THE ETHYLENE OXIDE (EtO) STANDARD (29 CFR 1910.1047)
OMB Control Number: 1218-0108
Expiration Date: December 31, 2023

SUPPORTING STATEMENT FOR THE COLLECTIONS OF INFORMATION IN THE ETHYLENE OXIDE (EtO) STANDARD (29 CFR 1910.1047)[1,2] (OFFICE OF MANAGEMENT AND BUDGET (OMB) CONTROL NO. 1218-0108 (December 2023)

This is a request to extend a currently approved data collection.

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Occupational Safety and Health Act's (OSH Act) main objective is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" (29 U.S.C. 651). To achieve this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" (29 U.S.C. 651).

For toxic substances, the OSH Act contains specific statutory language. Accordingly, and as appropriate, health standards must include provisions for monitoring and measuring worker exposure, medical examinations and other tests, control and technological procedures, suitable protective equipment, labels and other appropriate forms of warning, and precautions for safe use or exposure (29 U.S.C. 655 and 657). In addition, the OSH Act mandates "regulations requiring employers to maintain accurate records of worker exposure to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further requires that employers notify workers exposed to concentrations over specific limits of these exposures, and of the corrective action(s) they are taking (29 U.S.C. 657).

Under the authority granted by the OSH Act, the Occupational Safety and Health Administration (OSHA) published a health standard governing worker exposure to ethylene oxide (EtO) at 29 CFR 1910.1047 (the "Standard"). The basis for the Standard was a determination by OSHA, based on animal and human data, that exposure to EtO presents a carcinogenic, mutagenic, genotoxic, reproductive, neurologic, and sensitization hazard to workers (49 FR 25737). OSHA established a permissible exposure limit (PEL) for occupational exposure to EtO of 1 part per

1 The purpose of this supporting statement is to analyze and describe the burden hours and costs associated with provisions of the Standard that contain paperwork requirements. It does not provide information or guidance on how to comply with or to enforce the Standard.

2 The Construction and Shipyard Employment EtO Standards (29 CFR 1926.1147 and 29 CFR 1915.1047, respectively) incorporate 29 CFR 1910.1047 by reference.

million (ppm), assessed using an 8-hour time-weighted average (referred to hereafter as "TWA"). The Agency also developed an excursion limit (EL) of 5 ppm, determined during a 15-minute exposure period. Exposures below an action level (AL) of 0.5 ppm, measured as a TWA, exempts employers from some of the regulatory burdens of the Standard, such as worker exposure monitoring and medical surveillance.

2. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burdens.

The following are the collections of information as stated in the Standard, followed by discussions indicating how, by whom, and for what purpose the information is used.

A. Initial monitoring (§1910.1047(d)(1) and (d)(2))

§1910.1047(d)(1)(iii)

Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.

§1910.1047(d)(2)(i)

Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraph (a)(2) or (d)(2)(ii) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed.

Purpose: The employer has the duty to identify areas and operations that may require additional reduction in airborne EtO to meet the TWA and EL. Initial exposure-monitoring results also assist employers in determining the need for engineering controls, implementing or modifying work practices, and selecting appropriate respiratory protection to prevent workers from overexposure to EtO.

B. Monitoring frequency (periodic monitoring) (§1910.1047(d)(3))

§1910.1047(d)(3)(i)

If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 6 months.

§1910.1047(d)(3)(ii)

If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 3 months.

§1910.1047(d)(3)(iii)

The employer may alter the monitoring schedule from quarterly to semiannually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA.

§1910.1047(d)(3)(iv)

If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 15 minute excursion limit, the employer shall repeat such monitoring for each such employee at least every 3 months, and more often as necessary to evaluate exposure the employee's short-term exposures.

Purpose: Periodic monitoring allows employers to determine the impact of implemented controls, modifications in process, materials, or environmental conditions on worker exposures to EtO. Periodic exposure monitoring also enables workers to evaluate the effectiveness of control methods.

C. Additional monitoring (§1910.1047(d)(5))

Notwithstanding the provisions of paragraph (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to EtO or when the employer has any reason to suspect that a change may result in new or additional exposures.

Purpose: Changes in production, process, control equipment, and new personnel may lead to an increase in worker exposure levels. Additional monitoring is necessary so that the employer may take action to protect workers, such as providing appropriate respiratory equipment or instituting engineering controls. Additional monitoring ensures that the work area is safe or alerts the employer to the need to increase worker protection.

