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 Con 114(a) of Clean Air Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of reporting and recordkeeping burden for this collection of information is estimated to be proximately 108 hours per respondent setimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Direction Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to the

Introduction

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

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 instances and data fields shaded in gold contain instructions and supporting information that help facility with this quality Data fields shaded in gray indicate that these either do not need to be filled out or will be automatically filled out based Data fields shaded in red by facility indicate that these fields contain confidential business information (CBI), and releva "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, she V of the Instructions Document to create the non-CBI version of your response.

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

•	0
Introduction (this worksheet)	Introduction and instructions for completing and submitting this question
Terms (link)	Definitions or explanations of certain technical terms that are mentions
Facility Details (link)	Information about facility registration, ownership, general characteristic
Room Area (link)	Characteristics, inventory of components and control of individual room
EtO & EG Storage (link)	Questions regarding EtO storage in drums and containers, and ethylene
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, catalyt
EtO Monitoring (link)	Information about workspace monitoring, personal monitoring, room m
Miscellaneous (link)	Questions regarding facility's wastewater treatment and other items of
Additional Info (link)	Use this worksheet if you need extra space to provide any additional inf
Documents (link)	Designated space to attach documents requested throughout this quest
Certification (link)	Reporter's information and certification for completing and submitting

About the Supplements

OMB Control No. 2060-NEW Approval Expires mm/dd/yyyy

Itrol No. 2060-NEW). Responses to this collection of information mandatory under section of information unless it displays a currently valid OMB control number. The average public onse. Send comments on the Agency's need for this information, the accuracy of the provided actor, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, nis address.

eview project for 40 CFR part 63, subpart O, Ethylene Oxide (EtO) Commercial Sterilization source

structions

uestionnaire

d on facility's inputs in relevant fields

int data needs special handling

ade in red all cells with real CBI data in the CBI version, then follow the instructions in Section

rksheet):

rksneet):
onnaire
ed throughout this questionnaire
cs, facility-level data, legal documents, etc.
n areas where EtO is used or emitted
glycol (EG) tanks
;
ic oxidizers, thermal oxidizers, and others
nonitoring, etc. conducted by facility
EtO commercial sterilization operation
formation requested within this questionnaire
tionnaire
this questionnaire

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

Click here to go to "Introduction"

1. Definitions

Term	Defin
Accelerated aeration	Aeration conducted in a heated aeration chamber or cell, not an aeratic turbulence air created by multiple inlet ports along the length of the ae provide even distribution of air flow
Aeration cell/chamber	Any vessel that is used to facilitate off-gassing of ethylene oxide at a steclassified as a sterilization chamber
Aeration room	Any vessel or room that is used to facilitate off-gassing of ethylene oxid or room is classified as a sterilization chamber
Aeration room area	Any room areas that surround the aeration cell, aeration chamber, or a room areas that sterilized materials move through as they are placed in materials move through following the aeration process itself. Note that Aeration room area would include fugitive emissions, while aeration room.
Aeration room vent (ARV)	The point(s) through which the evacuation of ethylene oxide-laden air f
Balancer/abator system	An air pollution control device (APCD) that consists of a combination of
Cascading air	Ventilation air removed from one room area or process, with a lower Et ventilation air directly to another room area or process (e.g., ventilation aeration cell). Ventilation air removed from one room area or process reconcentration or process concentration of the room area or process in v
Chamber exhaust vent (CEV)	The point(s) through which ethylene oxide-laden gas is removed from the completion of sterilization and associated air washes. Also known as "based of the completion of sterilization and associated air washes."
Combination-chamber sterilizer	Any enclosed vessel in which both the sterilization process and the aera ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpo
Dwell period	The length of time that the product is exposed to ethylene oxide in ster
Engineering test	A test that measures the amount of pollutants being emitted, demonstrate efficiency of a control device used to reduce emissions at a facility. This
Ethylene oxide (EtO) service	A piece of equipment either contains or contacts ethylene oxide as a liq
Fugitive emissions	Emissions (of ethylene oxide) which are not routed through the existing
Natural draft opening (NDO)	Any permanent opening in the enclosure that remains open during ope installed
Non-colocated warehouse/distribution center	A warehouse or distribution center, used to store products that are sterethylene oxide commercial sterilizer rule under 40 CFR part 63, subpart

Performance test	A test that measures the amount of pollutants being emitted, demonstration of a control device used to reduce emissions at a facility. User efficiency, or control efficiency requirement
Research and laboratory facility	Any stationary source whose primary purpose is to conduct research an operated under the close supervision of technically trained personnel a in commerce, except in a de minimis manner
Single-item sterilizer	Any enclosed vessel in which sealed pouches containing product and et ethylene oxide sterilizes and aerates
Sterilization chamber vent (SCV)	The point (prior to vacuum pump) through which the evacuation of eth fumigation, including any subsequent air washes
Sterilization facility	Any stationary source where ethylene oxide is used in the sterilization c
Sterilization operation	Any time when ethylene oxide is removed from the sterilization chamber or when ethylene oxide is removed from the aeration room through the
Sterilizer chamber	Any enclosed vessel or room that is filled with ethylene oxide gas, or an fumigating at a sterilization facility. Includes any vessels or rooms when 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
cfm	Cubic feet per minute	NDO
CFR	Code of Federal Regulations	ppmv
EG	ethylene glycol	psig
EIS	Emission Inventory System	QA
EPA	Environmental Protection Agency	QC
EtO	ethylene oxide	R&D
ICR	information collection request	SCV

ition on room, combined with: (1) use of vacuum cycles, and/or (2) high ration cell and multiple outlet points along the top of the cell to erilization facility. If single-item sterilization occurs, the vessel is e at a sterilization facility. If single-item sterilization occurs, the vessel eration room. For example, aeration room areas may include either the the equipment where aeration occurs, or the room areas that aerated an "aeration room area" is different from an "aeration room." om itself would be a point source of emissions. rom an aeration room occurs a water balancer and a catalytic oxidizer O concentration, is vented as the input ventilation air or intake air from a warehouse is used as intake air to the aeration room or must have an equivalent or lower EtO concentration than the room air which it is reused he sterilization chamber during chamber unloading, following the ack vent" ation process occur within the same vessel, e.g., the vessel is filled with ise of sterilizing and is followed by off-gassing of ethylene oxide ilizer chamber for the purpose of sterilizing or fumigating the product rates the capture efficiency, or determines the destruction or removal testing is not related to compliance or regulatory requirements uid or gas at any concentration control equipment ration of the facility and is not connected to a duct in which a fan is ilized with ethylene oxide, that is not part of a facility subject to the

rates the capture efficiency, or determines the destruction or removal d to determine a facility's compliance with an emission limit, capture
id development into new processes and products, where such source is nd is not engaged in the manufacturer of products for commercial sale
hylene oxide gas for the purpose of sterilizing are placed, and the
ylene oxide from the sterilizer chamber occurs following sterilization or
or fumigation of materials
er through the sterilization chamber vent or the chamber exhaust vent e aeration room vent
ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or e both ethylene oxide sterilization and aeration occur within one

Term
identifier
inches of water
kilowatt hour
lower explosive limit
milligrams per liter
North American Industrial Classification System
natural draft opening
parts per million, volume
pressure per square inch, gauge
quality assurance
quality control
research and development
sterilization 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
------------------------------------	-----------------------------	---------------------

A. Facility Details

Table 1. Facility Information

Field #	A-1	A-2	A-3
Data	Primary NAICS code	EIS ID	Facility name
Instruction		Enter EIS ID for the facility	Enter facility name
Response			

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

Table 2. Parent Company Information

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

² To determine the employee threshold for a small business, you may look up the small business size standard using six-North American Industry Classification System codes?", table "Small Business Size Standards by NAICS Industry", column 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=85df5b1185a8b127a9b324c65

Table 3. Facility Documents

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

		Provide process flow diagrams of the EtO processes at your facility
Response	See instructions in "Documents" worksheet	See instructions in "Documents" worksheet

Table 4. Facility Buildings

Field #	A-26	A-27		-28
Data	Building ID	Building height	Building	g corner 1
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
Response				

Table 5. Facility-level Data

Field #	A-36	A-40
Data	EtO usage at your facility for the last 5 calendar years	Annual EtO <u>stack emissions</u> of facility for the last 5 years

Instruction	· · · ——	corresponding <u>EtO</u> <u>usage</u> in this column	Specify the <u>calendar</u> <u>year</u> . Select from the dropdown menu in this column	Enter the <u>value</u> of annual EtO emissions in this column (pounds)
Response				

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

Table 6. Materials Sterilized with EtO

Field #	A-37	A-38
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
	your facility in 2019. Enter one type in each cell. If you have more than 10 types, enter	Provide the approximate percentage of each type of materials sterilized with EtO in 2019 based on volume of material throughput (%)
Response		

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

Field #	A-48	A-49
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

	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	material throughput (%)
Response		

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

A-4	A-5	A-6	A-7
Facility address	Facility city	Facility state	Facility zip code
Enter the street address of facility verified by U.S. Postal Service (USPS). Do <u>not</u> include P.O. box in this field		dropdown menu in	Enter facility zip code verified by U.S. Postal Service (USPS)

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

A-15	A-16	A-17	A-18	A-	
Parent company city	Parent company state	Parent company zip code	Phone number	Is parent company	
Enter parent company city	dropdown menu in		Provide a contact phone number at the parent company	Select from the dropdov column ²	

digit NAICS codes. The size standards used to define Small Businesses are provided in 13 CFR 121, Small Business Size Reg 1 "Size standards in number of employees".

83f72c6&mc=true&node=pt13.1.121&rgn=div5. (click to visit)

A-23	A-24	A-:
Most recent air permit(s)	Application documents for the most recent air permit(s)	Startup, shutdown and

approved for your facility	most recent air permit(s) approved for your	Provide the startup, shu malfunction (SSM) plan facility
See instructions in "Documents" worksheet	See instructions in "Documents" worksheet	See instructions in "Do

A-	-29	A-30		A- :	
Building	corner 2	Building	corner 3	Building cor	
Enter the latitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the longitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the latitude of this building corner. Specify to the <u>6th</u> 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 <u>6th</u> decimal point	

A-41	A-42	A-,
Annual EtO <u>fugitive emissions</u> of facility for the last 5 years	Documentation for annual EtO emissions calculations	Average annual en operation (include th aver

<u>year</u> . Select from the	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
		See instructions in "Documents" worksheet	

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

'e those for major sources of HAP in 40 CFR 63.2, but that have taken a restriction so that its potential to emit (PTE) is les

A-39	A-3	39.1	A-3
Percentage of each type of materials sterilized with EtO in 2019 based on dollar amount	Packaging material used for products sterilized with EtO		Pallet material used f with
Provide the approximate percentage of each type of materials sterilized with EtO in 2019 based on <u>dollar amount</u> (%)	Specify the packaging material used for products sterilized with EtO at your facility		Specify the pallet materials used in EtO sterilizer chambers

A-50	A-51
Percentage of each type of material sterilized with non-EtO approaches in 2019 based on dollar amount	Packaging material used for products sterilized with non-EtO approaches

Provide the approximate percentage of each type of material sterilized with non-EtO approaches in 2019 based on dollar amount (%)	Specify the packaging material used for products sterilized with non-EtO approaches at your facility	Enter the <u>percent by volume</u> of product sterilized with non-EtO approaches that uses this packaging material (%)

siness information (CBI)? Specify in Cell N2 on	СВІ
I version 'Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

A-8	A-9		A-10
Phone number	Number of employees at facility	Operating status in current year	Comments
Provide a contact phone number at the facility	dropdown menu.	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

19	A-20
a small business?	Number of employees at parent company
wn menu in this	Select from the dropdown menu in this column

gulations. See §121.201, "What size standards has SBA identified by

25 malfunction (SSM) plan

itdown and approved for your
approved for your
ocuments" worksheet

31	A-	32	A-	33
ner 4 (if any)	Building corner 5 (if any) Building corner 6 (if any)		ner 6 (if any)	
Enter the longitude of this building corner. Specify to the 6th decimal point	Enter the latitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the longitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the latitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the longitude of this building corner. Specify to the <u>6th</u> decimal point

43	A-44	A-45
ergy cost of facility ne last 5 years in the age)	Average annual growth rate in revenues from EtO sterilization services for the last 5 years	Size category of facility with respect to hazardous air pollutant (HAP) emissions

Specify the dollar <u>year</u> in this column	Enter the <u>amount</u> in this column (dollars/year)	Select from the dropdown menu in this column ³

s than such amounts for major sources. Such restrictions must be enforceable as a practical matter. See 40 CFR 63.2, De

9.2
or products sterilized EtO
Enter the <u>percent by volume</u> of each type of pallet material used for EtO sterilization (%)

EIS ID (Auto-populated)

A-	A-11		A-12
Operating hours		Is there a plan to expand/modify/close this facility in the near fu	
operating hours on	Enter the <u>annual</u> operating hours on average of the facility (hours)		Provide a short explanation if you select "Yes" on the left

A-34		A-35
Building corner 7 (if any)		Additional comments
Enter the latitude of this building corner. Specify to the <u>6th</u> decimal point	Enter the longitude of this building corner. Specify to the 6th decimal point	Enter any additional comments that you may have regarding the information provided in this table about buildings and building corners

A-46	A-47
As a percentage of all products sterilized at your facility, what is the percentage of products sterilized with EtO?	As a percentage of all products sterilized at your facility, what is the percentage of products sterilized using non-EtO techniques or approaches?

