参考資料１０

Pilot project for the environmental technology verification
In the field of ethylene oxide treatment technology

Protocol for the verification of ethylene oxide treatment technology

Sept. 11, 2003

Environmental Management Bureau,
Ministry of the Environment

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Main section

I. Introduction

1. Target technologies

The ethylene oxide waste gas treatment technologies specified in this protocol for the verification are those (equipment and others) that process the waste gas from an ethylene oxide sterilizer (approximately 50 to 200 L in capacity) used in medical institutions, pharmaceutical plants, and the like by combustion, catalytic oxidation, hydrolysis, and others, and that may be additionally installed.

2. Types and outline of verification tests

(1) Types of verification tests

In the verification test, waste gas treatment technologies specific to environmental technology developers are verified, and the results evaluated. In the verification test, the following items will be verified for each target verification apparatus.

- Environmental protective effect under practical operational conditions in the range specified by an environmental technology developer
- Energy, materials, and cost required for operation
- Operational environment allowing normal operations
- Labor for operations and maintenance (hereinafter referred to as the “O&M”)

(2) Verification testing process

The verification test will primarily be conducted according to the steps specified below.

i Planning

The plan for the verification test (hereinafter referred to as the “Test Plan”) will be prepared before the test is conducted. The Test Plan will be prepared by a Verification Organization in cooperation with an environmental technology developer.

The main activities in the planning stage are as follows:

- Specifying the individuals and organizations involved in the test
- Specifying the general and technology-specific objectives of the test
- Specifying verification items
- Determining analytical and sampling methods and the test period
- Establishing a Test Plan that includes specific procedures, a schedule, and the individuals in charge, based on the results of the above items

ii Verification test

In this stage, a verification test will be conducted according to the Test Plan described above. The verification test verifies the conformity of a target verification apparatus with its objectives specified in the planning stage. The Verification Organization may, if necessary, subcontract part of the verification test to external test organizations.

iii Data assessment and reporting

In the final stage, all data collected will be analyzed for verification, and a report on the verification test (hereinafter referred to as the “Verification Report”) will be compiled. A Verification Organization is responsible for analysis of the data and reporting. To accelerate the above process, the Verification Organization may subcontract an external organization to

prepare a draft of the Verification Report.

The Verification Report will be submitted by the Verification Organization to the Ministry of the Environment. In the report, the suitability of the verification tests will be discussed by the working group on the ethylene oxide treatment technology (hereinafter referred to as the "working group") of the committee on the pilot project for the environmental technology verification. After being approved by the Ministry of the Environment, the report will be returned to the Verification Organization. The approved Verification Report will then be issued by the Verification Organization to the environmental technology developer and simultaneously disclosed to the public.

3. Definitions of terms and phrases

The definitions of the major terms and phrases are in accordance with those of the Japanese Industrial Standards (hereinafter referred to as "JIS"). The standards in JIS particularly relevant to this protocol for the verification (hereinafter referred to as "Protocol") are as follows:

JIS K 0050 "General rules for chemical analysis"

JIS K 0114 "General rules for gas chromatographic analysis"

JIS K 0123 "General rules for analytical methods in gas chromatography mass spectrometry"

JIS K 0211 "Technical terms for analytical chemistry (General part)"

JIS K 0214 "Technical terms for analytical chemistry (Chromatography part)"

JIS K 0215 "Technical Terms for analytical chemistry (analytical instrument part)"

JIS B 8530 "Glossary of terms for pollution control equipment"

In addition, the terms and phrases used in this Protocol are defined as set forth in Table 1.

Table 1 Definition of terms and phrases used in the protocol for the verification

Term/Phrase	Definition
Target verification technology	A method for treating ethylene oxide to be verified in the verification test. The target verification technology should have a clear scientific basis.
Target verification apparatus	An apparatus to be used in the verification test among the apparatuses / equipment representing the embodiments of the target verification technology
Verification items	Items to be analyzed for determination of the performance of a target verification apparatus
Test Site	An establishment where a target verification apparatus is to be installed and the verification test is to be conducted
Verification applicant	A person wishing to have his/her own technology verified. If the applied technology is selected as a target verification technology, the verification applicant will be referred to as an "environmental technology developer."
Environmental technology developer	A person who possesses a target verification technology. Until the applied technology is selected as a target verification technology, the person is referred to as a "verification applicant."

II. Verification test system

1. Ministry of the Environment

- Comprehensively administers the entire pilot project for the environmental technology verification
- Comprehensively discusses the verification test system
- Selects target verification technology fields for the verification test
- Establishes and administers the committee on the pilot project for the environmental technology verification and its working groups
- Creates a protocol for the verification
- Selects Verification Organizations
- Financially supports Verification Organizations by bearing the expenses relevant to the verification tests
- Approves reports on verification tests
- Creates a Environmental Technologies Verification database (hereinafter referred to as “ETV database) for their dissemination

2. The committee on the pilot project for the environmental technology verification

- Offers advice on the management of the entire pilot project for the environmental technology verification:
- Offers advice on the comprehensive evaluation of verification test results

3. Working group on the ethylene oxide treatment technology

- Offers advice on management of the entire pilot project for the environmental technology verification in the field of ethylene oxide treatment technology
- Offers advice on creating a protocol for the verification
- Offers advice on the selection of Verification Organizations
- Offers advice on approval of the Verification Report

4. Verification Organizations

- Administer all processes of the pilot project for the environmental technology verification in target verification technology fields under the auspices of the Ministry of the Environment
- Construct the quality management system shown in Appendix 0
- Invite the public to register the technologies and products that are suitable as the target of the verification test
- Establish and administer respective Technology Panels
- Establish a Test Plan in cooperation with environmental technology developers
- Conduct and manage verification tests based on the Test Plan
- Operate and maintain the target verification apparatuses according to the “O&M manuals” prepared by environmental technology developers. The persons in charge of O&M should be suitably qualified or experienced and have received adequate training.
- Restrict entry to the location of verification tests during the test period.
- Ensure the health and safety of all persons relevant to the verification tests at the Test Sites
- Set and adjust the test schedule by assuring the means of communication among all participants in the verification test, and providing transportation assistance and technical

advice as necessary

- When the verification test is subcontracted to an external organization, ensure that the quality management system which is required in the Protocol is indeed functioning properly at the subcontractor
- Audit the procedures for the verification test
- Take samples, inspection, measurement, and analysis in the verification test at the expense and under the responsibility of the Verification Organization
- Manage the data / information obtained in the verification tests
- Prepare The Verification Report based on analysis / evaluation of the data on the verification test
- Register in the ETV database the contents of the approved Verification Report

5. Technology Panels

- Offers advice on the Test Plan
- Offers advice on the problems that may occur during the verification tests
- Offers advice on the issuance of the Verification Report
- Offers advice on dissemination of the technologies verified in the verification test

6. Environmental technology developers

- Cooperate with Verification Organizations in establishment of the Test Plan, such as by providing information required for the verification test
- Provide as many target verification apparatuses that can be used at the Test Site as required. In addition, provide the Verification Organization with its “O&M manual.”
- Bear the costs and responsibility for the transportation, installation, removal, and others of the target verification apparatus
- Bear, in principle, the costs for O&M of the target verification apparatus. In addition, bear the costs for chemicals, supplies, and utilities that may be additionally required.
- Provide technological support to the Verification Organization by assisting in the operation and measurement of the target verification apparatus during the verification test period, if necessary
- Provide engineers for O&M of the target verification apparatus, if necessary. The engineers should be properly qualified or experienced and have received adequate training.
- Provide existing relevant performance data for the target verification technology if it has been tested at other sites.
- Cooperate with the Verification Organization in preparing the Verification Report

III. Selection of target verification technologies

1. Application

A verification applicant may apply to a Verification Organization for verification of the applicant's proprietary technology / product. Items to be specified in the application form are described below. The verification applicant should fill in the necessary information in the "Application form for verification" set forth in Appendix 1, and submit the application form together with the designated documents to the Verification Organization.

a. Company name, Address, Division of person in charge, Name of person in charge, etc.

b. In-house test results

c. Product data

d. Developmental status and past delivery record

e. Other relevant or unique features (if any)

f. Technical specification for the target verification apparatus

g. O&M manual*

(Note) The documents designated with * should be attached to the application form.

2. Selection of target verification technologies

Based on the description of the application and the advice from the Technology Panel, Verification Organization selects target verification technologies and obtains approval from the Ministry of the Environment. The selection criteria are as follows:

a. Technological requirements:

- Does the applied technology fall under the category of target verification technology fields described in "1. Target technologies" on page 1?
- Is the application form properly filled in?
- Is the technology in a commercialization stage?

b. Possibility of verification

- Is it possible to complete the verification from cost and organizational standpoints?
- Is it possible to establish a suitable Test Plan?

c. Environmental protective effect, etc.

- Is it possible to scientifically explain the principle and mechanism of the technology?
- Is there any possibility of the technology causing side environmental issues?
- Does it provide a high environmental protective effect?
- Is it an innovative technology?

In the selection stage, a verification applicant can confer with the Verification Organization concerning the specific methods of verification, including the period and date of tests.

IV. Preparation for the verification tests

1. Determination of verification items

(1) Verification items regarding waste gas treatment performance

The possible verification items regarding the waste gas treatment performance to be examined in the verification test are summarized in Table 2. These test items should be examined in the verification tests of all ethylene oxide treatment technologies. In addition to the test items specified above, the Verification Organization examines the necessity for other verification items and describes all of the verification items regarding the waste gas treatment performance specified in the Test Plan.

Table 2 Verification items regarding waste gas treatment performance

Test items	Description
Ethylene oxide concentration	Ethylene oxide concentrations at the inlet and outlet ducts of the ethylene oxide treating apparatus
Change in treatment efficiency	Change in ethylene oxide treatment efficiency calculated from the ethylene oxide concentrations at the inlet and outlet ducts of the ethylene oxide treating apparatus
Average treatment efficiency (mass balance)	Mass balance calculated from the total amounts of ethylene oxide entering into and discharged from the ethylene oxide treating apparatus

(2) Verification items regarding environmental load

The possible verification items regarding environmental load to be examined in the verification test are summarized in Table 3. In addition to the test items specified above, the Verification Organization examines the necessity for other verification items and describes all of the verification items regarding environmental load specified in the Test Plan.

Table 3 Verification items regarding environmental load

Category	Verification items	Description	Major relevant cost
Environmental impact	CO concentration	CO concentration (ppm) in the waste gas	—
	NOx concentration	NOx concentration (ppm) in the waste gas	—
	Amount of secondary products generated	Amount of secondary products generated per operation (if secondary products such as ethylene glycol and the like are generated)	Disposal cost
	Noise	Noise level (dB) during operation of the apparatus (main unit)	—

(3) Verification items regarding operations and maintenance

The verification items presumably required for quantitative and qualitative evaluation of the performance in and cost for O&M are summarized in Table 4.

The Verification Organization will, in addition to discussing other verification items, describe the verification items regarding O&M thus determined in the Test Plan.

Table 4 Verification items regarding operations and maintenance

Category	Verification items	Description	Major relevant cost
Electricity use and material consumption	Electricity consumption	Electricity consumption per operation (kWh/operation)	Cost for electricity
	Fuel consumption	Fuel consumption per operation (if a fuel such as town gas, LPG, or the like is consumed)	Cost for fuel
	Water consumption	Water consumption per operation (if water is consumed for treatment, cooling, and others)	Cost for water
	Other chemical consumption such as reactant	Chemical consumption per operation (if any chemicals such as reactant are consumed)	Cost for consumables
O&M performance	Number of operators, and the level of operator skill required for O&M of the target verification apparatus	Maximum number of operators and working days (man-days) for each operational item The technicality and difficulty of O&M shall be described.	—
	Safety of the target verification apparatus	Measures for ensuring safety (check valves, etc.)	—
	Measures in the event of emergency	Measures for ensuring safety in the event of failure in electricity or others and the inflow of a high concentration of ethylene oxide	—
	Consistency of the treatment performance	Deterioration in treatment efficiency over extended use, the life and exchange frequency of the catalyst and other components, etc.	—
	Method of restoring from problems	Ease of and problems in resumption	—
	Evaluation of O&M manual	Readability, understandability, and problems	—

2. Establishment of the Test Plan

The Verification Organizations establish the Test Plan based on information provided by the environmental technology developers and the advice of the Technology Panel. If the environmental technology developers do not give approval for the Test Plans, the Verification Organizations will consult as needed with the Ministry of the Environment to determine the necessary actions.