D. Employee notification of monitoring results (§1910.1047(d)(7))

§1910.1047(d)(7)(i)

The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

§1910.1047(d)(7)(ii)

The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the TWA and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit has been exceeded.

Purpose: This notification requirement assures that each worker receives accurate exposure data and, in addition, provides them with information regarding the specific actions the employer is taking to lower their exposures and to furnish them with a safe and healthful workplace in accordance with section 8(c)(3) of the Act.

E. Compliance program (§1910.1047(f)(2))

§1910.1047(f)(2)(i)

Where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce exposure to or below the TWA and to or below the excursion limit by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

§1910.1047(f)(2)(ii)

The compliance program shall include a schedule for periodic leak detection surveys and a written plan for emergency situations, as specified in paragraph (h)(1)(i) of this section.

§1910.1047(f)(2)(iii)

Written plans for a program required in paragraph (f)(2) shall be developed and furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

Purpose: This requirement commits the employer to evaluating worker exposure and establishing an organized and comprehensive program for reducing worker exposures to or below the PELs. Revising and updating the written program serves to remind employers to implement and maintain the exposure-control methods required by the Standard.

OSHA has determined that the requirement for employers to make information available upon

request to the Assistant Secretary is not a collection of information; OSHA typically requests access to records during an inspection, and information collected by the Agency during the investigation is not subject to the PRA under 5 CFR 1320.4(a)(2). While NIOSH may use records collected from employers for research purposes, the Agency does not anticipate NIOSH to request employers to make available records during the approval period. Therefore, the burden for the employer to make this information available to NIOSH is zero. OSHA is not taking burden for this activity under Item 12 of this Supporting Statement.

Respiratory protection (§1910.1047(g))

For employees who use respirators required by this section, the employer must provide each employee with an appropriate respirator that complies with requirements of this paragraph. Respirators must be used during the following times:

> *§1910.1047(g)(1)(i) -* Periods necessary to install or implement feasible engineering and work-practice controls.
>
> *§1910.1047(g)(1)(ii) -* Work operations, such as maintenance and repair activities and vessel cleaning, for which engineering and work-practice controls are not feasible.
>
> *§1910.1047(g)(1)(iii) -* Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA.
>
> *§1910.1047(g)(1)(iv) -* Emergencies.

Respirator program (§1910.1047(g)(2))

The employer must implement a respiratory protection program in accordance with 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

Purpose: The Respiratory Protection Standard assists employers in protecting the health of workers exposed to airborne contaminants and biological agents. The respiratory protection collections of information are contained the Respiratory Protection Information Collection Request (ICR), OMB Control Number 1218-0099. The Respiratory Protection ICR provides the justification, purpose, and burden hours and cost estimates for these provisions.

G. Emergency situations - Written plan (§1910.1047(h)(1))

§1910.1047(h)(1)(i)

A written plan for emergency situations shall be developed for each workplace where there is a

possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

§1910.1047(h)(1)(ii)

The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

§1910.1047(h)(1)(iii)

The plan shall include the elements prescribed in 29 CFR 1910.38 and 29 CFR 1910.39, "Emergency action plans" and "Fire prevention plans," respectively.

Purpose: Emergency and fire prevention plans provide workers with information to maximize their personal protection and minimize EtO exposures during an emergency.

H. Medical surveillance (§1910.1047(i)(1))

Employees covered (§1910.1047(i)(1)(i))

§1910.1047(i)(1)(i)(A) - The employer shall institute a medical surveillance program for all employees who are or may be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days a year.

§1910.1047(i)(1)(i)(B) - The employer shall make available medical examinations and consultations to all employees who have been exposed to EtO in an emergency situation.

Medical examinations and consultations (§1910.1047(i)(2))

Frequency (§1910.1047(i)(2)(i))

The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1)(i) of this section on the following schedules:

§1910.1047(i)(2)(i)(A) - Prior to assignment of the employee to an area where exposure may be at or above the action level for at least 30 days a year.

§1910.1047(i)(2)(i)(B) - At least annually each employee exposed at or above the action level for at least 30 days in the past year.

