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

Paperwork Reduction Act Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control N mandatory under section 114(a) of Clean Air Act. An agency may not conduct or sponsor, and a person is not required to resp currently valid OMB control number. The average public reporting and recordkeeping burden for this collection of informatio comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested meth Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 204 Do not send the completed form to this address.

Introduction

The U.S. Environmental Protection Agency (EPA) is requesting facility data and information to inform the Technology Review

About the Main Questionnaire

This main questionnaire contains worksheets and data fields shaded in different colors:

Worksheets and data fields shaded in green indicate that facility shall provide inputs according to the corresponding instruct
Worksheets and data fields shaded in gold contain instructions and supporting information that help facility with this questio
Data fields shaded in gray indicate that these either do not need to be filled out or will be automatically filled out based on f
Data fields shaded in red by facility indicate that these fields contain confidential business information (CBI), and relevant da
"Certification" worksheet in blue must be completed by facility before submission

If any information entered contains CBI, be sure to select "Yes" in the designated cell (Cell N2) on each worksheet, shade a on each worksheet or in Section IV of the Instructions Document.

This main questionnaire contains the following worksheets (you may click on the links below to visit each individual workshe

Introduction (this worksheet)	Introduction and instructions for completing and submitting this questionnaire
Terms (link)	Definitions or explanations of certain technical terms that are mentioned throughc
Facility Details (link)	Information about facility registration, ownership, general characteristics, facility-l
Room Area (link)	Characteristics, inventory of components and control of individual room areas whe
EtO & EG Storage (link)	Questions regarding EtO storage in drums and containers, and ethylene glycol (EG)
Sterilizer Chambers (link)	Operation, monitoring and control characteristics of sterilizer chambers
Aeration (link)	Details of aeration equipment
APCD Summary (link)	Information about all air pollution control devices operated by facility
APCD Details (link)	Details regarding air pollution control devices such as scrubbers, catalytic oxidizers
EtO Monitoring (link)	Information about workspace monitoring, personal monitoring, room monitoring,
Miscellaneous (link)	Questions regarding facility's wastewater treatment and other items of EtO comm
Additional Info (link)	Use this worksheet if you need extra space to provide any additional information r
Documents (link)	Designated space to attach documents requested throughout this questionnaire
Certification (link)	Reporter's information and certification for completing and submitting this questio

About the Supplements

There are 3 supplements to this main questionnaire, including:

OMB Control No. 2060-NEW

Approval Expires mm/dd/yyyy

No. 2060-NEW). Responses to this collection of information
pond to, a collection of information unless it displays a
n is estimated to be proximately 108 hours per response. Send
hods for minimizing respondent burden to the Regulatory
460. Include the OMB control number in any correspondence.

/ project for 40 CFR part 63, subpart O, Ethylene Oxide (EtO) Co

tions
onnaire
acility's inputs in relevant fields
ata needs special handling *

ll cells with CBI in red, then follow the instructions specified

eet):

out this questionnaire
evel data, legal documents, etc.
re EtO is used or emitted
tanks
, thermal oxidizers, and others
etc. conducted by facility
ercial sterilization operation
equested within this questionnaire
nnaire

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

Click here to go to "Introduction"

1. Definitions

Term	Definition
Accelerated aeration	Aeration conducted in a heated aeration chamber or cell, not an aeration room, co and/or (2) high turbulence air created by multiple inlet ports along the length of th along the top of the cell to provide even distribution of air flow
Aeration cell/chamber	Any vessel that is used to facilitate off-gassing of ethylene oxide at a sterilization fa the vessel is classified as a sterilization chamber
Aeration room	Any vessel or room that is used to facilitate off-gassing of ethylene oxide at a steril occurs, the vessel or room is classified as a sterilization chamber
Aeration room vent (ARV)	The point(s) through which the evacuation of ethylene oxide-laden air from an aer
Balancer/abator system	An air pollution control device (APCD) that consists of a combination of a water bal
Cascading air	Ventilation air removed from one room area or process, with a lower EtO concentr air or intake ventilation air directly to another room area or process (e.g., ventilatic air to the aeration room or aeration cell). Ventilation air removed from one room or lower EtO concentration than the room air concentration or process concentrati it is reused
Chamber exhaust vent (CEV)	The point(s) through which ethylene oxide-laden gas is removed from the sterilizat following the completion of sterilization and associated air washes. Also known as
Combination-chamber sterilizer	Any enclosed vessel in which both the sterilization process and the aeration proces vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for th by off-gassing of ethylene oxide
Dwell period	The length of time that the product is exposed to ethylene oxide in sterilizer chamb fumigating the product
Engineering test	A test that measures the amount of pollutants being emitted, demonstrates the ca destruction or removal efficiency of a control device used to reduce emissions at a compliance or regulatory requirements
Ethylene oxide (EtO) service	A piece of equipment either contains or contacts ethylene oxide as a liquid or gas a
Fugitive emissions	Emissions (of ethylene oxide) which are not routed through the existing control eq
Natural draft opening (NDO)	Any permanent opening in the enclosure that remains open during operation of th in which a fan is installed
Non-colocated warehouse/distribution center	A warehouse or distribution center, used to store products that are sterilized with facility subject to the ethylene oxide commercial sterilizer rule under 40 CFR part 6

Performance test	A test that measures the amount of pollutants being emitted, demonstrates the ca destruction or removal efficiency of a control device used to reduce emissions at a compliance with an emission limit, capture efficiency, or control efficiency requirer
Research and laboratory facility	Any stationary source whose primary purpose is to conduct research and developn where such source is operated under the close supervision of technically trained pe manufacturer of products for commercial sale in commerce, except in a de minimis
Single-item sterilizer	Any enclosed vessel in which sealed pouches containing product and ethylene oxid placed, and the ethylene oxide sterilizes and aerates
Sterilization chamber vent (SCV)	The point (prior to vacuum pump) through which the evacuation of ethylene oxide following sterilization or fumigation, including any subsequent air washes
Sterilization facility	Any stationary source where ethylene oxide is used in the sterilization or fumigatio
Sterilization operation	Any time when ethylene oxide is removed from the sterilization chamber through t chamber exhaust vent or when ethylene oxide is removed from the aeration room
Sterilizer chamber	Any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene o of sterilizing and/or fumigating at a sterilization facility. Includes any vessels or roo sterilization and aeration occur within one chamber

2. Acronyms

Acronym	Term	Acronym	
APCD	air pollution control device	ID	
ARV	Aeration room vent	in. H2O	
CAA	Clean Air Act	kWh	
CBI	Confidential business information	LEL	
CEMS	Continuous emissions monitoring system	mg/L	
CEV	Chamber exhaust vent	NAICS	North Americ
cfm	Cubic feet per minute	NDO	r
CFR	Code of Federal Regulations	ppmv	pa
EG	ethylene glycol	psig	pressu
EIS	Emission Inventory System	QA	
EPA	Environmental Protection Agency	QC	
EtO	ethylene oxide	R&D	res
ICR	information collection request	SCV	ste

mbined with: (1) use of vacuum cycles, e aeration cell and multiple outlet points
acility. If single-item sterilization occurs,
ization facility. If single-item sterilization
ation room occurs
ancer and a catalytic oxidizer
ation, is vented as the input ventilation on air from a warehouse is used as intake area or process must have an equivalent ion of the room area or process in which
ion chamber during chamber unloading, "back vent"
s occur within the same vessel, e.g., the e purpose of sterilizing and is followed
ber for the purpose of sterilizing or
pture efficiency, or determines the facility. This testing is not related to
at any concentration
uipment
e facility and is not connected to a duct
ethylene oxide, that is not part of a 3, subpart O

pture efficiency, or determines the facility. Used to determine a facility's ment
nent into new processes and products, ersonnel and is not engaged in the s manner
le gas for the purpose of sterilizing are
from the sterilizer chamber occurs
n of materials
the sterilization chamber vent or the through the aeration room vent
xide/inert gas mixture, for the purpose ms where both ethylene oxide

Term
identifier
inches of water
kilowatt hour
lower explosive limit
milligrams per liter
an Industrial Classification System
natural draft opening
rts per million, volume
ure per square inch, gauge
quality assurance
quality control
earch and development
rilization chamber vent

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

A. Facility Details

Table 1. Facility Information

Field #	A-1	A-2	A-3	A-
Data	Primary NAICS code	EIS ID	Facility name	Facility
Instruction	Enter the primary NAICS code for the facility [1]	Enter EIS ID for the facility	Enter facility name	Enter the street addr verified by U.S. Posta not include P.O. box
Response				

1 For assistance in determining your facility's NAICS code, see the website for the North American Industry Classification Syst

Table 2. Parent Company Information

Field #	A-13	A-14	A-15
Data	Parent company	Parent company address	Parent company city
Instruction	Enter parent company name	Enter the street address of parent company verified by U.S. Postal Service (USPS). Do not include P.O. box in this field	Enter parent company city
Response			

[2] To determine the employee threshold for a small business, you may look up the small business size standard using six-digit I size standards has SBA identified by North American Industry Classification System codes?", table "Small Business Size Standa

Website for the Small Business Administration: https://www.sba.gov/. (click to visit)

Code of Federal Regulations (CFR), part 121: https://www.ecfr.gov/cgi-bin/text-idx?SID=85df5b1185a8b127a9b324c6583f7

Table 3. Facility Documents

Field #	A-21	A-22	A-
Data	Facility diagrams	Process flow diagrams	Most recent

Instruction	Provide diagrams of your facility indicating all rooms, primary EtO emission points (e.g., regulated emission points), and secondary EtO emission points (e.g., fugitive emission points). Ensure that all NDOs are adequately labeled	Provide process flow diagrams of the EtO processes at your facility	Provide the most rec approved for your fa
Response	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet	See instructions work

Table 4. Facility Buildings

Field #	A-26	A-27	A-28		A-
Data	Building ID	Building height	Building corner 1		Building
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each building	Enter the (average) height of the building **(feet)**	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point
Response					

Table 5. Facility-level Data

Field #	A-36	A-40	A-
Data	EtO usage at your facility for the last 5 calendar years	Annual EtO stack emissions of facility for the last 5 years	Annual EtO fugitive for the la

Instruction	Specify the calendar year. Select from the dropdown menu in this column	Enter the corresponding EtO usage in this column **(pounds)**	Specify the calendar year. Select from the dropdown menu in this column	Enter the value of annual EtO emissions in this column **(pounds)**	Specify the calendar year. Select from the dropdown menu in this column
Response					

3 For definitions of major source and area source, see section 112, Hazardous Air Pollutants, paragraph (a)(1) and (2), respec
"Synthetic minor" for HAP means a source that otherwise has the potential to emit HAPs in amounts that are at or above tho

Table 6. Materials Sterilized with EtO

Field #	A-37	A-38	A-
Data	Materials sterilized with EtO (e.g., medical products, pharmaceutical products, spices, etc.) at your facility in 2019	Percentage of each type of materials sterilized with EtO in 2019 based on volume of throughput	Percentage of each sterilized with EtO dollar a
Instruction	List all types of materials sterilized with EtO at your facility in 2019. Enter one type in each cell. If you have more than 10 types, enter "Other materials sterilized with EtO" in Cell C89, then specify. For example: "Other materials sterilized with EtO (Type 10, Type 11, Type 12, etc.)"	Provide the approximate percentage of each type of materials sterilized with EtO in 2019 based on volume of material throughput **(%)**	Provide the approxin each type of materia EtO in 2019 based o **(%)**
Response			