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	

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

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

Table 1. Characteristics of Room Areas

Field #	B-1	B-2		
Data	Room area ID for all rooms and areas where EtO is used or emitted	Category of room area	Activ	
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 explanat area	
Response				
			_	
			<u> </u>	

Field #	B-1			
Data	Room area ID for all rooms and areas where EtO is used or emitted			
	on your entries in the	permit description, if available. Otherwise, use a unique identifier for each NDO	dropdown menu in this column	Orientation. Select from the dropdown menu in this column
Response				
Data	Room area ID for all rooms and areas where EtO is used or emitted	Are leak checks performed in the room area?	Compor	ent type

Instruction	Select from the dropdown menu. Scroll up to see options that are autopopulated 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)"
Response			

Table 4. Room Area Controls

Nο	(default)	

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

Field # B-1
Data Room area I rooms and where EtO is emitte

		1	
Instruction	Select from the dropdown menu. Scroll up to see options that are autopopulated 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
Response			
Response			

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

B-3	B-4	B-5	
ities conducted in room area	Floor area	Room height	
ion of the activities conducted in each room	(square feet)	(feet)	Enter temperature set
			point or range for summer in this column (Fahrenheit)
			(Eabrophoit)
			(raniennen)
-			
-			
_			
-			
	_		

B-12					
Natural draft opening (NDO) 1 (if any)					
Latitude Specify to the	Longitude Specify to	Cross-sectional area	Height above the	Is air forced out of this	
Latitude. Specify to the 6th decimal point	the <u>6th</u> decimal point	(square feet)	ground	NDO? Select from the	
			(feet)	dropdown menu in this column	
				this column	
Total correspond	What is the	Fuzzurza	flool, shool,	Average length of the	
Total component count	percentage of	rrequency o	f leak checks	Average length of time to perform leak checks	
	components that are				
	components that are included in regular leak checks?				

Specify the total number of components that of this type are included in regular leak checks (percent) Specify the total number of components that of the type are included in regular leak checks (percent) Specify the total number of components that are included in regular leak checks (percent) Specify the total of the type are included in regular leak checks (percent) Specify the total number of components that are included in regular leak checks are performed of time to perform leak checks per component type, per inspection (hours) Specify the total number of components that are included in regular leak checks are performed of time to perform leak checks per component type, per inspection (hours) Specify the total number of components that are regular leak checks are performed of time to perform leak checks are performed of time to perform leak checks per component type, per inspection (hours)	Specify the total	Specify the percentage	Specify how often leak checks are performed	Enter average length
of this type are included in regular leak checks (percent) leak checks (component type, per inspection (hours)	number of component	of components that		of time to perform
(percent) (percent)	of this type	are included in regular		leak checks per
(hours) (hours) (hours) (hours) (hours)		(nercent)		inspection
		(percent)		(hours)
				, ,

 \leftarrow Switch to "Yes" in Cell F130 on the left if Supplement 2 is used in lieu of this table

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

 $^{
m NW}$ BLANK, then fill out SUPPLEMENT 2 to the Section 114 ICR. Refer to the Instructions Document for more details ***

B-39	В-,
APCD 1 for room area	APCD 2 for roo

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 <u>average</u> 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 dropdor column If you select "Other (do here)", be sure to enter between the parenthes Example: "Other (your #
			:

siness information (CBI)? Specify in Cell N2 on	СВІ
I version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

B-6		B-7		B-8	
Temperature		Relative humidity		Pressure drop	
Enter temperature set point or range for winter in this column (Fahrenheit)	point or range for intermediate seasons in this column	Enter average or range of relative humidity (percent)	Enter the pressure drop across room area (inch H2O)	Specify definition of pre locations based on whic measured (e.g., farthest device inlet)	
	(Fahrenheit)				
				 	

				Natura	
				inatura	
Air velocity (feet/minute)	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	dropdown menu in this column	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	
		nere)", be sure to enter your response between the parentheses Example: "Other (your NDO)"			
		INDO)			
	!	!	!	!	
	Instrument and standar	d method for leak check	s		

Briefly describe the instrument and standard method used for leak checks	Describe the leak check
	<u> </u>

40	B-41
m area (if any)	APCD 3 for room area (if any)

è

	le	lanen in E	
wn menu in this	Enter the <u>average</u> air	APCD ID. Enter from	Select from the dropdown menu in this
1.1 19.1 1.4	flow routed from the	permit description, if	column
uble click and type	room to this APCD	available. Otherwise,	If you select "Other (double click and type
your response	(actual cubic feet per	use a unique identifier	here)", be sure to enter your response
<u>es</u>	minute, acfm)	for each APCD	between the parentheses
APCD)"			Example: "Other (your APCD)"
			
-			
-			

EIS ID (Auto-populated)

	B-9	B-10	B-11
	Air flow (ventilation)	Air flow (conditioned)	Number of air changes per hour
ssure drop, or th pressure drop is t point to control	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					
I draft opening (NDO) 2 (if any)					
Longitude. Specify to the <u>6th</u> decimal point	Cross-sectional area	Height above the ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	Air velocity	
the <u>6th</u> decimal point	(square feet)	ground	NDO? Select from the	(feet/minute)	
		(reet)	aropaown menu in		
			this column		
Leak check	procedure		Average cost	per inspection	
-		·		·	

procedure for each room area. Specifically, provide any action levels	Enter the dollar	Specify the dollar <u>year</u> in this column
	amount in this column	in this column

B-42	B-43	B-44	B-45
Material of duct work for room area venting	Total length of duct work for room area venting	Average thickness of duct work for room area venting	Is the cross section of duct work for room area venting circular or rectangular?

Enter the average air	Specify the material of	Enter the total length	Enter the average	Salact from the
Enter the <u>average</u> air flow routed from the	Specify the material of duct work	of duct work	Enter the <u>average</u> thickness of duct work	drondown menu in
room to this APCD	duct Work	(feet)	(inches)	this column
(actual cubic feet per		(icet)	(inches)	ins column
(actual cubic feet per minute, acfm)				
,				
	+			
	 			
	1			
	+			

B-14

Natural draft opening (NDO) 3

permit description, if	dropdown menu in this column	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the <u>6th</u> decimal point
	Example: "Other (your NDO)"			

Average percentage of	Definition of leak
leaking components	
identified	

Enter average percentage of leaking components identified during each leak check (percent)	If applicable, specify the definition or criteria of leak in the state/local regulations that require leak checks, or the definition that facility refers to
components identified	leak checks, of the definition that identity refers to
during each leak check	
(percent)	

B-46	B-47	B-48	B-49	B-:
Diameter of duct work (For circular duct work		Cross-sectional width of duct work	Are the dimensions of duct work constant	Diameter o (For circular dı
only)	(<u>For rectangular duct</u>	(<u>For rectangular duct</u>	throughout?	\ <u>i or circular di</u>
	<u>work only</u>)	<u>work only</u>)		

	I=	I=	In 1 1 6 11	I=
Enter the <u>average</u> diameter of duct work (feet)	Enter the <u>average</u>	Enter the <u>average</u> cross-sectional width	Select from the	Enter the <u>maximum</u> diameter of duct work
diameter of duct work	cross-sectional height	cross-sectional width	dropdown menu in this column	diameter of duct work
(feet)	of duct work	of duct work	this column	(feet)
	(feet)	(feet)		
	(,	(,		
-			 	

(:£)					
(if any)					
Cross-sectional area	Height above the	Is air forced out of this	Air velocity	NDO ID. Enter from	
Cross-sectional area (square feet)	Height above the ground (feet)	Is air forced out of this NDO? Select from the	(feet/minute)	permit description, if available. Otherwise, use a unique identifier for each NDO	
	(feet)	ldropdown menu in		available. Otherwise,	
		this column		use a unique identifier	
				for each NDO	
	!	ļ.	ļ.	ļ.	I
	Annlicable state	/local regulations		F	
	Applicable state	riocar regulations			

Specify any state/local regulations applicable to your facility for leak checks	Provide a brief descripti
эргэн, эн, энн, энн эргэн эргэн эн үхийн ан	

50	B-51	B-52
f duct work	Cross-sectional height of duct work	Cross-sectional width of duct work
uct work only)	(<u>For rectangular duct work only</u>)	(<u>For rectangular duct work only</u>)

	le	e , ,, , , ,	le	le i ii ii i
Enter the minimum diameter of duct work (feet)	Enter the <u>maximum</u>	Enter the <u>minimum</u> cross-sectional height of duct work	Enter the <u>maximum</u> cross-sectional width	Enter the <u>minimum</u> cross-sectional width
diameter of duct work	cross-sectional height	cross-sectional height	cross-sectional width	cross-sectional width
(feet)	of duct work	of duct work	of duct work	of duct work
	(feet)	(feet)	(feet)	(feet)

			B-15		
	Natural draft opening (NDO) 4 (if any)				
Turne Colorat from the	Owigantation Colort	li atituda Coasifuta tha	I amaituda Cuasifuta	Cross-sectional area	
Type. Select from the dropdown menu in	Orientation. Select	Latitude. Specify to the 6th decimal point	the <u>6th</u> decimal point	(square feet)	
this column	from the dropdown menu in this column	oth decimal point	die <u>oth</u> decimal point	(Square reet)	
If you select "Other					
(double click and type here)", be sure to					
here)", be sure to					
enter your response between the					
parentheses Example: "Other (your NDO)"					
Example: "Other (your					
NDO)"					
	:		<u>.</u>		
Repair method/procedu	re for the leaks identifie	d	Average cost per rep	air for leaks identified	

on of the repair method/procedure for the leaks identified	Enter the dollar	Specify the dollar year
	amount in this column	Specify the dollar <u>year</u> in this column
	Į.	