The items to be included in the Test Plan are listed in Appendix 2.

V. Verification test methods

1. Operations and maintenance

The target verification apparatus should be inspected periodically and kept in suitable condition in order to maintain stable operation and thereby ensure proper operation and increase the efficiency of operation throughout the test period. Regardless of whether the Verification Organization or another organization is responsible for the O&M, all procedures involving inspection, O&M should be adjusted in advance by the Verification Organization, described in the Test Plan, and confirmed by the concerned parties.

(1) Regular operations and maintenance

- O&M to ensure proper operation of the target verification apparatus during the test period should be performed in accordance with the O&M manual.
- Calibration should be performed in accordance with the O&M manual. Calibration should also be performed at least as frequently as specified in the O&M manual.
- In selecting the verification items regarding O&M, the problems that may arise when an operator is not sufficiently capable of conducting O&M should also be considered.

(2) Actions in the event of upset conditions

The Verification Organization will inform the environmental technology developer as soon as possible in the event of upset conditions. The Verification Organization should take the actions for restoring the apparatus to stable operation specified by the environmental technology developer. In the event of unforeseen circumstances, the Verification Organization will take the actions together with the environmental technology developer.

The data obtained under the upset conditions will not be used in the statistical analysis for the Verification Report, but shall be described and analyzed in the Verification Report. As soon as stable operation is resumed, alternative samples will be taken.

The conditions, cause and result, and method for resumption under upset conditions shall be described in the Verification Report. When the cause is unclear or it is not possible to judge whether the conditions are indeed unusual, the data obtained during the period is used in the statistical analysis for the Verification Report.

The Verification Organizations should install experimental apparatuses that are modified to ensure the safety of the experimental environment and the operators, even if such modifications may lead to inadequate operation or inadequate performance of the target verification apparatuses.

(3) Cost estimation

The Verification Organizations will collect and sort the data required for cost estimation for O&M, such as the costs for electricity and secondary products and for other consumables, in cooperation with the environmental technology developers.

2. Test conditions

(1) Types of tests

The following two types of tests should be conducted in the verification tests of the ethylene oxide waste gas treatment technologies. However, it is not necessary to conduct the tests if these tests are not suitable due to specific features of the target verification apparatus.

The Verification Organizations will examine the test conditions in greater detail, taking into account the practical use conditions of the ethylene oxide sterilizer, such as in the case of humidifying ethylene oxide gas or the like, and determine the Test Plans. In addition, the Verification Organizations will conduct the tests by keeping aspects of the test environments such as the temperature or the like as constant as possible so that there will be no difference in test conditions among the test periods and sites of the verification tests.

1. Standard ethylene oxide gas treatment test

In the standard ethylene oxide gas treatment tests, an ethylene oxide gas properly diluted with air is supplied into a target verification apparatus at a certain flow rate for 1 hour, and the verification items regarding waste gas treatment performance and environmental load after treatment, such as the ethylene oxide concentration and the like in the waste gas, are determined.

The concentration and flow rate of the ethylene oxide gas supplied will be so set by the environmental technology developer that the maximum amount of gas processed in the target verification apparatus can be determined. The detailed test conditions should be set forth in the Test Plan.

2. Waste gas treatment test simulating an ethylene oxide sterilizer

In the waste gas treatment test simulating an ethylene oxide sterilizer, a gas preadjusted by a simulator, which reproduces the exhaust pattern of ethylene oxide gas from ethylene oxide sterilizers, is supplied into the target verification apparatus, and the verification items regarding waste gas treatment performance and environmental load after treatment, such as the ethylene oxide concentration and the like in the waste gas, are determined.

The exhaust patterns reproduced by the simulator include pattern A, wherein an ethylene oxide sterilizer equipped with a gas container is postulated, and pattern B, wherein an ethylene oxide sterilizer with a gas cartridge is postulated. For each pattern, a chamber with a capacity of approximately 50 L or 150 L is employed. Accordingly, the ethylene oxide treatment performance will be examined in a total of four patterns for a target verification apparatus.

However, if any of the chamber capacities are not suitable due to specific features of the target verification apparatus, it is not necessary to conduct a test for such capacity. In addition, a chamber with a capacity of approximately 100 L may be employed depending on the features of the target verification apparatus.

[Pattern A]

Adjust the ethylene oxide gas concentration in the chamber to approximately 700 mg/L, using 20% ethylene oxide/CO_2 gas as the gas to be treated.

Use a dry pump, either built into the target verification apparatus or separately provided by the environmental technology developer, as the exhauster. However, a water-seal pump may be used instead if the wastewater from the water-seal pump is used repeatedly and is not discharged into sewage lines.

In pattern A, following depressurization (the pressure is set appropriately by the Verification Organization), pressurize the chamber to approximately 1,000 hPa (gauge pressure) by supplying ethylene oxide gas (gas pressurization), and maintain the same pressure for a certain period (sterilization). Following sterilization step, depressurize the chamber to approximately -700 hPa by evacuating the gas (gas evacuation), maintain the same pressure for a certain period (cleaning vacuumization), pressurize the chamber to atmospheric pressure (cleaning aeration), and maintain the atmospheric pressure for a certain period (cleaning). Subsequently, repeat the aeration process of evacuating to approximately-700 hPa (cleaning evacuation), performing cleaning vacuumization, performing cleaning aeration, and performing cleaning five times. If the Verification Organization judges that the ethylene oxide gas in the chamber is not completely exhausted even after five aeration processes, the number of aeration processes may be increased.

The time setting for the gas pressurization, sterilization, cleaning vacuumization, cleaning aeration, and cleaning steps will be determined by the Verification Organization. The time for the gas evacuation and cleaning evacuation steps will be determined based on the application submitted by the environmental technology developer. The time setting for each aeration step shall be the same in all aeration processes.

The accurate capacity of the chamber to be used in the test, detailed exhaust pattern, and others shall be described in the Test Plan.

[Pattern B]

Adjust the ethylene oxide gas concentration in the chamber to approximately 900 mg/L using 95% to 100% ethylene oxide gas as the gas to be treated.

Use an air ejector or dry pump as the exhauster. If an air ejector is used, use one with a flow rate of 100 L/min provided by the Verification Organization. If a dry pump is employed, use a dry pump either built into the target verification apparatus or separately provided by the environmental technology developer. However, a water-seal pump may be used instead if the wastewater from the water-seal pump is used repeatedly and is not discharged into sewage lines.

In pattern B, following depressurization, pressurize the chamber by supplying ethylene oxide gas (gas pressurization), and maintain the same pressure for a certain period (sterilization). The pressures in the depressurization and sterilization steps are set appropriately by the Verification Organization. Following the sterilization step, depressurize the chamber to approximately -800 hPa by evacuating the gas, open the valve of the chamber to allow air to enter at atmospheric pressure or below, and then conduct continuous ventilation (cleaning).

The time setting for the gas pressurization and sterilization steps will be determined by the Verification Organization. The time setting for the depressurization step will be determined based on the application submitted by the environmental technology developer. Air will be supplied in an amount 10 times larger than the capacity of the chamber in the cleaning step, but if the Verification Organization judges that the ethylene oxide gas in the chamber is not completely exhausted, the time for the cleaning step may be increased.

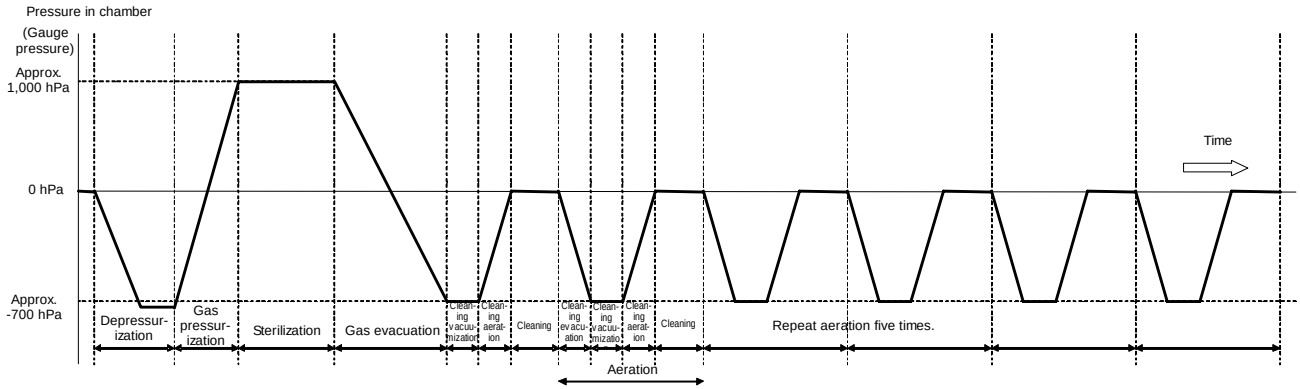
The accurate capacity of the chamber to be used in the test, detailed exhaust pattern, and others shall be described in the Test Plan.

Table 5 Types of waste gas treatment tests simulating an ethylene oxide sterilizer

Pattern	Chamber capacity	Gas to be treated	Description
A	Approximately 50 L and 150 L	20% Ethylene oxide/CO_2 gas	An ethylene oxide sterilizer equipped with a gas container is postulated.
B	Approximately 50 L and 150 L	95% to 100% Ethylene oxide gas	An ethylene oxide sterilizer equipped with a gas cartridge is postulated.

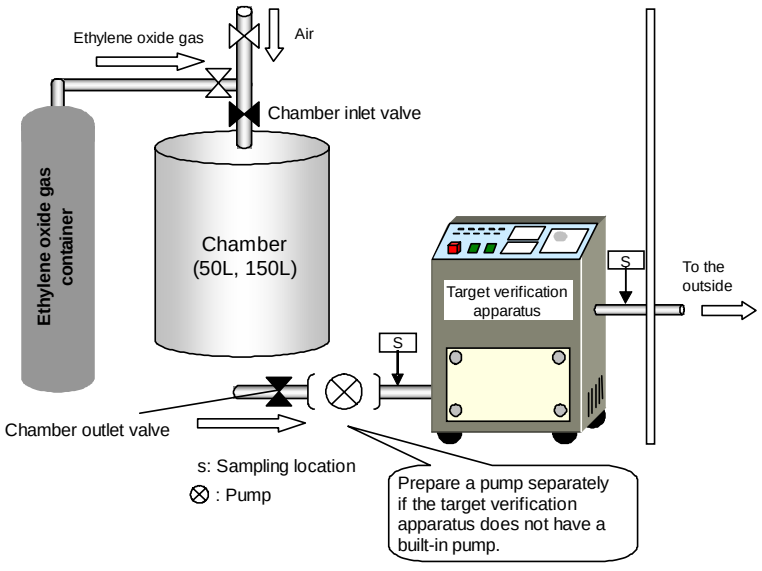
[Pattern A]

Fig. 1 Schematic illustration of the exhaust pattern



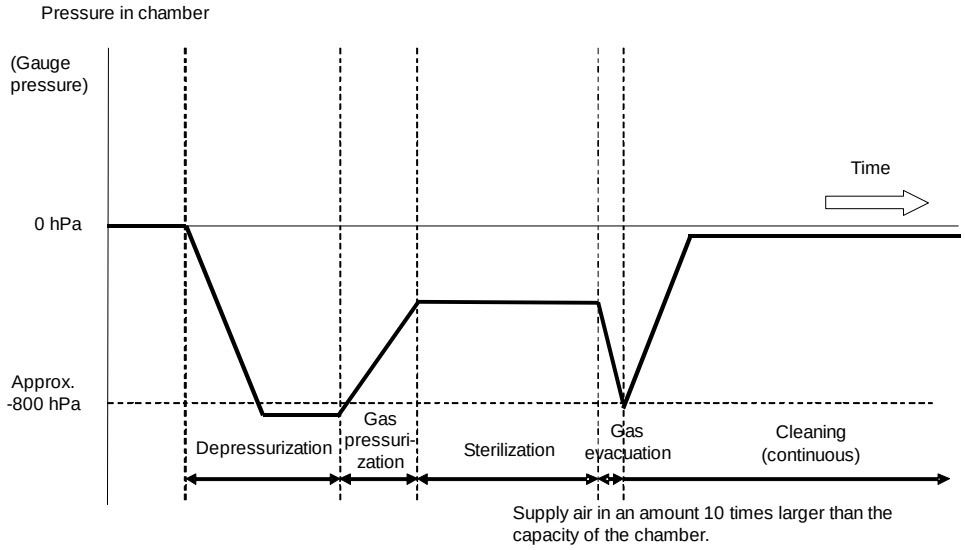
Step		Time (min)	Chamber inlet valve	Chamber outlet valve	Note
Gas pressurization		Set by the Verification Organization	Open	Closed	
Sterilization			Closed	Closed	
Gas evacuation		Set by the environmental technology developer	Closed	Open	
Cleaning vacuumization		Set by the Verification Organization	Closed	Closed	
Cleaning aeration			Open	Closed	
Cleaning			Closed	Closed	
Aeration	Cleaning evacuation	Set by the environmental technology developer	Closed	Open	Repeat five times
	Cleaning vacuumization	Set by the Verification Organization	Closed	Closed	
	Cleaning aeration		Open	Closed	
	Cleaning		Closed	Closed	

