

**Ethylene Oxide (EtO) Commercial Sterilization  
Section 114 Information Collection Request (ICR)**

**Instructions Document**

**(General Version)**

**Paperwork Reduction Act Burden Statement**

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**Note: This general version of Instructions Document should be used if your company did not receive the December 2019 questionnaire issued by the U.S. Environmental Protection Agency (EPA).<sup>1</sup> The companies that responded to the December 2019 questionnaire should use the special version of Instructions Document enclosed in the package received directly from the EPA.**

**I. Introduction**

Under the authority of section 114 of the Clean Air Act, this ICR is to be completed for operations at all facilities wholly owned by your company that are part of the ethylene oxide commercial sterilization source category, including those that may be subject to the requirements of 40 CFR part 63, subpart O. The operations for EtO commercial sterilization may include sterilizer chambers, chamber exhaust vents, aeration rooms, and associated fugitive emissions.

This section 114 ICR consists of a main questionnaire and three (3) supplements, in the form of Microsoft Excel workbooks, to allow for submission of information requested for operations in the EtO commercial sterilization source category. The supplements only need to be used if additional space is needed. This Instructions Document includes instructions for providing and submitting data and documents requested in this section 114 ICR.

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<sup>1</sup> Companies that received the December 2019 ICR include: Altair, Becton Dickinson, Cosmed Group, Elite Spice, Medline Industries, Medtronic, Midwest Sterilization Corporation, Sotera Health, and STERIS.

All recipients must complete and return the main questionnaire, along with any supplements that were used, by the date specified in the section 114 transmittal letter. Please see the contact information in **Section VII** below if you have questions regarding this request.

## II. About the Questionnaire and Supplements

Once the template Excel workbooks are downloaded from the EPA website, you must create and complete a main questionnaire for each of your EtO commercial sterilization facility. The file name must be changed to reflect the actual company, city and state (see **Section IV** below for more details).

In addition, there are 3 supplements to the main questionnaire should you need more space than what is available in the original tables (Section B, Table 3; Section B, Table 4; and Section I, Table 1) to provide the data requested. If you prefer to fill out any supplement in lieu of the original table, please select “Yes” in the designated cell above each original table where a supplement will be used, and leave the original table blank in the main questionnaire. The data fields in the main questionnaire will be automatically shaded in gray. The file name(s) of your supplement(s) must also be changed to reflect the actual company, city and state (see **Section IV** below for more details).

Please scroll down and across each worksheet and complete all sections in the main questionnaire, except Section M (which may be used should you need space to provide any additional information). You may use the checklist at the end of this Instructions Document to confirm that you have filled out all the tables in each section. More details may be found in the “Introduction” worksheet of the main questionnaire.

Please note, in the main questionnaire and supplements, that data fields for “annual” costs do not mean “annualized” cost. Annual costs represent expenses incurred annually to perform routine activities. You must specify the dollar year for each cost-related data field in the designated column. Please use a consistent dollar year throughout the survey, if possible.

## III. About the “Documents” Worksheet

In addition to completing the main questionnaire and any supplements, the EPA is requiring the submission of additional documents to complement the information requested. The “Documents” worksheet of the main questionnaire contains a full list of the documents that are requested. Specifically, these documents include:

- Facility diagram(s) that shows all EtO commercial sterilization operations at the facility up to and including the shipment of sterilized and fumigated products away from your facility;
- Process flow diagram(s) for all EtO commercial sterilization operations at your facility;

- The most recent air permit(s) for your facility;
- 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 your facility;
- A copy of your facility's Startup, Shutdown, and Malfunction (SSM) plan, or set of plans if more appropriate, for all EtO commercial sterilization operations;
- Documentation for the calculations and supporting information for all emissions factors and approaches used to determine the annual EtO emissions at your facility;
- 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;
- Records for parametric monitoring conducted on each APCD for Calendar Year 2020;
- Action levels and standard operating procedures (SOP) for room area monitoring;
- Results and records of any other EtO monitoring efforts conducted at your facility, such as near-source, ambient air, fence line monitoring, or dispersion modeling;
- Documentation of studies done on quantifying EtO residuals in your products; and
- Any process and instrumentation diagrams (P&IDs) that are not included in other documents requested.