B-53	B-54	B-55	B-
Installation year of duct work	Lifetime of duct work	Capital cost of duct work for room area venting (estimated or actual)	Installation cost of duventing (estimate)

Enter the calendar	Enter the expected	Enter the dollar	Specify the dollar year	Enter the dollar
year in which duct	Enter the expected lifetime of duct work	Enter the dollar amount in this column	in this column	amount in this column
work was installed	(years)			
	,			

Height above the	Is air forced out of this	Air velocity	NDO ID. Enter from	Type. Select from the
ground	NDO? Select from the	(feet/minute)	permit description, if	dropdown menu in
(feet)	dropdown menu in this column		available. Otherwise, use a unique identifier	this column
	LITIS COIUITIII		for each NDO	(double click and type
			Tor caciffic	here)", be sure to
				enter your response
				between the
				<u>parentheses</u> Example: "Other (your
				NDO)"
Are there any specialt	v components that are	Λ	thoro any other impedia	nonts that would prove
not readily available of	y components that are n site and that need to	Are	mere any other impedir	nents that would preven
be ordered in the ev	vent of a component			
replace	ement?			

	lea to the second		
Select from the	How long does it take, on average, for the facility to receive the	Select from the	List the impediments that would prevent immedifyou select "Yes" on the left)
dropdown menu in	on average, for the	dropdown menu in	(<u>if you select "Yes" on the left</u>)
this column	facility to receive the	this column	
	lcomponents?		
	(davs)		
	(days) (if you select "Yes" on the left)		
	the left)		
	the left,		
	+		
	+		
	-		
	<u> </u>		
	+		
	+		
	-	 	
	+		
	 		

56	B-57
ct work for room area ated or actual)	Room area air used as cascading air for reuse in another room or unit (For cascading only)

Specify the dollar <u>year</u> in this column	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, <u>list all the IDs and separate by commas (,)</u> . 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

	B-16							
	Natural draft opening (NDO) 5 (if any)							
		racara	rarare opening (1120) 5	(ii diriy)				
1	Out-untations Calast	- + + + + + + + + + + + + + + + + + +		C	Unink dan dan dan			
	Orientation. Select	Latitude. Specify to the 6th decimal point	the 6th decimal point	Cross-sectional area (square feet)	Height above the ground (feet)			
	from the dropdown menu in this column	otti decimai point	the oth decimal point	(square reet)	(feet)			
					,			
	İ	I	İ	İ	İ			

it imme	ediate re	pair of le	eaks?	

diate repair of leaks	

B-58
Stack ID to which the uncontrolled room area vents For room area vented to the atmosphere only)

Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack <u>height</u> (feet)	Enter the stack diameter (feet)	Enter the <u>temperature</u> at stack outlet (Fahrenheit)	Enter the <u>exhaust</u> <u>velocity</u> at stack outlet (feet/second)

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

B-60	B-60.1	
Stack coordinates (<u>For room area vented to the atmosphere</u> <u>only</u>)	Distance from room area outlet to stack (For room area vented to the atmosphere only)	

Enter the volumetric flow rate for this	Enter the latitude of	Enter the longitude of	Enter the distance	Provide a brief descripti room area is not: vente
flow rate for this emission source at	stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point	from outlet of the room area to the stack	room area is not: vente
stack outlet	otti decimai point	decimal point	(feet)	
(cubic feet per minute)				
illillute)				
			!	

	B-17			
Natura	al draft opening (NDO) 6	(if any)		
Latitude. Specify to the 6th decimal point	Longitude. Specify to	Cross-sectional area	Height above the	Is air forced out of this
<u>6th</u> decimal point	the <u>6th</u> decimal point	(square feet)	Height above the ground (feet)	NDO? Select from the
			(feet)	dropdown menu in this column
				triis coluiriii
				+
				+
				+

B-61 Other handling of air from room area	

ion of any air pollution control or handling procedure if air from this d 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 If yes, specify capture efficient this room area? Select from the dropdown menu in this column	iency for
the air emitted from this room are the room area? Select (%) from the dropdown	ea
from the dropdown	
menu in this column	
-	

				Natura
(feet/minute)	NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	this column	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point
				-

B-62 Room Air Capture

le le le le le le le le le le le le le l	le te il il il il i
If yes, specify the structure type or approach	If yes, specify the method(s) used to verify the capture efficiency of room air (e.g., Method
If yes, specify the structure type or approach used to capture the room area (e.g., permanent total enclosure)	capture efficiency of room air (e.g., Method
permanent total enclosure)	204)
	· · · · · · · · · · · · · · · · · · ·

B-18				
I draft opening (NDO) 7	(if any)			
Longitude. Specify to the <u>6th</u> decimal point	Cross-sectional area	Height above the	Is air forced out of this NDO? Select from the	Air velocity
the <u>oth</u> decimal point	(square feet)	ground (feet)	dropdown menu in	(reet/minute)
		(*****)	this column	
	!		!	

NDO ID. Enter from permit description, if available. Otherwise, use a unique identifier for each NDO	dropdown menu in	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the <u>6th</u> decimal point

(if any)				
(II ally)				
Cross-sectional area	Height above the	Is air forced out of this	Air velocity	NDO ID. Enter from
(square feet)	ground (feet)	Is air forced out of this NDO? Select from the	(feet/minute)	permit description, if available. Otherwise,
	(reet)	dropdown menu in this column		use a unique identifier
				use a unique identifier for each NDO
	ļ.	ļ.	ļ.	

			B-20		
		Natura	l draft opening (NDO) 9	(if any)	
Type. Select from the dropdown menu in this column If you select "Other (double click and type here)", be sure to	Orientation. Select from the dropdown menu in this column	Latitude. Specify to the 6th decimal point	Longitude. Specify to the <u>6th</u> decimal point	Cross-sectional area (square feet)	
enter your response between the parentheses					
Example: "Other (your NDO)"					
1		1	1	1	

ground (feet)	Is air forced out of this NDO? Select from the dropdown menu in this column	(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)
				(double click and type here)", be sure to enter your response between the parentheses Example: "Other (your NDO)"
	!			

B-21
Natural draft opening (NDO) 10 (if any)

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)
mena in this column				(reet)

Is air forced out of this NDO? Select from the	Air velocity		
NDO? Select from the	(feet/minute)		
dropdown menu 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" Click here to go to

C. EtO Drum and Container Storage

Field #	Data	Instru
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 (,). For example: Compa - 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 dropdov
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 dropdo
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 dropdo

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
Data	Ethylene glycol (EG) tank ID	Material of EG tank	Capacity of EG tank	Throughput 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)
Response				

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

ıction	Response	
company by commas iny 1 - 70%, Company 2		
iny 1 - 70%, Company 2		
wn menu		
wn menu		
wn menu		

D-5	D-6	D	-7	D.
Installation year of EG tank	EG tank		t of EG tank	Installation co
year in which EG tank	Enter the expected lifetime of EG tank (years)	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column
				_
1		1		

siness information (CBI)? Specify in Cell N2 on	CBI
I version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

-	

-8	D-9		D-10	
ost of EG tank	Annual cost of EG tank		Is the EG tank routed to any control device?	
Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD

EIS ID (Auto-populated)

D-11			D-	
APCD 1 for EG tank			APCD 2 for EC	
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)"	flow routed from the tank to this APCD	permit description, if available. Otherwise.	Select from the dropdor column If you select "Other (do here)", be sure to enter between the parenthes Example: "Other (your A	!
				•
				•
				•

12		D-13	D-14	D-15
3 tank (if any)		Material of duct work for EG tank	Total length of duct work for EG tank	Average thickness of duct work for EG tank
uble click and type your response	Enter the <u>average</u> air flow routed from the tank to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work	Enter the <u>total</u> length of duct work (feet)	Enter the <u>average</u> thickness of duct work (inches)

D-16	D-17	D-18	D-19	D-20
Is the cross section of duct work for EG tank circular or rectangular?	Diameter of duct work (<u>For circular duct work</u> <u>only</u>)	Cross-sectional height of duct work (<u>For rectangular duct</u> work only)	Cross-sectional width of duct work (<u>For rectangular duct</u> <u>work only</u>)	Are the dimensions of duct work constant throughout?
Select from the dropdown menu in this column	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

D-	D-21		-22	D-:
(<u>For circular d</u>	of duct work uct work only)	Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional w (<u>For rectangular</u>
Enter the <u>maximum</u> diameter of duct work (feet)		Enter the <u>maximum</u> cross-sectional height of duct work (feet)	Enter the minimum cross-sectional height of duct work (feet)	Enter the <u>maximum</u> cross-sectional width of duct work (feet)
		l		

23	D-24	D-25	D-	26
idth of duct work duct work only)	Installation year of duct work	Lifetime of duct work	Capital cost of duct work for EG tank (estimated or actual)	
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 <u>amount</u> in this column	Specify the dollar <u>year</u> in this column

	·27	D-28		
(estimated	luct work for EG tank d or actual)	Stack ID to which the uncontrolled EG tank vents (For uncontrolled EG tank only)		(<u>For</u>
Enter the dollar amount 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)

D-29		D-30		
Stack parameter uncontrolled EG tank o	only)		ordinates ed EG tank only)	
Enter the <u>temperature</u> at stack outlet (Fahrenheit)	velocity at stack outlet (feet/second)	flow rate for this	Enter the latitude of stack. Specify to the 6th decimal point	Enter the longitude of stack. Specify to the 6th decimal point

D-31
Distance from EG tank outlet to stack (For uncontrolled EG tank only)
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

E. Sterilization Chambers

Table 1. Summary for Sterilizer Chambers

Field #	Data	Resp
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
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)?
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 autopopulated 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
Response				

Table 3. Control Characteristics for Sterilizer Chambers

Field #	E-1	E-51		E-!
Data	Sterilizer unit ID	Is the sterilizer chamber vent (SCV) routed to any control device?		APCD 1 for sterilizer
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 dropdor column If you select "Other (dor here)", be sure to enter between the parenthes Example: "Other (your #
Response				

Table 4. Control Characteristics for Sterilizer Chambers (continued)

Field #	E-1	E-111	E-112	
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?	
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
Response				

Field#	E-134	E-135	
Data	Unit ID of vacuum	Associated sterilizer unit ID(s) and vent(s)	
Dutu	pump	, issociated stermizer drift is (s) drift vericle)	
Instruction	Enter from permit	Specify ID of the sterilizer unit associated with this vacuum pump. If mu	
	description, if	lare serviced by this vacuum pump, list all sterilizer unit IDs and separate	
	available. Otherwise,	that any sterilizer unit ID entered in this field is consistent with your en	
	use a unique identifier for each pump	worksheet. Also specify which vents on the sterilizer unit are routed to example: "SC-1 (SCV, CEV)"	
	lor cach pamp	Champie. 30 1 (30), CLV	
Response			
Кезропас			

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

onse		

E-4	E-5	E-6	E-7	
Does aeration of the sterilized product occur in the same sterilizer chamber?	Is this a single-item chamber?	Volume of sterilizer chamber	How many cycles per year are conducted in sterilizer chamber <u>in</u> <u>total</u> ?	(For combination steril
Select from the dropdown menu in this column (If you select "Yes" for any sterilizer, fill out Table 3 on "Aeration" worksheet)	Select from the dropdown menu in this column	(cubic feet)	the sterilizer chamber	Enter the <u>average</u> temperature of sterilizer chamber when in operation (Fahrenheit)
<u> </u>		l .	l .	

52			E-53
chamber vent (SCV)			APCD 2 for sterilizer chamber vent (SCV) (if any)
wn menu in this uble click and type your response es APCD)"	Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	available. Otherwise,	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)"
_			

E-113			E-1
APCD 1 for cover hood or vent	APCD 1 for cover hood or vent		APCD 2 for cover h
Select from the dropdown menu in this column	Enter the <u>average</u> air flow routed from the	APCD ID. Enter from permit description, if	Select from the dropdov column
If you select "Other (double click and type	cover hood or vent to	available. Otherwise.	If you select "Other (do
here)", be sure to enter your response between the parentheses	this APCD (actual cubic feet per	for each APCD	here)", be sure to enter between the parenthes
Example: "Other (your APCD)"	minute, acfm)	Tor each 7 th eB	Example: "Other (your /
		1	<u> </u>

		E-136				
		Basic information of vacuum pump				
Iltiple sterilizer units	Specify <u>make</u> of pump	Specify model of pump	Specify type of pump. Select from the			
e by commas (,). Ensure tries in Field E-1 of this			dropdown menu in this column			
the vacuum pump. For			If you select "Other (double click and type here)", be sure to enter your response			
the vacuum pump. For			between the parentheses			
			Example: "Other (your pump)"			
			example. Strict (your pamp)			
-						

siness information (CBI)? Specify in Cell N2 on	CBI
I version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

г 0			F 0	
E-8		E-9		
Temperature		Relative humidity		
izers, enter temperature for sterilization mode				
only)				
Enter the maximum	Enter the minimum	Entar the average	Enter the marineum	Entar the minimum
Enter the <u>maximum</u> temperature of	temperature of	Enter the <u>average</u> relative humidity	Enter the <u>maximum</u> relative humidity	Enter the <u>minimum</u> relative humidity
sterilizer chamber	sterilizer chamber	within sterilizer	within sterilizer	within sterilizer
when in operation		chamber when in	chamber when in	chamber when in
(Fahrenheit)	(Fahrenheit)	operation (percent)	operation	operation
(i dili cililote)	(am emicie,	operation (percent)	(percent)	(percent)
			,	" ,
•	•			

		E-54	
		APCD 3 for sterilizer chamber vent (SCV) (if any)	
Enter the <u>average</u> air	APCD ID. Enter from	Select from the dropdown menu in this	Enter the <u>average</u> air
flow routed from the	permit description, if	column	flow routed from the
vent to this APCD (actual cubic feet per	available. Otherwise,	If you select "Other (double click and type here)", be sure to enter your response	vent to this APCD (actual cubic feet per
minute, acfm)	for each APCD	between the parentheses	minute, acfm)
		Example: "Other (your APCD)"	
-			

.14		E-115	E-116	E-117
ood or vent (if any)		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
wn menu in this uble click and type your response es APCD)"	Enter the <u>average</u> air flow routed from the cover hood or vent to this APCD (actual cubic feet per minute, acfm)		Enter the <u>total</u> length of duct work (feet)	Enter the <u>average</u> thickness of duct work (inches)
-				
		l		

E-137	E-138	E-139	E-140
Seal type of vacuum pump	Capacity of vacuum pump	Installation year of vacuum pump	Expected lifetime of the vacuum 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)"	(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)

EIS ID (Auto-populated)

E	-10	E-11		E-12
	ssure	Does the sterilizer chamber have positive pressure cycles?		EtO dose per cycle
Enter the <u>average</u> <u>pressure</u> 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	Enter the <u>average</u> EtO dose per cycle (mg/L)	Enter the <u>maximum</u> EtO dose per cycle (mg/L)

E-55	E-56	E-57	E-58	E-59
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)	Is the cross section of duct work for sterilizer chamber vent (SCV) circular or rectangular?	Diameter of duct work (<u>For circular duct work</u> <u>only</u>)
Specify the material of duct work	Enter the <u>total</u> length of duct work (feet)	Enter the <u>average</u> thickness of duct work (inches)	Select from the dropdown menu in this column	Enter the <u>average</u> diameter of duct work (feet)
L	1	l		l .