Fig. 2 Schematic illustration of the test apparatus (example)



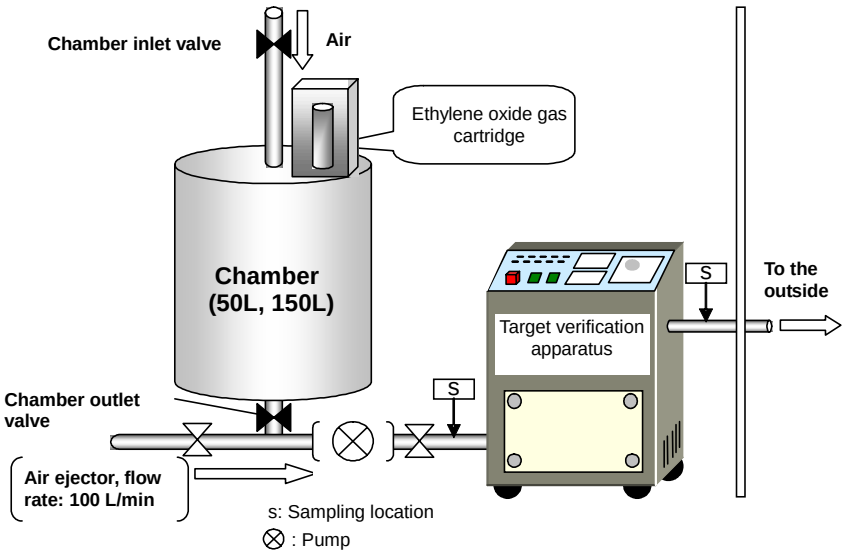
[Pattern B]

Fig. 3 Schematic illustration of the exhaust pattern



Step	Time (min)	Chamber inlet valve	Chamber outlet valve	Note
Gas pressurization	Set by the Verification Organization	Closed	Closed	Supply ethylene oxide gas from the cartridge.
Sterilization		Closed	Closed	
Gas evacuation	Set by the environmental technology developer	Closed	Open	
Cleaning (continuous)		Closed	Open	Continuous ventilation Supply air in an amount 10 times larger than the capacity of the chamber.

Fig. 4 Schematic illustration of the test apparatus (example)



(2) Test conditions to be recorded

The Verification Organizations shall record the following parameters and describe them in the Verification Report.

- The temperatures and static pressures of the waste gas in the inlet and outlet ducts of the target verification apparatus
- The flow rates of the waste gas in the inlet and outlet ducts of the target verification apparatus

3. Test methods

(1) Test methods for verification items regarding waste gas treatment performance

The test methods for the verification items regarding waste gas treatment performance are summarized in Table 6.

Test methods for items other than the test items specified below will be specified in the Test Plan with reference to the relevant JIS standards and regulations.

Table 6 Test methods for verification items regarding waste gas treatment performance

Test items	Method
Ethylene oxide concentration	Use a continuous total hydrocarbon analyzer for measurement of the ethylene oxide concentration in the inlet duct of target verification apparatus. Measure the ethylene oxide concentration in the outlet duct, using a continuous total hydrocarbon analyzer and by the solid absorption–solvent extraction–gas chromatography mass spectroscopy method. See the "Manual for measuring hazardous air pollutants (ethylene oxide)," (Air Pollution Control Division, Air Quality Bureau, Environment Agency, Mar. 1999) for details on the solid absorption–solvent extraction–gas chromatography mass spectroscopy method.
Change in treatment efficiency	Calculate the change in treatment efficiency from the ethylene oxide concentrations in the inlet and outlet ducts of target verification apparatus. Use, in principle, the data obtained by the continuous total hydrocarbon analyzer as the outlet concentration.
Average treatment efficiency (mass balance)	Calculate the average treatment efficiency from the ethylene oxide concentrations and flow rates in the inlet and outlet ducts of the target verification apparatus. Use the data obtained by the continuous total hydrocarbon analyzer or gas chromatography mass spectrometer as the outlet concentration.

1) Sampling

Take samples by the solid absorption sampling method using a sample tube in which a gas absorbent is packed, in accordance with the solid absorption–solvent extraction–gas chromatography mass spectroscopy method. Take a sample of the waste gas in the outlet duct of the target verification apparatus, absorb the gas in the sample tube and use it for determination of the gas concentration.

See JIS K 0095 (Method for sampling flue gas) for information on the sampling apparatus to be used.

2) Test conditions

Measure the temperature, static pressure, and flow rate of the waste gas in the inlet and outlet ducts of the target verification apparatus with reference to JIS B 9914 (Method of

measuring performance for gas treatment equipment). In particular, in the standard ethylene oxide gas treatment tests, the measurement time to be specified in the Verification Report is 15 minutes after the start of the ethylene oxide gas treatment. Alternatively, in the waste gas treatment tests simulating an ethylene oxide sterilizer, the time to be specified is 1 minute after the gas evacuation and the start of the fifth cleaning evacuation (measurement time for flow rate to be specified is for 1 minute after the gas evacuation and the start of cleaning evacuation) in pattern A, while it is 1 minute after the start of gas evacuation and 10 minutes after the start of continuous ventilation (when pressure is constant) in pattern B.

(2) Test methods for the verification items regarding environmental load

The test methods for the verification items regarding environmental load are summarized in Table 7.

Test methods for items other than the test items specified below shall be specified in the Test Plan with reference to the relevant JIS standards and regulations. The Verification Organizations should describe the test items and test methods in the Verification Report.

Table 7 Test methods for the verification items regarding environmental load

Category	Verification items	Method
Environmental impact	CO concentration	Refer to JIS K 0098 (Methods for determination of carbon monoxide in flue gas)
	NOx concentration	Refer to JIS K 0104 (Methods for determination of nitrogen oxides in flue gas) or JIS B 7982 (Automated measuring systems and analyzers for nitrogen oxides in flue gas).
	Amount of secondary products generated	Appropriately set by the Verification Organization
	Noise	Determine with reference to JIS Z 8731 (Acoustics - Description and measurement of environmental noise). When a blower is built in, determine the noise with reference to JIS B 8330 (Testing methods for turbo-fans). The detailed measurement conditions shall be set by the Verification Organization and described in the Test Plan.

(3) Test methods for the verification items regarding operations and maintenance

The test methods for the verification items regarding operations and maintenance are summarized in Table 8.

The unit prices used for estimation of the cost of electricity, water, and others shall be set appropriately by the Verification Organizations.

The Verification Organizations should describe the test items and test methods in the Verification Report.

Table 8 Test methods for the verification items regarding operations and maintenance

Category	Verification items	Method
Electricity use and material consumption	Electricity consumption	Determine from the value of the current integrators in all apparatuses (kWh/operation)
	Fuel consumption	Appropriately set by the Verification Organization
	Water consumption	As above
	Other chemical consumption such as reactant	As above
O&M performance	Number of operators and the level of operator skill required for O&M of the target verification apparatus	Evaluate based on the results of actual operation.
	Safety of the target verification apparatus	Evaluate the measures for ensuring safety (check valves, etc.) based on the technical specification submitted by the environmental technology developer.
	Measures in the event of emergency	Evaluate the measures against electricity failures based on the test results submitted by the environmental technology developer in the events of (1) electricity failure of the sterilizers; (2) electricity failure of the target verification apparatuses; and (3) resumption of power supply (resumption of power supply to sterilizers, target verification apparatuses, or both sterilizers and target verification apparatuses). Evaluate the measures against the inflow of a high concentration of ethylene oxide based on the test results submitted by the environmental technology developer.
	Consistency of the treatment performance	Evaluate deterioration in treatment efficiency over extended use, the life and exchange frequency of the catalyst and other components, and the like based on the data submitted by the environmental technology developer.
	Method of restoring from problems	Evaluate the ease of and problems in resumption based on the operations and maintenance manual and actual operational results.
	Evaluation of O&M	Evaluate based on the results of actual use.

4. Management of analytical accuracy

In order to ensure accuracy at a certain level in measurement of the targeted substance, the data should be managed properly during the entire test period, from sampling to analysis and quantitation. Conduct management to ensure analytical accuracy with reference to the "Manual for measuring hazardous air pollutants (ethylene oxide) (Environment Agency)," despite the fact that it does not specify the method for measuring waste gases but gases in general in the environmental air.

(Reference)

"Manual for measuring hazardous air pollutants (ethylene oxide) (Environment Agency)" (partially modified)

(1) Performance evaluation and maintenance of apparatuses and equipment

1) Sampling

Confirm in advance that the apparatus, materials, and reagents required for sampling do not interfere with measurement, and reduce the blank value of the targeted substance to be measured as much as possible, so that they will not produce measured values exceeding the targeted minimum limit of determination (0.01 μg/m^3).

In order to maintain a consistent level of quality, the method for managing the apparatus, materials, and reagents used during sampling should be standardized, and the standard should be documented for explanatory purposes.

1. Preparation and storage of sample tubes

Confirm prior to use that the sample tubes are contamination-free, by analyzing the tubes by GC-MS at a certain rate. In principle, do not use the sample tubes if any tubes of the same lot provide blank values (as expressed in terms of the concentration in air) exceeding the targeted minimum limit of determination.

Store the sample tubes of the same lot that are confirmed to be contamination-free in sealed containers containing activated carbon. Use sample tubes of the same lot during sampling.

2. Sampling apparatus

Clean the apparatus and others to be used for sampling, to sufficiently reduce the chance of contamination from the apparatuses and others. In addition, confirm that there is no leakage from the apparatus.

As the pressure progressively drops as the flow rate of the gas passing through the sample tube increases during sampling, confirm in advance the relationship between the flow rate and the pressure drop.

3. Storage of samples

When transparent glass sample tubes are used, store and transfer the sample tubes sealed and protected from light by wrapping them with aluminum foil or the like, in a sealed container containing activated carbon. Preferably, analyze them as soon as possible after sampling.

4. Ensuring the reliability of sampling

To ensure the reliability of sampling, confirm in advance the absorption efficiency and others.

In sampling using sample tubes, the absorption capacity of the absorbents, physical properties of the targeted substance (molecular weight, boiling point, etc.), flow rate, sampling time, concomitant substances, and the concentration in samples affect the absorption efficiency and recovery rate of the targeted substance. Therefore, if data on the effect of these factors is not available, confirm in advance that the absorption efficiency and recovery rate are not less than 80%. Furthermore, it is important to discuss in advance the flow rate of the gas passing through the sample tube during sampling, in consideration of the

breakthrough capacity of the sample tube.

The solvent extraction method generally requires a larger absorption amount of gas and thus the absorption efficiency thereof is more susceptible to temperature, humidity, and other factors. Accordingly, divide the absorbent into two tiers and sample each tier to be measured using different vials, roughly once every 10 samplings, and confirm that the targeted substance is not observed in the vial containing the second tier in an amount exceeding the predetermined value. If the targeted substance is observed in an amount exceeding the predetermined value in the vial containing the second tier, reexamine the flow rate and other factors and conduct sampling once again, as breakthrough of the targeted substance may have occurred.

2) Instrumental measurement

Confirm in advance that the apparatus, materials, and reagents required for sampling do not interfere with measurement, and reduce the blank value of the targeted substance to be measured as much as possible.

In order to maintain a consistent level of quality, the method for managing the apparatus, materials, and reagents used during sampling should be standardized.

