   _____

   In what type of container is it delivered?

   Cylinders Tank Capacity

   _____

   _____

   _____

5. What is your annual consumption of ethylene oxide? _____

   _____

   Cylinders Tank Capacity

   _____

   _____

   _____

6. Do you have a preventive maintenance program for your sterilizers?

   Yes _____ No _____

   If yes, how often is your equipment checked? _____

   _____

   _____

   _____

7. Do you have an environmental surveillance program; that is, do you have procedures for checking the ethylene oxide concentrations in the air of the room where ethylene oxide sterilization is carried out?

   Yes _____ No _____

   If yes, how often are these procedures carried out? _____

   _____

   _____

   What was the average of these detected concentrations? _____

   _____

   _____

   What type of measuring instrument do you use?

   Make Model Year

   _____

   _____

8. Is the ethylene oxide sterilization carried out in a closed room or is the equipment located in the services area? _____

   _____

9. Is there mechanical ventilation in the room where the sterilization is carried out? _____

   _____

10. How many workers are exposed to ethylene oxide in your service?

    _____

11. How many people are assigned to the changing of ethylene oxide cylinders? _____

    How often are they changed?

    Number of cylinders/month/sterilizer

    _____

12. As an average, for how many hours a day are the ethylene oxide sterilizers in operation? _____

13. Do you ever smell ethylene oxide in the sterilization services area? _____

14. Is there a waiting period before opening the sterilizer?

    — Always _____ — Sometimes _____

    — Often _____ — Never _____

15. Do the workers in the department consider exposure to ethylene oxide a risk? _____

16. What kind of information do you have concerning the risks associated with ethylene oxide use? _____

    _____

    _____

    _____

    Where did you get this information? _____

    _____

17. Have workers already reported health problems which could be connected to ethylene oxide exposure?

    Yes _____ No _____

    If yes, which ones? _____

    _____

    _____

Appendix II

Questionnaire Filled Out during the Sampling Visit

Questionnaire B

IRSST/ASSTSAS
Ethylene oxide — sterilization — hygiene study

Hospital: _____ Date: _____

Address: _____

_____

_____

People Interviewed	Duties	Telephone no.

Part A
Sterilizers and Aerators

Service or department	St/Ae	Mark

Model	Capacity	Year

Part B
Potentially Exposed Persons

Service or department	Duties	Number of people		
		Day	Evening	Night

Part C
Storing and Handling of Gas Cylinders

Capacity	Commercial Name	No. of cylinders per month	No. of sterilizers per cylinder

Part D
General Considerations

1. Preventive maintenance program: (what, by whom, how often)

_____

_____

_____

2. Environmental monitoring program: (what, where, when, instruments, results) _____

3. Information and training program for personnel: _____

4. Extent of personnel training: _____

5. Health/safety committee: _____

Part E

Sterilization Procedures

Sterilizations per shift	Time	Average duration
Day _____	From _____ to _____	_____
Evening _____	From _____ to _____	_____
Night _____	From _____ to _____	_____

Description of the procedure: length of the procedures, work practices

Loading: _____

Sterilization: _____

Exhaust: _____

Opening the door: _____

Aeration: _____

Storing of sterilized articles: _____

Part F

Mechanical Room

General ventilation: _____ Negative pressure: _____ (smoke test)

Positive pressure: _____

Drain: _____ Water/gas separator: _____

Local ventilation: _____

Appendix III

Sampling and Analytical Methods

III.1 Introduction

There are several methods for measuring ethylene oxide in the air of the working area. In the framework of this project, we had to choose from the available methods those that enabled us to answer the questions brought up when the workplace sampling strategy was developed. The following sections are a description and a critical analysis of the methods actually available for measuring ethylene oxide in the air and these sections give reasons for the choice of sampling and analytical methods used in this study.

The methods available can be divided into two types:

1. Methods using direct reading instruments;
2. Ethylene oxide sampling methods with subsequent analysis in the laboratory.

The advantage of direct reading instruments is the speed with which the result is obtained. Using this type of instrument, it is possible to obtain almost instantaneous readings of ethylene oxide concentrations in the air. It is also possible in some cases to carry out continuous monitoring of ethylene oxide concentrations in the air. On the other hand, the technical expertise required for the procedure as well as the cost of these instruments decreases the likelihood of their being used during an industrial hygiene study carried out by a hospital. The disadvantage of the second type of method is the delay in obtaining results. However, the relative costs and the ease of handling the sampling instruments are definite advantages, especially during an industrial hygiene study carried out by hospitals.