E-118	E-119	E-120	E-121	E-122
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 width of duct work (<u>For rectangular duct</u> <u>work only</u>)	Are the dimensions of duct work constant throughout?
Select from the dropdown menu in this column		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

E-:	141	E-142		
Capital cost of	vacuum pump	Annual cost of	vacuum pump	Handlin
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	If you selected "once-th how water is handled a

	E-13					
	Mumb	er of nitrogen washes pe	or cyclo	Nitrogen (
	Numb	er of filtrogen wasnes pe	er Cycle	Niti ogen t		
Enter the <u>minimum</u> EtO dose per cycle (mg/L)	Enter the <u>average</u> number of nitrogen washes per cycle	Enter the <u>maximum</u> number of nitrogen washes per cycle	Enter the <u>minimum</u> number of nitrogen washes per cycle	Enter the <u>average</u> amount of nitrogen used during each cycle (pounds)		

E-60	E-61	E-62	_	63
Cross-sectional height of duct work (<u>For rectangular duct</u> work only)	Cross-sectional width of duct work (<u>For rectangular duct</u> work only)	Are the dimensions of duct work constant throughout?		f duct work uct work only)
Enter the <u>average</u> cross-sectional height of duct work (feet)	cross-sectional width	Select from the dropdown menu in this column	Enter the <u>maximum</u> diameter of duct work (feet)	Enter the minimum diameter of duct work (feet)

	123	E-124		E-1	
	of duct work uct work only)	Cross-sectional height of duct work (For rectangular duct work only)		Cross-sectional w (<u>For rectangular</u>	
Enter the <u>maximum</u> 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 <u>maximum</u> cross-sectional width of duct work (feet)	
	I	i	1	I	

E-143
g and disposal of water for once-through vacuum pump
S
rough" as the type of vacuum pump, provide a brief description about nd disposed
na aisposea

E-14		E-	15	
used for washes during		Annual cost of nitrogen washes		Nun
Enter the <u>maximum</u> 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 <u>year</u> in this column	Enter the <u>average</u> number of air washes per cycle

E-	64	E-	65	E-66
Cross-sectional h (<u>For rectangular</u>	eight of duct work duct work only)	Cross-sectional width of duct work (For rectangular duct work only)		Installation year of duct work
Enter the <u>maximum</u> cross-sectional height of duct work (feet)	cross-sectional height of duct work	Enter the <u>maximum</u> 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

.25	E-126	E-127	E-1	128
idth of duct work duct work only)	Installation year of duct work	Lifetime of duct work	Capital cost of duct work for cover hood o vent (estimated or actual)	
Enter the minimum	Enter the calendar	Enter the expected	Enter the dollar	Specify the dollar <u>year</u>
cross-sectional width of duct work (feet)		lifetime of duct work (years)	amount in this column	in this column

E-16		E-17			
nber of air washes per cycle		Air used for washes during each cycle			
Enter the <u>maximum</u> number of air washes per cycle	Enter the minimum number of air washes per cycle	Enter the <u>average</u> amount of air used during each cycle (pounds)	Enter the <u>maximum</u> amount of air used during each cycle (pounds)	Enter the minimum amount of air used during each cycle (pounds)	

E-67	E-68		E-69		
	Capital cost of duct work for sterilizer chamber vent (SCV) (estimated or actual)				
Enter the expected lifetime of duct work (years)	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	

Enter the dollar would in this column in this colum					
vent (estimated or actual) cover hood or vent vents (For uncontrolled cover hood or vent only) Enter the dollar amount in this column in this column in this column in this column cover hood or vent only) Enter from permit description, if available. Otherwise, use a unique identifier cover hood or vent (For unco (For unco (For unco vent only)) Enter the dollar description, if available. Otherwise, use a unique identifier (feet)			E-130		
amount in this column in this column description, if (feet) diameter (feet) limited description, if description, if diameter (feet) limited li	vent (estima	ted or actual)	cover hood or vent vents (<u>For uncontrolled</u> <u>cover hood or vent</u> <u>only</u>)	(For unco	
	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	description, if available. Otherwise, use a unique identifier	Enter the stack height (feet)	<u>diameter</u>

E-18		E-19	E-	20
	of air washes	Average electricity used per gas wash (nitrogen washes and air washes combined)	Annual cost of electricity for gas was (nitrogen washes and air washes comb s and pined)	
Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	(kWh)	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column

E-70			E-71	
Stack ID to which the uncontrolled sterilizer chamber vent (SCV) vents (For uncontrolled SCV only)	Stack parameter			
Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack <u>height</u> (feet)	<u>diameter</u>	Enter the temperature at stack outlet (Fahrenheit)	Enter the <u>exhaust</u> <u>velocity</u> at stack outlet (feet/second)

E-131			E-	132
Stack parameter Introlled cover hood or vent only)			ordinates ver hood or vent only)	
Enter the <u>temperature</u> at stack outlet (Fahrenheit)	velocity at stack outlet	Enter the <u>volumetric</u> flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the <u>6th</u> decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point
		•		
				_
				_

E-21	F 22	E-23		
	E-22			
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 descript	i
				•
				•
				•
				•
				•
				•
				•
				•

		72	E-72.1	E-73
		ordinates olled SCV only)	Distance from SCV to stack (For uncontrolled SCV only)	Is there a chamber exhaust vent (CEV)?
Enter the <u>volumetric</u> flow rate for this emission source at stack outlet (cubic feet per minute)	stack. Specify to the	Enter the longitude of stack. Specify to the <u>6th</u> decimal point	Enter the distance from the uncontrolled SCV to the stack (feet)	Select from the dropdown menu in this column

E-132.1	E-133
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 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
1	

E-24	E-25	
Leak check procedure(s) for sterilizer chamber	Annual cost of leak checks for sterilizer chamber	
ion of the leak check procedure(s) for sterilizer chamber	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column

E-	·74	E-74.1	E-74.2	E-C
Is there a target EtO reached before ac	concentration that is tivation of the CEV?	Duration of CEV operation in each sterilization cycle	Average EtO concentration during CEV operation	Is an interlock system activation of the CE\ sterilizer door until a se reacl
Select from the dropdown menu in this column	Enter the value if you select "Yes" on the left (ppm)	CEV is in operation for each sterilization cycle (minutes)	concentration over the	

E-26	E-27
Average quantity of leaks identified per year	Repair method/procedure for the leaks identified
Enter average <u>quantity</u> of leaks found per year	Provide a brief description of the repair method/procedure for the leaks identified

75	E-76	E-77	E-	78	
present that prevents / and opening of the et EtO concentration is hed?	Installation year of interlock system	Expected lifetime of interlock system	Capital cost of interlock system		
wn menu in this	interlock system was	Enter the expected lifetime of the interlock system (years)	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	
-					

E-28		E-29		
	for the leaks identified	concentration monitor used within this sterilizer chamber?		
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Select from the dropdown menu in this column	Enter the <u>type</u> of EtO concentration monitor	Enter the manufacturer of EtO concentration monitor

_	70		
E-79		E-80	
Annual cost of i	interlock system	Standards or work practices followed for interlock sy	
Enter the dollar	Specify the dollar year	Provide a brief description of any standards or work practices followed:	
amount in this column	in this column	Provide a brief description of any standards or work practices followed that prevents activation of the CEV until a set concentration is reached	
	1	<u> </u>	

	E-30		
ription of the EtO conce	entration monitor used within this sterilizer chai	nber	
Enter the <u>model</u> of EtO concentration monitor	Specify the <u>method of detection</u> of EtO concentration monitor	Enter the <u>value</u> of detection level of EtO	Specify the <u>unit</u> of detection level of FtO
		concentration monitor	concentration monitor

	E-81		E-82
stem	Is the chamber exhaust vent (CEV) routed to any control device?		APCD 1 for chamber exhaust vent (CEV)
for interlock system	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)"
		1	

E-31	E-32	E-	33	E-:
Installation year of EtO concentration monitor	EtO concentration monitor	Capital cost of the EtO concentration monitor used within this sterilizer chamber		Installation cost of the monitor used within t
Enter the calendar year in which the EtO concentration monitor was installed	lifetime of the EtO	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column
_				

		E-83	
		APCD 2 for chamber exhaust vent (CEV) (if any)	
Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	permit description, if available. Otherwise,	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 <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)
-			

 1	

34		35	E-:	
e EtO concentration his sterilizer chamber	Annual cost of the EtO used within this s	concentration monitor sterilizer chamber	Standards or work practices followed for the sterilizer	
Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Provide a brief description of any standards or v concentration monitor used within the chambe	

	E-84		E-85
	Material of duct work for chamber exhaust vent (CEV)		
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 <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)	Specify the material of duct work

	1	

36	E-37			
EtO concentration monitor used within this chamber	Duration of product dwell time within the chamber at EtO dosing concentration			
vork practices followed for the EtO r	Enter the <u>average</u> duration (hours)	Enter the <u>maximum</u> duration (hours)	Enter the minimum duration (hours)	

E-86	E-87	E-88	E-89	E-90
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?	Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (<u>For rectangular duct</u> work only)
Enter the <u>total</u> length of duct work (feet)	thickness of duct work	Select from the dropdown menu in this column	Enter the <u>average</u> diameter of duct work (feet)	Enter the <u>average</u> cross-sectional height of duct work (feet)
-				

Total duration of time product stays within the sterilizer chamber before it is moved out Enter the average duration duration duration Enter the maximum duration Enter the minimum concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration that EtO is reduced to before meaning the following duration concentration concentr		F 00			5.4
Enter the <u>average</u> duration (hours) Enter the <u>maximum</u> duration duration (hours) Enter the <u>minimum</u> Specify the <u>unit</u> of concentration. Concentration (hours) Enter the <u>average</u> concentration. Select from the dropdown menu in (ppm or % LEL)		E-38			E-:
(hours) (hours) Select from the dropdown menu in (ppm or % LEL)	Total duration of the	me product stays within before it is moved out	the sterilizer chamber :	Concentration that Et	O is reduced to before mo
(hours) (hours) Select from the dropdown menu in (ppm or % LEL)	Enter the <u>average</u>	Enter the maximum	Enter the minimum	Specify the <u>unit</u> of	Enter the <u>average</u>
	duration (hours)	duration (hours)	duration (hours)	Select from the dropdown menu in	concentration that EtO is reduced to
					+

E-91	E-92	E-	93	E-1
Cross-sectional width of duct work (<u>For rectangular duct</u> <u>work only</u>)	Are the dimensions of duct work constant throughout?		f duct work uct work only)	Cross-sectional he (<u>For rectangular</u>
cross-sectional width	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)	Enter the <u>maximum</u> cross-sectional height of duct work (feet)

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

94		95	E-96	E-97		
eight of duct work	Cross-sectional w	idth of duct work	Installation year of duct work	Lifetime of duct work		
duct work only)	(<u>For rectangular</u>	duct work only)	duct work			
Enter the minimum	Enter the maximum	Enter the minimum	Enter the calendar	Enter the expected		
Enter the minimum cross-sectional height	cross-sectional width	cross-sectional width	year in which duct	Enter the expected lifetime of duct work		
of duct work	of duct work	of duct work	work was installed	(years)		
(feet)	(feet)	(feet)				
	l	I .	l .			