1. Reference and internal reference materials

In order to ensure the reliability of measured values, use reference materials with assured traceability as much as possible, as the measured values can only be obtained by comparing the results of measurement of the sample and the reference material.

2. Pretreatment

Suitable pretreatments are essential for analysis of the samples, and the suitability of the pretreatments affects the analytical results significantly. Accordingly, evaluate in advance the suitability of each procedure in the pretreatment process.

Confirm that the solvent used for extraction provides a blank value, as expressed in terms of the concentration in air, that is the targeted minimum limit of determination or less.

Attention should be paid to the extraction time, as the variation in it sometimes leads to changes in the recovery rate.

3. Adjustment of analytical instruments

For the analytical instruments to be used, set the most suitable conditions that allow optimal measurement of the samples with respect to their objects. During the adjustment, confirm the linearity and stability of sensitivity, the presence or absence of interfering factors that may lead to errors in measurement, and the method for correcting the interference.

i Tuning of MS

Introduce a reference material for mass calibration (PFTBA or PFK) into the MS and calibrate the mass patterns and resolution [1 mass unit (amu) or more in the range of mass numbers (m/z) of approximately 18 to 300] according to the mass calibration program therein, and check the principal functions of the mass spectrometer, such as sensitivity, and the like, at the same time.

Tune the MS in this way prior to measurement and in cases in which there is an abnormal response during continuous measurement. Always reconstruct a working curve after tuning, and measure the samples once again during continuous measurements, if necessary. The results of the tuning should be documented and stored.

ii Adjustment of GC

Set appropriate conditions, including the column chamber temperature, inlet port temperature, carrier gas flow rate, and others, and confirm that the responses are consistent, the retention time of the targeted substance is in the suitable range, and the relevant peaks are sufficiently separated. Set suitable values for the splitless time, purge gas flow rate, and others.

(2) Evaluation of the reliability of measurements

1) Variation in the sensitivity of instruments

Measure periodically, at least once per day, a reference solution containing the reference material at a concentration almost in the middle of the working curve, and confirm that the sensitivity of the internal reference material does not vary significantly from that when the working curve was prepared. In addition, confirm that the variation in relative sensitivity of the targeted and internal reference materials is within the range of ±20% from that when the working curve was prepared. If the relative sensitivity changes so as to be out of this range, remove the causes and repeat measurement of the samples measured previously. Furthermore, if the retention time gradually varies, such as due to deterioration of the separation column or the like, take necessary measures as needed. However, if it varies significantly in a shorter period of time (variation in retention time of ±5% or more a day, or in the ratio of the relative retention time between the targeted and internal reference materialss of ±2% or more a day), remove the causes and repeat measurement of the samples measured previously.

2) Determination of the minimum limit of detection and the minimum limit of determination

Conduct measurement in accordance with the predetermined procedures using the reference solution at the minimum concentration (close to the minimum limit of determination) used for preparation of the working curve, and determine the concentration expressed in terms of the concentration in the waste gas by converting the measured values according to the conversion equation for each measurement method. Measure 5 or more samples, calculate the standard deviation, and designate a value 3 times larger than it as the minimum limit of detection, and a value 10 times larger as the minimum limit of determination, as described below. When there is an operational blank value, measure the operational blank test solution in a similar manner, and calculate the standard deviation. Use the larger standard deviation obtained from the blank or minimum concentration sample mentioned above for calculation of the minimum limit of detection and determination.

Minimum limit of detection = 3 s ($\mu g/m^3$)

Minimum limit of determination = 10 s ($\mu g/m^3$)

Because the minimum limit of determination varies according to the apparatuses and conditions used for measurement, conduct measurement one or more times as needed when the analytical conditions for the instrument are set, and confirm that the blank value obtained is smaller than the targeted minimum limit of determination.

3) Measurement of operational blank values

The object of the operational blank tests is to confirm the degree of contamination derived from use of the sampling containers or sample tubes, or from the procedures for preparing test solutions or introducing the samples into analytical instruments, by conducting a series of procedures for sampling and measuring the targeted substance using zero gas samples, and thus to ensure a measurement environment that will not interfere with analysis of the samples. If the operational blank value, as expressed in terms of the concentration in the waste gas, exceeds 1/10 of the suppression standard limit for each targeted substance, sufficiently reexamine the sampling containers, analytical environment, analytical instrument, and the like in order to reduce the operational blank value, and repeat measurements.

4) Measurement and correction of traveling blank values

The object of the traveling blank tests is to confirm the presence or absence of contamination during the period from preparation for sampling to analysis of the samples, and to determine the traveling blank values by analyzing blank samples in a similar manner to that of the samples, except that the sampling procedures are not included. Conduct traveling blank tests on at least 3 samples or more at a frequency of approximately 10% of the total number of samples in a series of sampling, calculate the average (e) and standard deviation (s), and correct the measured values as follows: (See Fig. 1.)

1. If the average (e) of the traveling blank values (hereinafter referred to as the "traveling blank value") may be regarded as equivalent (equal or smaller) (e a) to the operational blank value (a), the contamination during transportation may be disregarded. Calculate the concentration by subtracting the operational blank value (a) from the measured value (d).
2. Alternatively, if the traveling blank value (e) is greater (e>a) than the operational blank value (a) due to contamination during transportation, in cases in which the minimum limit of determination (10 s), as expressed in terms of the concentration in air (f), calculated from the standard deviation (s) obtained through the measurement of traveling blank values, is the targeted minimum limit of determination (c) or less (f<=c), calculate the concentration by subtracting the traveling blank value (e) from the measured value (d).
3. If the minimum limit of determination derived from the traveling blank value (f) is greater (f>c) than the targeted minimum limit of determination (c) and the measured value of samples (d) is the minimum limit of determination derived from the traveling blank value (f) or more (d>=f), calculate the concentration by subtracting the traveling blank value (e) from the measured value (d).
4. However, if the minimum limit of determination derived from the traveling blank value (f) is greater (f>c) than the targeted minimum limit of determination (c) due to contamination during transportation (e>a) and the measured value of the sample (d) is smaller (d<f) than the minimum limit of determination derived from the traveling blank value (f), the reliability of the measured value is doubtful and, in principle, the data should be discarded. In such a case, investigate and remove the causes of contamination and repeat sampling.

5) Duplicate sampling

In order to ensure the overall reliability of the analysis from sampling, pretreatment procedures, and instrumental analysis, analyze two or more samples, which are taken under the same conditions and in the same manner, and confirm that the difference between the concentrations of the same targeted substance, as determined using samples containing it at a concentration exceeding the minimum limit of determination, is not greater than 30%. If the difference is greater than 30%, the reliability of the measured values is doubtful and, in principle, the data should be discarded. In such a case, check various factors, including the gas flow rate, presence of leaks in the system, analytical stability of the instrument, and others, and repeat analysis.

The duplicate sampling should be conducted at a frequency of approximately 10% of the total number of samples in a series of sampling.

(3) Management and evaluation of data

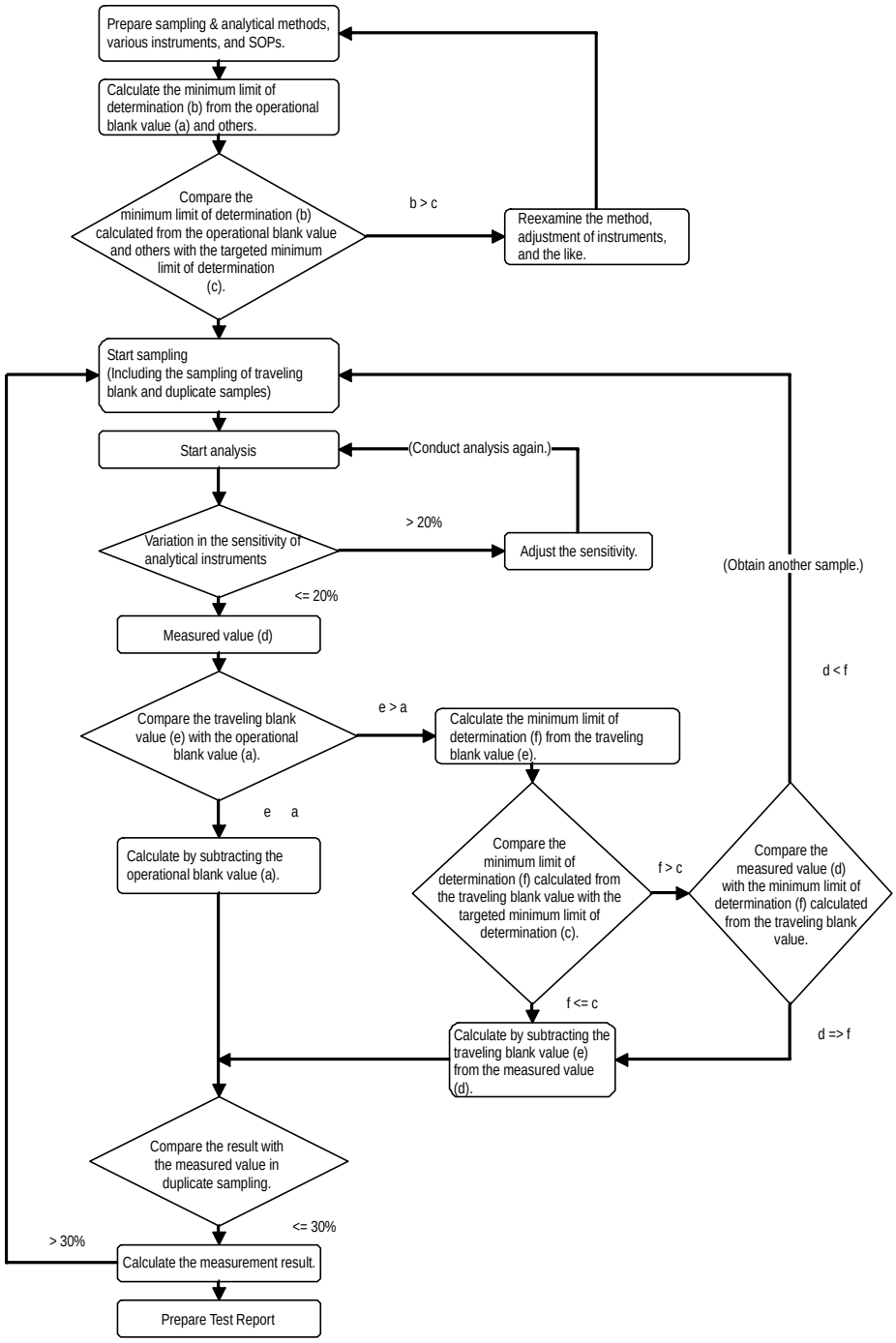
1) Precautions on sampling

It is necessary to evaluate the data obtained, taking into account the use conditions of the targeted substance and operational steps, as well as the location, date, time, and the like of sampling.

2) Handling of outliner and missing values

If the sensitivity of analytical instruments varies significantly, if the traveling blank value is large, indicating contamination of the samples, or if the results of duplicate sampling differ significantly, the reliability of the measured values is doubtful and it is therefore necessary to take proper actions, such as conducting repeated measurements or discarding the data and obtaining new samples, as described above. Such problems require a greater amount of labor, increased time, and higher costs, and the frequent incidence of outliner or missing values affects the reliability of all test results. Care should be taken to prevent the generation of outliner and missing values by checking carefully in advance or by other means. In addition, it is important to thoroughly examine and document the causes of the outliner and missing values and to use such data to prevent such occurrences in the future.

Fig. 5 Schematic illustration of accuracy control



* Targeted minimum limit of determination: A standard for judging the admissibility of the minimum limit of determination, the operational blank value, and the like. It is set at 0.01 μg/m^3 in the "Manual for measuring hazardous air pollutants (ethylene oxide)."

* Variation in the sensitivity of analytical instruments: (1) The variation in sensitivity in a series of measurements should be within the range of ±20% of that obtained when the working curve was prepared. (2) In GC-MS analysis, the intensity ratio obtained from the peak areas or peak heights measured by the mass number for quantitation and the mass number for confirmation of each targeted substance should be in the range of ±10% from that obtained when the working curve was prepared.

VI. Preparation of the Verification Report

The results obtained in the verification test shall be reported in the Verification Report. All data, including the results of the verification test for the period from startup to the end of operation, all actions taken for O&M, and any changes during the test period, shall be described in the Verification Report.

