**SUPPORTING STATEMENT**
**FOR PUBLIC COMMENT**

**EPA ICR No. 2623.01**

# INFORMATION COLLECTION EFFORT FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION FACILITIES

Sector Policies and Programs Division
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

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**SUPPORTING STATEMENT**
**INFORMATION COLLECTION EFFORT FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION FACILITIES**

**Part A of the Supporting Statement**

**1. Identification of the Information Collection**

*1(a) Title of the Information Collection*

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

*1(b) Short Characterization*

This information collection is being conducted by the U.S. Environmental Protection Agency's (EPA's) Office of Air and Radiation (OAR) pursuant to section 114 of the Clean Air Act, as amended ("CAA" or "the Act"), to inform an upcoming rule reviewing the national emissions standards for hazardous air pollutants (NESHAP) for ethylene oxide (EtO) commercial sterilization aimed at reducing emissions and updating the standards to reflect developments in practices, processes, and control technologies as required by CAA section 112(d)(6) . Section 114(a) of the CAA states, in pertinent part:

> For the purpose...(iii) carrying out any provision of this Chapter...(1) the Administrator may require any person who owns or operates any emission source...to-...(D) sample such emissions (in accordance with such procedures or methods, at such locations, at such intervals, during such periods and in such manner as the Administrator shall prescribe); (E) keep records on control equipment parameters, production variables or other indirect data when direct monitoring of emissions is impractical...(G) provide such other information as the Administrator may reasonably require...

The non-confidential information submitted in response to this information collection request will be made available to the public.

This is a one-time information collection. The NESHAP for EtO Commercial Sterilization and Fumigation Operations were finalized in December 1994 (59 FR 62585) at 40 CFR part 63, subpart O. The EPA completed a residual risk and technology review for the

NESHAP in 2006 and concluded, at that time, that no revisions to the standards were necessary (71 FR 17712, April 7, 2006).

In 2016, the EPA released its updated Integrated Risk Information System (IRIS) unit risk estimate (URE) for EtO, which indicated that cancer risks from EtO emissions were significantly higher than previously understood. Subsequently, the National Air Toxics Assessment (NATA) released in August 2018 identified EtO emissions as an important risk driver in several areas across the country.

In light of the IRIS URE update for EtO and the findings of the recent NATA, the EPA has been working to gather more information related to the emissions of EtO. The EPA specifically identified the EtO commercial sterilization facilities as a source contributing to these risks. Therefore, since 2019, the EPA has conducted meetings and has been in consultation with EtO trade associations, air pollution control device (APCD) manufacturers, industry representatives, community representatives, and state and local government agencies. The EPA has reviewed operating permits and conducted independent research on this sector's emissions and operating practices. The EPA also issued an Advance Notice of Proposed Rulemaking (ANPRM) and an initial section 114 questionnaire requesting facility-specific data on process controls and operational practices that may reduce the amount of EtO released into the ambient air. The EPA published the ANPRM on December 12, 2019 (84 FR 67889), with the 60-day public comment period ending on February 10, 2020. In December 2019, the EPA issued the questionnaire via email and U.S. mail to 9 companies. The questionnaire and instructions were posted to the EPA webpage[1] where they were accessed by companies. Companies were required to provide electronic responses within 60 days (*i.e.*, by February 6, 2020). Company responses to the initial questionnaire have been compiled and organized so that the EPA can better understand the source category.

While these data gathering efforts have been successful in identifying potential process controls and operational practices that may reduce the amount of EtO released into the ambient air, there are still several important information gaps that should be filled prior to evaluating regulatory options for any final rulemaking. Therefore, the EPA is only issuing this ICR to 61 facilities which together with the 9 companies that already responded will allow all EtO commercial sterilization facilities in the U.S. to be represented, as opposed to a survey of only

[1] https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities

some of the sources in the category. This ICR will not include any of the facilities that previously submitted a response to the December 2019 questionnaire. The data collected through this ICR will enable the EPA to have a more complete understanding of emissions, emissions sources, processes, and control technologies in use at EtO commercial sterilization facilities nationwide, providing the needed foundation for a rulemaking.

This ICR will use the same electronic questionnaire and format, with the addition of several tables and minor revisions to the instructions and questions, and it will be posted to the same EPA webpage as the December 2019 questionnaire. The current instructions and questionnaire for this ICR are included as Attachment 1 to this supporting statement. The required respondents will be emailed their section 114 letters with instructions on how to respond. Responses are required to be submitted 60 days after receipt of the section 114 request letters.