§1910.1047(i)(2)(i)(C) - At termination of employment or reassignment to an area where exposure to EtO is not at or above the action level for at least 30 days a year.

§1910.1047(i)(2)(i)(D) - As medically appropriate for any employee exposed during an emergency.

§1910.1047(i)(2)(i)(E) - As soon as possible, upon notification by an employee either (1) that the employee has developed signs or symptoms indicating possible overexposure to EtO, or (2) that the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee's ability to produce a healthy child.

§1910.1047(i)(2)(i)(F) - If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer shall provide such examinations to affected employees at the frequencies recommended by the physician.

Content (§1910.1047(i)(2)(ii))

§1910.1047(i)(2)(ii)(A) - Medical examinations made available pursuant to paragraphs (i)(2)(i)(A) through (D) of this section shall include:

§1910.1047(i)(2)(ii)(A)(1) - A medical and work history with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

§1910.1047(i)(2)(ii)(A)(2) - A physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

§1910.1047(i)(2)(ii)(A)(3) - A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

§1910.1047(i)(2)(ii)(A)(4) - Any laboratory or other test which the examining physician deems necessary by sound medical practice.

§1910.1047(i)(2)(ii)(B) - The content of medical examinations or consultation made available pursuant to paragraph (i)(2)(i)(E) of this section shall be determined by the examining physician and shall include pregnancy testing or laboratory evaluation of fertility, if requested by the employee and deemed appropriate by the physician.

Purpose: Documentation of the medical-examination results as required by the Standard provides a continuous record of worker health. Physicians use these records to determine the extent to which workers, since their last examination, experience health effects related to their EtO exposure. Further, the physician often needs information about a worker's previous medical conditions to make an accurate diagnosis of the new condition, ascertain its apparent cause, and identify a course of treatment. Medical records also permit workers to determine whether they

need treatment, or to evaluate the effectiveness of their employer's exposure-reduction program.

I. Information provided to the physician (§1910.1047(i)(3))

The employer shall provide the following information to the examining physician:

§1910.1047(i)(3)(i) - A copy of this standard and Appendices A, B, and C.

§1910.1047(i)(3)(ii) - A description of the affected employee's duties as they relate to the employee's exposure.

§1910.1047(i)(3)(iii) - The employee's representative exposure level or anticipated exposure level.

§1910.1047(i)(3)(iv) - A description of any personal protective and respiratory equipment used or to be used.

§1910.1047(i)(3)(v) - Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

Purpose: Making this information available to physicians assists them in evaluating the worker's health and fitness for specific job assignments involving EtO exposure. As noted earlier, if signs of organic damage appear, the physician often needs information about a worker's previous medical conditions to make an accurate diagnosis of the new condition, its apparent cause, and the course of treatment required. Medical records also ensure that workers can determine whether they require treatment, or to evaluate the effectiveness of the employer's exposure-reduction program.

J. Physician's written opinion (§1910.1047(i)(4))

§1910.1047(i)(4)(i)

The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

§1910.1047(i)(4)(i)(A) - The physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to EtO;

§1910.1047(i)(4)(i)(B) - Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators; and

§1910.1047(i)(4)(i)(C) - A statement that the employee has been informed by the

physician of the results of the medical examination and of any medical conditions resulting from EtO exposure that require further explanation or treatment.

§1910.1047(i)(4)(ii)

The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to EtO.

§1910.1047(i)(4)(iii)

The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

Purpose: The purpose of requiring the employer to obtain a physician's written opinion is to provide the employer with medical information to aid in determining the initial placement of workers, and to assess the worker's ability to use protective clothing and equipment. The physician's written opinion will also provide information to the employer about whether the worker has a condition indicating overexposure to EtO. The requirement that the physician's opinion be in writing will ensure that the information is properly memorialized for later reference. Providing workers with a copy of the physician's written opinion will inform them of the medical-examination results so that they can assist in determining the need for, and evaluate the effectiveness of, treatment or other interventions.

K. ***Signs and labels (§1910.1047(j)(2)(i))***

§1910.1047(j)(2)(i)-Signs

The employer must post warning signs in work areas where EtO exposures exceed or may exceed the TWA or EL. Employers must also affix warning labels to containers that may cause worker exposure at or above the TWA or EL. The Standard provides specific language for the required signs and the labels. Therefore, OSHA took no burden hours or costs for these requirements. (See "Paperwork Reduction Act den 5 CFR 1320.)