The Verification Report shall contain the following:

- Executive summary
- Introduction and background
- Identification and description of the target verification technology and apparatus (including capacity)
- Manufacturer of product (Name, address, TEL)
- Serial number
- Period and Test Site
- Conditions for the verification test and layout of apparatuses (including the layout of the target verification apparatus and others)
- Procedures and methods for the verification test (including those for analysis at the Test Site)
- Records of measurement procedures [sampling conditions (waste gas amount, waste gas temperature, detailed information on the source of release, etc.), various intermediate values before obtaining measured values, etc.]
- Information on accuracy control (setting of the measurement conditions of analytical instruments and the results, measured values of the minimum limit of detection and of determination, results of the operational blank test and traveling blank test, etc.)
- Report on the test period of the verification test (including observation, conditions, data summarized in graphs and tables, and results)
- Results and discussions of the verification test (The verification test results are discussed. The data shall be summarized in graphs and tables.)
- Other literature and data for reference
- Appendix (Test Plan, O&M manual, records of sampling and its confirmation, photo of the target verification apparatus, records of sample analysis and its confirmation, outline of the quality management system, general description of the quality control of data, unprocessed data, etc.)

The Verification Organization prepares a draft of the Verification Report and, after obtaining the consent of the environmental technology developer concerning the description and discussions by the Technology Panel, finalizes the Verification Report. The Verification Report submitted to the Ministry of the Environment shall be discussed by the working group and approved by the Ministry of the Environment. In addition, the Verification Organization shall prepare a brief summary of the verification test results with reference to Appendix 3.

VII. Remarks in conducting the verification test

1. Quality control of data

(1) The method for quality control of data

The quality of data obtained on the verification items should be managed in accordance with the method specified in section V. Verification test methods, 4. Management of analytical accuracy.

(2) Measurement and data acquisition

For quality control of data, the following requirements should be given during measurement and data acquisition:

- Any assumptions on which the Test Plan is based, as well as all sampling locations and the samples to be collected there, should be reported to and approved by the Technology Panel during design of the Test Plan.
- Any time sampling and analysis of samples are conducted, a record of these actions and confirmation should be kept.
- Any non-standard sampling methods and devices or analytical methods and instruments that may affect the representativeness of data should be validated and documented.
- The requirements for sample handling, storage location, and transportation should also be described. The description shall include sample labels, custody forms, and sample custody log.
- All analytical methods and instruments used should be documented.
- The requirements for the calibration of all analytical instruments and procedures, including the calibration standards, should be specified in the Test Plan.
- Any type of data not obtained by measurement, such as that obtained through interviews and the like, should be examined to determine the limits of its use.

2. Management, analysis, and presentation of data

The data obtained in the verification test includes quantitative data such as verification data on the consistency of waste gas treatment performance and data on the amount of waste gas, as well as qualitative data such as that on the reliability and operability of the system and operators demands. The methods for management, analysis, and presentation of these data are as follows:

(1) Data management

Data should be managed securely, as described in “Appendix 0: Quality management system to be constructed at the Verification Organizations, 3. Quality management system, (3) Control of documents and records” on page 27.

(2) Data analysis and presentation

The data obtained in the verification test should be analyzed statistically and presented. The data not subjected to the statistical analisys (including that obtained under upset conditions) shall be included in the Verification Report as an appendix.

i Data analysis and presentation of concentration data

- Graph illustrating the change in gas concentration in the inlet duct
- Graph illustrating the change in gas concentration in the outlet duct
- Graph illustrating the change in the efficiency of treating ethylene oxide
- Date and time of sampling, and sample number

ii Data on verification items regarding O&M

- Summary of observations
- Summary of the operability and reliability of the target verification apparatus (indicating both stable operation and upset conditions)
- Summary of the usefulness of the O&M manual
- Summary of the reliability of the target verification apparatus and the variations in verification items regarding O&M observed during the verification test
- Summary of the skills required for O&M

3. Environment, health and safety

The Verification Organization should take strict environment, health and safety measures with respect to the verification test. The environment, health and safety management program should be included in the Test Plan. In the management program, relevant environmental problems and potential hazards regarding the verification test and Test Site should be identified, and countermeasures against them should be specified. The Verification Organization should inform the personnel at the Test Site, including employers and employees who are not involved in the verification test, of the potential hazards and the countermeasures against them. The following items are to be discussed in the environment, health and safety management program:

- Precaution regarding the operation of the target verification apparatus, emission of processed wastewater, and generation of secondary products
- Biological, chemical and electrical hazards
- Handling, storage and discharge of the chemicals relevant to the verification test
- Handling and discharge of residues and waste relevant to the verification test
- Material Safety Data Sheet
- Compliance with local regulations regarding electricity and plumbing
- Exhaust and ventilation systems, when gases are generated in the target verification apparatus
- Prevention of fires
- Confirmation of emergency contacts (emergency medical, fire fighting, etc.)
- Ensuring of occupational health and safety
- Others

The entire environment, health and safety management program, including Material Safety Data Sheets, should be properly stored and available for inspection by anyone at the Test Site. The address and phone number of emergency contacts, and of the nearest hospital should be listed on one page. The sheet should be displayed in a suitable location, protected with a transparent plastic cover.

Appendix 0: Quality management system to be constructed at the Verification Organizations

Introduction

The Verification Organizations participating in the pilot project for the environmental technology verification should desirably construct the quality management system in accordance with JIS Q 17025: 2000 (ISO/IEC17025: 1999) “General requirements for the competence of testing and calibration laboratories.” In this Appendix, some elements of the quality management system that are required to be constructed at Verification Organizations that do not have such a quality management system in accordance with the above standard will be described.

1. Scope

The quality management system specified in this Appendix is applicable to all departments or procedures relevant to the verification test in the Verification Organization. In addition, if part of the verification test is subcontracted to an external organization, that organization is also included in the scope of application.

The Verification Organization in which all departments relevant to the verification test have already received the following certification, JIS Q 17025: 2000 (General requirements for the competence of testing and calibration laboratories) or JIS Q 9001: 2000 (Quality management systems - Requirements), will be regarded as satisfying the requirements specified in this Appendix.

2. References

JIS Q 17025: 2000 (IS0/IEC 17025: 1999) General requirements for the competence of testing and calibration laboratories

JIS Q 9001: 2000 (IS09001: 2000) Quality management systems - Requirements

3. Quality management system

(1) Organization and responsibility

The organization concerned shall be an entity that can be held legally responsible.

The responsibilities of key personnel in the organization relevant to the verification tests shall be clearly defined. Appoint a member of the staff as quality manager (however named) who, irrespective of his or her other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times.

(2) Quality system

The organization concerned shall establish, implement, and maintain a quality management system appropriate to the scope of its activities regarding the verification test.

In the quality management system, the quality policy regarding the verification test and the procedures for the quality management system shall be documented. These documents shall be communicated to and understood by the appropriate personnel.

The policy shall include the following:

a) The organization's commitment to ensuring the quality of verification tests

b) The organization's statement on the quality standard of the verification tests

c) The objectives of the quality system

d) A description of the construction and implementation of the quality management system

In addition, the system for promoting verification tests, as well as the role, responsibility, and authority of the personnel concerned, shall be documented.

(3) Control of documents and records

The organization concerned shall control documents such as the standards regarding the verification tests (protocol for the verification and relevant standards) and the Test Plan, as well as drawings, software, specifications, written directives, and manuals.

With respect to document control, the following shall be ensured:

a) All documents shall be reviewed and approved for use by authorized personnel prior to their issuance.

b) All documents shall contain a description of the relevant documents to ensure that appropriate documents can be found easily and are available at any time at all Test Sites.

c) Invalid and/or obsolete documents shall be promptly removed or be assuredly prevented from unintended use.

d) The management method for documents as data shall be specified and maintained.

e) The form for records and the location of documents, as well as the inspection method, shall be specified and maintained.

In addition, records regarding the verification tests shall be identified, properly collected, indexed, specified for usage, filed for applications, maintained, and adequately discharged, and the storage period for them shall be decided. In particular, records in the original copy of the test data, data and information that enables trace audits, records of calibrations, records of the persons involved, each individual report published, and copies of calibration certificates shall be stored for a predetermined period.

(4) Subcontracting of the tests

If the organization concerned subcontracts to perform the verification test, the organization shall select a competent external organization, and demand the same quality management as that of the Verification Organization.

(5) Purchase of goods and services

The organization concerned shall examine, by appropriate measures such as inspection, whether the goods and services purchased from external sources that may affect the quality of verification tests satisfy the requirements specified in the protocol for the verification, and shall not use them for the verification tests until this examination is completed.

In addition, the organization shall evaluate the suppliers of goods and services, and make a list of the approved suppliers.

(6) Control of complaints and nonconforming tests

The organization concerned shall have a system and method that shall be implemented when any of its verification tests or the results of these tests do not conform to the protocol for the verification or other specifications for any reason. The organization shall have a system and method for handling contingencies such as complaints from environmental technology developers, the inhibition of impartiality, information leaks, and others. These systems shall include a person in charge and personnel required for the handling of such cases.

(7) Corrective and preventive actions

When any of its verification tests or the results of these tests do not or may not conform to the protocol for the verification or other specifications, the organization concerned shall investigate the reasons therefor and take corrective or preventive actions.

(8) Audit

The organization concerned shall conduct audits to judge whether the verification test has been properly conducted. When the verification test is subcontracted to an external organization, the operations of the subcontracted organization shall be audited.

The audit shall be conducted at least once during the test period. If the verification test lasts 2 years or more, the audit shall be conducted periodically, and the frequency of audit shall desirably be more than once per year.

In addition, the audit shall be conducted by personnel who are independent of the verification test to as great an extent as possible. The results of the audit shall be reported to the superintendent of the organization concerned.

4. Technical requirements

(1) Personnel

The organization concerned shall ensure the competence of all who operate specific equipment for the verification test, perform tests, evaluate results, and sign test reports. The personnel performing specific tasks shall be qualified on the basis of appropriate education, training, and/or demonstrated skills, as required.

(2) Accommodation and environmental conditions

The facilities for the verification test, including but not limited to energy sources, lighting, and environmental conditions, shall be such as to facilitate correct performance of the tests. The organization concerned shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when the verification test is undertaken at sites other than a permanent laboratory facility.

The organization concerned shall monitor, control, and record environmental conditions of the test in accordance with the protocol for the verification, the Test Plan, and other standards. Tests shall be stopped when the environmental conditions jeopardize the results of the tests.

(3) Test methods and method validation

The organization concerned shall use appropriate methods and procedures for all tests within its scope and determine the test methods in accordance with the protocol for the verification.

When the method to be used is not specified in the protocol for the verification, the organization concerned shall select either an appropriate method disclosed in international standards, regional or national standards, scientific texts, or the like, or a method specified by the manufacturer of the equipment. When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the verification applicant, and their validity shall be appropriately examined prior to use. Validation is the confirmation by examination that the requirements for a specific intended use are fulfilled. The validation shall be conducted based on discussion and subsequent approval by the Technology Panel.

When computers or automated equipment are used for data management, the organization concerned shall provide suitable environmental and operational conditions for the purpose of managing the computers and automated equipment properly, to ensure that there is no loss or improper conversion of data as a result of accidental erasure.

(4) Equipment

The organization concerned shall be furnished with (or leased) all items of the equipment required for the execution of verification tests. If a piece of equipment can only be operated by authorized personnel, the organization concerned shall specify the equipment. Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service until it has been repaired and confirmed to perform correctly.

(5) Measurement traceability

All equipment used for tests that has a significant effect on the accuracy or validity of the result of the verification test shall be calibrated before being put into service.

(6) Sampling

The organization concerned shall take samples of reagents, materials, or products in accordance with the protocol for the verification.

(7) Handling of test and calibration items

If necessary, the organization concerned shall transport, receive, handle, protect, store, retain, and/or dispose of test items in accordance with the protocol for the verification.

(8) Verification of data and assurance of test result quality

The data resulting from the verification test shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the review of the results. This verification shall be conducted by a person other than the one who conducts the verification test.

(9) Reporting the results

The organization concerned shall report the results of the test conducted accurately, clearly, unambiguously, and objectively in accordance with the protocol of the verification tests.

Appendix 1: Application form for verification

The verification applicant should submit the application form specified below. In particular, be sure to fill in the columns designated with *, which indicates important information for the selection of verification target technologies.