## 2. Need for and Use of the Collection

*2(a) Need/Authority for the Collection*

The NESHAP for EtO Commercial Sterilization and Fumigation Operations were finalized in December 1994 (59 FR 62585) at 40 CFR part 63, subpart O. The NESHAP establishes emission standards for both major and area sources that use at least 1 ton of EtO in sterilization or fumigation operations in each 12-month period. The standards require existing and new major sources to control emissions to the level achievable by the maximum achievable control technology (MACT) and require existing and new area sources to control emissions using generally available control technology (GACT). The current standards address EtO emissions originating at the sterilization chamber vent (SCV) and the aeration room vent (ARV). To fulfill its requirements under sections 112(d) and 112(f) of the CAA, the EPA completed a residual risk and technology review (RTR) for the NESHAP in 2006 and concluded, at that time, that no revisions to the standards were necessary (71 FR 17712, April 7, 2006). An ICR was not conducted for the 2006 RTR.

As described in section 1(b) of this supporting statement, in 2016 the EPA updated the IRIS URE for EtO. Using the new EtO IRIS URE, the 2014 NATA report (released in 2018) indicated that risks from EtO emissions are higher than previously understood. As a result, the EPA has implemented a data gathering initiative for sources of EtO including EtO commercial

sterilization facilities. As part of their data gathering initiative, the EPA has been in consultation with industry, trade organizations, APCD manufacturers, community groups, and state and local government agencies and has been conducting research into existing source permits, permit applications, and available control technologies. In addition to these efforts, an ANPRM was also issued requesting comment from stakeholders regarding various issues including the risk modeling file and EtO annual usage, control of fugitive emissions, CEV control and safety considerations, other point source control options, and types of sterilization facilities including small business considerations. Alongside the ANPRM, the EPA also completed a CAA section 114 questionnaire in December 2019 that was distributed to 9 companies engaged in EtO commercial sterilization.

Under the authority of section 114(a), the EPA is sending this ICR to the EtO commercial sterilization industry, though responses will not be required for facilities that completed the December 2019 questionnaire. This ICR will serve several purposes.

First, the most recent sector-level data were collected by the EPA over 25 years ago for use in the development of the original NESHAP. This information is outdated, and this ICR in conjunction with the December 2019 questionnaire will be used to update the sector-level data.

Next, section 112(d)(6) of the CAA requires the EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes, and control technologies. The section 112(d)(6) technology review is required to recur at least every 8 years. A technology review is due for the EtO Commercial Sterilization NESHAP as the last one was completed in 2006.

Finally, the overarching goal of these information collection efforts will be to identify practices and technological advances that will result in mitigation of ambient air emissions. In reviewing the December 2019 questionnaire responses, the EPA found that each EtO commercial sterilization facility’s equipment, equipment configuration, processes, and pace of technological advancement is unique, necessitating the collection of additional data to have a complete understanding of the sector-level emissions and mitigation techniques. The data collected through this ICR in conjunction with the December 2019 questionnaire will provide the EPA an updated, comprehensive, and consistent dataset. This dataset will allow the EPA to identify mitigation techniques that could inform the future review and revision of the standards. These

mitigation actions may target primary point emissions sources including the SCV and ARV, and/or they may address emissions sources that currently do not have standards in the NESHAP.

*2(b) Use/Users of the Data*

As mentioned above, this ICR in conjunction with the December 2019 questionnaire will provide the EPA with an updated, comprehensive, and consistent dataset. The dataset will include current lists of emission sources including those that are not currently subject to requirements in the EtO Commercial Sterilization NESHAP, current EtO emissions monitoring practices, current APCD configurations and associated efficiencies, current emission reduction strategies for the sector, and cost information. This dataset can then be analyzed by the EPA to identify best practices and emission mitigation opportunities that could be used to inform future rulemakings. The data will also help the EPA to estimate the potential costs of various emissions control technologies and practices. This information could inform upcoming reviews to address EPA's obligations under section 112(d)(6) of the CAA and/or amend the NESHAP as necessary to mitigate risk from EtO emissions.

The non-confidential information collected with this ICR will also be available to the public, including industry trade groups that may find it useful for their ongoing data gathering efforts, analyses, and publications. In addition, such trade groups may wish to use the data collected to review the EPA's potential future regulatory options. Non-confidential business information (CBI) gathered in this ICR could also be helpful for states and locals to encourage voluntary emission reduction strategies.