E-43	E-	E-44		
Method of water disposal		ed with water disposal		
Provide a brief description about how water is disposed after being used to capture EtO for re-use	Enter the dollar <u>amount</u> in this column	in this column		
	l .			

E-98		E-99		E-100
Capital 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?
Enter the dollar amount in this column	Specify the dollar <u>year</u>	Enter the dollar	Specify the dollar <u>year</u>	Select from the
amount in this column	in this column	amount in this column	in this column	dropdown menu in this column

E-45	E-46	E-47		48
What is the percentage of EtO recovered by this system?	Year in which the EtO recovery system was installed	Expected lifetime of the EtO recovery system		recovery system used ilizer chamber
(percent)		Enter the expected lifetime of the EtO recovery system (years)	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column

E-101	E-102	E-103	E-:	104
If not, was a damper system installed for the purpose of adjusting the flow rate to the control device upon CEV activation?	Year in which the damper system was installed	Expected lifetime of the damper system	Capital cost of the damper system	
Select from the dropdown menu in this column	Enter the calendar year	Enter the expected lifetime of the damper system (years)	Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column

E-	49	E-50		
Installation cost of the EtO recovery system used with this sterilizer chamber		associated with waste disp	recovery system used imber (excluding costs ewater treatment and osal)	
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	
L		1		

E-105			106	E-1
Installation cost of the			e damper system	APCD installed solel controlling emissi
Enter the dollar Sp amount in this column in	ecify the dollar <u>year</u> this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Specify ID of the APCD i controlling CEV emission are involved, list all APC commas (,). Ensure that in this field is consistent elsewhere in this questi
				<u> </u>

.07	E-108			E-109
y for the purpose of ons from the CEV	Stack ID to which the uncontrolled chamber exhaust vent (CEV) vents (For uncontrolled CEV only)			Stack parameter For uncontrolled CEV onl
ns. If multiple APCDs D IDs and separate by any APCD ID entered	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	(feet)	Enter the stack <u>diameter</u> (feet)	Enter the temperature at stack outlet (Fahrenheit)
				_
-				
				_
=				
				
				<u> </u>

 1	1	

Enter the exhaust velocity at stack outlet (cubic feet per minute) Enter the exhaust (countrolled CEV only) Enter the latitude of stack. Specify to the decimal point (cubic feet per minute) Enter the latitude of stack. Specify to the decimal point (cubic feet per minute) Enter the latitude of stack. Specify to the decimal point (cubic feet per minute) Enter the latitude of stack. Specify to the decimal point (cubic feet per minute)	
velocity at stack outletflow rate for this emission source at stack outletstack. Specify to the decimal pointstack. Specify to the decimal pointfrom the uncontrol (EV to the stack (feet))	
	ed
	\dashv
	_
	\dashv
	一
	\dashv
	\dashv
	一
	4
	\dashv
	一

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

F. Aeration

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

Field #	F-1	B-1	F-2	F-3
Data	Aeration unit ID	Room area in which aeration unit is located	Associated EIS release point ID	Type of aeration unit
	Enter from permit description, if available. Otherwise, use a unique identifier for each aeration unit	dropdown menu. Scroll up to see	Enter the EIS release point ID associated with the aeration unit, if any	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	
Data	Sterilizer unit ID	Temperature		
Instruction	This column will be auto-populated based on your entries in the previous fields	temperature of aeration room when in operation	Enter the <u>maximum</u> temperature of aeration room when in operation (Fahrenheit)	Enter the minimum temperature of aeration room when in operation (Fahrenheit)
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 fa any areas where there is a hood to collect the EO

Field #	Data	Instruction
F-47	room/chamber	Provide details on where the sterilized product sterilizer room area following removal from the time the sterilized product sits in the sterilizer resterilized product is moved from the sterilizer reaeration room area

F-48	area	Provide details on where the sterilized and aera after being removed from aeration chamber, lesserilized and aerated product sits after being reroom, and distance the sterilized and aerated pwarehouse area
F-49		Provide details on length of time sterilized and a in the warehouse before being loaded on truck for shipment offsite

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

F-4	F-5		F-6
Does the aeration unit use accelerated aeration?	Characteristics of accelerated aeration	(<u>For aeration cell/cham</u> already have be	isions of aeration cell/ch hber only. Dimensions of en provided on "Room A
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 equipment)"	Enter the <u>height</u> of aeration unit (feet)	Enter the <u>width</u> of aeration unit (feet)

F-	-44	F-45		
Relative humidity		Pressure	Length of time that pro	
ls 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)	Specify pressure condition during aeration process	Enter the <u>average</u> length of time that products are being held in aeration room (hours)	

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

	Response
is placed in the	
chamber, the length of	
oom area, the distance	
oom area to the	

nted product is placed ngth of time the emoved from aeration roduct is moved to	
aerated product is held or other conveyance	

siness information (CBI)? Specify in Cell N2 on	СВІ
Il version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

	F-7 F-			
amber aeration rooms should rea" worksheet)		Temperature		Relative
Enter the <u>length</u> of aeration unit (feet)	Enter the <u>average</u> temperature of aeration room when in operation (Fahrenheit)	temperature of aeration room when in operation	temperature of aeration room when in operation	Is a specific humidity needed for aeration? Select from the dropdown menu in this column

F-46	
oducts are being held ir being transferred	aeration room before
Enter the <u>maximum</u> 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)

ced, (3) distance product is moved, and (4) note

EIS ID (Auto-populated)

8	F-8.1	F-9		F-:	
numidity	Average EtO concentration	Pressure (For aeration cell/chamber only)		Pressur <u>(For aeratior</u>	
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)	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 pre pressure drop is measur device)	
				<u> </u>	
				 	
				 	
				 	
				 	
	1	1	i	I	

10	F-11	F-:	
re drop	Facial velocity	Location and length of time that sterilized pr	
<u>1 room only)</u>	(For aeration room	being placed in the	
<u>-11001111 01111 1/1</u>	only)	being placed in the	
	5 t tl (; t		
ssure drop, or locations based on which red (e.g., farthest point to inlet of control	Enter the facial velocity in aeration	Provide details on where the sterilized product	
red (e.g., farthest point to inlet of control	room	placed in hallway area outside door of aeration product sits in the aeration room area before be	
	(feet per minute, fpm)	product sits in the actuation room area before by	
	(you may choose to fill		
	out either F-10, F-11,		
	or both)		
-			

12		F-13	
oduct is placed in aeration room area before aeration chamber	Length of time that pro	oduct is being held in aei transferred	ration unit before being
chamber), and the length of time the sterilized eing placed in the aeration chamber	length of time that products are being held in aeration room	Enter the <u>maximum</u> 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)

F-14	F-15	F-16		
Are leak checks performed on aeration unit?	Frequency of leak checks for aeration unit	Average length of time to perform a leak check		
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 descripti	

F-17 F-18		10
Leak check procedure(s) for aeration unit	Annual cost of leak checks for aeration unit	
1		
on of the leak check procedure(s) for aeration unit	Enter the dollar amount in this column	Specify the dollar <u>year</u>
	amount in this column	III this column

F-19	F-20
Average quantity of leaks identified per year	Repair method/procedure for leaks identified
year	
Enter average quantity	Provide a brief description of the repair method/procedure for the leaks identified
of leaks found per year	

F-21		F-22		F-S
Average cost per repair for leaks identified		Is aeration room vent (ARV) routed to any control device?		APCD 1 for aeratio
Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	dropdown menu in this column	APCD ID. Enter from permit description, if available. Otherwise, use a unique identifier for each APCD	Select from the dropdov column If you select "Other (doundere)", be sure to enter between the parenthese Example: "Other (your)
L	l		1	

23			F-24	
n room vent (ARV)		APCD 2 for aeration room vent (ARV) (if any)		
, ,			, , , , , , , , , , , , , , , , , , , ,	
wn menu in this	Enter the <u>average</u> air	APCD ID. Enter from	Select from the dropdown menu in this	
WITTHETIU III UIIS	flow routed from the		column	
uble click and type	vent to this APCD	available. Otherwise,	If you select "Other (double click and type	
<u>your response</u>	(actual cubic feet per	use a unique identifier	here)", be sure to enter your response	
<u>es</u> \PCD)"	minute, acfm)	for each APCD	between the parentheses Example: "Other (your APCD)"	
או כטן			Example: Other (your Areb)	
-				

	F-25	F-26	F-27	F-28
	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?
Enter the <u>average</u> air flow routed from the vent to this APCD (actual cubic feet per minute, acfm)		Enter the <u>total</u> 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-(
Diameter of duct work (For circular duct work only)	Cross-sectional height of duct work (<u>For rectangular duct</u> <u>work only</u>)	Cross-sectional width of duct work (<u>For rectangular duct</u> <u>work only</u>)	Are the dimensions of duct work constant throughout?	Diameter o (<u>For circular d</u> ı
Enter the average	Enter the <u>average</u>	Enter the average	Select from the	Enter the maximum
diameter of duct work (feet)	cross-sectional height of duct work (feet)	Enter the <u>average</u> cross-sectional width of duct work (feet)	dropdown menu in this column	Enter the <u>maximum</u> diameter of duct work (feet)

33	F-34		F-35	
f duct work	Cross-sectional h	eight of duct work	Cross-sectional width of duct work	
<u>uct work only</u>)	(<u>For rectangular</u>	duct work only)	(<u>For rectangular</u>	duct work only)
Enter the minimum diameter of duct work	Enter the <u>maximum</u>	Enter the minimum	Enter the <u>maximum</u> cross-sectional width	Enter the <u>minimum</u> cross-sectional width
diameter of duct work	cross-sectional height	cross-sectional height	cross-sectional width	cross-sectional width
(feet)	of duct work	of duct work	of duct work	of duct work
	(feet)	(feet)	(feet)	(feet)

F-36	F-37	F-38		F-C
Installation year of duct work	Lifetime of duct work	Capital cost of duct w vent (ARV) (esti	ork for aeration room mated or actual)	Installation cost of du room vent (ARV) (e
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 <u>year</u> in this column	Enter the dollar amount in this column

39	F-40			F-41
act work for aeration stimated or actual)	Stack ID to which the aeration room vents (ARV) is routed to (For uncontrolled ARV only)		(<u>F</u>	Stack parameter For uncontrolled ARV onl
Specify the dollar <u>year</u> in this column	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	Enter the stack <u>height</u> (feet)	Enter the stack diameter (feet)	Enter the temperature at stack outlet (Fahrenheit)

		F-	42	F-42.1
y)		Stack coo (For uncontro	ordinates illed ARV only)	Distance from ARV to stack (For uncontrolled ARV only)
Enter the <u>exhaust</u> <u>velocity</u> at stack outlet (feet/second)	Enter the <u>volumetric</u> flow rate for this emission source at stack outlet (cubic feet per minute)	Enter the latitude of stack. Specify to the <u>6th</u> decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point	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

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 additi

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

Table 2. Emissions and CEMS

Field #	G-1	G-2	G-
Data	APCD ID	Type of APCD	Peak hourly emis:
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 <u>value</u> of peak hourly emission rate
Response			

_	 	

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

ional stack on "Additional Info" worksheet (Section M)

onal stack on "Additional Info" worksheet (Section M)					
	C	G-4		G-5	
	Description of APCD				
Specify the <u>manufacturer</u> of APCD	Specify the <u>model</u> of APCD	Enter the <u>value</u> of maximum capable volumetric flow of APCD	Specify the <u>unit</u> of maximum capable volumetric flow of APCD	Enter from permit description, if available. Otherwise, use a unique identifier for each stack	