Table 7. Materials Sterilized with Non-EtO Techniques and Approaches

Field #	A-48	A-49	A-
Data	Materials sterilized with non-EtO approaches (e.g., medical products, pharmaceutical products, spices, etc.) at your facility in 2019	Percentage of each type of material sterilized with non-EtO approaches in 2019 based on volume of throughput	Percentage of eac sterilized with non- 2019 based on

Instruction	List all types of materials sterilized with non-EtO approaches at your facility in 2019. Enter one type in each cell. If you have more than 10 types, enter "Other materials sterilized with non-EtO" in Cell C105, then specify. For example: "Other materials sterilized with non-EtO (Type 10, Type 11, Type 12, etc.)"	Provide the approximate percentage of each type of material sterilized with non-EtO approaches in 2019 based on volume of material throughput **(%)**	Provide the approxi each type of materia non-EtO approaches dollar amount **(%)**
Response			

Does any information entered on this worksheet contain confidential business information (CBI)? Specify in ***Cell N2*** *on the right →* ***Be sure to shade each cell that contains CBI in red***
Before saving the ***non-CBI version*** *of your response, select and copy the Sample CBI Cell (****Cell O2****), and paste directly into each cell that contains CBI.* ***Make sure that all "CBI" cells are shaded in red***

-4	A-5	A-6	A-7	A-8	A-9
address	Facility city	Facility state	Facility zip code	Phone number	Number of employees at facility
ress of facility al Service (USPS). Do in this field	Enter facility city	Select from the dropdown menu in this column	Enter facility zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the facility	Select from the dropdown menu. Full-time, part-time, and temporary employees should be counted equally

em (NAICS), maintained by the U.S. Census Bureau: https://www.census.gov/eos/www/naics/. (click to visit)

A-16	A-17	A-18	A-19	A-
Parent company state	Parent company zip code	Phone number	Is parent company a small business?	Number of empl comp
Select from the dropdown menu in this column	Enter parent company zip code verified by U.S. Postal Service (USPS)	Provide a contact phone number at the parent company	Select from the dropdown menu in this column [2]	Select from the drop column

NAICS codes. The size standards used to define Small Businesses are provided in 13 CFR 121, Small Business Size Regulations. Se ards by NAICS Industry", column "Size standards in number of employees".

?c6&mc=true&node=pt13.1.121&rgn=div5. (click to visit)

23	A-24	A-25
air permit(s)	Application documents for the most recent air permit(s)	Startup, shutdown and malfunction (SSM) plan

ent air permit(s) cility	Provide the application documents for the most recent air permit(s) approved for your facility	Provide the startup, shutdown and malfunction (SSM) plan approved for your facility
in "Documents" sheet	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet

29	A-30		A-31		A-
corner 2	Building corner 3		Building corner 4 (if any)		Building corr
Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point

41	A-42	A-43	A-
emissions of facility st 5 years	Documentation for annual EtO emissions calculations	Average annual energy cost of facility operation (include the last 5 years in the average)	Average annual grov from EtO sterilizati last 5

Enter the value of annual EtO emissions in this column **(pounds)**	Provide calculations and supporting documentation for both stack emissions and fugitive emissions, including all emission factors used to determine the annual EtO emissions	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the amount in this column **(dollars/year)**
	See instructions in "Documents" worksheet			

ctively: https://www3.epa.gov/ttn/atw/112a_def.html. (click to visit)

se for major sources of HAP in 40 CFR 63.2, but that have taken a restriction so that its potential to emit (PTE) is less than such

39	A-39.1		A-39.2	
n type of materials in 2019 based on amount	Packaging material used for products sterilized with EtO		Pallet material used for products sterilized with EtO	
mate percentage of ls sterilized with n dollar amount	Specify the packaging material used for products sterilized with EtO at your facility	Enter the percent by volume of product sterilized with EtO that uses this packaging material **(%)**	Specify the pallet materials used in EtO sterilizer chambers	Enter the percent by volume of each type of pallet material used for EtO sterilization **(%)**

50	A-51
h type of material -EtO approaches in dollar amount	Packaging material used for products sterilized with non-EtO approaches

nate percentage of l sterilized with in 2019 based on	Specify the packaging material used for products sterilized with non-EtO approaches at your facility	Enter the percent by volume of product sterilized with non-EtO approaches that uses this packaging material **(%)**

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

A-10		A-11		
Operating status in current year	Comments	Operating hours		Is there a plan to e
Select from the dropdown menu in this column	If you choose an option other than "operating" in the previous column, please add a brief comment in this column	Enter the daily operating hours on average of the facility **(hours)**	Enter the annual operating hours on average of the facility **(hours)**	Select from the dropdown menu in this column

20
loyees at parent pany
down menu in this

e §121.201, "What

32	A-33		A-34		
ner 5 (if any)	Building corner 6 (if any)		Building corner 7 (if any)		A
Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the 6th decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter any additional the information prov building corners

44	A-45	A-46	A-
wth rate in revenues on services for the years	Size category of facility with respect to hazardous air pollutant (HAP) emissions	As a percentage of all products sterilized at your facility, what is the percentage of products sterilized with EtO?	As a percentage of a at your facility, wha of products sterili techniques or

Specify the dollar year in this column	Select from the dropdown menu in this column [3]	Specify the percentage of products sterilized with EtO, based on all products sterilized at your facility, including both EtO sterilization and non-EtO sterilization. Note that the values entered in this field and Field A-47 should sum to 100% **(%)**	Specify the percenta sterilized with non-E based on all product facility, including bot and non-EtO steriliza values entered in thi 46 should sum to 10 **(%)**

amounts for major sources. Such restrictions must be enforcea

A-12
expand/modify/close this facility in the near future?
Provide a short explanation if you select "Yes" on the left

A-35
Additional comments
comments that you may have regarding vided in this table about buildings and

47
ll products sterilized at is the percentage zed using non-EtO approaches?

ge of products
tO approaches,
s sterilized at your
h EtO sterilization
ation. Note that the
s field and Field A-
0%

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

B. Individual Room Area (All Areas where EtO is Used or Emitted)

Table 1. Characteristics of Room Areas

Field #	B-1	B-2	B-3
Data	Room area ID for all rooms and areas where EtO is used or emitted	Category of room area	Activities conducted in roor
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each room	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your room area)"	Provide a brief explanation of the activitie each room area
Response			

Table 2. Natural Draft Openings (NDO)

Field #	B-1				
Data	Room area ID for all rooms and areas where EtO is used or emitted				Natural d
Instruction	This column will be auto-populated based on your entries in the previous fields	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point
Response					

Table 3. Leak Checks of Components in EtO Service

No (default)	← *Switch*

If leak checks are performed on multiple types of components in a room area, use another row in this table, repeat your entri

****** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F82 above, leave this table below BLA***

Field #	B-1	B-22	B-23	B-24

Data	Room area ID for all rooms and areas where EtO is used or emitted	Are leak checks performed in the room area?	Component type	Total component count
Instruction	Select from the dropdown menu. Scroll up to see options that are auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your component)"	Specify the total number of component of this type
Response				

Table 4. Room Area Controls

No (default) | *← Switch t*

If any of your room area is routed to more than 3 APCDs or more than 1 stack, use another row in this table, repeat the room

***** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F120 above, leave this table below BL***

Field #	B-1	B-38		B-

Data	Room area ID for all rooms and areas where EtO is used or emitted	Is air from the room area vented to an APCD, used as cascading air, vented to the atmosphere, or handled in any other ways?	APCD 1 for	
Instruction	Select from the dropdown menu. Scroll up to see options that are auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the drop column If you select "Other (type here)", be sure response between th Example: "Other (yo
Response				

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

	B-4	B-5	B-6		
n area	Floor area	Room height	Temperature		
es conducted in	**(square feet)**	**(feet)**	Enter temperature set point or range for summer in this column **(Fahrenheit)**	Enter temperature set point or range for winter in this column **(Fahrenheit)**	Enter temperature set point or range for intermediate seasons in this column **(Fahrenheit)**

B-12					
draft opening (NDO) 1 (if any)					
Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO

to "Yes" in Cell F82 on the left if Supplement 1 is used in lieu of this table

es in Fields B-1 and B-22, then fill out the other fields as necessary

NK, then fill out SUPPLEMENT 1 to the Section 114 ICR. Refer to the Instructions Document for more details ***

B-25	B-26	B-27	B-

What is the percentage of components that are included in regular leak checks?	Frequency of leak checks	Average length of time to perform leak checks	Instrument and standard
Specify the percentage of components that are included in regular leak checks **(percent)**	Specify how often leak checks are performed	Enter average length of time to perform leak checks per component type, per inspection **(hours)**	Briefly describe the instrument and stand

to "Yes" in Cell F120 on the left if Supplement 2 is used in lieu of this table

area ID in Field B-1, then fill out the other fields as necessary

ANK, then fill out SUPPLEMENT 2 to the Section 114 ICR. Refer to the Instructions Document for more details * * *

39	B-40

room area		APCD 2 for room area (if any)		
...down menu in this ... (double click and ... to enter your ... he parentheses ... ur APCD)"	Enter the average air flow routed from the room to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the room to this APCD **(actual cubic feet per minute, acfm)**

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

B-7	B-8		B-9	B-10
Relative humidity	Pressure drop		Air flow (ventilation)	Air flow (conditioned)
Enter average or range of relative humidity **(percent)**	Enter the pressure drop across room area **(inch H2O)**	Specify definition of pressure drop, or locations based on which pressure drop is measured (e.g., farthest point to control device inlet)	Enter average or range of ventilation air flow **(actual cubic feet per minute, acfm)**	Enter average or range of conditioned air flow **(actual cubic feet per minute, acfm)**

B-13

Natural draft opening (NDO) 2 (if any)

Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**

l method for leak checks	Leak check procedure
lard method used for leak checks	Describe the leak check procedure for each room area. Specifically, provide any action levels

APCD 3 for room area (if any)			Material of duct work for room area venting	Total length of duct work for room area venting
APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the room to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**

B-11
Number of air changes per hour
Enter average or range of number of air changes per hour

		Natural c			
Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point

Average cost per inspection		Average percentage of leaking components identified	Definition of leak
Enter the dollar amount in this column	Specify the dollar year in this column	Enter average percentage of leaking components identified during each leak check **(percent)**	If applicable, specify the definition or criteria of leak in the sta that require leak checks, or the definition that facility refers tc

B-44	B-45	B-46	B-47	B-48	B-49

Average thickness of duct work for room area venting	Is the cross section of duct work for room area venting circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?
Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column

draft opening (NDO) 3 (if any)

Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO

	Applicable state/local regulations	Rep
te/local regulations	Specify any state/local regulations applicable to your facility for leak checks	Provide a brief descr identified

Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)	
Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**