**3. Non-duplication, Consultations, and Other Collection Criteria**

*3(a) Non-duplication*

The EPA recognizes that a small fraction of the information requested in the information collection effort may already be included in the submittals made by individual companies, pursuant to state and national emissions inventories, operating permits applications, initial notification forms, and compliance reports. As part of its data gathering initiative, the EPA has independently searched for and requested such information from state environmental agencies and EPA regions. Much of the available data has been reviewed by the EPA. While these available data have provided some information, particularly for emission sources regulated by the NESHAP, they do not typically provide information for emissions sources not subject to the federal standards. Additionally, in the EPA's review of permits and compliance reporting, it was

noted that there is variation in state and local level requirements, including the format of such data, resulting in variation of available data. Such variation in the level of detail of permits and compliance reports means that it is extremely time consuming for the EPA to extract the level of process detail needed for regulatory analyses from existing documents and that data gaps will remain even after data from existing documents are compiled. Information collected directly from EtO commercial sterilization facilities will provide the most timely and complete current dataset with the greatest practical utility for the purposes of performing data analyses.

*3(b) Public Notice Required Prior to ICR Submission to OMB*

This ICR is being submitted to the Office of Management and Budget (OMB) as required by the Paperwork Reduction Act of 1995 (PRA) and the subsequent rule issued by the OMB on August 29, 1995 (60 FR 44978). Public comments were previously requested via the *Federal Register* (85 FR 35931) on June 12, 2020, during a 60-day comment period. The ICR being submitted to the OMB includes revisions to address the public comment received during that review period.

*3(c) Consultations*

The EPA has been in ongoing consultation with the affected industry regarding our data gathering efforts to better understand existing source emissions and control technologies. The industry was also consulted during the development and deployment of the December 2019 questionnaire. As described, essentially the same questionnaire instructions and format that were distributed in December 2019 will be used for this ICR questionnaire, with addition of several tables and minor revisions to the instructions and questions.

*3(d) Effects of Less Frequent Collection*

This ICR will require the owner/operator of each EtO commercial sterilization facility that did not receive the December 2019 questionnaire to complete an electronic questionnaire regarding general facility information, room areas, EtO and ethylene glycol (EG) storage, sterilizer chambers, aeration equipment, APCD, existing EtO monitoring practices, other miscellaneous items associated with EtO commercial sterilization operations, stand-alone warehouses, and information on alternatives to EtO. The questionnaire will also require facilities to submit electronic copies (e.g., PDF, Excel) of their facility diagrams, process flow diagrams, air quality operating permits, air quality permit applications, startup, shutdown and malfunction

(SSM) plans, annual emissions calculations, performance and engineering test results, monitoring records and standard operating procedures (SOPs), EtO residual study results, and process and instrumentation diagrams (P&ID). The ICR is a one-time effort, thus the EPA could not consider less frequent collection.

*3(e) General Guidelines*

This ICR will adhere to the guidelines for Federal data requestors, as provided at 5 CFR 1320.5.

*3(f) Confidentiality*

Respondents will be required to respond under the authority of CAA section 114. If a respondent believes that disclosure of certain information requested would compromise a trade secret, it should be clearly identified as such in accordance with the ICR questionnaire instructions and will be treated as confidential until and unless it is determined in accordance with established EPA procedure as set forth in 40 CFR Part 2 not to be entitled to confidential treatment. All information submitted to the EPA for which a claim of confidentiality is made will be safeguarded according to the EPA policies set forth in Title 40, Chapter 1, Part 2, Subpart B–Confidentiality of Business Information (see 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 28, 1978; 43 FR 42251, September 28, 1978; 44 FR 17674, March 23, 1979, 50 FR 51661, Dec. 18, 1985, 58 FR 461, Jan. 5, 1993, 76 FR 30817, May 26, 2011; 76 FR 64015, Oct. 17, 2011). Any information subsequently determined to constitute a trade secret will be protected under 18 U.S.C. 1905. If no claim of confidentiality accompanies the information when it is received by the EPA, it may be made available to the public without further notice (40 CFR 2.203, September 1, 1976). Because CAA section 114(c) exempts emission data from claims of confidentiality, the emission data provided may be made available to the public. Therefore, emissions data should not be marked confidential. A definition of what the EPA considers emissions data is provided in 40 CFR 2.301(a)(2)(i).

*3(g) Sensitive questions*

This section is not applicable because this ICR will not involve matter of a sensitive nature.