19	G-20		
sion rate of APCD	Is any continuous emissions monitoring system (CEMS) used to measure EtO concentration from the APCD?		De
Specify the <u>unit</u> of peak hourly emission rate	Select from the dropdown menu in this column	Enter the <u>type</u> of CEMS	Enter the manufacturer of CEMS

siness information (CBI)? Specify in Cell N2 on	CBI
I version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

		G-6		
		Stack parameter		
Enter the stack <u>height</u>	Enter the stack	Enter the temperature	Enter the exhaust	Enter the volumetric
feet)	diameter	at stack outlet	velocity at stack outlet (feet/second)	flow rate for this
	(feet)	(Fahrenheit)	(feet/second)	emission source at stack outlet
				Stack outlet
				(cubic feet per minute)
				·
		1		

	G-21		
escription of the CEMS (used to measure EtO concentration from the APG	CD	
Enter the model of	Specify the <u>method</u> of detection of CEMS	Enter the value of	Specify the unit of
CEMS	' ' ===	Enter the <u>value</u> of detection level of	Specify the <u>unit</u> of detection level of
		CEMS	CEMS

EIS ID (Auto-populated)

G	i-7	G-8	G-9	G-
	ordinates	Installation year of APCD	Expected lifetime of APCD	Capital cos
Enter the latitude of stack. Specify to the <u>6th</u> decimal point	Enter the longitude of stack. Specify to the <u>6th</u> decimal point	Enter the calendar year in which APCD was installed	Enter the expected lifetime of APCD (years)	Enter the dollar <u>amount</u> in this column

G-22	G-23	G-	24	G-:
Installation year of CEMS	Expected lifetime of CEMS	concentration	used to measure EtO from the APCD	Installation cost of CEM concentration
Enter the calendar year in which the CEMS was installed		Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Enter the dollar amount in this column

10	G-	11	G-
st of APCD		cost of APCD	Other one-time
Specify the dellar year	Enter the dellar	Specify the dellar year	If any specify other one time sects of ADCD
Specify the dollar <u>year</u> in this column	amount in this column	lin this column	If any, specify other one-time costs of APCD (e.g., programming a data acquisition system)
in this column	m this column	in this column	(e.g., programming a data dequisition system)

25		26	G-:
IS used to measure EtO from the APCD	Annual cost of CEMS concentration	used to measure EtO from the APCD	Standards or work practices followed for CEM! AP
Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Provide a brief description of any standards or v measure EtO concentration from the APCD

12		G-13 G-			
				G-	
e costs of APCD		Annual monitor	ing cost of APCD	Annual repair and routi	
				AP	
Cutoutha total dallau	Cuasify the dellar year	Cutou the adellou	Cuasify the dellar year	Cutou the deller	
Enter the <u>total</u> dollar <u>amount</u> in this column	in this column	Enter the dollar amount in this column	in this column	amount in this column	
amount in this column	iii tiiis colulliii	amount in this column	iii tiiis colulliii	arriourit ili tilis coluilli	
				<u> </u>	
1	I	I	ı	i	

27		G-28
S used to measure EtO concentration from the CD	Engineering or non-regulatory emission test perform	
vork practices followed for the CEMS used to	regulatory emission test performed for each APCD in the last 5 years (mm/dd/yyyy). If	Enter the <u>average</u> dollar <u>amount</u> for each engineering emission test in this column

14	G-15		
ne maintenance cost of	Other annual	costs of APCD	
CD			
Specify the dollar <u>year</u>	Describe other annual costs of APCD	Enter the <u>total</u> dollar <u>amount</u> in this column	Specify the dollar <u>year</u>
in this column		amount in this column	in this column
			I

11 11 1 5	,		
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		

10
See
<u></u>
ıstr
.nc.
tio
ns
'n
"D
oct
Ħ
eni
LS.
8
See instructions in "Documents" worksheet
she
et
, ,

G-16		G-17
Is a balancer/snubber system used to moderate EtO concentration before the gas stream enters the control device (e.g., a water bath that absorbs EtO)?		est performed in the last
Select from the dropdown menu in this column	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 <u>average</u> dollar <u>amount</u> for each performance test in this column

		C 10
5 years (if any)		G-18 How does the APCD handle variability in flow rate and other relev
	Provide a copy of each performance test performed in the last 5 years in its entirety for each APCD	Provide a brief description about how the APCD handles variability in florelevant parameters
	See in:	
	structi	
	ons in	
	"Docu	
	ments	
	See instructions in "Documents" worksheet	
	(sheet	
	Ĵ	

See instructions in "Documents" worksheet		
instructions in "Documents"	Se	
in "Documents"	<u>e</u> :	
in "Documents"	nstr	
in "Documents"	uct	
in "Documents"	ion	
"Documents"	s In	
	ocu	
	me	
	nts	
orksheet		
sheet	ork	
	she	
	et	

vant parameters? ow rate and other

•

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

H. Details of Air Pollution Control Devices

Table 1. Wet Scrubber & Glygen Absorber Unit

Instruction Instruction Instruction This column will be auto-populated based on your entries in the previous fields Response Response	Field #	G-1	H-1	
on your entries in the previous fields			Design and operation specifications	
Response	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 specification scrubber/glygen absorber unit	
	Response			

Table 2. Dry-bed Scrubber

- 1			
	Field #	G-1	H-12

Data	APCD ID	Design and operation specifications
Data	APCDID	Design and operation specifications
Instruction	This column will be	Provide a brief description of the design and key operation specification scrubber
	auto-populated based on your entries in the previous fields	scrubber
	on your entries in the	
	previous fields	
Response		

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

Field #	G-1	H-30
Data	APCD ID	Design and operation specifications
		Provide a brief description of the design and key operation specificatior 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 specification 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 specification
Response		

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

	Н	-2	H	
	Ethylene glycol (EG	generated annually	Ethylene glycol (EG) tank ID(s) to which v	
ns of the wet	Enter the <u>amount</u> in this column	Specify the <u>unit</u> in this column	Specify the EG tank ID each wet scrubber/glyge there are multiple EG tanks involved, <u>list all EG that any EG tank ID entered in this field is consist worksheet</u> , Field D-1	

11.40	11.4.4	
H-13	H-14	

	Type of media/sorbent used	Volume of	U
		media/sorbent	
ns of the dry-bed	Specify the type of media/sorbent used for the dry-bed scrubber	Enter the volume of	Enter the dollar
is of the dry bed	ldry-hed scrubber	media/sorbent used	amount in this column
	ary bed scrabber	for the dry-bed	amount in this column
		scrubber	
		scrubber (cubic feet)	
		(cubic reet)	
-			

	H-31	H-32		
	Type of catalyst	Volume of catalyst		
ns of the catalytic	Specify the type of catalyst used in catalytic oxidizer or combo water balancer/catalytic oxidizer		Enter the unit cost in this column	

	H-51	H-52	H-	53
	Average operating temperature	Operating temperature records for thermal oxidizer from the last calendar year	Annual natural gas usage to maintain the operating temperature	
ns of the thermal	operating temperature of thermal oxidizer (Fahrenheit)	Provide the operating temperature records for thermal oxidizer from the last calendar year	Enter the <u>amount</u> in this column	Specify the <u>unit</u> in this column
		Se		
		See instr		
		<u> </u>		

uc	
uctions	
nei	
"Documents"	
or.	
worksheet	
eet	

	H-62
	Process/APCD monitoring plan for APCD
ns of the 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

siness information (CBI)? Specify in Cell N2 on	СВІ
Il version Cell O2) and paste directly into each cell with The Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

wet scrubber/glygen absorber unit feeds n absorber unit feeds EG to, if applicable, if tank IDs and separate by commas (J. Ensure stent with your entries in "EtO & EG Storage" Provide a brief explanation of how ethylene glycol is disposed (e.g., mul sewer, manufacturer pickup, etc.) sewer, manufacturer pickup, etc.)			
n absorber unit feeds EG to, if applicable, If Provide a brief explanation of how ethylene glycol is disposed (e.g., mu	-3	H-4	
n absorber unit feeds EG to, if applicable, If Provide a brief explanation of how ethylene glycol is disposed (e.g., mu	vet scrubber/glygen absorber unit feeds	Ethylene glycol (EG) disposal	
n absorber unit feeds EG to, if applicable. If tank IDs and separate by commas (). Ensure stent with your entries in "ETO & EG Storage" Provide a brief explanation of how ethylene glycol is disposed (e.g., mure sewer, manufacturer pickup, etc.) Provide a brief explanation of how ethylene glycol is disposed (e.g., mure sewer, manufacturer pickup, etc.)		, , , , ,	
n absorber unit feeds EG to, if applicable. If tank IDs and separate by commas (.). Ensure stent with your entries in "EtO & EG Storage" Provide a brief explanation of how ethylene glycol is disposed (e.g., muisewer, manufacturer pickup, etc.) sewer, manufacturer pickup, etc.)			
n absorber unit feeds EG to, if applicable. If tank IDs and separate by commas (.). Ensure stent with your entries in "EtO & EG Storage" Provide a brief explanation of how ethylene glycol is disposed (e.g., multiple sewer, manufacturer pickup, etc.) sewer, manufacturer pickup, etc.)			
n absorber unit feeds EG to, if applicable. If tank IDs and separate by commas (1, Ensure stent with your entries in "EtO & EG Storage" sewer, manufacturer pickup, etc.) Provide a brief explanation of how ethylene glycol is disposed (e.g., multank IDs and separate by commas (1, Ensure stent with your entries in "EtO & EG Storage" sewer, manufacturer pickup, etc.)			
tank IDs and separate by commas (.). Ensure stent with your entries in "EtO & EG Storage" sewer, manufacturer pickup, etc.) sewer, manufacturer pickup, etc.)	n absorber unit feeds EG to, if applicable. If	Provide a brief explanation of how ethylene glycol is disposed (e.g., mui	
stent with your entries in "EtO & EG Storage."	tank IDs and separate by commas (,). Ensure	sewer, manufacturer pickup, etc.)	
	stent with your entries in "EtO & EG Storage"		
	-		
	-		

H-14.1	H-15	H-16	H-1

nit cost of media/sorbe		Installation year of current media/sorbent		Initial Capital cost
Specify the <u>unit of</u> <u>measurement</u> in this column. For example: \$ per cubic feet, \$ per ton, etc.	Specify the dollar <u>year</u> in this column	current media/sorbent	lifetime of the	Enter the dollar <u>amount</u> in this column

H-32.1	H-33	H-34	H-3	
Unit cost of catalyst	Installation year of current catalyst	Expected lifetime of catalyst	Initial Capital o	
Specify the <u>unit of</u> measurement in this column. For example: \$ per cubic feet, \$ per ton, etc.	year in which the current catalyst was	Enter the expected lifetime of the catalyst used (years)	Enter the dollar amount in this column	

ļ		

H-	54	H-55	
the operating	l gas used to maintain temperature	Process/APCD monitoring plan for thermal oxidize	
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Provide a brief description of the process/APCD monitoring plan for the Specify if measurements of the gas stream are part of these plans	

	H-63				
		Parameter 1 mo	nitored for APCD		
Name of Parameter 1	Set value of Parameter 1	<u>Unit</u> of Parameter 1	Monitoring frequency	Explain any <u>corrective a</u> readings outside the lim	
			or Parameter 1	readings outside the iiii	



	Н	-5	H-	
	Annual cost of ethyle	ne glycol (EG) disposal	Process/APCD monitoring plan for	
	,	0, , , ,		
nicipal sewer, industrial	Enter the dollar	Specify the dollar <u>year</u>	Provide a brief description of the process/APCD absorber unit. Specify if measurements of the g	
	amount in this column	in this column	absorber unit. Specify if measurements of the g	
			plans	
-				
_				
-				

/ A	11.47.0	11.47	
D 1	H-16 /	H-1/	
.0.1	П-10.2	11 1/	

of media/sorbent			Can the media/sorbent be regenerated?	
Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	this column	How frequently is the media/sorbent regenerated, if applicable?