[Applicant]

Company name*	
Address*	
Division and name of person in charge*	
Contact address*	TEL: FAX:
	e-mail:
Name of technology/product*	

1. In-house test results

Items				Unit	Measured value, etc.
Test method (Describe the method of determining concentration)					
Test conditions	Treatment time			min	
	Gas to be treated				
	Sterilizer used				
	Capacity of the sterilizer used			L	
	Influent gas	Temperature		°C	
		Static pressure		hPa	
		Flow rate	During gas evacuation	Nm^3/min	
			During cleaning evacuation	Nm^3/min	
Test results	Maximum exhaust concentration of ethylene oxide	During gas evacuation		ppm	
		During cleaning evacuation		ppm	
	Waste gas	Temperature		°C	
		Static pressure		hPa	
Maximum amount of treatment per unit time				g/min	

* If continuously measured data on the exhaust concentration of ethylene oxide is available, attach the relevant data.

* The influent gas is a gas supplied into the target verification apparatus for measurement of the treatment efficiency.

2. Product data (Submit a technical specification as an attached document.)

Items		Description
Name of the target verification apparatus*		
Serial number		
Name of the manufacturer*		
Contact address*	TEL	( ) –
	Website	http://
	E-mail	@
	FAX	( ) –
Dimensions*	W(mm)	
	D(mm)	
	H(mm)	
Weight (kg)*		
Capacity of sterilizer used (L)		
Requirements for sterilizer to be connected	Communication device required for operation	Not available - Available Specify the device in detail: ( )
	Requirements for compatible sterilizer, e.g., shape	
	Special remarks, such as types of compatible sterilizers	
Necessity of pre- and post-treatment		Not necessary - Necessary Specify the treatment in detail: ( )

Items	Description			
Additional equipment*	Not available - Available Specify the equipment in detail: ( )			
Life of the target verification apparatus*				
Approximate cost Examples of expense items of the initial cost: Installation cost, construction cost, etc. Examples of expense items of the running cost: Consumables, disposal of secondary products, electricity, etc	Expense item		Unit cost	Quantity	Total
	Initial cost				
	Running cost (per operation)				
	Yen/m^3 of effluent				

3. Developmental status and past delivery record

Check the number that best describes the current situation.

1. The apparatus is only available as a pilot unit and is not commercialized.
2. The apparatus has already been commercialized and is available as a product.
3. The apparatus has past delivery records.

↓

Specify the past records in detail:

( )

4. Other relevant or unique features (if any)

[Documents to be attached to this application form]

- ○ Basic technical specification for the target verification apparatus
- ○ Results of in-house performance tests [Attach not only the performance of treating ethylene oxide gas, but also the measures against electricity failure (during electricity failure of the sterilizers; electricity failure of the target verification apparatuses; and resumption of power supply (resumption of power supply to sterilizers, target verification apparatuses, or both)) and the results of tests on the inflow of a high concentration of ethylene oxide, and the like, if available.]
- ○ O&M manual

The O&M manual should include information on the following:

- ● Installation of the target verification apparatus
- ● Startup
- ● Operation (standard operational pattern, required treatment time)
- ● Maintenance and management
- ● Restart of operation following an emergency stop
- ● Calibration and exchange of components
- ● Troubleshooting
- ● Spare parts
- ● Optimization of operation and environmental protection
- ● Ability to handle variations in test conditions

Appendix 2: Test Plan

The Test Plan provides a general description of the objectives and procedures of verification tests, such as the design of verification tests and the various procedures in the verification tests. The Test Plan should also include the control of data quality, data handling, data presentation, and the environment, health and safety management program.

For preparation of the Test Plan, suitable information should be provided by the environmental technology developers. The Verification Organization and the Technology Panel are basically responsible for preparation of the Test Plan.

The content of the Test Plan may vary according to circumstances, but should include at least the following:

1. Cover sheet/approval of the verification test participants/table of contents

A cover sheet for the Test Plan, signatures of pilot project participants (environmental technology developers, etc.) who approved the Test Plan, and the table of contents are given.

2. Description and objectives of the verification tests

The objective and a description of the verification tests are given.

3. Participating organizations and personnel responsibilities

The organizations participating in the verification tests and the responsibilities of the representatives are described.

4. The target verification technology and apparatus description

- Principle of the target verification technology, system configuration including pre- and post-processing
- Dimensions and weight of the target verification apparatus
- Required consumables, expendables, electricity and other power use
- Methods for installation, startup, operation, regular maintenance, and troubleshooting of the target verification apparatus
- Physical and chemical nature of the secondary products discharged from the target verification apparatus, frequency of generation, and fraction relative to that of treated ethylene oxide
- The level of operator skill required to successfully operate the target verification apparatus
- Noise and foul odor control, housing rewuirement

5. Design of verification tests

(1) Verification tests for the verification items regarding waste gas treatment performance

- Verification items regarding ethylene oxide treatment
- Sampling methods, apparatuses for sampling, methods of storing samples, and storage period
- Analytical methods and instruments, analytical schedule
- Calibration methods and calibration schedule

(2) Verification tests for the verification items regarding environmental load

- Verification items regarding environmental load
- Analytical methods and instruments, analytical schedule

(3) Verification tests for the verification items regarding operations and maintenance

- Verification items regarding operations and maintenance
- Operational schedule, person in charge, and documentation formats
- Methods of evaluating the data provided by the environmental technology developer
- Other verification items, evaluation methods, and information collection schedule

6. Quality control of data

- Methods of documenting measurement procedures
- Information on accuracy control
- Necessity for supplying additional quality management information (All unprocessed data shall be stored as the Appendix of the Verification Report.)

7. Management, analysis and presentation of data

(1) Data management

The Test Plan should include a description of data management and handling. The methods for managing and handling various types of data that are produced in the verification tests, such as field notes, O&M forms, laboratory reports, computer worksheets, graphs, tables, photos, videos, and the like, should be specified.

The Verification Organization designates one data-quality manager.

(2) Analysis and presentation

The Test Plan should include a detailed description of the methods for analyzing and integrating data. Accordingly, statistical methods and equations for use in analysis, as well as data for use in the presentation and the presentation format of the data should be specified.

8. Audit

The Test Plan should also include information on the audit group.

9. Appendix

The following should be described in the Test Plan as an Appendix:

- O&M manual provided by the environmental technology developer
- Environmental, hygienic, and safety management program (including material safety data sheets)
- Other literature and data for reference

Appendix 3: Image of a brief summary of the verification test results

1. Format for providing a brief summary of data

(1) Apparatus

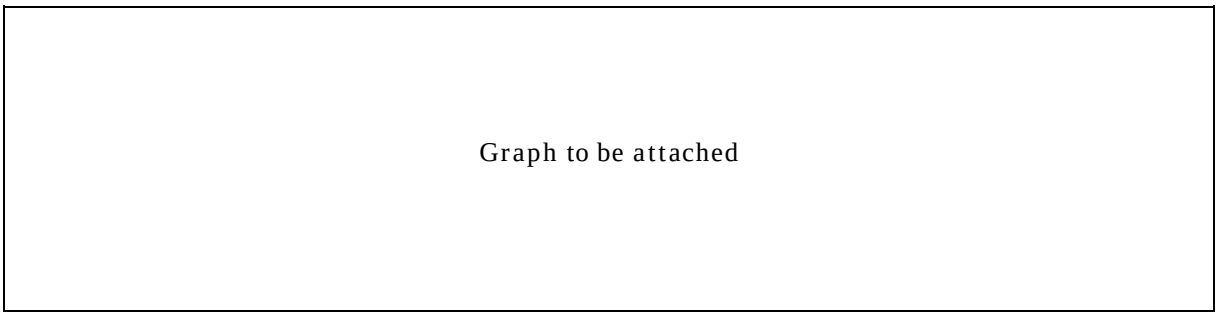
Name of the target verification apparatus	
Manufacturer	
Description of apparatus	
Test Site	
Name of the person in charge of measurement	
Test period	From to

(2) Verification items regarding waste gas treatment performance

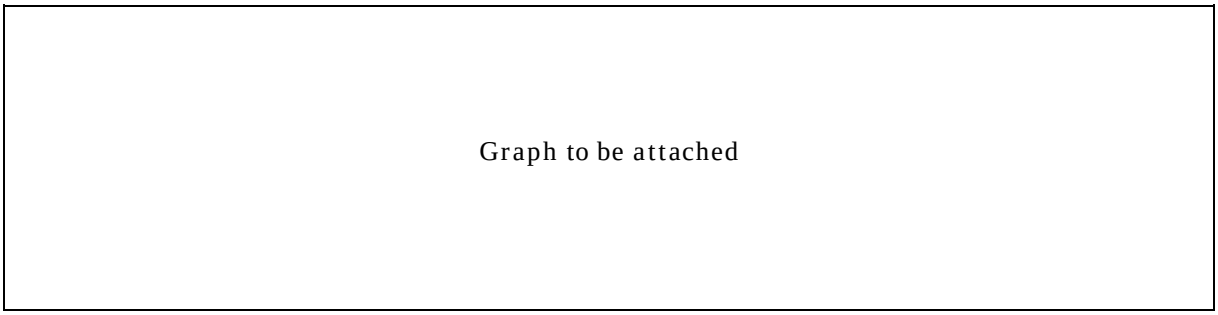
[Standard ethylene oxide gas treatment test]

Items			Unit	Measured value
Test conditions	Treatment time		min	
	Ethylene oxide gas concentration		%	
	Influent gas	Temperature	℃	
		Static pressure	hPa	
		Flow rate	Nm^3/min	
Test results	Ethylene oxide average exhaust concentration		ppm	
	Average treatment efficiency (mass balance)		%	
	Amount of treatment per unit time		g/min (Maximum amount of gas treated)	
			g/min (Average amount of gas treated)	
	Waste gas	Temperature	℃	
		Static pressure	hPa	

(Chart illustrating the change in ethylene oxide gas exhaust concentration)



(Chart illustrating the change in treatment efficiency)

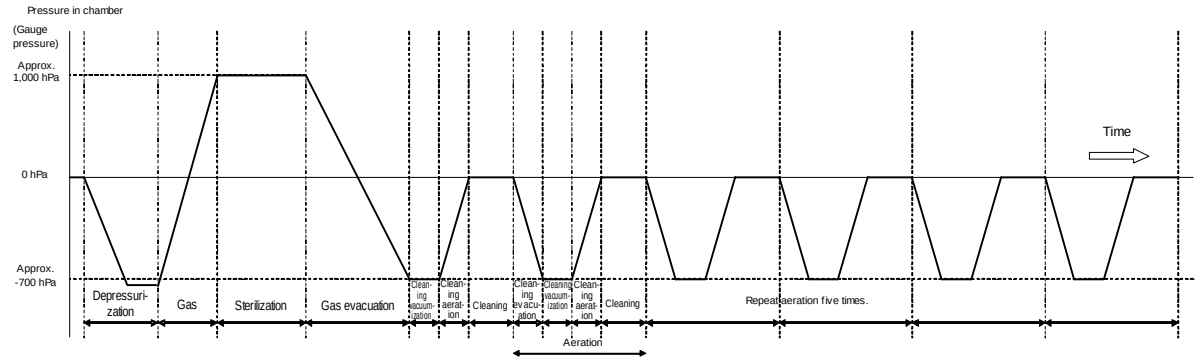


[Waste gas treatment test simulating an ethylene oxide sterilizer]

(Pattern A: Prepare two chambers with capacities of approximately 50 L and 150 L)