## 4. The Respondents and the Information Requested

*4(a) Respondents/NAICS Codes.*

Respondents affected by this action are owners/operators of facilities that are major or area sources of HAP that use EtO in sterilization or fumigation operations. The North American Industry Classification System (NAICS) codes for respondents affected by the information collection include 339112 for Surgical and Medical Instrument Manufacturing, 339113 for Surgical Appliance and Supplies Manufacturing, 325412 for Pharmaceutical Preparation Manufacturing, 311942 for Spice and Extract Manufacturing, 311423 for Dried and Dehydrated Food Manufacturing, and 561910 for Packaging and Labeling Services. Respondents do not include hospitals, doctor offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals. Beehive fumigators are also excluded. The EPA has determined the list of facilities subject to the EtO Commercial Sterilization NESHAP in consultation with the EPA regional offices and the Food and Drug Administration (FDA). As described previously, EPA already received responses from 9 companies to the December 2019 questionnaire. Thus, only the remaining 61 facilities will be required to respond to this ICR questionnaire.

*4(b) Information Collected*

(i) *Data Items*. As noted in section 1(b), the same format used in the December 2019 questionnaire will be used for this ICR questionnaire, with addition of three tables and minor revisions to the instructions and questions. Documents for the December 2019 questionnaire are currently available on the EPA webpage: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities. The questionnaire requires respondents to provide general facility information, room areas, EtO and EG storage, sterilizer chambers, aeration equipment, APCD, existing EtO monitoring practices, other miscellaneous items associated with EtO commercial sterilization operations, stand-alone warehouses, and information on alternatives to EtO. The questionnaire also requires respondents to provide applicable attachments including facility diagrams, process flow diagrams, air quality operating permits, SSM plans, annual emissions calculations, performance and engineering test results, monitoring records and SOPs, EtO residual study results, and P&ID. The questionnaire is to be completed based on existing company records.

*(ii) Respondent Activities.* The activities a respondent must undertake to fulfill the requirements of the information collection are presented in Attachment 2. These include i) reading instructions; ii) providing information on each affected source through electronic questionnaire including providing applicable attachments within the questionnaire; and iii) submitting information to the EPA electronically.

## 5. The Information Collected – Agency Activities, Collection Methodology, and Information Management

*5(a) Agency Activities*

A list of activities required of the EPA is provided in Attachment 3. These include i) answering respondent questions; ii) reviewing and analyzing responses; and iii) assessing requests for confidentiality. It should be noted that there are minimal costs associated with the development of the questionnaire and no costs for the EPA webpage as these were incurred in the December 2019 questionnaire effort.

*5(b) Collection Methodology and Management*

In collecting and analyzing the information associated with this ICR, the EPA will use personal computers and applicable spreadsheet and database software. To ensure uniformity in the format of the requested data and, thus, increase the ease of database entry, standardized questions and Microsoft Excel© spreadsheet forms will be distributed to respondents. The Microsoft Excel© spreadsheet forms used to collect information have been programmed with drop-down menus to pre-populate certain emission unit identification fields to reduce common respondent transcription errors that can impede database functionality. The EPA will ensure the accuracy and completeness of the collected information by reviewing each submittal. The EPA may place follow-up calls or send emails to facilities should questions remain after reviewing all materials submitted. Following QA of each submittal, the spreadsheet information from each facility will be uploaded into a Microsoft Access© database for further analysis.

*5(c) Small Entity Flexibility*

All respondents required to comply with the EtO Commercial Sterilization ICR will be subject to the same requirements. The EPA expects that some respondents will be small entities. The goal in issuing the same questionnaire to all respondents, regardless of their status as small entities, is to ensure consistency in the data collected. By gathering sufficient information on small entities, the EPA will be better positioned to identify potential avenues to reduce impacts

on small businesses in potential rulemakings for the sector. The EPA has opted to use an electronic format for the questionnaire, which allows some automation in the form and response fields, to reduce the burden and improve the data accuracy from all respondents, including small entities.

*5(d) Collection Schedule*

The EPA anticipates it will issue the CAA section 114 letters in December 2020. These CAA section 114 letters would require respondents to complete and submit the questionnaire within 60 days of receipt.