In the "Documents" worksheet, please be sure to specify in the designated columns the total number of CBI vs. non-CBI documents you intend to submit either as (1) attachments to this worksheet or (2) individual files via a media. More details can be found in the "Documents" worksheet of the main questionnaire.

#### **IV. Naming Conventions for Your Questionnaire, Supplements, and Documents**

Before submitting your questionnaire and supplements (if used) to U.S. EPA, please ensure that you adhere to the following naming conventions:

- CBI version of Excel workbooks with responses

[Company]\_[CityState]\_EtO\_114ICR\_Main\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup1\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup2\_CBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup3\_CBI

*Example filename: Acme\_JonestownMN\_EtO\_114ICR\_Main\_CBI.xlsx*

- Non-CBI version of Excel workbooks with responses

[Company]\_[CityState]\_EtO\_114ICR\_Main\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup1\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup2\_NonCBI

[Company]\_[CityState]\_EtO\_114ICR\_Sup3\_NonCBI

*Example filename: Acme\_JonestownMN\_EtO\_114ICR\_Main\_NonCBI.xlsx*

- Documents

[Company]\_[CityState]\_[Field # in the main questionnaire (dash) numbering, if multiple documents are provided]\_[CBI/NonCBI]

*Example filename: Acme\_JonestownMN\_A-21-2\_NonCBI.pdf*

*Acme\_JonestownMN\_I-15-3\_CBI.pdf*

## V. Procedure for Creating the non-CBI and CBI Versions of Your Response

To ensure safe and appropriate handling of any confidential business information (CBI) that you may provide, each “green” worksheet (where facility information is to be entered) in the main questionnaire and supplements contains a question in Cell N2 asking whether any CBI is entered in this specific worksheet. This question must always be completed by selecting from the dropdown menu in Cell N2.

Please follow the procedures below to create the CBI and non-CBI versions of your response, respectively.

- (1) After downloading the template Excel workbooks from the EPA’s website, create a copy of the main questionnaire for each of your facilities following the naming conventions in **Section IV**. If there is no CBI in the data you are going to submit, name the file as “...\_NonCBI”, then skip to step (6). If there is CBI in your data, name the file as “...\_CBI”. This workbook will be the CBI version of your response.
- (2) Review the instructions and complete the main questionnaire in its entirety with full, real data including CBI. If any supplement needs to be used, create a copy of the supplement for each of your facilities following the naming conventions specified in **Section IV**, with the file name ending in “...\_CBI” also. The supplement is part of the CBI version of your response. The same procedures and conventions below should be followed for your supplement.
  - Leave the data field blank if you do not have any data to provide to the EPA. Please do not enter “0”, “N/A”, “Not Applicable”, or any other text. If any data requested does not apply to your facility, please enter “N/A” or “Not Applicable” as appropriate.

- Manually shade each cell containing CBI in red. These cells should look like the example shown in Picture 1 below. Do not shade the entire table if CBI is only entered in certain cells.

A-39.1	
Packaging material used for products sterilized with EtO	
Specify the packaging material used for products sterilized with EtO at your facility	Enter the <u>percent</u> <u>by volume</u> of product sterilized with EtO that uses this packaging material (%)
Cardboard	60.00%

Picture 1. Sample CBI data field in the CBI version of response, with real CBI data

- Remember to select “Yes” from the dropdown menu in Cell N2 if CBI is entered in this worksheet, as shown in Picture 2 below.