B-15

Natural draft opening (NDO) 4 (if any)

Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**

air method/procedure for the leaks identified	Average cost per repair for leaks identified		Are there any specia are not readily avail need to be ordere component r
iption of the repair method/procedure for the leaks	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column

B-53	B-54	B-55	B-56

Installation year of duct work	Lifetime of duct work	Capital cost of duct work for room area venting (estimated or actual)		Installation cost of duct work for room area venting (estimated or actual)	
Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

					Natural c
Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point

lity components that able on site and that d in the event of a eplacement?	Are there any other impediments that would prevent immediate repair of leaks?	
How long does it take, on average, for the facility to receive the components? **(days)** (if you select "Yes" on the left)	Select from the dropdown menu in this column	List the impediments that would prevent immediate repair of leaks (if you select "Yes" on the left)

Room area air used as cascading air for reuse in another room or unit (For cascading only)	Stack ID to which the uncontrolled room area vents (For room area vented to the atmosphere only)	
Specify the room area ID or unit ID the air is vented to if the room area air is used as cascading air for reuse in another room or unit (i.e., vented as the input air to another area). If multiple room areas/units are involved, list all the IDs and separate by commas (,). Ensure that any room area ID entered in this field is consistent with your entries in Field B-1 of this worksheet, and that any unit ID is consistent with your entries elsewhere in this questionnaire	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**

B-16						
draft opening (NDO) 5 (if any)						
Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	

Stack parameter (For room area vented to the atmosphere only)				Stack coordinates (For room area vented to the atmosphere only)	
Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point

B-17					
Natural draft opening (NDO) 6 (if any)					
Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**

Distance from room area outlet to stack (For room area vented to the atmosphere only)	Other handling of air from room area	
Enter the distance from outlet of the room area to the stack **(feet)**	Provide a brief description of any air pollution control or handling procedure if air from this room area is not: vented to an APCD; used as cascading air; or vented to the atmosphere	Is there a structure or approach to capture the air emitted from the room area? Select from the dropdown menu in this column

		Natural			
Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point

Room Air Capture		
If yes, specify the capture efficiency for this room area **(%)**	If yes, specify the structure type or approach used to capture the room area (e.g., permanent total enclosure)	If yes, specify the method(s) used to verify the capture efficiency of room air (e.g., Method 204)

B-18					
draft opening (NDO) 7 (if any)					
Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO

B-19					
Natural draft opening (NDO) 8 (if any)					
Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**

		Natural d			
Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point

B-20					
draft opening (NDO) 9 (if any)					
Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO

B-21					
Natural draft opening (NDO) 10 (if any)					
Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the 6th decimal point	Cross-sectional area **(square feet)**	Height above the ground **(feet)**

Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity **(feet/minute)**

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

C. EtO Drum and Container Storage

Field #	Data	Instruction
C-0	What companies supply EtO drums or cartridges to your facility? Specify the name and percent (%) by weight for each company	Separate data for each company by commas (,). For example: Company 1 - 70%, Company 2 - 30%
C-1	How many EtO drums and/or containers are typically stored at the facility at once?	
C-2	Permitted amount of EtO storage	**(pounds)**
C-3	Is there a designated area for storing EtO drums and/or containers?	Select from the dropdown menu
C-4	Describe the designated area for EtO drum and/or container storage	
C-5	Describe the storage location for full and empty storage media (e.g., indoors in an enclosed room)	
C-6	Specify the maximum number of full EtO storage media (e.g., twelve 55-gallon drums) kept at the facility in the last 12 months	
C-7	Is the ambient air in the storage areas continually monitored for ethylene oxide?	Select from the dropdown menu
C-8	Describe the make/model and range of the instrumentation used for continuous monitoring of the storage areas	
C-9	How often are new drums or containers delivered to facility and empty drums or containers picked up and sent offsite?	
C-10	What is the procedure for checking drums or containers before accepting them onsite? If drums or containers do not meet the requirements, what corrective actions are taken, and how many drums or containers per year are the corrective actions performed on?	
C-11	Are drums or containers placed next to sterilizer chambers when they are in use?	Select from the dropdown menu

C-12	Describe how EtO is charged to the sterilizer chamber	

D. Ethylene Glycol (EG) Tanks

Field #	D-1	D-2	D-3	D-4	D-5
Data	Ethylene glycol (EG) tank ID	Material of EG tank	Capacity of EG tank	Throughput of EG tank	Installation year of EG tank
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each EG tank	Specify the material of EG tank	Enter the capacity of EG tank **(gallons)**	Enter the average daily throughput of EG tank **(gallons per day)**	Enter the calendar year in which EG tank was installed
Response					

Does any information entered on this worksheet contain confidential business information (CBI)?
Specify in ***Cell N2*** *on the right →* ***Be sure to shade each cell that contains CBI in red***
Before saving the ***non-CBI version*** *of your response, select and copy the Sample CBI Cell (****Cell O2****), and paste directly into each cell that contains CBI.* ***Make sure that all "CBI" cells are shaded in red***

Response

D-6	D-7		D-8		D-
Expected lifetime of EG tank	Capital cost of EG tank		Installation cost of EG tank		Annual cost
Enter the expected lifetime of EG tank **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

-9	D-10	D-11		
t of EG tank	Is the EG tank routed to any control device?	APCD 1 for EG tank		
Specify the dollar year in this column	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the tank to this APCD **(actual cubic feet per minute, acfm)**

D-12			D-13	D-14
APCD 2 for EG tank (if any)			Material of duct work for EG tank	Total length of duct work for EG tank
APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the tank to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**

D-15	D-16	D-17	D-18	D-19	D-20
Average thickness of duct work for EG tank	Is the cross section of duct work for EG tank circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?
Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column

D-21		D-22		D-23	
Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)	
Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**

D-24	D-25	D-26		D-27	
Installation year of duct work	Lifetime of duct work	Capital cost of duct work for EG tank (estimated or actual)		Installation cost of duct work for EG tank (estimated or actual)	
Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

D-28	D-29				
Stack ID to which the uncontrolled EG tank vents (For uncontrolled EG tank only)	Stack parameter (For uncontrolled EG tank only)				
Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**	Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**

D-30		D-31
Stack coordinates (For uncontrolled EG tank only)		Distance from EG tank outlet to stack (For uncontrolled EG tank only)
Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point	Enter the distance from outlet of the uncontrolled EG tank to the stack **(feet)**

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

E. Sterilization Chambers

Table 1. Summary for Sterilizer Chambers

Field #	Data	Response
E-0	Enter the total number of sterilizer chambers at your facility	

Table 2. Sterilizer Chamber Operation and Monitoring Characteristics

Field #	E-1	B-1	E-2	E-3	E-4
Data	Sterilizer unit ID	Room area in which sterilizer unit is located	Associated EIS release point ID	Is this an R&D chamber (under the definition of research and laboratory facility)?	Does aeration of the sterilized product occur in the same sterilizer chamber?
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each sterilizer	Select from the dropdown menu. Scroll up to see options that are auto-populated based on your entries in the previous fields	Enter the EIS release point ID associated with the sterilizer unit, if any	Select from the dropdown menu in this column	Select from the dropdown menu in this column (If you select "Yes" for any sterilizer, fill out **Table 3** on "Aeration" worksheet)
Response					

Table 3. Control Characteristics for Sterilizer Chambers

Field #	E-1	E-51	E-52	
Data	Sterilizer unit ID	Is the sterilizer chamber vent (SCV) routed to any control device?	APCD 1 for sterilizer chamber vent (SCV)	
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"
Response				

Table 4. Control Characteristics for Sterilizer Chambers (continued)

Field #	E-1	E-111	E-112	E-1	
Data	Sterilizer unit ID	Is there a cover hood or vent over the sterilizer chamber door (e.g., hooded vent above the sterilizer chamber door)?	Is the cover hood or vent routed to any control device?	APCD 1 for cove	
Instruction	This column will be auto-populated based on your entries in the previous fields	Select from the dropdown menu in this column	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the drop column If you select "Other (type here)", be sure response between th Example: "Other (yo
Response					

Table 5. Vacuum Pumps

Field #	E-134	E-135
Data	Unit ID of vacuum pump	Associated sterilizer unit ID(s) and vent(s)
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each pump	Specify ID of the sterilizer unit associated with this vacuum pump. If multiple sterilizer units are serviced by this vacuum pump, list all sterilizer unit IDs and separate by commas (,). Ensure that any sterilizer unit ID entered in this field is consistent with your entries in Field E-1 of this worksheet. Also specify which vents on the sterilizer unit are routed to the vacuum pump. For example: "SC-1 (SCV, CEV)"
Response		

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

E-5	E-6	E-7	E-8		
Is this a single-item chamber?	Volume of sterilizer chamber	How many cycles per year are conducted in sterilizer chamber in total?	Temperature (For combination sterilizers, enter temperature for sterilization mode only)		
Select from the dropdown menu in this column	**(cubic feet)**	Enter the total number of cycles conducted in the sterilizer chamber each year	Enter the average temperature of sterilizer chamber when in operation **(Fahrenheit)**	Enter the maximum temperature of sterilizer chamber when in operation **(Fahrenheit)**	Enter the minimum temperature of sterilizer chamber when in operation **(Fahrenheit)**

	E-53				
	APCD 2 for sterilizer chamber vent (SCV) (if any)				APC
Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"		Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD

.13		E-114		
er hood or vent		APCD 2 for cover hood or vent (if any)		
down menu in this (double click and to enter your he parentheses ur APCD)"	Enter the average air flow routed from the cover hood or vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the cover hood or vent to this APCD **(actual cubic feet per minute, acfm)**

E-136			E-137
Basic information of vacuum pump			Seal type of vacuum pump
Specify make of pump	Specify model of pump	Specify type of pump. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your pump)"	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your pump)"

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

E-9			E-10		E-11
Relative humidity			Pressure		Does the sterilizer chamber have positive pressure cycles?
Enter the average relative humidity within sterilizer chamber when in operation **(percent)**	Enter the maximum relative humidity within sterilizer chamber when in operation **(percent)**	Enter the minimum relative humidity within sterilizer chamber when in operation **(percent)**	Enter the average pressure within the chamber during EtO dwell period **(psig)**	Enter the magnitude of vacuum on average that is applied during evacuation **(psig)**	Select from the dropdown menu in this column

E-54		E-55	E-56	E-57
CD 3 for sterilizer chamber vent (SCV) (if any)		Material of duct work for sterilizer chamber vent (SCV)	Total length of duct work for sterilizer chamber vent (SCV)	Average thickness of duct work for sterilizer chamber vent (SCV)
Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(inches)**

E-115	E-116	E-117	E-118	E-119	E-120
Material of duct work for cover hood or vent	Total length of duct work for cover hood or vent	Average thickness of duct work for cover hood or vent	Is the cross section of duct work for the cover hood or vent circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)
Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**

E-138	E-139	E-140	E-141		E-1
Capacity of vacuum pump	Installation year of vacuum pump	Expected lifetime of the vacuum pump	Capital cost of vacuum pump		Annual cost of
(cubic feet per minute, cfm)	Enter the calendar year in which the vacuum pump was installed	Enter the expected lifetime of the EtO concentration monitor **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column