## 6. Estimating the Burden and Cost of the Collection

*6(a) Estimating Respondent Burden*

The data collection activities a respondent must undertake to fulfill the requirements of the information collection are presented in Attachment 2. As shown in Attachment 2, data collection activities of the ICR questionnaire include i) reading instructions; ii) providing information on each affected source through the electronic questionnaire and providing applicable attachments requested in the questionnaire; and iii) submitting information to the EPA through electronic questionnaire instrument. The respondent burden for this ICR questionnaire was estimated using the responses from the December 2019 questionnaire. The EPA used the December 2019 questionnaire responses to determine the average number of key emissions sources per respondent (e.g., room areas, sterilizer chambers, aeration equipment, etc.). The EPA also tallied the related number of questions for each emission source. The EPA used these values to estimate the average number of total expected responses by emission source per respondent for this ICR questionnaire. We note that the number of questions was used rather than the number of responses received by the December 2019 respondents in the burden estimate because some questions may not have been answered if they were not applicable due to specific equipment configuration. Table 1 shows the average number of key emission units, the corresponding ICR questionnaire worksheet name, and the number of questions for each emissions source. As an example, we estimate that the expected number of responses in Table 1 of the Room Area worksheet to be 66 for the average of 6 room areas reported by the December 2019 questionnaire respondents and the 11 related Room Area questions. It should be noted that there are tables in the questionnaire that are not related to multiple pieces of equipment such as parent company information (Facility Details worksheet, Table 2. Parent Company Information)

or EtO drum and container storage (EtO & EG Storage worksheet; C. EtO Drum and Container Storage section). For these tables, the number of anticipated responses for this ICR questionnaire were assumed to be equal to the average number of responses received in the December 2019 questionnaire. The count of total anticipated responses was then multiplied by the amount of time expected to be needed to gather the information and enter the data into the questionnaire (an average of approximately 2 minutes per response). Additionally, each December 2019 questionnaire respondent had an average of 10 attachments that are estimated to take 1 hour each to locate, scan, and attach to the survey. For the three additional tables included in the questionnaire in response to public comments, we estimated the average number of responses based on the anticipated number of stand-alone warehouses and the anticipated number of alternatives to EtO sterilization in use at each facility, along with the number of questions. The respondent burden in hours is shown in Attachment 2 for each worksheet of the ICR questionnaire.

**Table 1.** Average Count of Key Equipment and ICR Questions in Facility Responses to December 2019 Questionnaire

| WORKSHEET NAME | TABLE NAME | AVERAGE NO. OF UNITS REPORTED | | NO. OF QUESTIONS |
|---|---|---|---|---|
| | | COUNT | UOM | |
| Facility Details | Table 4. Facility Buildings | 2 | Buildings | 10 |
| Room Area | Table 1. Characteristics of Room Areas | 6 | Room Areas | 11 |
| Room Area | Table 2. Natural Draft Openings (NDO) | 2 | NDOs | 10 |
| Room Area | Table 3. Leak Checks of Components in EtO Service | 6 | Checks | 17 |
| Room Area | Table 4. Room Area Controls | 8 | Room Area Controls | 27 |
| EtO & EG Storage | D. Ethylene Glycol (EG) Tanks | 1 | Tanks | 31 |
| Sterilizer Chambers | Table 2. Sterilizer Chamber Operation and Monitoring Characteristics | 7 | Sterilizer Chambers | 51 |
| Sterilizer Chambers | Table 3. Control Characteristics for Sterilizer Chambers | 6 | Controls for Sterilizer Chambers | 64 |
| Sterilizer Chambers | Table 5. Vacuum Pumps | 6 | Pumps | 10 |
| Aeration | Table 1. Aeration that Occurs in Separate Unit (Aeration Room & Aeration Cell/Chamber) | 5 | Aeration Room & Cell/Chamber | 45 |
| Aeration | Table 2. Aeration that Occurs within Sterilizer Chamber | 2 | Aeration within Sterilizer Chamber | 4 |
| APCD Summary | Table 1. APCD Characteristics | 4 | APCDs | 16 |
| APCD Details | Table 1. Wet Scrubber & Glygen Absorber Unit | 1 | Wet Scrubber & Glygen Absorber Units | 11 |
| APCD Details | Table 3. Catalytic Oxidizer & Balancer/Abator | 1 | Catalytic Oxidzer & Balancer/Abator | 26 |
| EtO Monitoring | Table 1. Personal Monitoring (Badges) for EtO | 44 | Personal Monitors | 11 |
| EtO Monitoring | Table 2. Room Area Monitoring for EtO | 4 | Room Area Monitors | 9 |
| Miscellaneous | K. Unique Cycles and EtO Reduction | 1 | Unique Cycle and EtO Reduction | 13 |
| Additional Info | N/A | 9 | Additional Information (rows of data) | 3 |
| Attachments | N/A | 10 | Attachments | N/A |

*6(b) Estimating Respondent Costs*

Attachment 2 also presents the estimated costs for the required data collection activities. The basis for the i) labor cost estimate and the ii) capital and operations (overhead) cost estimates follow. Labor rates and associated costs are based on Bureau of Labor Statistics data.