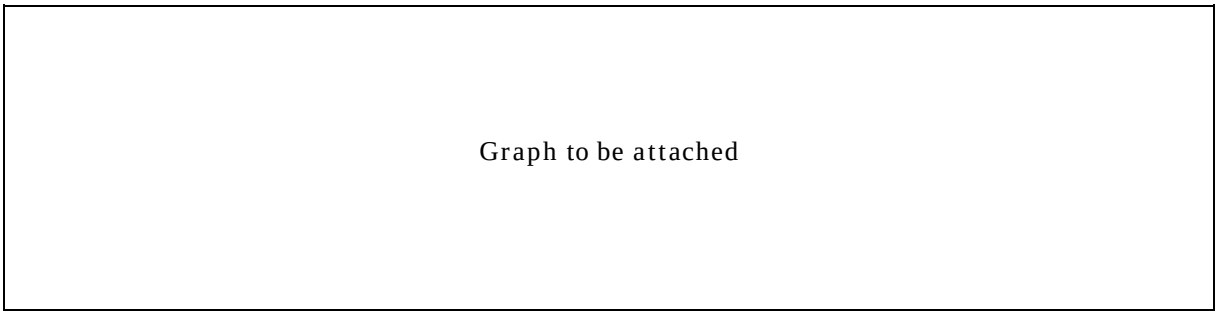
Items				Unit	Measured value
Test conditions	Treatment time			min	
	Chamber capacity			L	
	Influent gas	Temperature		°C	
		Static pressure		hPa	
		Flow rate	During gas evacuation	Nm^3/min	
			During cleaning evacuation	Nm^3/min	
Test results	Ethylene oxide average exhaust concentration	During gas evacuation		ppm	
		During cleaning evacuation		ppm	
	Average treatment efficiency (mass balance)			%	
	Waste gas	Temperature		°C	
		Static pressure		hPa	

(Exhaust pattern)

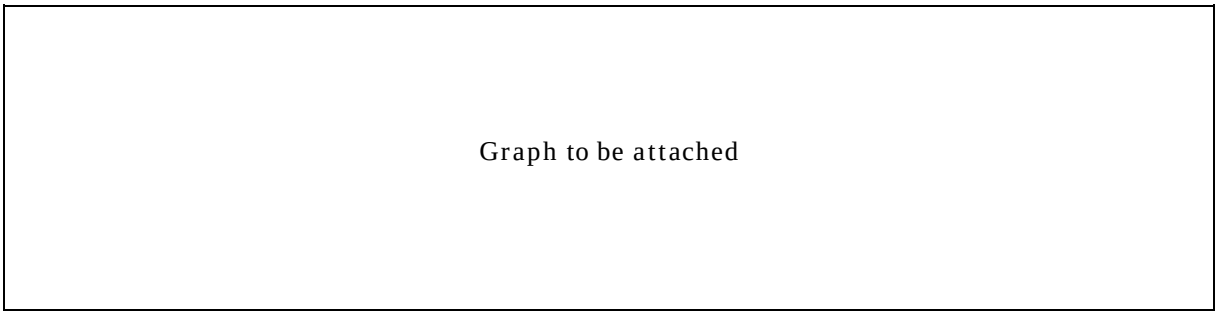


Step		Time (min)
Depressurization		
Gas pressurization		
Sterilization		
Gas evacuation		
Cleaning vacuumization		
Cleaning aeration		
Cleaning		
Aeration	Cleaning evacuation	
	Cleaning vacuumization	
	Cleaning aeration	
	Cleaning	

(Chart illustrating the change in concentration)



(Chart illustrating the change in treatment efficiency)

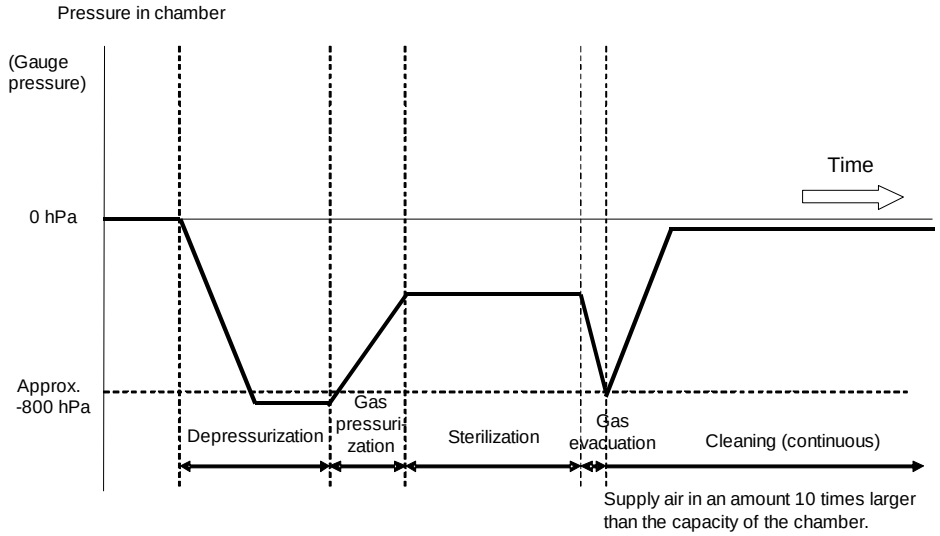


(Pattern B：Prepare two chambers with capacities of approximately 50 L and 150 L.)

Exhauster: [Air ejector or dry pump]

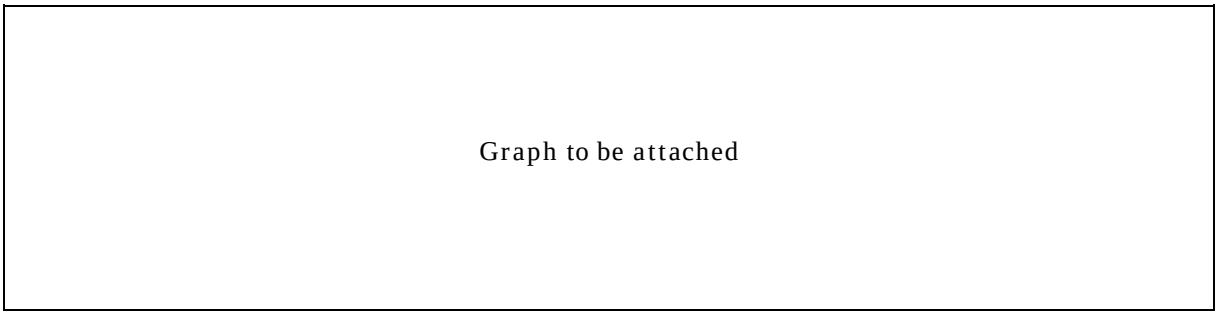
Items				Unit	Measured value
Test conditions	Treatment time			min	
	Chamber capacity			L	
	Influent gas	Temperature		℃	
		Static pressure		hPa	
		Flow rate	During gas evacuation	Nm^3/min	
			During cleaning evacuation	Nm^3/min	
Test results	Ethylene oxide average exhaust concentration	During gas evacuation		ppm	
		During cleaning evacuation		ppm	
	Average treatment efficiency (mass balance)			%	
	Waste gas	Temperature		℃	
		Static pressure		hPa	

(Exhaust pattern)

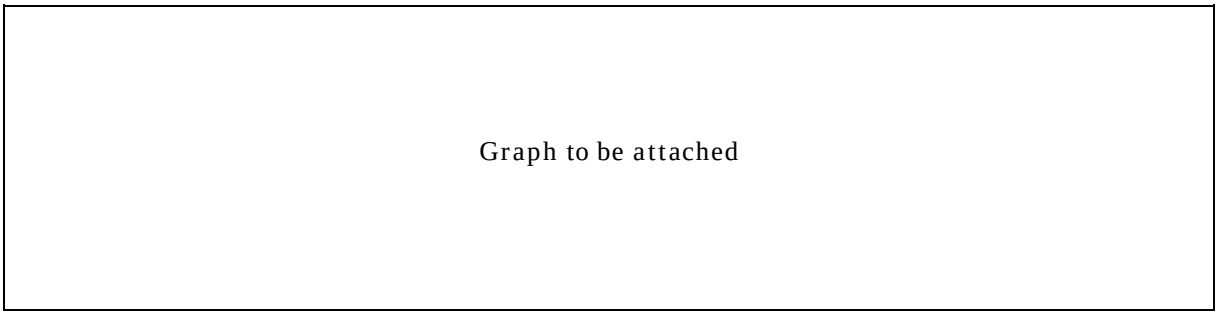


Step	Time (min)
Depressurization	
Gas pressurization	
Sterilization	
Gas evacuation	
Cleaning (continuous)	

(Chart illustrating the change in concentration)



(Chart illustrating the change in treatment efficiency)



(3) Verification items regarding environmental load

[Pattern A: Chamber capacity L]

Items	Unit	Measured value
CO concentration	ppm	
NOx concentration	ppm	
Amount of secondary products generated	Arbitrary	
Noise	dB	

[Pattern B: Chamber capacity L]

Items	Unit	Measured value
CO concentration	ppm	
NOx concentration	ppm	
Amount of secondary products generated	Arbitrary	
Noise	dB	

(4) Verification items regarding operations and maintenance

[Pattern A: Chamber capacity L]

Items	Unit	Measured value
Electricity consumption	kWh/operation	
Fuel consumption	Arbitrary	
Water consumption	L/operation	
Other chemical consumption such as reactant	Arbitrary	

[Pattern B: Chamber capacity L]

Items	Unit	Measured value
Electricity consumption	kWh/operation	
Fuel consumption	Arbitrary	
Water consumption	L/operation	
Other chemical consumption such as reactant	Arbitrary	

Items	Findings
Number of operators and the level of operator expertise required for O&M of the apparatus	
Safety of the target verification apparatus	
Measures in the event of emergency (during electricity failure)	(1) During electricity failure of the sterilizers: (2) During electricity failure of the target verification apparatuses: (3) During resumption of the power supply:
Measures in the event of emergency (During the inflow of high-concentration ethylene oxide)	
Consistency of treatment performance	
Method of restoring from problems	
Evaluation of O&M manual	
Others (Heat generation in target verification apparatus, etc.)	

(5) Product data

Items		Description
Name of the target verification apparatus		
Serial number		
Name of manufacturer (distributing agent)		
Contact address	TEL	( ) –
	Website	http://
	E-mail	@
	FAX	( ) –
Dimensions	W(mm)	
	D(mm)	
	H(mm)	
Weight (kg)		
Capacity of the sterilizer used (L)		
Requirements for the sterilizer to be connected	Communication device required for operation	Not available - Available Specify the device in detail: ( )
	Requirements for compatible sterilizer, e.g., shape	
	Special remarks, such as types of compatible sterilizers	
Necessity of pre- and post-treatment		Not necessary - Necessary Specify the treatment in detail: ( )
Additional equipment		Not available - Available Specify the equipment in detail: ( )
Life of the target verification apparatus		

Items	Description			
Approximate cost Examples of expense items of the initial cost: Installation cost, construction cost, etc. Examples of expense items of the running cost: Consumables, disposal of secondary products, electricity, etc.	Expense item	Unit cost	Quantity	Total
	Initial cost			
	Running cost (Per operation, per unit amount of gas treated)			

(6) Miscellaneous

Indicate points to keep in mind.

Reference

I. Brief overview of the pilot project for the environmental technology verification

1. Objectives

Many innovative environmental technologies that are already in a practically applicable stage and seem to be useful have not come into wide use because end users, including local municipal entities, companies, consumers, and the like, cannot use the technologies with confidence due to the lack of objective evaluation of the environmental protective effect and the like.

Accordingly, in this pilot project for the environmental technology verification, with respect to the innovative environmental technologies that have not been widely accepted as described above, the environment protective effect and others will be objectively verified by an independent organization on an experimental basis.

It is hoped that the pilot project for the environmental technology verification will accelerate the dissemination of the environmental technologies developed by venture companies and the like, and contribute to the activation of economic activity through environmental protection and the advancement of regional environmental industries.

2. What the “verification” means

In the pilot project for the environmental technology verification, the environmental protective effect and the like of particular environmental technologies will be verified through the collection of objective data based on various tests and others. There is a similar term, “certification,” in which the suitability to the standard of an environmental technology is judged in terms of the performance that a technology should provide. The present project does not conduct such “certification.”

3. System for promoting the project

The pilot project for the environmental technology verification will be carried out by the Ministry of the Environment in cooperation with the “Verification Organizations” (local municipal entities, etc.), which are independent organizations that conduct technology verification under the entrustment and contract of the Ministry of the Environment.

4. Procedures of the project

The pilot project for the environmental technology verification will generally be conducted in accordance with the following procedures:

(1) The Ministry of the Environment will identify the needs of the technology developers / distributing agents, users, and others, through the use of questionnaires or the like.

(2) The Ministry of the Environment will select target verification technology fields based on discussions in the committee on the pilot project for the environmental technology verification.

(3) The Ministry of the Environment will prepare a “protocol for the verification,” which establishes the specific methods of technology verification regarding the selected target verification technology fields.

(4) The Ministry of the Environment will select the “Verification Organizations,” which are the independent organizations that conduct the verification tests.