4.1	H-3	34.2	H-35	H-3
cost of catalyst	Annual Replacemo	ent cost of catalyst	Operating temperature of catalyst bed	Cost of catalys
Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Enter the operating temperature of catalyst bed (Fahrenheit)	Enter the dollar amount in this column

Ī	1	1	

			H-	·56	
er				ed for thermal oxidizer	
thermal oxidizer.	Name of Parameter 1	<u>Set value</u> of Parameter 1	<u>Unit</u> of Parameter 1	Monitoring frequency of Parameter 1	

				1 / 4
				1-64
			Parameter 2 monit	tored for APCD (if any)
ctions taken for	Name of Parameter 2	Set value of Parameter	<u>Unit</u> of Parameter 2	Monitoring frequency of Parameter 2
nit(s) for Parameter 1		2		of Parameter 2
		I	l	I

-6			H-
wet scrubber/glygen absorber unit	Parameter 1 monitored for we		
monitoring plan for the wet scrubber/glygon	Name of Parameter 1	Cat value of Daramatar	Unit of Daramatar 1
monitoring plan for the wet scrubber/glygen as stream or sorbent material are part of these	Name of Parameter 1	1	Offic of Parameter 1
as stream of sorbene material are part of these		-	
-			

Media/sorbent renegeration		
What method is used to regenerate the media/sorbent, if applicable?	How many times is the	To what removal
what <u>method</u> is used to regenerate the media/sorbent, if applicable:	How many times is the media/sorbent	lefficiency is the
	regenerated prior to	efficiency is the media/sorbent
	regenerated prior to disposal, if applicable?	restored after
		regeneration? (percent)
		(percent)
	!	!

5.1	H-35.2	H-35.3	H-36	
t replacement	Frequency of catalyst replacement	Average volume of catalyst replacement		isage to maintain the emperature
in this column	average the catalyst is			Specify the <u>unit</u> in this column

			H-:
		Pa	arameter 2 monitored fc
Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	Set value of Parameter	<u>Unit</u> of Parameter 2
readings outside the limit(s) for Parameter 1		2	

			H-
	Parameter 3 monito		
		la	
Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3	Unit of Parameter 3

-7			
: scrubber/glygen absor	ber unit	Paramet	
Monitoring frequency	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	<u>Set value</u> of Parameter
of Parameter 1	readings outside the limit(s) for Parameter 1		2

H-10 H-20			
11-17 11-20	H	H-19	

Average cost of a medi ev	ia/sorbent regeneration ent	Sorbent disposal	Annual cost of s
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Specify how sorbert is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)	Enter the dollar amount in this column

H-	37	H-	38	H-39
	as used by the catalytic ter balancer/catalytic lizer	oxidizer or combo water balancer/catalytic oxidizer		Can the catalyst be regenerated?
Enter the dollar amount in this column	Specify the dollar <u>year</u> in this column	Enter the dollar <u>amount</u> in this column	in this column	Select from the dropdown menu in this column

	•	

57			
or thermal oxidizer (if an	ny)		Pa
Monitoring frequency of Parameter 2	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

65			
red for APCD (if any)			
Monitoring frequency	Explain any corrective actions taken for	Name of Parameter 4	Set value of Parameter
of Parameter 3	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 3		4
]	1

H			
2 monitored for wet so	rubber/glygen absorber	unit (if any)	
<u>Unit</u> of Parameter 2	Monitoring frequency	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 2	Name of Parameter 3
	of Parameter 2	readings outside the limit(s) for Parameter 2	

21	⊔ 22 I	
/ I	Π-//	
	'' ==	

orbent disposal	Is the media/sorb	ent activity monitored or tested in any way?	Is the media/sorbei				
Specify the dollar <u>year</u> in this column	Select from the dropdown menu in this column	If yes, provide a brief description in this column	Select from the dropdov If you select "No (double response between the response in the respons				
			 				
			 				
	!	!	'				
		1: 12					
		H-40 Catalyst renegeration					
How frequently is the catalyst regenerated, if applicable?	What <u>method</u> is used t	to regenerate the catalyst, if applicable?	How many times is the catalyst regenerated				
applicable?			prior to disposal, if applicable?				

-

	50		
	-58		
arameter 3 monitored for	or thermal oxidizer (if an	ıy)	
<u>Unit</u> of Parameter 3	Monitoring frequency	Explain any corrective actions taken for	Name of Parameter 4
	of Parameter 3	readings outside the limit(s) for Parameter 3	

Н	H-(
Parameter 4 monito	ored for APCD (if any)		Monitoring records for calenda
<u>Unit</u> of Parameter 4	Monitoring frequency of Parameter 4	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 4	Provide all monitoring r calendar year
			אטועאונפנר אווא מרווחוים ווי מרמווופוויס אחועאונפנר
			1

H-9							
Dorons star			unit (if any)				
Parameter	Parameter 3 monitored for wet scrubber/glygen absorber unit (if any)						
<u>Set value</u> of Parameter	Unit of Parameter 3	Monitoring frequency	Explain any corrective actions taken for				
3	OTTIC OF FAIRMINE CO. O	of Parameter 3	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 3				

H-23	H-24

nt change out done based on manufacturer suggestion?	Process/APCD monitoring plan for dry-bed scrubb
wn menu in this column e click and type here)", be sure to enter your parentheses lanation)"	Provide a brief description of the process/APCD monitoring plan for the Specify if measurements of the gas stream or sorbent material are part

H-	41	H-42
Average cost of a catal	yst regeneration event	Catalyst disposal
Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> in this column	Specify how catalyst is disposed (e.g., hazardous waste landfill, MSW landfill, etc.)

1	

H-59						
Parameter 4	I monitored for thern	nal oxidizer (if an	y)			
Set value of Parameter Unit of Pa	rameter 4 Monito	oring frequency	Explain any <u>corrective actions</u> taken for			
4	of Para	ameter 4	readings outside the limit(s) for Parameter 4			

_	

7	_
h	/
v	,

or APCD from the last ar year

ecords from the last

H-10							
	Parameter 4 monitored for wet scrubber/glygen absorber unit (if any)						
Name of Parameter 4	<u>Set value</u> of Parameter 4	<u>Unit</u> of Parameter 4	Monitoring frequency of Parameter 4	Explain any <u>corrective a</u> readings outside the lim			

H-25

er	Parameter 1 monitored for dry-bed scrubber					
dry-bed scrubber. of these plans	Name of Parameter 1	<u>Set value</u> of Parameter 1	<u>Unit</u> of Parameter 1	Monitoring frequency of Parameter 1		

H-43	H-44
Annual cost of catalyst disposal	Process/APCD monitoring plan for catalytic oxidizer or combo wate oxidizer
Enter the dollar amount in this column Specify the dollar year in this column	Provide a brief description of the process/APCD monitoring plan for the combo water balancer/catalytic oxidizer. Specify if measurements of th sorbent material are part of these plans

H-60 Monitoring records for thermal oxidizer from the last calendar year Provide all monitoring records from the last calendar year See instr
Provide all monitoring records from the last calendar year
calendar year
S

	"uctions in "Documents" worksheet	

	H-11
	Monitoring records for wet scrubber/glygen absorber unit from the last calendar year
ctions taken for nit(s) for Parameter 4	Provide all monitoring records from the last calendar year
	See in
	struction
	See instructions in "Documents" worksheet
	cuments
	"worksh
	neet

	Parameter 2 monitored fo			
Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 1	Name of Parameter 2	<u>Set value</u> of Parameter 2	<u>Unit</u> of Parameter 2	

			Н	-45	
r balancer/catalytic		Parame	ter 1 monitored for cata	alytic oxidizer & balancer	,
catalytic oxidizer or e gas stream or	<u>Name</u> of Parameter 1	<u>Set value</u> of Parameter 1	<u>Unit</u> of Parameter 1	Monitoring frequency of Parameter 1	

	I	

r dry-bed scrubber (if any)			Pa
Monitoring frequency of Parameter 2	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 2	<u>Name</u> of Parameter 3	<u>Set value</u> of Parameter 3

			H-	
·/abator		Parameter	2 monitored for catalytic	
Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 1	<u>Name</u> of Parameter 2	<u>Set value</u> of Parameter 2	<u>Unit</u> of Parameter 2	

H-27		

<u>Unit</u> of Parameter 3	Monitoring frequency of Parameter 3	Explain any <u>corrective</u> readings outside the lir	actions taken for mit(s) for Parameter 3	Name of Parameter 4
6 oxidizer & balancer/a	bator (if any)			Parameter :
Monitoring frequency of Parameter 2	Explain any <u>corrective</u> readings outside the lin	actions taken for mit(s) for Parameter 2	Name of Parameter 3	Set value of Parameter 3

rameter 3 monitored for dry-bed scrubber (if any)

-	

Parameter 4 monitored for dry-bed scrubber (if any)					
<u>Set value</u> of Parameter 4	<u>Unit</u> of Parameter 4	Monitoring frequency of Parameter 4	Explain any <u>corrective actions</u> taken for readings outside the limit(s) for Parameter 4		

H-			
3 monitored for catalytic			
			Name of Parameter 4
	of Parameter 3	readings outside the limit(s) for Parameter 3	

Monitoring records for dry-bed scrubber from the last calendar year			
Provide all monitoring records from the last calendar year			
See instr			
uctions in "I			
Documents'			
See instructions in "Documents" worksheet			

H-48 Parameter 4 monitored for catalytic oxidizer & balancer/abator (if any)					
raidifficer i montored for educiyate oxidizer & balancer/abator (ii dily)					
<u>Set value</u> of Parameter <u>Unit</u> of Parameter	4 Monitoring frequency	Explain any <u>corrective actions</u> taken for			
4	of Parameter 4	readings outside the limit(s) for Parameter 4			

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

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

I. EtO Monitoring

Table 1. Personal Monitoring (Badges) for EtO

No (default)

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 belov

Field #	I-1	I-2	I-2
Data	Unique ID	Date	Room area(s) involved and time spent or
	or documentation, if available. Otherwise,	Enter date of the personal monitoring event (mm/dd/yyyy)	Specify ID(s) of the room area(s) involved in this provide an estimate of the percentage of time s there are multiple room areas involved, separat Area 1 (40%), Room Area 2 (25%), Room Area 3 Ensure that any room area ID entered in this fie 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
	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	
	noted in I-16 and I-17	

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

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

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

	I-3
is personal (badge) monitoring event	Description of work conditions
nis personai (badge) monitoring event	Description of work conditions
ersonal (badge) monitoring event, and	Provide a brief description of the work conditions of facility during each
nt in each room area in parentheses "()". If your entries by commas (,). Example: "Room	event
your entries by commas (,). Example: "Room	
35%)". is consistent with your entries in "Room	
is consistent with your entries in Room	
	<u> </u>

101		
I-9.1	1-9.2	
Sampling method of room area monitoring	Level of detection (LOD) as required by th sampling method	
Specify the sampling method used for the room area monitoring	Enter the <u>value</u> of LOD in this column Enter the <u>unit</u> of LOD in this column	

Response		

See instructions in "Documents" worksheet

siness information (CBI)? Specify in Cell N2 on	CBI
I version Cell O2) and paste directly into each cell with he Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

	I-3.1		3.2	
	Sampling method of personal (badge) monitoring	Level of detection (LOD) required by the sampling method		
personal monitoring	Specify the sampling method used for the personal (badge) monitoring	Enter the <u>value</u> of Detection Level in this column	Enter the <u>units</u> of Detection Level in this column	

	I-10		I-11	I-1
EtO concentration of room area where EtO is used or emitted		How many measurement points are there within the room area?	What is the frequency point within th	
Enter the <u>average</u> EtO concentration (ppmv)	Enter the <u>maximum</u> EtO concentration (ppmv)	Enter the minimum EtO concentration (ppmv)	Enter the amount of measurement points within the room area	Specify the frequency o point within the room a
		-		

EIS ID (Auto-populated)	

	I-4		I-5
Monitoring result		Monitoring result flag	
Enter the <u>average</u> concentration monitored (ppm)	Enter the <u>maximum</u> concentration monitored (ppm)	Enter the minimum concentration monitored (ppm)	Specify any action level, error, or flag of monitoring result

12	I-	13	
of monitoring at each ne room area?	Instru	ment 1	
f monitoring at each rea	Specify the instrument used to monitor the room area	Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument

I-6	I-7	
Averaging periods	Instrument 1	
Specify any averaging periods for each personal monitoring event	Specify the instrument used during each personal monitoring event	Enter the <u>value</u> of detection level of instrument

l-	-14		I-15
Instrume	nt 2 (if any)		Action levels and SOPs for room area monitoring
Specify the instrument used to monitor the room area	Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument	Provide documents specifying action levels and SOPs for room area monitoring
]
			_
			-
			-
	1		-
			1
	1		S
			See instructions in "Documents" worksheet
			nsti
			ruct
			ion
			s in
			"Dc
			ocur
			mer
	<u> </u>		ts"
			- ≪ o
			rks
			hee
	+		-
			-
	1		-
	+		†
			1
	†		†
	1		1
			1