*(i) Estimating Labor Costs.* Attachment 2 presents the estimated costs for the required recordkeeping and reporting activities. Labor rates were based on May 2019 raw labor rates for the Medical Equipment and Supplies Manufacturing Sector (NAICS 339100), loaded using an overhead factor of 110 percent, consistent with other ICRs. The resulting loaded hourly rates in 2019 dollars are $149.88 for management personnel, $93.66 for engineering personnel, and $43.64 for clerical personnel. These values were taken from the Bureau of Labor Statistics Occupational Employment Statistics Survey Web site, https://www.bls.gov/oes/current/naics4_339100.htm#11-0000, and reflect the latest values available (accessed April 2020).

*(ii) Estimating Operating and Maintenance (O&M) Costs.* Costs for mailing questionnaire responses to the EPA including digital media (CD, DVD, or flash drive) and postage are estimated at $920 for the source category. This is only required for facilities claiming data as CBI. We estimate that 90 percent of respondents will make a claim of CBI and need to mail their responses.

*(iii) Estimating Capital/Start-up Costs.* We do not anticipate any capital costs.

*(iv) Annualizing Capital Costs.* We do not anticipate any capital costs so there are no annualized capital costs.

*6(c) Estimating Agency Burden and Costs*

The costs the Federal Government would incur are presented in Attachment 3. The EPA labor rates are from the Office of Personnel Management (OPM) 2019 General Schedule which excludes locality rates of pay. These rates can be obtained from Salary Table 2019-GS, available on the OPM website at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/#url=2019. The government employee labor rates in 2019 dollars are $17.42 per hour for clerical (GS-7, Step 1), $36.75 for technical (GS-13, Step 1), and $51.08 for managerial (GS-15, Step 1). These rates were increased by 60 percent to include fringe benefits and overhead. The fully

burdened wage rates used to represent Agency labor costs are $27.87 for clerical at, $58.80 for technical, and $81.73 for managerial.

*6(d) Estimating the Respondent Universe and Total Burden and Costs*

The respondent universe will represent 61 facilities. Owners and operators of all 61 of these facilities will be required to complete some portion of the electronic questionnaire. As described in section 6(a) of this supporting statement, the respondent burden was estimated using the average number of responses received from the December 2019 questionnaire respondents, plus estimates for the tables included in response to public comments. The average number of responses per respondent was applied to the count of 61 facilities to estimate the burden of this ICR questionnaire. An estimate of the amount of time required to prepare a response was applied to the count of facilities to estimate the amount of burden. The labor rates described in section 6(c) were applied to the burden to estimate the total costs for respondents.

*6(e) Bottom Line Burden Hours and Costs Tables*

*(i) Respondent tally*. The bottom-line industry burden hours and costs, presented in Attachment 2, are calculated by summing the person-hours column and by summing the cost column. The burden and cost to the industry for 61 respondents is 6,573 hours and $604,027, which includes O&M costs of $920 for digital media (CD, DVD, or flash drive) and postage to mail in questionnaire responses containing CBI to the EPA. The costs presented in this section are in 2019 dollars.

*(ii) Agency tally.* The bottom line Agency burden and cost, presented in Attachment 3 is calculated in the same manner as the industry burden and cost. The estimated burden and cost for 61 respondents is 1,596 hours and $92,579, which includes $1,440 in O&M costs for computer storage of data received. The costs presented in this section are in 2019 dollars.

*(iii) The complex collection*. This ICR is a simple collection; therefore, this section does not apply.

*(iv) Variations in the annual bottom line*. This section does not apply as this is a one-time collection.

*6(f) Reasons for Change in Burden*

This is the initial estimation of burden for this information collection; therefore, this section does not apply.

*6(g) Burden Statement*

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

The total cost burden for the EtO Commercial Sterilization information collection request is estimated to be 6,573 hours and $604,027. This ICR does not include any requirements that would cause the respondents to incur either capital or start-up costs. O&M costs of $920 are estimated for digital media (CD, DVD, or flash drive) and postage to mail in questionnaire responses containing CBI to the EPA.

To comment on the EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, the EPA has established a docket for this ICR under Docket ID No. EPA-HQ-OAR-2019-0178, which is available for online viewing at http://www.regulations.gov. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov/ or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at https://www.epa.gov/dockets.

An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the

public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include EPA Docket ID No. EPA-HQ-OAR-2019-0178 in any correspondence.