E-12			E-13		
EtO dose per cycle			Number of nitrogen washes per cycle		
Enter the average EtO dose per cycle **(mg/L)**	Enter the maximum EtO dose per cycle **(mg/L)**	Enter the minimum EtO dose per cycle **(mg/L)**	Enter the average number of nitrogen washes per cycle	Enter the maximum number of nitrogen washes per cycle	Enter the minimum number of nitrogen washes per cycle

E-58	E-59	E-60	E-61	E-62	E-(
Is the cross section of duct work for sterilizer chamber vent (SCV) circular or rectangular?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter o (For circular du
Select from the dropdown menu in this column	Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the maximum diameter of duct work **(feet)**

E-121	E-122	E-123		E-124	
Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only)		Cross-sectional height of duct work (For rectangular duct work only)	
Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**

.42	E-143
vacuum pump	Handling and disposal of water for once-through vacuum pump
Specify the dollar year in this column	If you selected "once-through" as the type of vacuum pump, provide a brief description about how water is handled and disposed

E-14			E-15		
Nitrogen used for washes during each cycle			Annual cost of nitrogen washes		Numb
Enter the average amount of nitrogen used during each cycle **(pounds)**	Enter the maximum amount of nitrogen used during each cycle **(pounds)**	Enter the minimum amount of nitrogen used during each cycle **(pounds)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the average number of air washes per cycle

63	E-64		E-65		E-66
f duct work uct work only)	Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work
Enter the minimum diameter of duct work **(feet)**	Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed

E-125		E-126	E-127	E-128	
Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work	Lifetime of duct work	Capital cost of duct work for cover hood or vent (estimated or actual)	
Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column

E-16		E-17			E-
ber of air washes per cycle		Air used for washes during each cycle			Annual cost
Enter the maximum number of air washes per cycle	Enter the minimum number of air washes per cycle	Enter the average amount of air used during each cycle **(pounds)**	Enter the maximum amount of air used during each cycle **(pounds)**	Enter the minimum amount of air used during each cycle **(pounds)**	Enter the dollar amount in this column

E-67	E-68		E-69		E-70
Lifetime of duct work	Capital cost of duct work for sterilizer chamber vent (SCV) (estimated or actual)		Installation cost of duct work for sterilizer chamber vent (SCV) (estimated or actual)		Stack ID to which the uncontrolled sterilizer chamber vent (SCV) vents (For uncontrolled SCV only)
Enter the expected lifetime of duct work **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack

E-129		E-130	E-131		
Installation cost of duct work for cover hood or vent (estimated or actual)		Stack ID to which the cover hood or vent vents (For uncontrolled cover hood or vent only)	Stack parameter (For uncontrolled cover hood or		
Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**	Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**

18	E-19	E-20		E-21	E-2
of air washes	Average electricity used per gas wash (nitrogen washes and air washes combined)	Annual cost of electricity for gas washes (nitrogen washes and air washes combined)		Are leak checks performed on sterilizer chamber?	Frequency of leak c chan
Specify the dollar year in this column	**(kWh)**	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Specify the frequenc sterilizer chamber

E-71					E-7
Stack parameter (<u>For uncontrolled SCV only</u>)					Stack coo (<u>For uncontro</u>
Enter the stack <u>height</u> **(feet)**	Enter the stack <u>diameter</u> **(feet)**	Enter the <u>temperature</u> at stack outlet **(Fahrenheit)**	Enter the <u>exhaust velocity</u> at stack outlet **(feet/second)**	Enter the <u>volumetric flow rate for this emission source</u> at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the <u>6th</u> decimal point

		E-132		E-132.1	E-133
vent only)		Stack coordinates (For uncontrolled cover hood or vent only)		Distance from cover hood or vent to stack (For uncontrolled cover hood or vent only)	Is any SCV or CEV of the sterilizer unit routed to a vacuum pump?
Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point	Enter the distance from the uncontrolled cover hood or vent to the stack **(feet)**	Select from the dropdown menu in this column If your answer is "Yes" in any row below, fill out Table 5

22	E-23	E-24
checks for sterilizer nber	Average length of time to perform a leak check	Leak check procedure(s) for sterilizer chamber
y of leak checks for	Enter average length of time to perform a leak check **(minutes)**	Provide a brief description of the leak check procedure(s) for sterilizer chamber

72	E-72.1	E-73	E-74		E-74.1
ordinates lled SCV only)	Distance from SCV to stack (For uncontrolled SCV only)	Is there a chamber exhaust vent (CEV)?	Is there a target EtO concentration that is reached before activation of the CEV?		Duration of CEV operation in each sterilization cycle
Enter the longitude of stack. Specify to the 6th decimal point	Enter the distance from the uncontrolled SCV to the stack **(feet)**	Select from the dropdown menu in this column	Select from the dropdown menu in this column	Enter the value if you select "Yes" on the left **(ppm)**	Enter the time that the CEV is in operation for each sterilization cycle **(minutes)**

E-25		E-26	E-27
Annual cost of leak checks for sterilizer chamber		Average quantity of leaks identified per year	Repair method/procedure for the leaks identi
Enter the dollar amount in this column	Specify the dollar year in this column	Enter average quantity of leaks found per year	Provide a brief description of the repair method/procedure fo identified

E-74.2	E-75	E-76	E-77	E-
Average EtO concentration during CEV operation	Is an interlock system present that prevents activation of the CEV and opening of the sterilizer door until a set EtO concentration is reached?	Installation year of interlock system	Expected lifetime of interlock system	Capital cost of i
Enter the average EtO concentration over the duration of the CEV operation, if available. This should NOT be the EtO concentration at the start of operation **(ppm)**	Select from the dropdown menu in this column	Enter the calendar year in which the interlock system was installed	Enter the expected lifetime of the interlock system **(years)**	Enter the dollar amount in this column

	E-28		E-29		
ified	Average cost per repair for the leaks identified		Is an EtO concentration monitor used within this sterilizer chamber?		Descripti
r the leaks	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Enter the type of EtO concentration monitor	Enter the manufacturer of EtO concentration monitor

78	E-79		E-80
nterlock system	Annual cost of interlock system		Standards or work practices followed for interlock
Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief description of any standards or work practices interlock system that prevents activation of the CEV until a set reached

E-30				E-31
on of the EtO concentration monitor used within this sterilizer chamber				Installation year of EtO concentration monitor
Enter the model of EtO concentration monitor	Specify the method of detection of EtO concentration monitor	Enter the value of detection level of EtO concentration monitor	Specify the unit of detection level of EtO concentration monitor	Enter the calendar year in which the EtO concentration monitor was installed

	E-81	E-82			
system	Is the chamber exhaust vent (CEV) routed to any control device?	APCD 1 for chamber exhaust vent (CEV)			
followed for t concentration is	Select from the dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	

E-32	E-33		E-34		E-3
Expected lifetime of EtO concentration monitor	Capital cost of the EtO concentration monitor used within this sterilizer chamber		Installation cost of the EtO concentration monitor used within this sterilizer chamber		Annual cost of the monitor used wit chan
Enter the expected lifetime of the EtO concentration monitor **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column

E-83			E-8	
APCD 2 for chamber exhaust vent (CEV) (if any)			APCD 3 for chamber exh	
APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the drop column If you select "Other (type here)", be sure response between th Example: "Other (yo

35	E-36	
EtO concentration hin this sterilizer nber	Standards or work practices followed for the EtO concentration monitor used within this sterilizer chamber	Duration of produc
Specify the dollar year in this column	Provide a brief description of any standards or work practices followed for the EtO concentration monitor used within the chamber	Enter the average duration **(hours)**

84		E-85	E-86	E-87	E-88
haust vent (CEV) (if any)		Material of duct work for chamber exhaust vent (CEV)	Total length of duct work for chamber exhaust vent (CEV)	Average thickness of duct work for chamber exhaust vent (CEV)	Is the cross section of duct work for chamber exhaust vent (CEV) circular or rectangular?
pdown menu in this (double click and to enter your he parentheses ur APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(inches)**	Select from the dropdown menu in this column

E-37		E-38			
t dwell time within the chamber at EtO dosing concentration		Total duration of time product stays within the sterilizer chamber before it is moved out			Concentration th
Enter the maximum duration **(hours)**	Enter the minimum duration **(hours)**	Enter the average duration **(hours)**	Enter the maximum duration **(hours)**	Enter the minimum duration **(hours)**	Specify the unit of concentration. Select from the dropdown menu in this column

E-89	E-90	E-91	E-92	E-93	
Diameter of duct work (<u>For circular duct work only</u>)	Cross-sectional height of duct work (<u>For rectangular duct work only</u>)	Cross-sectional width of duct work (<u>For rectangular duct work only</u>)	Are the dimensions of duct work constant throughout?	Diameter of duct work (<u>For circular duct work only</u>)	
Enter the <u>average</u> diameter of duct work **(feet)**	Enter the <u>average</u> cross-sectional height of duct work **(feet)**	Enter the <u>average</u> cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the <u>maximum</u> diameter of duct work **(feet)**	Enter the <u>minimum</u> diameter of duct work **(feet)**

E-39			E-40	E-41	E-42
at EtO is reduced to before moving the product out of this sterilizer chamber			Is EtO from sterilizer captured for re-use?	Is water used during this process?	Amount of water disposed annually
Enter the average concentration that EtO is reduced to **(ppm or % LEL)**	Enter the maximum concentration that EtO is reduced to **(ppm or % LEL)**	Enter the minimum concentration that EtO is reduced to **(ppm or % LEL)**	Select from the dropdown menu in this column	Select from the dropdown menu in this column	**(gallons)**

E-94		E-95		E-96	E-97
Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work	Lifetime of duct work
Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**

E-43	E-44		E-45
Method of water disposal	Annual costs associated with water disposal		What is the percentage of EtO recovered by this system?
Provide a brief description about how water is disposed after being used to capture EtO for re-use	Enter the dollar amount in this column	Specify the dollar year in this column	**(percent)**

E-98		E-99		E-100	E-101
Capital cost of duct work for chamber exhaust vent (CEV) (estimated or actual)		Installation cost of duct work for chamber exhaust vent (CEV) (estimated or actual)		Is any APCD installed solely for the purpose of controlling emissions from the CEV?	If not, was a damper system installed for the purpose of adjusting the flow rate to the control device upon CEV activation?
Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column	Select from the dropdown menu in this column

E-46	E-47	E-48		E-49	
Year in which the EtO recovery system was installed	Expected lifetime of the EtO recovery system	Capital cost of the EtO recovery system used with this sterilizer chamber		Installation cost of the EtO recovery system used with this sterilizer chamber	
Enter the calendar year	Enter the expected lifetime of the EtO recovery system **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

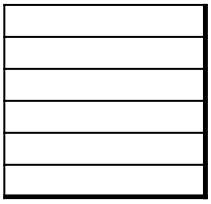
E-102	E-103	E-104		E-105	
Year in which the damper system was installed	Expected lifetime of the damper system	Capital cost of the damper system		Installation cost of the damper system	
Enter the calendar year	Enter the expected lifetime of the damper system **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

