Ethylene Oxide (EtO) Commercial Sterilization CAA Section 114 Information Collection Request (ICR) Supplement 1 - Section B, Table 3

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 c reporting and recordkeeping burden for this collection of information is estimated to be proximately 108 hours per respondent burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Dire 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 this Supplement

This is a supplement to the Section 114 ICR. You may use this supplement if more space is needed to provide the data r

Please follow the instructions below if you prefer to use this supplement:

(1) Fill out the Facility Details section in this supplement so that data entered here can be linked to your main question (2) Validate your entries in Field B-1 of this supplement based on the main questionnaire. This means that <u>every entry i</u> worksheet, Table 1, of the main questionnaire;

(3) In the main questionnaire - Leave the original table BLANK in order to avoid duplicates. Be sure to select "Yes" in Ce

This supplement 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 in: Worksheets and data fields shaded in gold contain instructions and supporting information that help facility with this que Data fields shaded in gray indicate that these either do not need to be filled out or will be automatically filled out basec 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, sho V of the Instructions Document to create the non-CBI version of your response. 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 ector, 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

requested in Section B (Room Area), Table 3 of the main questionnaire.

naire upon submission; <u>n Field B-1 of this supplement should be found in the same field (Field B-1) in "Room Area"</u>

Il F92 above the original table, indicating that this supplement is used.

structions u<mark>estionnaire</mark> I 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

Ethylene Oxide (EtO) Commercial Sterilization CAA Section 114 Information Collection Request (ICR) Supplement 1 - Section B, Table 3

A. Facility Details

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

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

Table 3. Leak Checks of Components in EtO Service

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

Field #	B-1	B-22	B-23
Data	Room area ID for all rooms and areas where EtO is used or emitted	Are leak checks performed in the room area?	Component type
Instruction	Ensure that all entries in this column can be found in the main questionnaire, "Room Area" worksheet, Table 1, Field B-1. Please double check before submission	Select from the dropdown menu in this column	Select from the dropdown menu in this column <u>If you select "Other (double click and type here)", be sure to enter your response between the parentheses</u> Example: "Other (your component)"
Response			

Does any information entered on this worksheet contain confidential bu the right \rightarrow **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

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)

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

B-24	B-25	B-26	B-27
Total component count	What is the percentage of components that are included in regular leak checks?	Frequency of leak checks	Average length of time to perform leak checks
Specify the total number of component of this type	Specify the percentage of components that are included in regular leak checks (percent)	Specify how often leak checks are performed	Enter average length of time to perform leak checks per component type, per inspection (hours)

siness information (CBI)? Specify in Cell N2 on	СВІ
N 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
Phone number
Provide a contact phone number at the facility

В-28		
Instrument and standard method for leak checks		
Briefly describe the instrument and standard method used for leak checks	Describe the leak check	

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EIS ID (Auto-populated)

B-29	B-30	
Leak check procedure	Average cost per inspection	
procedure for each room area. Specifically, provide any action levels	Enter the dollar Specify the dollar <u>yea</u> <u>amount</u> in this column in this column	

D 01	D 00
B-31	B-32
Average percentage of leaking components identified	Definition of leak
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

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B-33		
Applicable state/local regulations	R	
Specify any state/local regulations applicable to your facility for leak checks	Provide a brief descripti	
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B-34	B-35	
Repair method/procedure for the leaks identified	Average cost per repair for leaks identified	
ion of the repair method/procedure for the leaks identified	Enter the dollar <u>amount</u> in this column in this column	

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-	-36		B-37	
Are there any specialty components that are not readily available on site and that need to be ordered in the event of a component replacement?		Are	there any other impediments that would preven	
Select from the dropdown menu in this column	How long does it take, on average, for the facility to receive the components? (days) (if you select "Yes" on the left)	Select from the dropdown menu in this column	List the impediments that would prevent imme (<u>if you select "Yes" on the left</u>)	