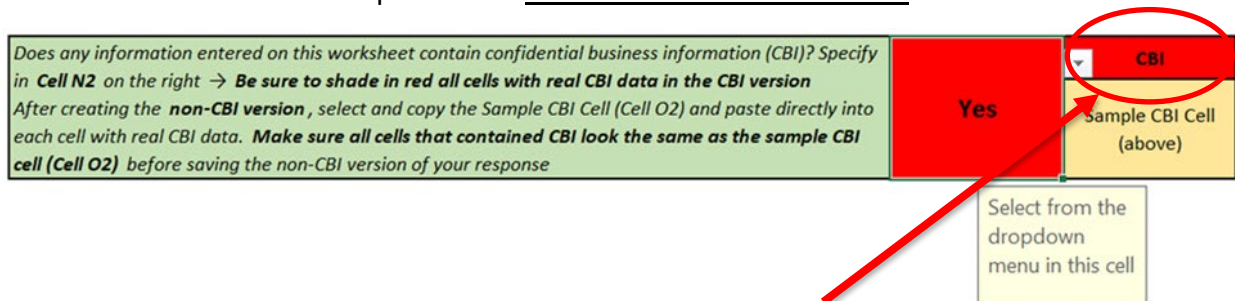
<i>Does any information entered on this worksheet contain confidential business information (CBI)? Specify in <b>Cell N2</b> on the right → <b>Be sure to shade in red all cells with real CBI data in the CBI version</b>  After creating the <b>non-CBI version</b>, select and copy the Sample CBI Cell (Cell O2) and paste directly into each cell with real CBI data. <b>Make sure all cells that contained CBI look the same as the sample CBI cell (Cell O2)</b> before saving the non-CBI version of your response</i>	<b>Yes</b>	<b>CBI</b>
		Sample CBI Cell (above)

Select from the dropdown menu in this cell

Picture 2. Select “Yes” in Cell N2 if CBI is entered in this worksheet

- In the “Documents” worksheet, specify in the designated columns the total number of CBI vs. non-CBI documents you intend to submit to the EPA either as (1) attachments to this worksheet or (2) individual files via a media. The quantities of documents are non-CBI by default. If you choose to provide the documents as attachments, include all the CBI and non-CBI documents you would like to submit. Please attach only 1 document to each cell, and shade in red all cells containing CBI documents. There is no sample CBI cell in this worksheet.
- In the “Certification” worksheet, check the applicable boxes to acknowledge appropriate handling of CBI in this CBI version of your response.
  - When you are finished, make sure every data field that contains CBI looks the same as the example in Picture 1, and Cell N2 on each “green” worksheet is up to date. Then save and close this workbook.

- (5) Create a copy of the main questionnaire, along with any supplement, that you just finished and change the file name to "...\_NonCBI" according to **Section IV**. This workbook will be the non-CBI version of your response upon completion.
- (6) Review each worksheet and make sure that only non-CBI data are entered in this workbook.
- Again, please leave the data field blank if you do not have any data to provide to the EPA. Please do not enter "0", "N/A", "Not Applicable", or any other text. If any data requested does not apply to your facility, please enter "N/A" or "Not Applicable" as appropriate.
  - To hide and protect your CBI data, copy the sample CBI cell (as shown in Picture 3 below) and paste into the cell(s) containing CBI. Do not change your answer in Cell N2. When you are finished, every data field that contained CBI before should look the same as the sample CBI cell (see the example in Picture 4 below).
    - If a data field contains merged cells across multiple rows or columns, copying and pasting the sample CBI cell may result in duplicate sample CBI cells or missing formatting. In this case, please (1) use the "merge across" feature of Excel to combine those duplicate cells, and/or (2) manually shade the cells back in red. In the end, there should be only 1 cell with the same formatting of the sample CBI cell in each row of each data field.



Picture 3. Sample CBI cell (Cell O2)

A-39.1	
Packaging material used for products sterilized with EtO	
Specify the packaging material used for products sterilized with EtO at your facility	Enter the <u>percent by volume</u> of product sterilized with EtO that uses this packaging material (%)
Cardboard	CBI

Picture 4. Sample CBI data field in the non-CBI version of response, after real CBI data are masked

- In the “Documents” worksheet, if you have attached documents in the CBI version of your response, please remove all the CBI documents and preserve only the non-CBI documents. Do not change the total number of CBI vs. non-CBI documents entered in the designated columns. This worksheet should then contain only the non-CBI documents you would like to submit.

(7) Check and update your entries in the “Certification” worksheet.

(8) When you are finished, make sure there is no CBI data or document in this non-CBI version of your response, and every data field that contained CBI before looks the same as the sample CBI cell. Then save and close this workbook.