E-50	
Annual cost of the EtO recovery system used with this sterilizer chamber (excluding costs associated with wastewater treatment and disposal)	
Enter the dollar amount in this column	Specify the dollar year in this column

E-106		E-107	E-108	
Annual cost of the damper system		APCD installed solely for the purpose of controlling emissions from the CEV	Stack ID to which the uncontrolled chamber exhaust vent (CEV) vents (For uncontrolled CEV only)	
Enter the dollar amount in this column	Specify the dollar year in this column	Specify ID of the APCD installed solely for controlling CEV emissions. If multiple APCDs are involved, list all APCD IDs and separate by commas (,). Ensure that any APCD ID entered in this field is consistent with your entries elsewhere in this questionnaire	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**

E-109				E-110	
Stack parameter (For uncontrolled CEV only)				Stack coordinates (For uncontrolled CEV only)	
Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point

E-110.1
Distance from CEV to stack (For uncontrolled CEV only)
Enter the distance from the uncontrolled CEV to the stack **(feet)**



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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

F. Aeration

Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber)

Field #	F-1	B-1	F-2	F-3	F-4
Data	Aeration unit ID	Room area in which aeration unit is located	Associated EIS release point ID	Type of aeration unit	Does the aeration unit use accelerated aeration?
Instruction	Enter from permit description, if available. Otherwise, use a unique identifier for each aeration unit	Select from the dropdown menu. Scroll up to see options that are auto-populated based on your entries in the previous fields	Enter the EIS release point ID associated with the aeration unit, if any	Select from the dropdown menu in this column	Select from the dropdown menu in this column
Response					

Table 2. Aeration that Occurs within Sterilizer Chamber

If no data is auto-populated in Field E-1 of this table, skip to Table 3

Field #	E-1	F-43			F-
Data	Sterilizer unit ID	Temperature			Relative
Instruction	This column will be auto-populated based on your entries in the previous fields	Enter the <u>average</u> temperature of aeration room when in operation **(Fahrenheit)**	Enter the <u>maximum</u> temperature of aeration room when in operation **(Fahrenheit)**	Enter the <u>minimum</u> temperature of aeration room when in operation **(Fahrenheit)**	Is a specific humidity needed for aeration? Select from the dropdown menu in this column
Response					

Table 3. Movement of Sterilized Products through the Facility

Describe how sterilized product is moved from one area of the facility to another. For each product move through the facility distance product is moved, and (4) note any areas where there is a hood to collect the EO

Field #	**Data**	**Instruction**

F-47	From sterilizer chamber to aeration room/chamber	Provide details on where the sterilized product is placed in the sterilizer room area following removal from the chamber, the length of time the sterilized product sits in the sterilizer room area, the distance sterilized product is moved from the sterilizer room area to the aeration room area
F-48	From aeration room/chamber to warehouse area	Provide details on where the sterilized and aerated product is placed after being removed from aeration chamber, length of time the sterilized and aerated product sits after being removed from aeration room, and distance the sterilized and aerated product is moved to warehouse area
F-49	At warehouse area	Provide details on length of time sterilized and aerated product is held in the warehouse before being loaded on truck or other conveyance for shipment offsite

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

F-5	F-6			
Characteristics of accelerated aeration	Dimensions of aeration cell/chamber (For aeration cell/chamber only. Dimensions of aeration rooms should already have been provided on "Room Area" worksheet)			
Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your equipment)"	Enter the height of aeration unit **(feet)**	Enter the width of aeration unit **(feet)**	Enter the length of aeration unit **(feet)**	Enter the average temperature of aeration room when in operation **(Fahrenheit)**

44	F-45	F-46		
humidity	Pressure	Length of time that products are being held in aeration room before being transferred		
If yes, enter the specific humidity that is needed for aeration **(percent)**	Specify pressure condition during aeration process	Enter the average length of time that products are being held in aeration room **(hours)**	Enter the maximum length of time that products are being held in aeration room **(hours)**	Enter the minimum length of time that products are being held in aeration room **(hours)**

provide, provide details on the following variables: (1) length of time that product sits, (2) where the product is placed, (3)

Response

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

F-7		F-8		F-8.1	F-9
Temperature		Relative humidity		Average EtO concentration	Pressure (For aeration cell/chamber only)
Enter the maximum temperature of aeration room when in operation **(Fahrenheit)**	Enter the minimum temperature of aeration room when in operation **(Fahrenheit)**	Is a specific humidity needed for aeration? Select from the dropdown menu in this column	If yes, enter the specific humidity that is needed for aeration **(percent)**	Enter the average EtO concentration in the aeration unit **(ppm)**	Enter the average pressure within the unit **(psig)**

F-10		F-11	
Pressure drop (For aeration room only)		Facial velocity (For aeration room only)	Location and length b
Enter the pressure drop across aeration room **(inch H2O)** (you may choose to fill out either F-10, F-11, or both)	Specify definition of pressure drop, or locations based on which pressure drop is measured (e.g., farthest point to inlet of control device)	Enter the facial velocity in aeration room **(feet per minute, fpm)** (you may choose to fill out either F-10, F-11, or both)	Provide details on w area (e.g., placed in length of time the st placed in the aeratio

F-12	F-13		
of time that sterilized product is placed in aeration room area efore being placed in the aeration chamber	Length of time that product is being held in aeration unit before being transferred		
here the sterilized product is placed in the aeration room hallway area outside door of aeration chamber), and the erilized product sits in the aeration room area before being n chamber	Enter the <u>average</u> length of time that products are being held in aeration room **(hours)**	Enter the <u>maximum</u> length of time that products are being held in aeration room **(hours)**	Enter the <u>minimum</u> length of time that products are being held in aeration room **(hours)**

F-14	F-15	F-16	F-
Are leak checks performed on aeration unit?	Frequency of leak checks for aeration unit	Average length of time to perform a leak check	Leak check procedur
Select from the dropdown menu in this column	Specify the frequency of leak checks for sterilizer chamber	Enter average length of time to perform a leak check **(minutes)**	Provide a brief description of the leak che

17	F-18		F-19	
e(s) for aeration unit	Annual cost of leak checks for aeration unit		Average quantity of leaks identified per year	Re
ck procedure(s) for aeration unit	Enter the dollar amount in this column	Specify the dollar year in this column	Enter average quantity of leaks found per year	Provide a brief descr identified

F-20	F-21		F-22
epair method/procedure for leaks identified	Average cost per repair for leaks identified		Is aeration room vent (ARV) routed to any control device?
iption of the repair method/procedure for the leaks	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column

F-23			F-[illegible]	
APCD 1 for aeration room vent (ARV)			APCD 2 for aeration ro	
APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the drop column If you select "Other (type here)", be sure response between th Example: "Other (yo

24		F-25	F-26	F-27	F-28
om vent (ARV) (if any)		Material of duct work for aeration room vent (ARV)	Total length of duct work for aeration room vent (ARV)	Average thickness of duct work for aeration room vent (ARV)	Is the cross section of duct work for aeration room vent (ARV) circular or rectangular?
down menu in this "(double click and to enter your he parentheses ur APCD)"	Enter the average air flow routed from the vent to this APCD **(actual cubic feet per minute, acfm)**	Specify the material of duct work	Enter the total length of duct work **(feet)**	Enter the average thickness of duct work **(feet)**	Select from the dropdown menu in this column

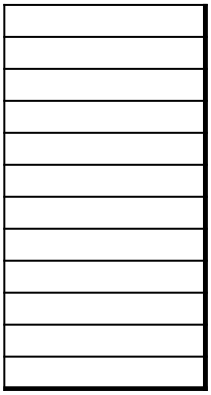
F-29	F-30	F-31	F-32	F-33	
Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (For rectangular duct work only)	Cross-sectional width of duct work (For rectangular duct work only)	Are the dimensions of duct work constant throughout?	Diameter of duct work (For circular duct work only)	
Enter the average diameter of duct work **(feet)**	Enter the average cross-sectional height of duct work **(feet)**	Enter the average cross-sectional width of duct work **(feet)**	Select from the dropdown menu in this column	Enter the maximum diameter of duct work **(feet)**	Enter the minimum diameter of duct work **(feet)**

F-34		F-35		F-36	F-37
Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work	Lifetime of duct work
Enter the maximum cross-sectional height of duct work **(feet)**	Enter the minimum cross-sectional height of duct work **(feet)**	Enter the maximum cross-sectional width of duct work **(feet)**	Enter the minimum cross-sectional width of duct work **(feet)**	Enter the calendar year in which duct work was installed	Enter the expected lifetime of duct work **(years)**

F-38		F-39		F-40	
Capital cost of duct work for aeration room vent (ARV) (estimated or actual)		Installation cost of duct work for aeration room vent (ARV) (estimated or actual)		Stack ID to which the aeration room vents (ARV) is routed to (For uncontrolled ARV only)	
Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**

F-41				F-42	
Stack parameter (For uncontrolled ARV only)				Stack coordinates (For uncontrolled ARV only)	
Enter the stack diameter **(feet)**	Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point

F-42.1
Distance from ARV to stack (For uncontrolled ARV only)
Enter the distance from the uncontrolled ARV to the stack **(feet)**



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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

G. Summary of Air Pollution Control Devices

Table 1. APCD Characteristics

If an APCD exhausts to more than one stack, provide the information requested in Fields G-5 through G-7 for each additional

Field #	G-1	G-2	G-3	
Data	APCD ID	Type of APCD	Associated EIS release point ID	
Instruction	This column will be auto-populated based on your entries in the previous fields	This column will be auto-populated based on your entries in the previous fields	Enter the EIS release point ID associated with this APCD, if any	Specify the manufacturer of APCD
Response				

Table 2. Emissions and CEMS

Field #	G-1	G-2	G-19	
Data	APCD ID	Type of APCD	Peak hourly emission rate of APCD	
Instruction	This column will be auto-populated based on your entries in the previous fields	This column will be auto-populated based on your entries in the previous fields	Enter the value of peak hourly emission rate	Specify the unit of peak hourly emission rate
Response				

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

stack on "Additional Info" worksheet (Section M)

G-4			G-5		
Description of APCD			Stack ID to which the APCD vents		
Specify the model of APCD	Enter the value of maximum capable volumetric flow of APCD	Specify the unit of maximum capable volumetric flow of APCD	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack height **(feet)**	Enter the stack diameter **(feet)**

G-20	G-21			
Is any continuous emissions monitoring system (CEMS) used to measure EtO concentration from the APCD?	Description of the CEMS used to measure EtO cc			
Select from the dropdown menu in this column	Enter the type of CEMS	Enter the manufacturer of CEMS	Enter the model of CEMS	Specify the method c CEMS

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

G-6			G-7		G-8
Stack parameter			Stack coordinates		Installation year of APCD
Enter the temperature at stack outlet **(Fahrenheit)**	Enter the exhaust velocity at stack outlet **(feet/second)**	Enter the volumetric flow rate for this emission source at stack outlet **(cubic feet per minute)**	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point	Enter the calendar year in which APCD was installed