(A)The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILTY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA

AUTHORIZED PERSONNEL ONLY

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i)(A) of this section:

DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

Purpose: These signs alert workers of regulated areas, and to take necessary protective steps before entering the area. Regulated areas may also exist on a temporary basis, for example, during maintenance. The use of warning signs in these types of situations is also important, since the temporary high exposures would represent a new or unexpected exposure to workers who are regularly scheduled to work at these sites. The posting of warning signs at the occurrence of a maintenance situation, or during an emergency if there is time, will help prevent unnecessary exposures to workers who may not otherwise know or expect excessive EtO exposure levels, and serves to warn workers of the need to wear respirators.

§1910.1047(j)(2)(ii)-Labels.

The employer shall ensure that precautionary labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph, reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers. The labels shall comply with the requirements of 29 CFR 1910.1200(f) of OSHA's Hazard Communication standard, and shall include the following legend:

> §1910.1047(j)(2)(ii)(B): Prior to June 1,2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in paragraph (J)(2)(ii)(B)(j)(1)(i) of this section:
>
> **DANGER**
> **CONTAINS ETHYLENE OXIDE**
> **CANCER HAZARD AND REPRODUCTIVE HAZARD**

and

> §1910.1047(j)(2) - A warning statement against breathing airborne concentrations of EtO.

§1910.1047(j)(2)(ii)(C)

The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.

Purpose: Warning labels assure that downstream employers and workers are informed of the hazards of EtO, and that these employers may need to implement special practices to prevent exposure. Furthermore, hazard labels alert other employers who, in the absence of such labels, might not know that EtO is present in their workplace and, consequently, that they must comply with the Standard.

M. Information and training (§1910.1047(j)(3))

§1910.1047(j)(3)(i)

The Standard's information and training requirements are not considered collections of information. Therefore, OSHA takes no burden hours and costs for this requirement.

The employer shall provide employees who are potentially exposed to EtO at or above the action level or above the excursion limit with information and training on EtO at the time of initial assignment and at least annually thereafter.

§1910.1047(j)(3)(ii)

Employees shall be informed of the following:

§1910.1047(j)(3)(ii)(A) - The requirements of this section with an explanation of its contents, including Appendices A and B;

§1910.1047(j)(3)(ii)(B) - Any operations in their work area where EtO is present;

§1910.1047(j)(3)(ii)(C) - The location and availability of the written EtO final rule; and

§1910.1047(j)(3)(ii)(D) - The medical surveillance program required by paragraph (i) of this section with an explanation of the information in Appendix C.

§1910.1047(j)(3)(iii)

Employee training shall include at least:

§1910.1047(j)(3)(iii)(A) - Methods and observations that may be used to detect the

presence or release of EtO in the work area (such as monitoring conducted by the employer, continuous monitoring devices, etc.);

§1910.1047(j)(3)(iii)(B) - The physical and health hazards of EtO;

§1910.1047(j)(3)(iii)(C) - The measures employees can take to protect themselves from hazards associated with EtO exposure, including specific procedures the employer has implemented to protect employees from exposure to EtO, such as work practices, emergency procedures, and personal protective equipment to be used; and

§1910.1047(j)(3)(iii)(D) - The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

Purpose: The information and training requirements of the Standard are essential to inform workers of the health hazards of EtO exposure, and to provide them with the understanding required to minimize these health hazards. In addition, training provides information to workers that enable them to recognize how and where EtO exposure occurs, and what steps to take, including work practices, to limit such exposure. Another benefit of training is that it serves to explain and reinforce the information presented to workers on warning signs, labels, and MSDSs. This warning information will be successful and relevant only if workers understand the information and are aware of the actions they must take to avoid or minimize EtO exposure.