III.2 Sampling and Analytical Methods Using Direct Reading Instruments

a) Detection by infrared spectroscopy (IR)

Direct reading infrared analyzers are equipped with a gas cell having a mirror, into which the sample is continuously introduced by a pump with a high flow rate (8 L/min). Two different wavelengths (11.8 μm and 3.3 μm) can be used to analyze the ethylene oxide contained in the cell. These wavelengths are obtained by choosing the appropriate optical filter on the instrument. For the same concentration of ethylene oxide, the 11.8 μm wavelength is more sensitive than the 3.3 μm wavelength. However, this wavelength (11.8 μm) has the disadvantage of being sensitive to interference by Freon 12®. In the case where ethylene oxide is used in the form of a mixture with Freon 12®, the 3.3 μm wavelength should be used rather than the 11.8 μm wavelength. On the other hand, humidity can interfere with the analysis when the 3.3 μm wavelength is used.

When Freon 12® and humidity are both present during ethylene oxide sterilization, the use of the two wavelengths should be foreseen. However, when the results are interpreted, these two variables must be taken into consideration.

Before the analyses are carried out, the instrument must be calibrated with standards prepared using a static volumetric method (17). These standards are prepared in a gas bag or directly in the gas cell of the instrument. This calibration is very stable for a minimum of six hours. Using this instrument makes it possible to measure ethylene oxide concentrations from 3 to 800 ppm.

b) Detection by photoionization (GC-PI)

The principle of photoionization detection consists of irradiating the substance to be detected with ultraviolet light whose photons have the energy necessary to ionize the substance.

Ionizing the substance produces electrons that are captured by the photoionization detector. The signal produced is amplified, then reproduced on a chart (chromatogram).

The linearity of the photoionization detector response as a function of ethylene oxide concentration was checked for concentrations from 0.1 to 20 ppm. When the concentration is higher than 20 ppm, the sample has only to be diluted with a gas which does not contain ethylene oxide. A calculation is then done so that this dilution factor is taken into account.

During sampling when Freon 12® is present, a direct reading instrument equipped with a chromatographic column should be used. Instruments not equipped with a column cannot separate ethylene oxide from Freon 12® and consequently give an incorrect result for the ethylene oxide concentration.

This type of instrument has a certain sensitivity to variations in temperature, making it necessary to analyze an ethylene oxide standard in order to check whether detector response remains constant as the temperature fluctuates.

The use of a sampling loop rather than a gas syringe is suggested because the former proves to be more convenient during sampling.

c) Detection by flame ionization (GC-FI)

This section presents a second sampling method using GC. It allows the measurement of higher concentrations than does the GC-PI method described in the preceding section.

The substance arriving at the flame ionization detector is ionized by a hydrogen flame burning in air. The signal produced is amplified, then recorded on a chart.

The flame ionization detector gives a response to all organic substances. This implies that if the measurement takes place in the field, a direct reading instrument having a chromatographic column should be used in order to separate the ethylene oxide from the Freon 12®.

The procedure is facilitated by the use of a gas sampling loop rather than a gas syringe as a means of introducing the gas.

This type of detector allows the measurement of concentrations from 1.0 to 5000 ppm ethylene oxide.

III.2.1 Choice of Sampling and Analytical Methods Calling For Direct Reading Instruments

Due to the availability of an infrared analyzer and a gas chromatograph having a photoionization detector, a chromatograph having a flame ionization detector was not used.

The infrared analyzer allowed the measurement of high ethylene oxide concentrations which can fluctuate rapidly. Since the effective range of this instrument is from 3 to 800 ppm, it was necessary to use a chromatograph having a photoionization detector for concentrations lower than 3 ppm. The chromatograph allowed the detection of extremely low concentrations, in the order of 0.1 ppm.

The rapid response time of these instruments (20 sec to 2 min) was used to advantage in the industrial hygiene studies, making it possible to follow temporal and spatial changes in gas concentrations.

III.3 Sampling Methods Having Laboratory Analysis

a) Activated charcoal tubes (AC)

1- NIOSH Method S-286 (18)

Two activated charcoal tubes containing 400 and 200 mg of charcoal are placed in series, connected by Tygon® tubing. In the first tube, the second section of charcoal was removed and in the second, the first section was removed.