			G-22	G-23	G-
oncentration from the APCD			Installation year of CEMS	Expected lifetime of CEMS	Capital cost of CEM EtO concentratio
of detection of	Enter the value of detection level of CEMS	Specify the unit of detection level of CEMS	Enter the calendar year in which the CEMS was installed	Enter the expected lifetime of the CEMS **(years)**	Enter the dollar amount in this column

G-9	G-10		G-11		
Expected lifetime of APCD	Capital cost of APCD		Installation cost of APCD		
Enter the expected lifetime of APCD **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	If any, specify other APCD (e.g., program acquisition system)

24	G-25		G-26		
IS used to measure n from the APCD	Installation cost of CEMS used to measure EtO concentration from the APCD		Annual cost of CEMS used to measure EtO concentration from the APCD		Standards or v
Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Provide a brief descr CEMS used to measu

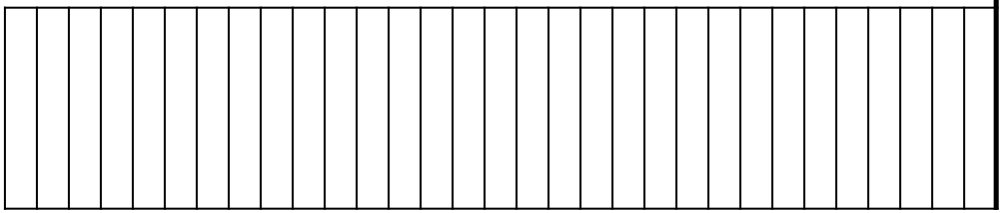
G-12			G-13		G-
Other one-time costs of APCD			Annual monitoring cost of APCD		Annual repair and r cost of
one-time costs of ming a data	Enter the total dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column

G-27	G-28	
work practices followed for CEMS used to measure EtO concentration from the APCD	Engineering or non-regulatory emission test perfor	
iption of any standards or work practices followed for the ure EtO concentration from the APCD	Specify the dates of any engineering or non-regulatory emission test performed for each APCD in the last 5 years **(mm/dd/yyyy)**. If there are multiple dates, separate by commas (,)	Enter the average dollar amount for each engineering emission test in this column

14	G-15			G-
outine maintenance f APCD	Other annual costs of APCD			Is a balancer/snubl moderate EtO conce gas stream enters (e.g., a water bath
Specify the dollar year in this column	Describe other annual costs of APCD	Enter the total dollar amount in this column	Specify the dollar year in this column	Select from the drop column

med in the last 5 years (if any)	
Specify the dollar year in this column	Provide a copy of each engineering or non-regulatory emission test performed in the last 5 years in its entirety for each APCD
	See instructions in "Documents" worksheet

See instructions in "Documents" worksheet



16	G-17			
ber system used to entration before the the control device that absorbs EtO)?	Performance test performed in the last 5 years (if any)			
down menu in this	Specify the dates of any performance test performed for each APCD in the last 5 years **(mm/dd/yyyy)**. If there are multiple dates, separate by commas (,)	Enter the average dollar amount for each performance test in this column	Specify the dollar year in this column	Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD
				See instructions in "Documents" worksheet

See instructions in "Documents" worksheet

G-18
How does the APCD handle variability in flow rate and other relevant parameters?
Provide a brief description about how the APCD handles variability in flow rate and other relevant parameters

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

Click here to go to "Introduction"	*Click here to go to "Terms"*	*Click here to go to "Additional Info"*

H. Details of Air Pollution Control Devices

Table 1. Wet Scrubber & Glygen Absorber Unit

Field #	G-1	H-1
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the wet scrubber/glygen absorber unit
Response		

Table 2. Dry-bed Scrubber

Field #	G-1	H-12
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the dry-bed scrubber
Response		

Table 3. Catalytic Oxidizer & Combination Water Balancer/Catalytic Oxidizer

Field #	G-1	H-30
Data	APCD ID	Design and operation specifications

Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the catalytic oxidizer or combo water balancer/catalytic oxidizer
Response		

Table 4. Thermal Oxidizer

Field #	G-1	H-50
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the thermal oxidizer
Response		

Table 5. Other APCDs

Field #	G-1	H-61
Data	APCD ID	Design and operation specifications
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the design and key operation specifications of the APCD
Response		

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

H-2		H-3
Ethylene glycol (EG) generated annually		Ethylene glycol (EG) tank ID(s) to which wet scrubber/glygen absorber unit feeds
Enter the amount in this column	Specify the unit in this column	Specify the EG tank ID each wet scrubber/glygen absorber unit feeds EG to, if applicable. If there are multiple EG tanks involved, list all EG tank IDs and separate by commas (,). Ensure that any EG tank ID entered in this field is consistent with your entries in "EtO & EG Storage" worksheet, Field D-1

H-13	H-14	H-14.1		
Type of media/sorbent used	Volume of media/sorbent	Unit cost of media/sorbent		
Specify the type of media/sorbent used for the dry-bed scrubber	Enter the volume of media/sorbent used for the dry-bed scrubber **(cubic feet)**	Enter the dollar amount in this column	Specify the unit of measurement in this column. For example: $ per cubic feet, $ per ton, etc.	Specify the dollar year in this column

H-31	H-32	H-32.1
Type of catalyst	Volume of catalyst	Unit cost of catalyst

Specify the type of catalyst used in catalytic oxidizer or combo water balancer/catalytic oxidizer	**(cubic feet)**	Enter the unit cost in this column	Specify the unit of measurement in this column. For example: $ per cubic feet, $ per ton, etc.	Specify the dollar year in this column

H-51	H-52	H-53		H-54	
Average operating temperature	Operating temperature records for thermal oxidizer from the last calendar year	Annual natural gas usage to maintain the operating temperature		Annual cost of natural gas used to maintain the operating temperature	
Enter the average operating temperature of thermal oxidizer **(Fahrenheit)**	Provide the operating temperature records for thermal oxidizer from the last calendar year	Enter the amount in this column	Specify the unit in this column	Enter the dollar amount in this column	Specify the dollar year in this column

	See instructions in "Documents" worksheet				

H-62		
Process/APCD monitoring plan for APCD		
Provide a brief description of the process/APCD monitoring plan for the APCD. Specify if measurements of the gas stream or sorbent material are part of these plans	Name of Parameter 1	Set value of Parameter 1

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

H-4	H-5	
Ethylene glycol (EG) disposal	Annual cost of ethylene glycol (EG) disposal	
Provide a brief explanation of how ethylene glycol is disposed (e.g., municipal sewer, industrial sewer, manufacturer pickup, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column

H-15	H-16	H-16.1		H-16.2	
Installation year of current media/sorbent	Expected lifetime of media/sorbent	Initial Capital cost of media/sorbent		Annual Replacement cost of media/sorbent	
Enter the calendar year in which the current media/sorbent was installed	Enter the expected lifetime of the media/sorbent used **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

H-33	H-34	H-34.1	H-34.2
Installation year of current catalyst	Expected lifetime of catalyst	Initial Capital cost of catalyst	Annual Replacement cost of catalyst

Enter the calendar year in which the current catalyst was installed	Enter the expected lifetime of the catalyst used **(years)**	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column

H-55		
Process/APCD monitoring plan for thermal oxidizer		P
Provide a brief description of the process/APCD monitoring plan for the thermal oxidizer. Specify if measurements of the gas stream are part of these plans	Name of Parameter 1	Set value of Parameter 1

H-63				
Parameter 1 monitored for APCD				
Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2

H-6		
Process/APCD monitoring plan for wet scrubber/glygen absorber unit	Parameter	
Provide a brief description of the process/APCD monitoring plan for the wet scrubber/glygen absorber unit. Specify if measurements of the gas stream or sorbent material are part of these plans	Name of Parameter 1	Set value of Parameter 1

H-17	H-18		
Can the media/sorbent be regenerated?	Media/sorbent renegeration		
Select from the dropdown menu in this column	How frequently is the media/sorbent regenerated, if applicable?	What method is used to regenerate the media/sorbent, if applicable?	How many times is the media/sorbent regenerated prior to disposal, if applicable?

H-35	H-35.1	H-35.2	H-35.3	H-
Operating temperature of catalyst bed	Cost of catalyst replacement	Frequency of catalyst replacement	Average volume of catalyst replacement	Annual natural gas the operating

Enter the operating temperature of catalyst bed **(Fahrenheit)**	Enter the dollar amount in this column	Specify the dollar year in this column	Specify how often on average the catalyst is replaced **(years)**	Enter the average volume of catalyst replaced every time **(cubic feet)**	Enter the amount in this column

H-56				
arameter 1 monitored for thermal oxidizer			Parar	
Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2

H-64				
Parameter 2 monitored for APCD (if any)				
Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

H-7				
1 monitored for wet scrubber/glygen absorber unit			Parameter 2 m	
Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2

	H-19		H-20	H-
	Average cost of a media/sorbent regeneration event		Sorbent disposal	Annual cost of s
To what removal efficiency is the media/sorbent restored after regeneration? **(percent)**	Enter the dollar amount in this column	Specify the dollar year in this column	Specify how sorbert is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column

36	H-37	H-38	H-39
usage to maintain temperature	Annual cost of natural gas used by the catalytic oxidizer or combo water balancer/catalytic oxidizer	Annual cost of electricity used by the catalytic oxidizer or combo water balancer/catalytic oxidizer	Can the catalyst be regenerated?

Specify the unit in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column

H-57

neter 2 monitored for thermal oxidizer (if any)

Parar

Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

H-65				
Parameter 3 monitored for APCD (if any)				
Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4

H-8				
nonitored for wet scrubber/glygen absorber unit (if any)			Parameter 3 m	
Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

21	H-22		H-23
orbent disposal	Is the media/sorbent activity monitored or tested in any way?		Is the media/sorbent change out d manufacturer suggestio
Specify the dollar year in this column	Select from the dropdown menu in this column	If yes, provide a brief description in this column	Select from the dropdown menu in this c If you select "No (double click and type h enter your response between the parentl Example: "No (your explanation)"

H-40
Catalyst renegeration

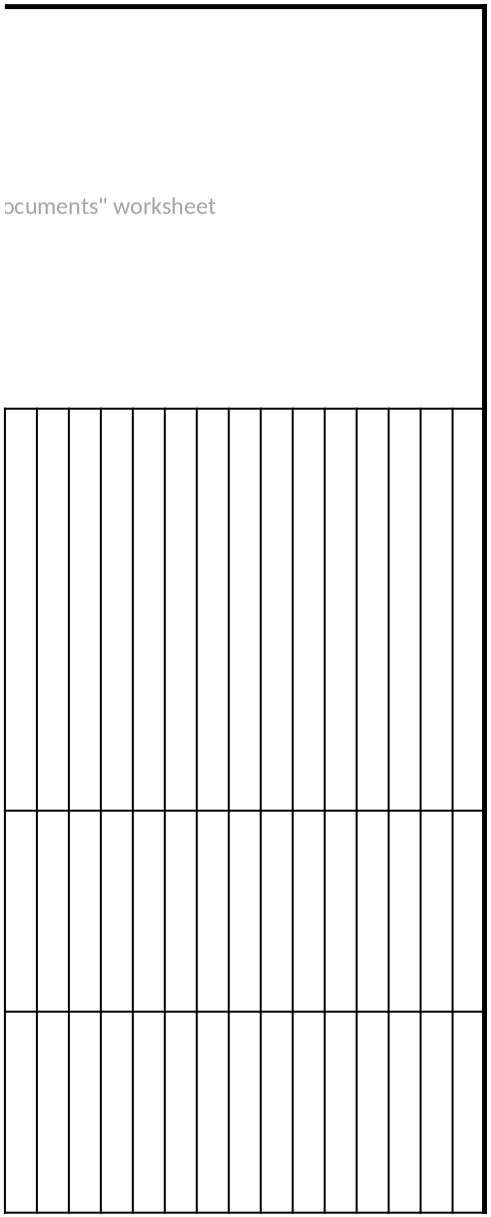
How frequently is the catalyst regenerated, if applicable?	What method is used to regenerate the catalyst, if applicable?	How many times is the catalyst regenerated prior to disposal, if applicable?	To what removal efficiency is the catalyst restored after regeneration? **(percent)**

meter 3 monitored for thermal oxidizer (if any) | Parar

Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4

H-66			H-67
Parameter 4 monitored for APCD (if any)			Monitoring records for APCD from the last calendar year
Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
			See instructions in "D