N. Objective data for exempted operations (§1910.1047(k)(1))

§1910.1047(k)(1)(i)

Where the processing, use, or handling of products made from or containing EtO are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

§1910.1047(k)(1)(ii)

This record shall include at least the following information:

§1910.1047(k)(1)(ii)(A) - The product qualifying for exemption;

§1910.1047(k)(1)(ii)(B) - The source of the objective data;

§1910.1047(k)(1)(ii)(C) - The testing protocol, results of testing, and/or analysis of the material for the release of EtO;

§1910.1047(k)(1)(ii)(D) - A description of the operation exempted and how the data support the exemption; and

§1910.1047(k)(1)(ii)(E) - Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

§1910.1047(k)(1)(iii)

The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

Purpose: The purpose of requiring an employer to document and maintain these determinations is to assure that workers and their representatives, who must have access to these determinations as specified by paragraph (k)(4) of the Standard, that the determinations are reasonable. This provision ensures that the determinations are valid and that they will protect workers from exposure to EtO at or above the AL. Maintaining the records also allows OSHA to ascertain whether an employer is complying with the Standard; thereby, providing additional assurance that workers are receiving adequate protection from EtO exposures.

O. Exposure measurements (§1910.1047(k)(2))

§1910.1047(k)(2)(i)

The employer shall keep an accurate record of all measurements taken to monitor employee exposure to EtO as prescribed in paragraph (d) of this section.

§1910.1047(k)(2)(ii)

This record shall include at least the following information:

§1910.1047(k)(2)(ii)(A) - The date of measurement;

§1910.1047(k)(2)(ii)(B) - The operation involving exposure to EtO which is being monitored;

§1910.1047(k)(2)(ii)(C) - Sampling and analytical methods used and evidence of their accuracy;

§1910.1047(k)(2)(ii)(D) - Number, duration, and results of samples taken;

§1910.1047(k)(2)(ii)(E) - Type of protective devices worn, if any;

§1910.1047(k)(2)(ii)(F) - Name and exposure of the employees whose exposures are represented.

§1910.1047(k)(2)(iii)

The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

Purpose: This document retention requirement enables employers, and workers and their designated representatives, to identify the levels, durations, and extent of EtO exposures (including overexposures). Additionally, this requirement allows the employers to determine if existing controls are protecting workers or whether additional controls are necessary to provide the required protection. Lastly, it enables the employer to access the relationship between EtO exposure and the subsequent development of medical diseases. Retaining these records for 30 years is necessary to document any association that may exist between EtO exposures and the development of long-latency illnesses caused by these exposures.

P. Medical surveillance (§1910.1047(k)(3))

§1910.1047(k)(3)(i)

The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (i)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

§1910.1047(k)(3)(ii)

The record shall include at least the following information:

§1910.1047(k)(3)(ii)(A) - The name of the employee;

§1910.1047(k)(3)(ii)(B) - Physicians' written opinions;

§1910.1047(k)(3)(ii)(C) - Any employee medical complaints related to exposure to EtO; and

§1910.1047(k)(3)(ii)(D) - A copy of the information provided to the physician as required by paragraph (i)(3) of this section.

§1910.1047(k)(3)(iii)

The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

Purpose: Medical-surveillance records assist workers and their physicians in determining the need for treatment or other interventions as a result of the workers' exposure to EtO. This information also will alert employers when worker overexposure to EtO occurs, thereby enabling employers to take the action(s) required to reduce EtO exposures. Maintaining these records for long periods is necessary because of the long latency associated with the development of diseases caused by EtO exposure.

Q. Availability (§1910.1047(k)(4))[3]

§1910.1047(k)(4)(i)

The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying

§1910.1047(k)(4)(ii)

The employer, upon request, shall make any exemption and exposure records required by paragraphs (k)(1) and (2) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

§1910.1047(k)(4)(iii)

The employer, upon request, shall make employee medical records required by paragraph (k)(3) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

Purpose: Workers and worker representatives use exposure-monitoring and medical-surveillance records to assess worker medical status over the course of employment to evaluate the effectiveness of the worker's exposure-reduction program, and for other reasons.

R. Transfer of records (§1910.1047(k)(5))

§1910.1028(k)(5)

The employer shall comply with the requirements involving transfer of records set forth in 29

3 As discussed above regarding § 1910.1047(f)(2)(iii), OSHA has determined that the requirement for employers to make information available upon request to the Assistant Secretary is also not a collection of information; OSHA typically requests access to records during an inspection, and information collected by the Agency during the investigation is not subject to the PRA under 5 CFR 1320.4(a)(2). While NIOSH may use records collected from employers for research purposes, the Agency does not anticipate NIOSH to request employers to make available records during the approval period. Therefore, the burden for the employer to make this information available to NIOSH is zero.