## INFORMATION COLLECTION EFFORT FOR ETHYLENE OXIDE COMMERCIAL STERILIZATION FACILITIES

**Part B of the Supporting Statement**

This part is not applicable because statistical methods are not used in data collection associated with the questionnaire.

## Attachment 1.

## Questionnaire Content[2]

The electronic questionnaire may be found in separate files accompanying this supporting statement, including the following:

| File name | Description |
|---|---|
| *EtO_114ICR_InstructionsDoc_2020.docx* | This is the questionnaire instruction document. This file provides instructions for completing and submitting the questionnaire (including confidential and non-confidential responses). |
| *EtO_114ICR_Main_2020.xlsx* | This multi-tabbed spreadsheet file is the main portion of the questionnaire. |
| *EtO_114ICR_Sup1_2020.xlsx* | This multi-tabbed spreadsheet file provides additional rows for completing Section B, Table 3 of the questionnaire, if needed. |
| *EtO_114ICR_Sup2_2020.xlsx* | This multi-tabbed spreadsheet file provides additional rows for completing Section B, Table 4 of the questionnaire, if needed. |
| *EtO_114ICR_Sup3_2020.xlsx* | This multi-tabbed spreadsheet file provides additional rows for completing Section I, Table 1 of the questionnaire, if needed. |

[2] Following publication of the second notice for this ICR in the Federal Register, the most current version of the ICR documents will be maintained for public review in Docket ID No. EPA-HQ-OAR-2019-0178.

# Attachment 2.
# Industry Burden and Costs

| Respondent Activity | (A) Hours per Occurrence | (B) Occurrences/ Respondent/Year | (C) Hours/ Respondent/ Year (A x B) | (D) Respondents/ Year[1] | (E) Technical Hours/Year (C x D) | (F) Managerial Hours/Year (E x 0.05) | (G) Clerical Hours/Year (E x 0.10) | (H) Cost/ Year[2] |
|---|---|---|---|---|---|---|---|---|
| 1. APPLICATIONS (Not Applicable) | | | | | | | | |
| 2. SURVEY AND STUDIES (Not Applicable) | | | | | | | | |
| 3. ACQUISITION, INSTALLATION, AND UTILIZATION OF TECHNOLOGY AND SYSTEMS (Not Applicable) | | | | | | | | |
| 4. REPORT REQUIREMENTS | | | | | | | | |
| A. Read Instructions | | | | | | | | |
| EtO Commercial Sterilization facilities | 4 | 1 | 4 | 61 | 244 | 12 | 24.4 | $25,746 |
| B. Required Activities | | | | | | | | |
| i. Complete and submit survey spreadsheet tabs, as follows: | | | | | | | | |
| EtO Commercial Sterilization facilities | | | | | | | | |
| Facility Details | 4.5 | 1 | 4.5 | 61 | 275 | 14 | 27.45 | $28,965 |
| Room Area | 13.5 | 1 | 13.5 | 61 | 824 | 41 | 82.35 | $86,894 |
| EtO & EG Storage | 1.5 | 1 | 1.5 | 61 | 92 | 5 | 9.15 | $9,655 |
| Sterilizer Chambers | 25.5 | 1 | 25.5 | 61 | 1,556 | 78 | 155.55 | $164,133 |
| Aeration | 7.5 | 1 | 7.5 | 61 | 458 | 23 | 45.75 | $48,274 |
| APCD Summary | 4.5 | 1 | 4.5 | 61 | 275 | 14 | 27.45 | $28,965 |
| APCD Details | 3 | 1 | 3 | 61 | 183 | 9 | 18.3 | $19,310 |
| EtO Monitoring | 16.5 | 1 | 16.5 | 61 | 1,007 | 50 | 100.65 | $106,204 |
| Miscellaneous | 1.5 | 1 | 1.5 | 61 | 92 | 5 | 9.15 | $9,655 |
| Additional Info | 1.5 | 1 | 1.5 | 61 | 92 | 5 | 9.15 | $9,655 |
| Attachments | 10 | 1 | 10 | 61 | 610 | 31 | 61 | $64,366 |
| Certification | 0.2 | 1 | 0.2 | 61 | 12 | 1 | 1.22 | $1,287 |
| C. Create Information (Included in 4B) | | | | | | | | |
| D. Gather Existing Information (Included in 4B) | | | | | | | | |
| E. Write Report (Not Applicable) | | | | | | | | |
| 5. RECORDKEEPING REQUIREMENTS (Not applicable) | | | | | | | | |
| **TOTAL ANNUAL LABOR BURDEN AND COST** | | | | | 5,716 | 286 | 572 | **$603,107** |
| | | | | | Total Labor: | | 6,573 | |
| | | | | | Avg. hr./facility: | 108 | Avg. $/facility: | $9,887 |
| ANNUAL CAPITAL COSTS (Not Applicable) | | | | | | | | |
| ANNUALIZED CAPITAL COSTS (Not Applicable) | | | | | | | | |
| TOTAL ANNUAL COSTS (O&M)[3] | | | | | | | | $920 |