ɔcuments" worksheet



H-9				
nonitored for wet scrubber/glygen absorber unit (if any)			Parameter 4 m	
Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4

	H-24	
one based on n?	Process/APCD monitoring plan for dry-bed scrubber	
olumn ere)", be sure to heses	Provide a brief description of the process/APCD monitoring plan for the dry-bed scrubber. Specify if measurements of the gas stream or sorbent material are part of these plans	Name of Parameter 1

H-41	H-42	H-43
Average cost of a catalyst regeneration event	Catalyst disposal	Annual cost of catalyst disposal

Enter the dollar amount in this column	Specify the dollar year in this column	Specify how catalyst is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column	Specify the dollar year in this column

H-59			H-60
neter 4 monitored for thermal oxidizer (if any)			Monitoring records for thermal oxidizer from the last calendar year
Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year

			See instructions in "Documents" worksheet

H-10			H-11
nonitored for wet scrubber/glygen absorber unit (if any)			Monitoring records for wet scrubber/glygen absorber unit from the last calendar year
Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
			See instructions in "Documents" worksheet

H-25	
Parameter 1 monitored for dry-bed scrubber	

Set value of Parameter 1	Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2

H-44	
Process/APCD monitoring plan for catalytic oxidizer or combo water balancer/catalytic oxidizer	Parameter

Provide a brief description of the process/APCD monitoring plan for the catalytic oxidizer or combo water balancer/catalytic oxidizer. Specify if measurements of the gas stream or sorbent material are part of these plans	Name of Parameter 1	Set value of Parameter 1

H-26	
Parameter 2 monitored for dry-bed scrubber (if any)	

Set value of Parameter 2	Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3

H-45	
1 monitored for catalytic oxidizer & balancer/abator	Parameter 2 m

Unit of Parameter 1	Monitoring frequency of Parameter 1	Explain any corrective actions taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter 2

H-27	
Parameter 3 monitored for dry-bed scrubber (if any)	

Set value of Parameter 3	Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4

H-46	
onitored for catalytic oxidizer & balancer/abator (if any)	Parameter 3 m

Unit of Parameter 2	Monitoring frequency of Parameter 2	Explain any corrective actions taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

H-28				H-
Parameter 4 monitored for dry-bed scrubber (if any)				Monitoring reco scrubber from the
Set value of Parameter 4	Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitorir last calendar year

H-47	
onitored for catalytic oxidizer & balancer/abator (if any)	Parameter 4 m

Unit of Parameter 3	Monitoring frequency of Parameter 3	Explain any corrective actions taken for readings outside the limit(s) for Parameter 3	Name of Parameter 4	Set value of Parameter 4

29
ords for dry-bed last calendar year
ng records from the

See instructions in "Instruments" worksheet

H-48	H-49
onitored for catalytic oxidizer & balancer/abator (if any)	Monitoring records for catalytic oxidizer & combo water balancer/catalytic oxidizer from the last calendar year

Unit of Parameter 4	Monitoring frequency of Parameter 4	Explain any corrective actions taken for readings outside the limit(s) for Parameter 4	Provide all monitoring records from the last calendar year
			See instructions in "Documents" worksheet

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

Click here to go to "Introduction" | Click here to go to "Terms" | Click here to go to "Additional Info"

I. EtO Monitoring

Table 1. Personal Monitoring (Badges) for EtO

No (default) ← Switch

List all personal monitoring events during the last 5 years

*** Note: If you need to enter more than 30 rows of data, please select "Yes" in Cell F10 above, leave this table below BLA

Field #	I-1	I-2	I-2.1
Data	Unique ID	Date	Room area(s) involved and time spent on this personal (badg
Instruction	Enter from test report or documentation, if available. Otherwise, use a unique identifier for each personal monitoring event	Enter date of the personal monitoring event **(mm/dd/yyyy)**	Specify ID(s) of the room area(s) involved in this personal (bad event, and provide an estimate of the percentage of time sper in parentheses "()". If there are multiple room areas involved, entries by commas (,). Example: "Room Area 1 (40%), Room A Area 3 (35%)". Ensure that any room area ID entered in this field is consistent in "Room Area" tab, Table 1, Field B-1
Response			

Table 2. Room Area Monitoring for EtO

Field #	B-1	I-9
Data	Room area ID for all rooms and areas where EtO is used or emitted	Description of room area monitoring
Instruction	This column will be auto-populated based on your entries in the previous fields	Provide a brief description of the monitoring procedure for each room
Response		

Table 3. Other Monitoring for EtO

Field #	Data	
I-16	Describe any other types of EtO monitoring that have been conducted by the facility, such as near-source, ambient air sampling, or fenceline monitoring efforts	

I-17	Describe any dispersion modeling efforts conducted by the facility	
I-18	Provide the records for any type of monitoring or modeling efforts noted in I-16 and I-17	

Does any information entered on this worksheet contain confidential business information (CBI)?
Specify in ***Cell N2*** *on the right →* ***Be sure to shade each cell that contains CBI in red***
Before saving the ***non-CBI version*** *of your response, select and copy the Sample CBI Cell (****Cell O2****), and paste directly into each cell that contains CBI.* ***Make sure that all "CBI" cells are shaded in red***

to "Yes" in Cell F10 on the left if Supplement 3 is used in lieu of this table

NK, then fill out SUPPLEMENT 3 to the Section 114 ICR. Refer to the Instructions Document for more details ***

	I-3	I-3
e) monitoring event	Description of work conditions	Sampling method c monit
lge) monitoring nt in each room area separate your rea 2 (25%), Room t with your entries	Provide a brief description of the work conditions of facility during each personal monitoring event	Specify the sampling the personal (badge)

I-9.1	I-9.2		I-10	
Sampling method of room area monitoring	Level of detection (LOD) as required by the sampling method		EtO concentration of room area where Et	
Specify the sampling method used for the room area monitoring	Enter the value of LOD in this column	Enter the unit of LOD in this column	Enter the average EtO concentration **(ppmv)**	Enter the maximum EtO concentration **(ppmv)**

Response

See instructions in "Documents" worksheet

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

.1	I-3.2		I-4		
of personal (badge) toring	Level of detection (LOD) required by the sampling method		Monitoring result		
method used for monitoring	Enter the value of Detection Level in this column	Enter the units of Detection Level in this column	Enter the average concentration monitored **(ppm)**	Enter the maximum concentration monitored **(ppm)**	Enter the minimum concentration monitored **(ppm)**

	I-11	I-12	I-1
:O is used or emitted	How many measurement points are there within the room area?	What is the frequency of monitoring at each point within the room area?	Instrur
Enter the <u>minimum</u> EtO concentration **(ppmv)**	Enter the amount of measurement points within the room area	Specify the frequency of monitoring at each point within the room area	Specify the instrument used to monitor the room area

I-5	I-6	I-
Monitoring result flag	Averaging periods	Instrur
Specify any action level, error, or flag of monitoring result	Specify any averaging periods for each personal monitoring event	Specify the instrument used during each personal monitoring event

13		I-14		
ment 1		Instrument 2 (if any)		
Enter the value of detection level of instrument	Specify the unit of detection level of instrument	Specify the instrument used to monitor the room area	Enter the value of detection level of instrument	Specify the unit of detection level of instrument

7		I-8		
ment 1		Instrument 2 (if any)		
Enter the value of detection level of instrument	Specify the unit of detection level of instrument	Specify the instrument used during each personal monitoring event	Enter the value of detection level of instrument	Specify the unit of detection level of instrument

I-15
Action levels and SOPs for room area monitoring
Provide documents specifying action levels and SOPs for room area monitoring
See instructions in "Documents" worksheet

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

J. Wastewater

Field #	J-1	J-2		J-3	J-4
Data	Daily average wastewater flow rate for EtO commercial sterilization activities at the facility	Annual EtO emissions from wastewater at facility for the last 5 years		Average EtO concentration in wastewater when it leaves the vacuum pump or liquid-gas separator	Average EtO concentration in wastewater when collected in a holding tank or basin
Instruction	**(gallons/day)**	Enter calendar year in this column	Enter the value of annual EtO emissions in this column **(pounds)**	**(ppmv)**	**(ppmv)**
Response					

K. Unique Cycles and EtO Reduction

Enter data for each individual category, respectively

If the facility does not plan to re-validate cycles in an effort to reduce EtO use, responses are not required for Fields K-2 throu

Field #	K-1	K-2	K-3	K-
Data	How many unique cycles are run at this facility?	How many unique cycles have been re-validated thus far?	How many unique cycles does the facility still have left to re-validate	How long will it tal validation of
Instruction	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the value in this column
Response for all products in total				
Response for 510(k) products (Class I and Class II devices)				

Response for Pre-Market Approval (PMA) products (Class III devices)				

L. Other Questions regarding EtO Commercial Sterilization

Table 1. EtO and Facility Operation

Field #	Data
L-1	How is EtO handled during malfunction events of process equipment (vented, held within chamber/room, etc)?
L-2	How is EtO handled during malfunction events of APCD (vented, held within chamber/room, etc)? Also provide standard operation practices or protocol in the event of a power outages
L-3	Provide documentation of any studies done on quantifying EtO residuals in your products
L-4	Are there generators on site to keep facility running in the event of a power outage?
L-5	Provide percent emission reduction, associated costs, and description of QA/QC for voluntary measures
L-6	Is the facility operating at full capacity or can current capacity increase to accommodate higher volumes of product? If not operating at full capacity, provide estimate of feasible increase in capacity as a percentage (%) of current output
L-7	Provide any process and instrumentation diagrams (P&ID) that are not included in other documents requested

Table 2. Standalone Non-Colocated Warehouse, Distribution Center, or Enclosed Building for Sterilized

Field #	L-8	L-9
Data	Offsite locations sterilized products are sent	Are any of the products sterilized in your separate standalone non-colocated ware center, or enclosed building that is not c §63.360 and where sterilized product is period longer than 24 hours prior to