When this is done, the first tube represents the first section and the second tube, the back-up. Once the sampling has been completed, the two tubes are separated and individually sealed, thus preventing any migration of captured gas. The sampling flow rate and total volume recommended by NIOSH are 50 mL/min and 5 L respectively.

2- OSHA Method (19)

This method uses the conventional charcoal tube containing 100 and 50 mg of charcoal with a sampling flow rate of 50 mL/min and a total volume of 3 L. Due to the small amount of adsorbent used, this method is not recommended.

3- Qazi-Ketcham Method (20)

This method uses a tube containing 700 and 390 mg of activated charcoal selected for EtO sampling. This method was checked for total volumes of 5 L and 10 L and sampling flow rates of 20 to 500 mL/min. According to the authors, the detection limit for a volume of 10 L is 0.15 ppm.

The advantages of using activated charcoal tubes:

— sampling is easy to carry out and can be used for measuring environmental or personal exposure;

— EtO analysis is easy to carry out using gas chromatography (GC);

— using GC makes it possible to eliminate interference, such as that from Freon 12®.

The disadvantages of using activated charcoal tubes:

— saturation of the active sites on the charcoal and displacement of the ethylene oxide can occur if the sampling is long-term or if the physical and chemical conditions (temperature, humidity, Freon) are extreme. It is possible, by placing two tubes in series, to avoid these problems while carrying out long-term sampling in the presence of Freon and humidity;

— the sampling flow rate can be a factor which limits sensitivity if short-term exposure must be evaluated;

— in the OSHA and Qazi-Ketcham methods, the migration of ethylene oxide from one section to another can occur between sampling and analysis. To control this, the tubes must be stored in a freezer.

b) Bubbler

The method developed by Romano and Renner (21) uses a bubbler containing 10 mL of 0.1 N H_2SO_4. When the ethylene oxide comes in contact with the solution, it is hydrolyzed to ethylene glycol. In the laboratory, the acid solution is neutralized and analyzed by gas chromatography. Before and after sampling the bubbler must be weighed to make sure that there has been no evaporation of the collecting solution. The sampling parameters are as variable for the flow rate as for the volume (12 to 418 L). A modification of this method was used in a study on the exposure of hospital personnel to ethylene oxide in Belgium (22).

Advantages of a bubbler:

— the absorption efficiency is independent of atmospheric conditions at the time of sampling;

— the derivative formed (ethylene glycol) is much more stable than ethylene oxide;

— it is not necessary to calculate the desorption coefficient.

Disadvantages of the bubbler:

— this kind of sampler is awkward and is not suitable for measuring personal exposure levels;

— ethylene glycol is a substance which is difficult to analyze by gas chromatography.

c) Sampling bags

This method consists of introducing a volume of air from the working area into a sampling bag. An aliquot of air is then injected into a gas chromatograph to analyze it.

Advantages of sampling bags:

— The sampling rate is not a critical parameter. A very short exposure period can be evaluated;

— Sampling is independent of atmospheric conditions;

— The sample of air can be analyzed using a gas chromatograph equipped with a photoionization or a flame ionization detector;

— The sample can also be analyzed using infrared spectrophotometry.

Disadvantages of bags:

— These bags are awkward to use and to carry;

— The detection limit is higher than in other methods using a larger volume of air.

®: Registered Trademark
Tygon is a trademark of the Norton Company

d) Passive dosimeters

The sampling principle of passive dosimeters is based on the molecular diffusion principle of gases and vapors in air (23). These dosimeters contain an adsorbent similar to activated charcoal. The organic molecules near the adsorbent are trapped by it and because of this, sampling can be carried out. The sampling rate is proportional to the diffusion coefficient of the substance sampled and to the dimensions of the dosimeter.

The 3M company manufactures a special dosimeter for ethylene oxide (23). Its particular feature is that the adsorbent is covered with hydrobromic acid. When ethylene oxide comes in contact with the adsorbent, it forms 2-bromoethyl alcohol. The analysis is carried out using gas chromatography.

Advantages of the 3M passive dosimeter:

— Sampling can be done very easily. No calibration in the field is required;

— The dosimeters are very light. They do not inconvenience any of the workers;

— The product (2-bromoethyl alcohol) is a substance much more stable than ethylene oxide.