	I-8		
	Instrument 2 (if any)		
Specify the <u>unit</u> of detection level of instrument	Specify the instrument used during each personal monitoring event	Enter the <u>value</u> of detection level of instrument	Specify the <u>unit</u> of detection level of instrument

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

J. Wastewater

Field #	J-1	J.	-2	J-3
Data	Daily average wastewater flow rate for EtO commercial sterilization activities at the facility		s from wastewater at e last 5 years	Average EtO concentration in wastewater when it leaves the vacuum pump or liquid-gas separator
Instruction	(gallons/day)	Enter <u>calendar year</u> in this column	Enter the <u>value</u> of annual EtO emissions in this column (pounds)	(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 t

Field #	K-1	K-2	K-3
Data	How many unique cycles are run at this facility?	How many unique cycles have been revalidated thus far?	How many unique cycles does the facility still have left to re- validate
Instruction	Enter the amount of unique cycles	Enter the amount of unique cycles	Enter the amount of unique cycles
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 cham
L-2	How is EtO handled during malfunction events of APCD (vented, held within chamber/room, etc 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 n
L-6	Is the facility operating at full capacity or can current capacity increase to accommodate higher not operating at full capacity, provide estimate of feasible increase in capacity as a percentage (
L-7	Provide any process and instrumentation diagrams (P&ID) that are not included in other docum

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

Field #	L-8			
Data	Offsite locations sterilized produc	ts are sent	Are any of the products standalone non-colocat building that is not cur product is stored for a	
	are moved offsite, where are they sent to (e.g., standalone non-colocated warehouse,		Select from the dropdor	
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)"
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 bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

"Additional Info"

J-4	J-5	J-	
Average EtO concentration in wastewater when collected in a holding tank or basin	Wastewater disposal or treatment for EtO commercial sterilization activities	Annual average cost of treatment for EtO con activ	
	Briefly specify how wastewater is disposed of or treated for EtO commercial sterilization activities	Enter the dollar <u>amount</u> in this column	

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

mough K-4 und K-7 through K-13					
K	- 4	K-5			
How long will it take to complete re-validation of these cycles?		Cost of validating unique cycles			
Enter the <u>value</u> in this column	Specify the <u>unit</u> in this column	Provide information on the cost to validate a sterilization cycle, includin R&D engineers, operators, technicians, etc. to complete the sterilizatior the reports and file with the FDA; (2) costs for laboratory analyses; and length of time from start to finish (weeks) required to complete validaticycle			

	Instruction		
ber/room, etc)?			
c)? Also provide			
		See instru	
	Select from the dropdown menu		
neasures			
volumes of product? If (%) of current output			
ents requested		See instru	

lized Products

L-9		
sterilized in your facility shipped to a separate ed warehouse, distribution center, or enclosed rently subject to §63.360 and where sterilized time period longer than 24 hours prior to re- shipment?		ted warehouse, distribution of the control of the c
wn menu in Cell F56 below	Name of the standalone non-colocated warehouse, distribution center, or enclosed building	Street address verified I (USPS). Do <u>not</u> include F

			1-	12	
L-13 Details of alternative sterilization method					
Percentage of this product that may be sterilized with the alternative method (%)	Time needed to switch from EtO to the alternative (months)	Capital cost to switch from EtO to the alternative. Enter the dollar <u>amount</u> in this column		Annual cost to switch from EtO to the alternative. Enter the dollar amount in this column	

siness information (CBI)? Specify in Cell N2 on	СВІ
I version Cell O2) and paste directly into each cell with the Sample CBI Cell (Cell O2) before saving the	Sample CBI Cell (above)

6	J-7	J-8
wastewater disposal or mmercial sterilization rities	Are there any other processes within the facility that generate EtO-laden wastewater?	Other processes generating EtO-laden wastewater within the facility
Specify the dollar <u>year</u> in this column		List all other processes generating EtO-laden wastewater within the facility. Enter one process per each row

	., ,	., -	***
	K-6	K-7	K-8
	What is the current average EtO dose among the products?	What is the target average EtO dose?	What is the anticipated average percent change in <u>number of nitrogen washes</u> upon completion of the re-validations?
ng: (1) hours of time for n cycle runs, compile (3) information on the ion for a sterilization	(mg/L)	(mg/L)	(percent)

Response	
	7
ctions in "Documents" worksheet	
	\exists
ctions in "Documents" worksheet	

1.40					
L-10 on center, or enclosed building that is not currently subject to §63.360 and where sterilized e period longer than 24 hours prior to re-shipment				How long are the proc facility generally h standalone non-co distribution center, or in Field L-10	
oy U.S. Postal Service 2.O. box in this field	City	State. Select from the dropdown menu in this column	Zip code verified by U.S. Postal Service (USPS)	(Days)	

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

EIS ID (Auto-populated)

J-9	J-10	J-1	
Daily average wastewater flow rate for each process other than EtO commercial sterilization	Wastewater disposal or treatment for each process other than EtO commercial sterilization	Annual cost of wast treatment for each pr commercial	
		Enter the dollar amount in this column	

K-9	K-10	K-	
What is the anticipated average percent change in <u>number of air washes</u> upon completion of the re-validations?	What is the anticipated average percent change in time spent on gas washing upon completion of the re-validations?	What is the anticipa change in <u>dwell period</u> of the re-v	
(percent)	(percent)	(percent)	

lucts sterilized in your eld in the separate ocated warehouse, enclosed building listed on the left?

11	J-12
tewater disposal or rocess other than EtO sterilization	Annual average wastewater flow for <u>all</u> <u>operations</u> at the facility (includes both EtO commercial sterilization and other activities)
Specify the dollar <u>year</u> in this column	(gallons/year)

11	K-12		13
ted average percent time upon completion alidations?	What is the anticipated average percent change in <u>aeration time</u> upon completion of the re-validations?	What are the anticipate from reduc	ted annual cost savings ed EtO use?
	(percent)	Enter the dollar <u>amount</u> in this column	Specify the dollar <u>year</u> 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 bek

l	

Does any information entered on this worksheet contain confidential bu the right → **Be sure to shade in red all cells with real CBI data in the CB** After creating the **non-CBI version**, select and copy the Sample CBI Cell (real CBI data. **Make sure all cells that contained CBI look the same as t** non-CBI version of your response

ow unless you may use any of the supplements to the Section 114 ICR. For each entr	
	Response

Siness information (CBI)? Specify in Cell N2 on Il version
(Cell O2) and paste directly into each cell with the Sample CBI Cell (Cell O2) before saving the

Sample CBI Cell (above)

mber to which your data refers

EIS ID (Auto-populated)

-	
-	
-	
-	
-	
-	

·

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

N. Documents

The documents requested throughout this questionnaire and the associated field numbers and descriptions are sun

Specify in Column G and Column H of the table below the total number of CBI and non-CBI documents of each cates

Option 1 (recommended for submitting more than 12 documents in any category): Submit your documents as stanc Option 2: Add your documents to the table below as attachments. Please attach only 1 document to each cell (maxi Instructions on how to attach documents are provided in Cell O10 on the right.

If you choose Option 2, make sure that the CBI version of your response contains all the CBI and non-CBI documents

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)	performed in the last 5 years <u>in its entirety</u> for each APCD
G-28	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 bu the right → **Be sure to shade in red all cells with CBI files in the CBI ver**: After creating the non-CBI version, remove all the CBI documents and pr **change the total number of CBI vs. non-CBI documents entered in Colu**

"Additional Info"

nmarized in this table below. Please refer to Sections V of the Instructions Document and properly name your docume gory that you intend to submit to the EPA. Do not change these quantities between the CBI and non-CBI version of you lalone PDF files via email (non-CBI documents only) or a media (e.g., thumb drive, CD or DVD) following Section VI of the mum of 12 documents in each category). If your documents attached here contain CBI, shade in red all cells containing s, while the non-CBI version contains only the non-CBI documents you would like to submit to the EPA.

Total Quantity of CBI Documents	Total Quantity of non- CBI Documents		
_			

-		
-		

-		

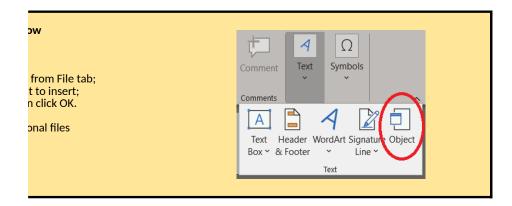
siness information (CBI)? Specify in **Cell N2** on sion
reserve only the non-CBI documents. **Do not**rmn **G and Column H**

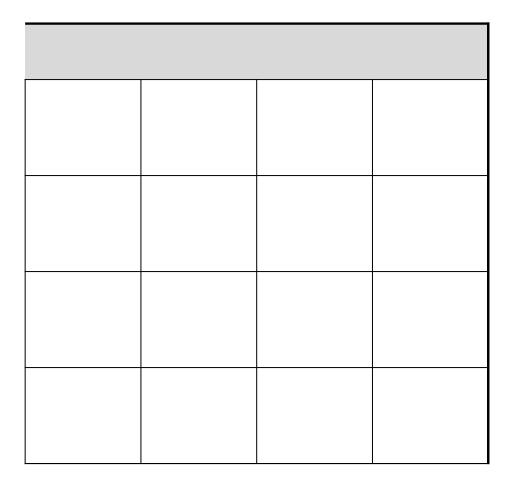
ents first before proceeding.	Steps to attach documents to the table bek
ir response. e Instructions Document; CBI documents, and select "Yes" in Cell N2 of this worksheet.	 (1) Click on the field to attach files; (2) Go to the Insert tab → Text, click Object; (3) In the Object dialog box, click the Create (4) Click Browse, and select the file you wan (5) Select the Display as Icon check box, thei Repeat the above steps to attach any additional contents.

Documents			

		1
l	l	

EIS ID (Auto-populated)





	_	1

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

Click here to go to "Introduction"

Acknowledgmer	nt of CBI Handling	
Before certifying and submitting this questionnaire, please make sure that you have selected "Yes" in Cell N2 on all		
Refer to Section V in the Instructions Document when creating the <u>non-CBI version</u> of your response. Confirm that <u>a</u> <u>"Documents" worksheet</u> before saving the non-CBI version.		
Please submit both	the CBI and non-CBI version of your response to the EPA. The non-CBI version will be made available.	
By che	cking this box, I acknowledge that I have read, understand, and agree to the instructions and pro	
(<u>Check</u>	this box only if this is the non-CBI version of your response) By checking this box, I confirm that	
Certification by R	eporter	
Complete the fields belo questions, if any, on the	w for the person who completes the questionnaire and who is available for follow-up 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	

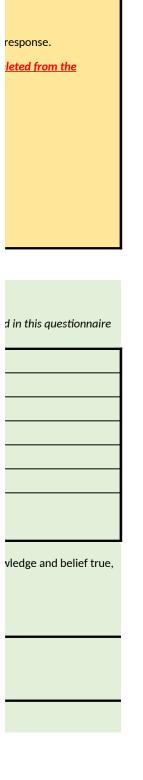
Certification by Professional Engineer
Complete the fields below for the professional engineer (PE) who certifies the information provided in this questionnaire

·	
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

he worksheets where CBI data were entered,	and shaded in red all cells with real CBI data in the CBI version of your i
l cells that contained CBI before look the sam	e as the Sample CBI Cell (Cell O2), and any attached CBI document is de
able to the public.	
ocedure of handling CBI data and documents su	bmitted within this response.
all CBI data and documents have been remove	d from this response.
C4°C4° l F	Care Planta Danas and L
Certification by F	acility Personnel
Please complete the fie (may be the owner or le	lds below for the facility personnel who certifies the information provided egal 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 know accurate, and complete.
	Signature
	Date

Certification by Certified Industrial Hygienist			
Complete the fields belo questionnaire	ow for the certified industrial hygienist (CIH) who certifies the information		
Name			
Title			
Organization			
Email			
Phone			
Fax			
General comments			
	I certify that the statements and information are to the best of my knov accurate, and complete.		
	Signature		

Date



n provided in this
vledge and belief true,