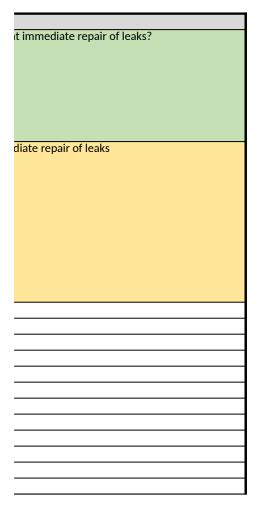
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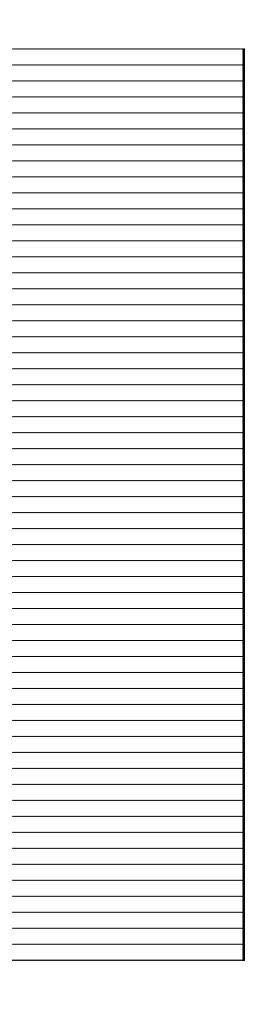
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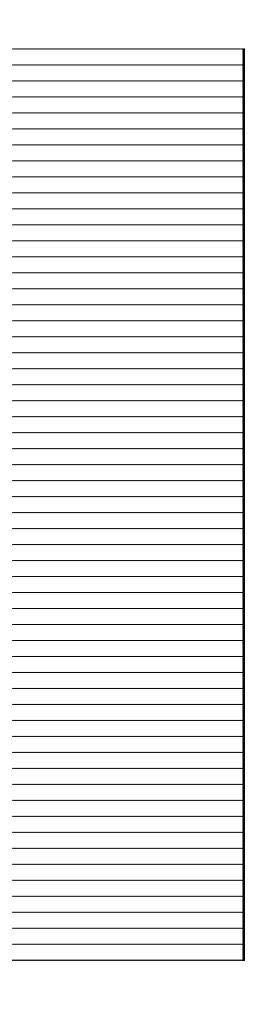
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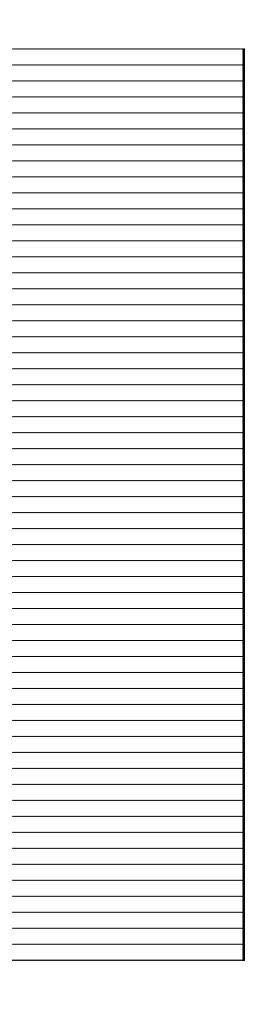
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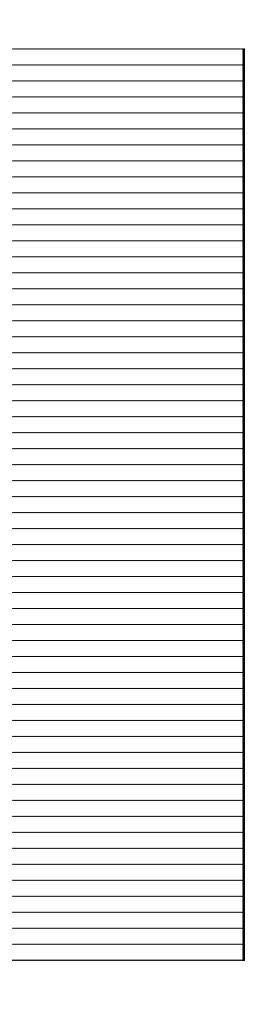
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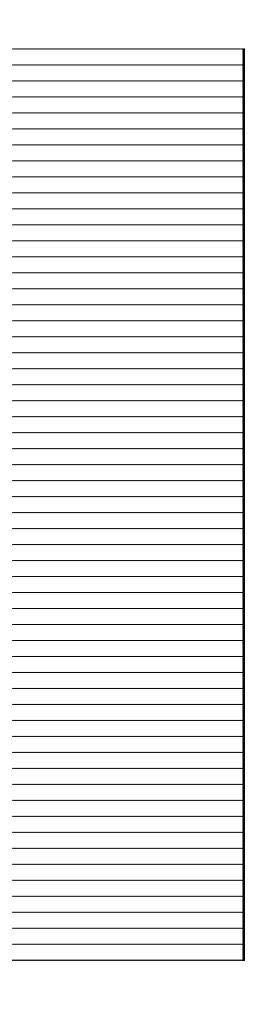


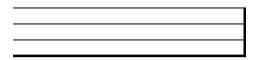












Ethylene Oxide (EtO) Commercial Sterilization CAA Section 114 Information Collection Request (ICR)

Click here to go to "Introduction"

Acknowledgment of CBI Handling	
Before certifying and submitting this questionnaire, please make su	re that you have <u>selected "Yes" in Cell N2 on all</u>
Refer to Section V in the Instructions Document when creating the <u>r</u> <u>"Documents" worksheet</u> before saving the non-CBI version.	on-CBI version of your response. Confirm that <u>c</u>
Please submit both the CBI and non-CBI version of your response to	the EPA. The non-CBI version will be made avai
By checking this box, I acknowledge that I have read, u	nderstand, and agree to the instructions and pre
(Check this box only if this is the non-CBI version of you	<u>ir response</u>) By checking this box, I confirm that

Certification by Reporter

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

Name	
Title	
Organization	
Email	
Phone	
Fax	
General comments	
	I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.
	Signature
	Date

Certification by Professional Engineer

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

Name				
Title				
Organization				
Email				
Phone				
Fax				
General comments				
	I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete.			
Signature				
Date				

the worksheets where CBI data were entered, and shaded in red all cells with real CBI data in the CBI version of your Ill cells that contained CBI before look the same as the Sample CBI Cell (Cell O2), and any attached CBI document is de

lable to the public.

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

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

Certification by Facility Personnel

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

Name		
Title		
Organization		
Email		
Phone		
Fax		
General comments		
	I certify that the statements and information are to the best of my know accurate, and complete.	
Signature		
	Date	

Certification by Certified Industrial Hygienist

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

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			

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