

ETHYLENE OXIDE COMMERCIAL STERILIZATION SECTION 114 SURVEY

Survey and Submittal Instructions and Summary of Supplemental Data Requested

I. Introduction

Under the authority of Section 114 of the Clean Air Act, this Section 114 survey is to be completed for operations at all facilities wholly owned by your company that are subject to the requirements of 40 CFR part 63, subpart O. The operations covered by these requirements include sterilization chamber vents, aeration room vents, chamber exhaust vents, and fugitive emissions.

This Section 114 survey consists of a Microsoft Excel survey form and submission of supplemental data and information for operations in the ethylene oxide commercial sterilization and fumigation source category. This document includes Instructions for the Ethylene Oxide Commercial Sterilization Section 114 Survey.

All recipients must complete and return the survey by the date specified in the letter. If you have questions regarding this request, please contact Mr. Jonathan Witt, Office of Air and Radiation, at (919) 541-5645 or witt.jon@epa.gov.

II. Instructions for Obtaining the Excel Survey Form

You must create and complete a **separate** Excel survey file for each of your ethylene oxide commercial sterilization facilities. Before submitting the file, the file name should be changed to reflect the actual company **and facility** (see Section IV).

Facilities must scroll down and across each worksheet in the Excel workbook and complete all tables. See the checklist at the end of this document to confirm that you have filled out each table in the Excel survey form.

Note that requests in the Excel survey form for “annual” costs do not mean “annualized” cost. Annual costs represent expenses incurred annually to perform routine activities. Please use a consistent dollar year throughout the survey.

III. Supplemental Data and Information Requested

In addition to completing the Excel survey form, we are requiring the submission of supplemental data and information to support multiple parts of the survey. As listed on the “Attachments” worksheet, we are requiring submission of the following:

- A facility diagram(s) that shows all ethylene oxide commercial sterilization operations at the facility up to and including the shipment of sterilized and fumigated products away from the facility;
- A process flow diagram(s) for all of the ethylene oxide commercial sterilization process
- The most recent air permit(s) for the facility;

- The permit application documents associated with the initial air permit and any subsequent permit application documents submitted for the purpose of revisions to the air permit (if applicable) up to and including any permit applications for the most recent air permit(s) for the facility;
- A copy of the facility's Startup, Shutdown, and Malfunction Plan (SSMP), or set of plans if more appropriate, for all of your ethylene oxide commercial sterilization operations;
- Documentation for the calculations and supporting information for all emissions factors and approaches used to determine the annual ethylene oxide emissions;
- All performance test(s) conducted over the last 5 years for each air pollution control device (APCD);
- All engineering test(s) conducted over the last 5 years for each APCD;
- The records for parametric monitoring conducted on each APCD for the last calendar year (CY2018);
- The action levels and standard operating procedures for room area monitoring;
- The results and records of any other ethylene oxide monitoring conducted by the facility, such as near-source, ambient air, or fenceline monitoring;
- The results and records of dispersion modeling conducted by the facility; and
- Any process and instrumentation diagrams (P&IDs) that are not included in previous attachments

Instructions and additional requirements related to the supplemental data and information are contained within the Excel survey form.

IV. File Naming Conventions for Your Survey Response

Before submitting any files or data to EPA, please ensure you adhere to the following naming conventions:

Non-confidential business information (CBI) response-filled Excel survey form:

- [Company]_[Facility]_EtO_114Survey_NonCBI

CBI response-filled Excel survey form:

- [Company]_[Facility]_EtO_114Survey_CBI

You must submit the files for the supplemental information as Adobe PDF documents using the following file naming conventions:

- [Company]_[Facility]_FacDiagram
- [Company]_[Facility]_[EtOUnitID]_ProcessFlow
- [Company]_[Facility]_[Year]_Permit
- [Company]_[Facility]_[Year]_PermitApplic
-

- [Company]_[Facility]_[EthyleneOxideUnitID]_SSMP
- [Company]_[Facility]_CalcEm
- [Company]_[Facility]_[EtOUnitID]_[APCD ID]_[Year]_PerfTest
- [Company]_[Facility]_[EtOUnitID]_[APCD ID]_[Year]_EngTest
- [Company]_[Facility]_[APCD ID]_[Year]_ParaMonit
- [Company]_[Facility]_[RoomAreaID]_[Year]_Monit
- [Company]_[Facility]_OtherMonit
- [Company]_[Facility]_[Year]_DispModel
- [Company]_[Facility]_[EthyleneOxideUnitID]_P&ID

Each worksheet in the Excel workbook contains a question at the top asking whether any CBI is entered on the worksheet. This question should be completed as appropriate.