| Respondent Activity | (A) Hours per Occurrence | (B) Occurrences/ Respondent/Year | (C) Hours/ Respondent/ Year (A x B) | (D) Respondents/ Year[1] | (E) Technical Hours/Year (C x D) | (F) Managerial Hours/Year (E x 0.05) | (G) Clerical Hours/Year (E x 0.10) | (H) Cost/ Year[2] |
|---|---|---|---|---|---|---|---|---|
| TOTAL ANNUALIZED COSTS (Annualized capital + O&M costs) | | | | | | | | $920 |
| **TOTAL LABOR AND O&M COSTS** | | | | | | | | **$604,027** |

1. The number of respondents per year is based on the facility counts listed in Section 4(a) of the Supporting Statement.

2. Based on mean hourly wages in Bureau of Labor Statistics, accessed April 2020 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 339100—Medical Supplies and Equipment Manufacturing, available at https://www.bls.gov/oes/current/naics4_339100.htm#11-0000. Final loaded labor rates are: Technical: $93.66/hour (SOC 17-2000: Engineers), Managerial: $149.88/hour (SOC 11-1021: General and Operations Managers), Clerical: $43.64/hour (SOC 43-0000: Office and Administrative Support Occupations); all labor rates include 110 percent increase to account for fringe benefits and overhead expenses).

3. Postage costs for mailing questionnaire responses to the EPA are estimated at $9.75 for Federal Express letter-size envelope flat rate (1 per respondent). The costs of digital media (CD, DVD, or flash drive) are estimated to be $7 each.

# Attachment 3.
# Agency Burden and Costs

| Agency Activity | (A) EPA Hours/ Occurrence | (B) Occurrences/ Respondent/Year | (C) EPA Hours/Respondent/Year (A x B) | (D) Respondents/Year[1] | (E) EPA Technical Hours/Year (C x D) | (F) EPA Managerial Hours/Year (E x 0.05) | (G) EPA Clerical Hours/Year (E x 0.1) | (H) Cost, $/Year[2] |
|---|---|---|---|---|---|---|---|---|
| Develop/revise questionnaire spreadsheets and instructions | N/A | N/A | N/A | N/A | N/A | N/A | N/A | $0 |
| Develop survey webpage | N/A | N/A | N/A | N/A | N/A | N/A | N/A | $0 |
| Answer respondent questions via phone, email, and/or frequently asked questions posted on webpage[3] | 1 | 1 | 1 | 15 | 15 | 1 | 2 | $1,002 |
| Analyze requests for confidentiality[4] | 1 | 1 | 1 | 55 | 55 | 3 | 5 | $3,605 |
| Review and analyze responses (including follow-up) | 20 | 1 | 20 | 61 | 1220 | 61 | 122 | $80,122 |
| Analyze previous emissions test, performance test or engineering study data[5] | 4 | 4 | 16 | 6 | 98 | 5 | 10 | $6,410 |
| | | | | | | | | |
| Total Annual Hours/Cost | | | | | 1,388 | 69 | 139 | $91,139 |
| | | | | | | Total Labor: | 1,596 | |
| Expenses (O&M)[6] | | | | | | | | |
| Computer storage of data | | | | | | | | $1,440 |
| Total O&M Expenses | | | | | | | | $1,440 |
| TOTAL ANNUAL LABOR BURDEN AND COST | | | | | | | | **$92,579** |

1. The number of respondents per year is based on the facility counts listed in Section 4 of the Supporting Statement.

2. Based on GS Scale 2019: Technical/GS 13-1: $36.75/hour, Managerial/GS 15-1: $51.08/hour, Clerical/GS 7-1: $17.42/hour. All agency labor rates have been scaled using a multiplier of 1.6 to account for overhead and fringe benefit costs.

3. Assumes that 25 percent of the facilities will have questions.

4. Assumes that 90 percent of facilities will have confidential data.

5. Assumes that 10 percent of facilities will have performance test, emissions test, or other engineering study provided as an attachment to the ICR requiring additional review . Assume 1 hour to perform additional analyses of these attachments.

6. Data storage at $6/GB/month assuming 10 GB data for 24 months.