Once completed, the CBI version of your response (main questionnaire and any supplement) must contain the full data and documents that you wish to submit to the EPA, while the non-CBI version must only contain the non-CBI portion of the data and documents. Please submit both the CBI and non-CBI versions of your response to the EPA following the submittal procedures specified in **Section VI** below.

## VI. Instructions for Submitting Your Responses

For the non-CBI version of your completed Excel workbooks (main questionnaire and supplements), you may submit using one of the following methods. If you choose to submit your documents as standalone PDF files, please only send the non-CBI documents along with the non-CBI version of your main questionnaire and supplements.

- Email

For files that are less than 10 MB, email your non-CBI response to Ms. Charlene Spells at [Spells.Charlene@epa.gov](mailto:Spells.Charlene@epa.gov) with a subject line of “EtO Section 114 ICR Response for [Company] [CityState]”

- Mail

You may save your files on a media such as thumb drive, CD or DVD, and mail to:  
*Ethylene Oxide Commercial Sterilization Section 114 ICR 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*

For the CBI version (full version) of your completed Excel workbooks (main questionnaire and supplements), you must save your files on a separate media such as thumb drive, CD, or DVD. Please clearly mark the media with “Confidential Business Information”, and mail to:

*U.S. EPA 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 choose to submit your documents as standalone PDF files, all the documents must be saved on the same media with your Excel workbooks (main questionnaire and supplements). The CBI version of your Excel workbooks should be complemented by all the CBI and non-CBI documents, while the non-CBI version of your Excel workbooks should be complemented by only the non-CBI documents.

**DO NOT ELECTRONICALLY TRANSMIT CBI (e.g., via email, fax or ftp) TO THE EPA.**

## **VII. Contact Information**

For general questions regarding this request, please contact Ms. Charlene Spells, Office of Air and Radiation, U.S. EPA, at (919) 541-5255 or [Spells.Charlene@epa.gov](mailto:Spells.Charlene@epa.gov).

For questions on the Excel workbooks (main questionnaire and supplements) and this Instructions Document, please contact Mr. Jeremy Guo, Air Quality Engineering, RTI International, at [jig@rti.org](mailto:jig@rti.org).



### Checklist of Tables in the Main Questionnaire

	<b>A. Facility Details</b>
<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
<input type="checkbox"/>	Table 6. Materials Sterilized with EtO
<input type="checkbox"/>	Table 7. Materials Sterilized with Non-EtO Techniques and Approaches
	<b>B. Individual Room Area (All Areas where EtO is Used or Emitted)</b>
<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 ( <i>Optional Supplement 1</i> )
<input type="checkbox"/>	Table 4. Room Area Controls ( <i>Optional Supplement 2</i> )
<input type="checkbox"/>	<b>C. EtO Drum and Container Storage</b>
<input type="checkbox"/>	<b>D. Ethylene Glycol (EG) Tanks</b>
	<b>E. Sterilization Chambers</b>
<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
	<b>F. Aeration</b>
<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
	<b>G. Summary of Air Pollution Control Devices</b>
<input type="checkbox"/>	Table 1. APCD Characteristics
<input type="checkbox"/>	Table 2. Emissions and CEMS
	<b>H. Details of Air Pollution Control Devices</b>
<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 & Combination Water Balancer/Catalytic Oxidizer

<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 ( <i>Optional Supplement 3</i> )
<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"/>	Table 1. EtO and Facility Operation
<input type="checkbox"/>	Table 2. Standalone Non-Colocated Warehouse, Distribution Center, or Enclosed Building for Sterilized Products
<input type="checkbox"/>	Table 3. Alternative Sterilization
<input type="checkbox"/>	M. Additional Information
<input type="checkbox"/>	N. Documents
	Certification
<input type="checkbox"/>	Acknowledgment of CBI Handling
<input type="checkbox"/>	Certification by Reporter
<input type="checkbox"/>	Certification by Facility Personnel
<input type="checkbox"/>	Certification by Professional Engineer
<input type="checkbox"/>	Certification by Certified Industrial Hygienist