- If you are reporting CBI, please answer this question with “Yes,” and shade each cell that contains CBI in red. Please do not mark all information in red highlight if only part of the information in the worksheet is CBI.
- If you have CBI, you should complete the survey form in its entirety, being sure to mark each worksheet, and save this file as the CBI version, using the naming convention explained previously.
- Before you submit, you should also create a non-CBI version of the Excel survey form. To create a non-CBI version, do a “Save As” to save the CBI file as a non-CBI file using the naming convention above. From the non-CBI version, delete only the CBI text from each red cell and save a final non-CBI version. (Note: You should retain the red highlight in the cell, but **no text or information should be provided in the red cells in the non-CBI version. It should be a blank red cell.**)
- Before you submit, be sure to proof the non-CBI file to confirm that all CBI has been removed.
- Submit both the CBI and non-CBI versions to EPA, following the submittal procedures below.

V. Instructions for Submitting Your Survey Response

Submit non-CBI portions of your response using one of the following methods:

- **Email** – For files that are less than 10 MB, email your non-confidential files to witt.jon@epa.gov with a subject line of “EtO Section 114 Survey Response for [Company] [Facility].”
- **Mail** – You may mail your response on a thumb drive, CD, or DVD to:

Ethylene Oxide Commercial Sterilization Section 114 Survey Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

If you are submitting CBI, you must also mail a separate thumb drive, CD, or DVD containing the entire response-filled survey database with CBI and non-CBI portions to Ms. Tiffany Purifoy at the address below. Clearly mark the disk and/or the materials with the words “Confidential Business Information.” **DO NOT ELECTRONICALLY TRANSMIT (i.e., via email, fax or ftp) CONFIDENTIAL BUSINESS INFORMATION TO EPA.**

U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
U.S. EPA Mailroom (C404-02)
Attn: Ms. Tiffany Purifoy, Document Control Officer (ESD #322)
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

If you have questions regarding this request, please contact Mr. Jonathan Witt, Office of Air and Radiation, at (919) 541-5645 or witt.jon@epa.gov.

Checklist to Confirm All Excel Survey Form Tables Have Been Completed Prior to Submission

	Excel Survey Form tables
	A. Facility Details
<input type="checkbox"/>	Table 1. Facility Information
<input type="checkbox"/>	Table 2. Parent Company Information
<input type="checkbox"/>	Table 3. Facility Documents
<input type="checkbox"/>	Table 4. Facility Buildings
<input type="checkbox"/>	Table 5. Facility-level Data
	B. Individual Room Area (All Areas where EtO is Used or Emitted)
<input type="checkbox"/>	Table 1. Characteristics of Room Areas
<input type="checkbox"/>	Table 2. Natural Draft Openings (NDO)
<input type="checkbox"/>	Table 3. Leak Checks of Components in EtO Service
<input type="checkbox"/>	Table 4. Room Area Controls
<input type="checkbox"/>	C. EtO Drum and Container Storage
<input type="checkbox"/>	D. Ethylene Glycol (EG) Storage
	E. Sterilization Chambers
<input type="checkbox"/>	Table 1. Summary for Sterilizer Chambers
<input type="checkbox"/>	Table 2. Sterilizer Chamber Operation and Monitoring Characteristics
<input type="checkbox"/>	Table 3. Control Characteristics for Sterilizer Chambers
<input type="checkbox"/>	Table 4. Control Characteristics for Sterilizer Chambers (continued)
<input type="checkbox"/>	Table 5. Vacuum Pumps
	F. Aeration
<input type="checkbox"/>	Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber)
<input type="checkbox"/>	Table 2. Aeration that Occurs within Sterilizer Chamber
<input type="checkbox"/>	Table 3. Movement of Sterilized Products through the Facility
	G. Summary of Air Pollution Control Devices
<input type="checkbox"/>	Table 1. APCD Characteristics
<input type="checkbox"/>	Table 2. Emissions and CEMS
	H. Details of Air Pollution Control Devices
<input type="checkbox"/>	Table 1. Wet Scrubber and Glygen Absorber Unit
<input type="checkbox"/>	Table 2. Dry-bed Scrubber
<input type="checkbox"/>	Table 3. Catalytic Oxidizer & Balancer/Abator
<input type="checkbox"/>	Table 4. Thermal Oxidizer

<input type="checkbox"/>	Table 5. Other APCDs
	I. EtO Monitoring
<input type="checkbox"/>	Table 1. Personal Monitoring (Badges) for EtO
<input type="checkbox"/>	Table 2. Room Area Monitoring for EtO
<input type="checkbox"/>	Table 3. Other Monitoring for EtO
<input type="checkbox"/>	J. Wastewater
<input type="checkbox"/>	K. Unique Cycles and EtO Reduction
<input type="checkbox"/>	L. Other Questions regarding EtO Commercial Sterilization
<input type="checkbox"/>	M. Additional Information
<input type="checkbox"/>	N. Attachments
<input type="checkbox"/>	Certification