Instruction	When the products sterilized in your facility are moved offsite, where are they sent to (e.g., standalone non-colocated warehouse, manufacturer, hospital, etc.)?	Enter the percent by weight of the sterilized products sent to each type of offsite location **(%)**	Select from the dropdown menu in Cell F
Response			

Table 3. Alternative Sterilization

Field #	L-12	
Data	Alternative sterilization method	
Instruction	Specify the alternative sterilization method(s) that can be applied to each product class, if any. Select from the dropdown menu. If you select "Other (double click and type here)", be sure to enter your response between the parentheses Example: "Other (your alternative)"	Percentage of this product that may be sterilized with the alternative method **(%)**
Response for 510(k) products (Class I and Class II devices)		
Response for Pre-Market Approval		

(PMA) products (Class III devices)		

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

J-5	J-6		J-7
Wastewater disposal or treatment for EtO commercial sterilization activities	Annual average cost of wastewater disposal or treatment for EtO commercial sterilization activities		Are there any other processes within the facility that generate EtO-laden wastewater?
Briefly specify how wastewater is disposed of or treated for EtO commercial sterilization activities	Enter the dollar amount in this column	Specify the dollar year in this column	Select from the dropdown menu in this column

gh K-4 and K-7 through K-13

-4	K-5	K-6
ke to complete re-these cycles?	Cost of validating unique cycles	What is the current average EtO dose among the products?
Specify the unit in this column	Provide information on the cost to validate a sterilization cycle, including: (1) hours of time for R&D engineers, operators, technicians, etc. to complete the sterilization cycle runs, compile the reports and file with the FDA; (2) costs for laboratory analyses; and (3) information on the length of time from start to finish **(weeks)** required to complete validation for a sterilization cycle	**(mg/L)**

Instruction	Response
	See instructions in "Documents" worksheet
Select from the dropdown menu	
	See instructions in "Documents" worksheet

l Products

	L-10
facility shipped to a ehouse, distribution currently subject to s stored for a time o re-shipment?	Information on the standalone non-colocated warehouse, distribution center, or enclosed building tha where sterilized product is stored for a time period longer than 24 hours prior

56 below	Name	Street address verified by U.S. Postal Service (USPS). Do not include P.O. box in this field	City

L-13					
Details of alternative sterilization method					
Time needed to switch from EtO to the alternative **(months)**	Capital cost to switch from EtO to the alternative. Enter the dollar amount in this column	Capital cost to switch from EtO to the alternative. Specify the dollar year in this column	Annual cost to switch from EtO to the alternative. Enter the dollar amount in this column	Annual cost to switch from EtO to the alternative. Specify the dollar year in this column	Change in annual cost with respect to using EtO. If alternative costs are less than EtO, please enter a negative value. Enter the dollar amount in this column

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

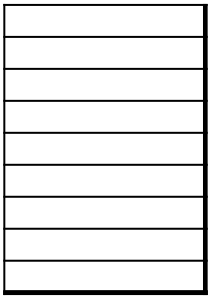
J-8	J-9	J-10
Other processes generating EtO-laden wastewater within the facility	Daily average wastewater flow rate for each process other than EtO commercial sterilization	Wastewater disposal or treatment for e than EtO commercial sterili
List all other processes generating EtO-laden wastewater within the facility. Enter one process per each row	**(gallons/day)**	For each process, briefly specify how was of or treated

K-7	K-8	K-9	K-
What is the target average EtO dose?	What is the anticipated average percent change in number of nitrogen washes upon completion of the re-validations?	What is the anticipated average percent change in number of air washes upon completion of the re-validations?	What is the anticipa change in time spe upon completion of
(mg/L)	**(percent)**	**(percent)**	**(percent)**

	L-11
t is not currently subject to §63.360 and to re-shipment	How long are the products sterilized in your facility generally held in the separate standalone non-colocated warehouse, distribution center, or enclosed building listed in Field L-10 on the left?

State. Select from the dropdown menu in this column	Zip code verified by U.S. Postal Service (USPS)	**(Days)**

Change in annual cost with respect to using EtO. Specify the dollar <u>year</u> in this column



	J-11		J-12
ach process other ization	Annual cost of wastewater disposal or treatment for each process other than EtO commercial sterilization		Annual average wastewater flow for all operations at the facility (includes both EtO commercial sterilization and other activities)
tewater is disposed	Enter the dollar amount in this column	Specify the dollar year in this column	**(gallons/year)**

10	K-11	K-12	K-
ted average percent ent on gas washing the re-validations?	What is the anticipated average percent change in dwell period time upon completion of the re-validations?	What is the anticipated average percent change in aeration time upon completion of the re-validations?	What are the antic savings from re
	(percent)	**(percent)**	Enter the dollar amount in this column

13
ipated annual cost duced EtO use?
Specify the dollar year in this column

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

Click here to go to "Introduction"	*Click here to go to "Terms"*

M. Additional Information

If you need extra space to provide additional information requested throughout this questionnaire, fill out this table below ur

Worksheet	Field #	

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right → **Be sure to shade each cell that contains CBI in red***
*Before saving the **non-CBI version** of your response, select and copy the Sample CBI Cell (**Cell O2**), and paste directly into each cell that contains CBI. **Make sure that all "CBI" cells are shaded in red***

nless you may use any of the supplements to the Section 114 ICR. For each entry, specify the worksheet and field number to w

Response

	CBI
	Sample CBI Cell (above)

EIS ID (Auto-populated)	

hich your data refers

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

Click here to go to "Introduction"	Click here to go to "Terms"	Click here to go to "Additional Info"

N. Documents

Refer to the Instructions Document for naming conventions, and name your documents as appropriate before submitt

There are two options to submit documents requested throughout this questionnaire:
Option 1: Submit your documents as standalone PDF files through email (only for non-CBI documents) or mail in a media
Instructions Document for details. If you need to submit more than 10 documents in any category below, this option is re
Option 2: Attach your documents to the table below. The relevant field numbers and descriptions are summarized in this

Please specify in Column H of the table below the total number of CBI and non-CBI documents you intend to submit in ea

Before saving the **non-CBI version** of your response, if any document attached here contains CBI, **be sure to select "Yes"**

Field #	Data	Instruction
A-21	Facility diagrams	Provide diagrams of your facility indicating all rooms, primary EtO emission points (e.g., regulated emission points), and secondary EtO emission points (e.g., fugitive emission points)
A-22	Process flow diagrams	Provide process flow diagrams of the EtO processes at your facility
A-23	Most recent air permit(s)	Provide the most recent air permit(s) approved for your facility
A-24	Application documents for the most recent air permit(s)	Provide the application documents for the most recent air permit(s) approved for your facility

A-25	Startup, shutdown and malfunction (SSM) plan	Provide the startup, shutdown and malfunction (SSM) plan approved for your facility
A-42	Documentation for annual emissions calculations	Provide calculations and supporting documentation for all emission factors used to determine the annual emissions
G-17	Performance test performed in the last 5 years (if any)	Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD
G-28	Engineering emission test performed in the last 5 years (if any)	Provide a copy of each engineering emission test performed in the last 5 years in its entirety for each APCD
H-11	Monitoring records for wet scrubber from the last calendar year	Provide all monitoring records from the last calendar year
H-29	Monitoring records for dry-bed scrubber from the last calendar year	Provide all monitoring records from the last calendar year
H-49	Monitoring records for catalytic oxidizer & combo water balancer/catalytic oxidizer from the last calendar year	Provide all monitoring records from the last calendar year
H-52	Operating temperature records for thermal oxidizer from the last calendar year	Provide the operating temperature records for thermal oxidizer from the last calendar year
H-60	Monitoring records for thermal oxidizer from the last calendar year	Provide all monitoring records from the last calendar year

H-67	Monitoring records for APCD from the last calendar year	Provide all monitoring records from the last calendar year
I-15	Action levels and SOPs for room area monitoring	Provide documents specifying action levels and SOPs for room area monitoring
I-18	Provide the records for any type of monitoring efforts you have mentioned in Fields I-16 and I-17	
L-3	Provide documentation of any studies done on quantifying EtO residuals in your products	
L-7	Provide any process and instrumentation diagrams (P&ID) that are not included in other documents requested	

Does any information entered on this worksheet contain confidential business information (CBI)?
*Specify in **Cell N2** on the right →*
*Before saving the **non-CBI version** of your response, ensure that **all CBI documents are deleted, and Column H of the table below are filled out as appropriate***

ing.

(e.g., thumb drive, CD or DVD) with documents loaded. See Section VI, "Instructions for Submitting Your Responses", of the ecommended;
s table. Ensure that any IDs referenced are consistent with data reported throughout this questionnaire.

ach category regardless of the submission option you choose.

in Cell N2 of this worksheet, and delete all CBI documents

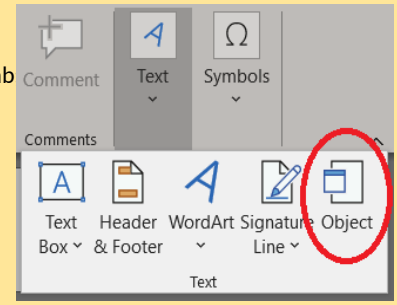
Total Quantity of CBI & non-CBI Documents					Docu

EIS ID (Auto-populated)	

Steps to attach documents to the table below

(1) Click on the field to attach files;
(2) Go to the Insert tab → Text, click Object;
(3) In the Object dialog box, click the Create from File tab
(4) Click Browse, and select the file you want to insert;
(5) Select the Display as Icon check box, then click OK.

Repeat the above steps to attach any additional files



nents				

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

Click here to go to "Introduction"

Acknowledgment of CBI Handling

Before certifying and submitting this questionnaire, please make sure that you have *selected "Yes" in Cell N2 on all the v*
CBI version of your response.

When creating a non-CBI version of your response, please save this Excel workbook as a new copy following the naming
CBI before are now showing "CBI" with a red shade, and any embedded CBI document is deleted from the "Documents

Please submit both the CBI version and the non-CBI version of your response to EPA. The non-CBI version will be made a

By checking this box, I acknowledge that I have read, understand, and agree to the instructions and proced

(Check this box only if this is the non-CBI version of your questionnaire) By checking this box, I confirm that

☐

☐

Certification by Reporter

Complete the fields below for the person who completes the questionnaire and who is available for follow-up questions, if any, on the information provided in this questionnaire

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Certification by Professional Engineer

Complete the fields below for the professional engineer (PE) who certifies the information provided in this questionnaire

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

worksheets where CBI was entered, and shaded all fields that contain CBI in red. This should be the

convention specified in Section V of the Instructions Document. Confirm that ***all fields that contained*** *" worksheet.* Refer to Section IV in the Instructions Document for full details.

vailable to the public.

ure of handling CBI data and documents submitted within this response.

all CBI data and documents have been deleted from this response.

Certification by Facility Personnel

Please complete the fields below for the facility personnel who certifies the information provided in this questionnaire (may be the owner or legal operator of the facility)

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date

Certification by Certified Industrial Hygienist

Complete the fields below for the certified industrial hygienist (CIH) who certifies the information provided in this questionnaire

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	

☐ I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.

Signature

Date