Disadvantages of the 3M passive dosimeter:

— For evaluating the ethylene oxide in the air, the precision and accuracy criteria must be checked and validated if need be;

— This type of sampling is not recommended for short-term exposure;

— The sensitivity of the analytical method is average. According to the 3M Company, the detection limit is 2 ppm/hour;

— As in activated charcoal tubes, the reagent can become saturated if the ethylene oxide concentrations are too high or if the humidity is high.

III.3.1 Choice of a Sampling/Analytical Method

The sampling sites and the sampling times in some way represent limitations for certain sampling methods. The use of a bubbler was rejected not only because of operating difficulties, but also because this technique requires a sampling time of at least 120 minutes (21). Passive dosimeters have similar problems. In addition, the precision and accuracy criteria for dosimeters are not well enough defined for them to be used in this study. The sampling bags were not used because of the availability of a portable gas chromatograph having a photoionization detector and because of the availability of an infrared analyzer.

Among the methods using activated charcoal tubes, the Qazi-Ketcham method was used for the following reasons:

— The tubes are available;

— The sampling parameters are relatively flexible in that the possible sampling times are variable;

— The chromatographic analysis is easy to carry out;

— The sampling is easy to carry out also;

— The precision and accuracy criteria were checked following several laboratory trials and the method from this point of view proved to be satisfactory.

Appendix IV

List of the Main Distributors of Sterilizers

Four makes of sterilizers are presently available in Quebec.

AMSCO:
AMSCO
550, boul. Montpellier
St-Laurent, Québec
H4N 2G7
Telephone: 744-2821

CASTLE:
Taylor Instrument
216, boul. Brunswick
Pointe-Claire, Québec
H9R 1A6
Telephone: 697-7510

VERNITRON:
Bermédic Matériel Médical Inc.
1055, rue Victoria
St-Lambert, Québec
J4R 1P6
Telephone: 465-6738

3M:
3M Canada
680, rue Lépine
Dorval, Québec
H9P 2S5
Telephone: 631-7600

It should be noted that the companies manufacturing AMSCO and CASTLE sterilizers control the greatest share of the market. Since 3M sterilizers are smaller, there are fewer of them than the two others. Only one VERNITRON is in use in Quebec and it is in a pharmaceutical firm.

Sterilizers using Anprolene® are sold by Bard.

C.R. Bard Inc.
731 Central Ave.
Murray Hill
New Jersey

According to the survey carried out at the beginning of the study, only seven hospitals were probably using this method. However, it is very possible that the use of Bard sterilizers is more common in medical and dental clinics.

Appendix V

Geographical Distribution of the Hospitals

Table 36

Regional Distribution of the Hospitals and of the Exposed Employees

Region	Hospitals	Exposed employees
01	4.8%	2.8%
02	3.9%	4.2%
03	15.7%	16.6%
04	6.6%	5.5%
05	4.8%	4.9%
06A	32.8%	49.0%
06B	6.1%	3.8%
06C	10.5%	6.6%
07	4.4%	2.1%
08	3.9%	2.7%
09 and 10	6.6%	1.5%

Region	Counties
01	Bonaventure, Gaspé, Îles-de-la-Madeleine, Matane, Matapédia, Rimouski.
02	Chicoutimi, Lac Saint-Jean, Abitibi-Est.
03	Beauce, Bellechasse, Charlevoix, Dorchester, Frontenac, Kamouraska, Lévis, L'Islet, Lotbinière, Mégantic, Montmagny, Montmorency, Portneuf, Québec, Rivière-du-Loup, Témiscouata, Wolfe.
04	Arthabaska, Champlain, Drummond, Lotbinière, Maskinongé, Mégantic, Nicolet, Saint-Maurice, Yamaska.
05	Compton, Frontenac, Richmond, Sherbrooke, Stanstead, Wolfe.
06A	Île-de-Montréal, Île Jésus.
06B	Argenteuil, Berthier, Deux-Montagnes, Joliette, Labelle, L'Assomption, Montcalm, Terrebonne.
06C	Bagot, Beauharnois, Brôme, Chambly, Châteauguay, Huntingdon, Iberville, Laprairie, Missisquoi, Richelieu, Rouville, Saint-Hyacinthe, Saint-Jean, Shefford, Soulanges, Vaudreuil, Verchères, Yamaska.
07	Gatineau, Hull, Labelle, Papineau, Pontiac.
08	Abitibi, Témiscamingue.
09	Saguenay (Côte-Nord)
10	Territoire Nouveau-Québec

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