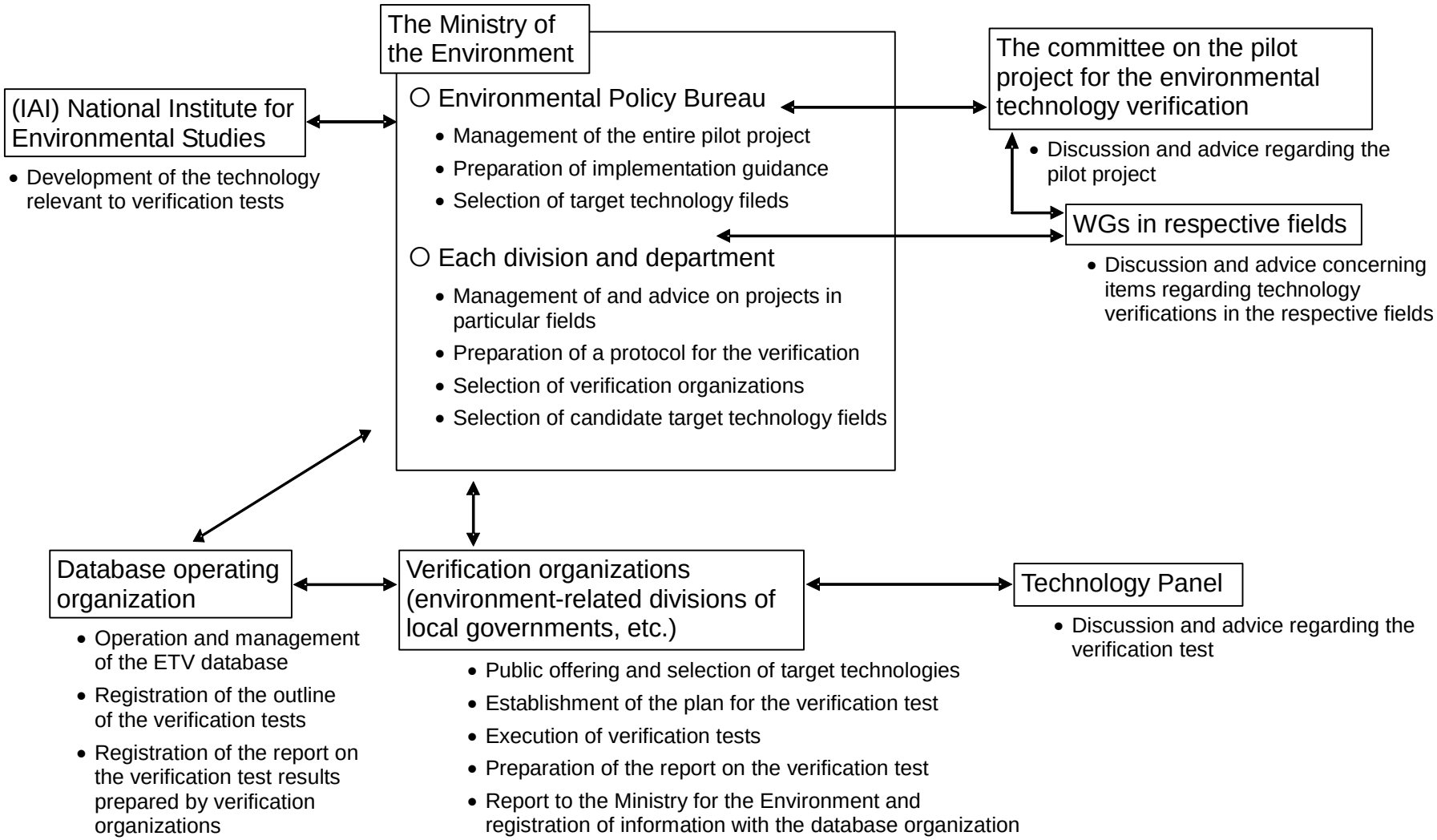
(5) The Verification Organizations will invite applications from companies and the like for the technology to be verified.

(6) The Verification Organization will select the technologies to be verified in the project from among the applications, following discussion in a panel consisting of the specialists.

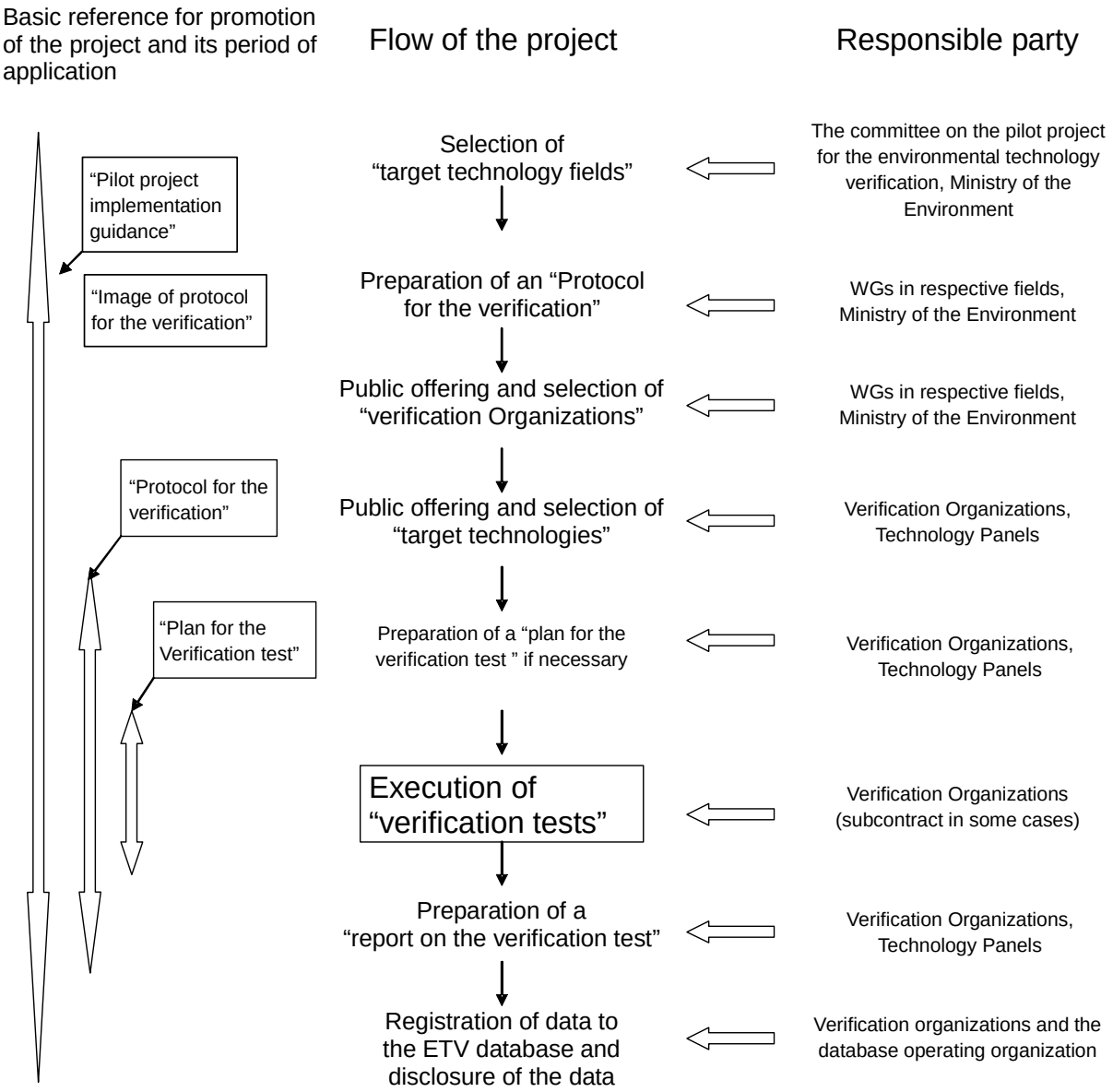
(7) The Verification Organizations will conduct verification tests on the selected technologies in accordance with the protocol for the verification.

(8) The Verification Organizations will summarize the results of the test in report form, notify the technology developers/distributing agents of them, and report to the Ministry of the Environment. In addition, the report will be registered in a database on the Internet and made available to the public.

II. System for promotion of the “pilot project for the environmental technology verification”



III. Flow of the pilot project for the environmental technology verification



IV. Prospectus for organizing the working group on the ethylene oxide treatment technology in the committee on the pilot project for the environmental technology verification for 2003

1. Objective of the working group

The working group on the ethylene oxide treatment technology is established for the purpose of discussing based on specialized knowledge the “ethylene oxide treatment technology” in the technology areas in which technology verification is scheduled to be conducted in 2003, in the pilot project for the environmental technology verification and thus promoting the project smoothly and efficiently.

2. Items to be investigated and discussed

(1) Fields of ethylene oxide treatment technology

i Preparation of a protocol for the verification

ii Selection of Verification Organizations

iii Confirmation of Verification Reports

iv Other items relevant to execution of the project

(2) How future verification tests shall be conducted, and the selection of candidate technology fields

3. Organization and others

(1) The working group consists of 10 or fewer members.

(2) The working group has a chairperson.

(3) The chairperson will supervise the working group.

(4) The members will be appointed by UFJ Institute Ltd., from among academic experts, well-informed individuals, and the like relevant to verification tests on ethylene oxide treatment technology, with the approval of the Environmental Management Bureau of the Ministry of the Environment.

(5) The members will be under commission for the period from the date of appointment by UFJ Institute Ltd. to the end of the same fiscal year.

(6) In addition, participants and interested parties in the pilot project for the environmental technology verification may also attend the meetings of the working group as observers and the like, if necessary.

4. Disclosure of the discussion and others, etc.

Meetings of the working group will, in principle, be held in public. However, the chairperson may hold a closed meeting of the working group if a public meeting may cause significant obstacles to fair and neutral discussion, and provide particular individuals with unfair benefit or detriment.

5. Secretariat

The general affairs of the working group will be processed by UFJ Institute Ltd., with the consent of the Environmental Management Bureau of the Ministry of the Environment.

The committee on the pilot project for the environmental technology verification for 2003
List of the members of the working group on the ethylene oxide treatment technology

Yoshiharu Iwasaki	Chief Director, Tokyo Metropolitan Research Institute for Environmental Protection
Akira Obuchi	Group Leader, Catalytic and Electrochemical Purification Group, Institute for Environmental Management Technology, National Institute of Advanced Industrial Science and Technology
Seitaro Kato	Lecturer, Faculty of Science and Engineering, Chuo University
Kazuhiko Sakamoto	Dean, Faculty of Engineering, Saitama University
Yohei Yamakawa	Director, Administrative Department, Musashino Red Cross Hospital (former director of Pharmaceutical Affairs, Bureau of Public Health, Tokyo Metropolitan Government)

< Secretariat (Ministry of the Environment) >

Kenichi Ando	Director, Environmental Control Technology Office, Environmental Management Bureau
Seisuke Izawa	Deputy Director, as above
Kazumi Shindo	Assistant Director, as above
Satoshi Inoue	Special Researcher, as above
Yoshiaki Kaneko	Deputy Director, Air Quality Management Division, Environment Management Bureau
Takehiko Fukushima	Deputy Director, Environment Health and Safety Division, Environment Health Department
Norihiro Kino	Deputy Director, Office of Environmental Research and Technology, Environmental Policy Bureau

< Secretariat (UFJ Institute Ltd.) >

Eiko Saito	Chief researcher, Environmental Policy Consulting Department
Takashi Morimoto	Researcher, Environmental Policy Consulting Department
Ogi Kanaya	Researcher, Environmental Policy Consulting Department

V. Particulars discussed in the working group on the ethylene oxide treatment technology

First meeting: 10:00 to 12:00, July 15, 2003

- Pilot project for the environmental technology verification
- Ethylene oxide treatment technology
- Protocol for the verification (draft)

Second meeting: 9:00 to 12:00, August 5, 2003

- Opinions on the protocol for the verification (draft)
  - Shimakawa Seisakusho Co., Ltd.
  - Achieve Corporation
  - Miura Co., Ltd.
  - Sakura Seiki Co., Ltd.
  - Muraki Co., Ltd.
  - Pax Co., Ltd.
- Protocol for the verification (draft)

Third meeting: 10:00 to 12:00, September 2, 2003

- Protocol for the verification (second draft)
- Public offering and selection of Verification Organizations