CFR 1910.1020(h).

Paragraph (h) of §1910.1020 requires employers who cease to do business to transfer medical and exposure-monitoring records to the successor employer, who then must receive and maintain the records. If no successor employer is available, the employer must, at least three months before ceasing business, notify current workers who have records of their right to access these records.

OSHA considers the employer's transfer of records to a successor employer to be usual and customary communications during the transition from one employer to a successor employer. In this regard, the employer would communicate the location of all records, including worker exposure-monitoring and medical records, at the facility to the successor employer during the transfer of business operations, as a matter of usual and customary business practice.
In addition, OSHA accounts for the burden hours and costs resulting from the worker notification requirements under the Information Collection Request (ICR) for its Access to Employee Exposure and Medical Records Standard (§1910.1020), OMB Control No. 1218-0065.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burdens.

Employers may use automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology (e.g., electronic submission of responses), when establishing and maintaining the required records. The Agency wrote the paperwork requirements of the Standard in performance-oriented language, i.e., in terms of what data to collect, not how to record the data.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item A.2. above.

The information required to be collected and maintained is specific to each employer and worker involved, and is not available from, or duplicated, by another source. The information required by the Standard is available only from employers. At this time, there is no alternate information source available.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The collections of information do not have a significant impact on a substantial number of small

entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, and any technical or legal obstacles to reducing burden.

The information collection frequencies specified by this Standard are the minimum OSHA believes are necessary to ensure that employers and OSHA can effectively monitor the exposure and health status of workers working with EtO.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Paragraph (d)(7) of the Standard requires employers to notify each worker, in writing, of their exposure-monitoring results within 15 working days after receiving the results. If the results

show that a worker's exposure to EtO exceeds the TWA or exceeds the excursion limit, the employer must notify them of this finding, and inform them of the corrective action the employer is taking to prevent overexposure and potential adverse health effects. Additionally, paragraph (i)(4)(iii) of the Standard requires employers to provide a copy of the physician's written opinion to the affected worker within 15 days from its receipt.

8. If applicable, provide a copy and identify the data and page number of publication in the *Federal Register* of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every three years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the *Federal Register* on August 3, 2023 (88 FR 51354) soliciting comments from the public and other interested parties on the information collection requirements contained in the Ethylene Oxide Standard (29 CFR 1910.1047) under Docket Number OSHA-2009-0035. The notice was part of a preclearance consultation program that provides interested parties with an opportunity to comment on OSHA's request for an extension by the Office of Management and Budget (OMB) of a previous approval of the information collection requirements found in the above standard.

The agency received one comment on October 2, 2023, in response to this notice from Matthew Garamone of Becton, Dickinson and Company (BD) under docket number OSHA-2009-0035-0016. Mr. Garamone expressed five concerns in reference to this information collection request on Ethylene Oxide (29 CFR 1910.1047).

A. In the commenter's first concern he stated that, "The current standard requires employee notification of ethylene oxide (EtO) exposures within 15 working days after the receipt of the results of any monitoring performed, either individually in writing or by posting the results in an appropriate location that is accessible to employees. BD recommends a change to the standard to ease the burden on notifying employees of their ethylene oxide (EtO) exposures to allow for electronic notification rather than notification to each person

in writing. With current technology and use of electronic communication commonplace, BD believes revising the standard to allow for electronic notification to each individual would be more efficient cutting down on the time required to perform the notification while still meeting the notification requirement. In light of the fact that BD performs routine and regular exposure monitoring of EtO exposures, this time savings from this change to electronic notification would be sizeable. BD also believes that posting of exposure monitoring results can be construed to violate Privacy Laws. Personnel exposure monitoring data could be considered a medical record and therefore posting is not the preferred route of employee notification."

Under §1910.1047(d)(7)(i), OSHA standard states that "The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees." This notification requirement assures that each worker receives accurate exposure data and, in addition, provides them with information regarding the specific actions the employer is taking to lower their exposures and to furnish them with a safe and healthful workplace in accordance with section 8(c)(3) of the OSH Act. Employers may use automated, electronic, mechanical, or other technological techniques to notify employees of the results of any possible exposure. The paperwork requirement of the Standard is written in performance-oriented language. Electronic notification satisfies the requirement that notification be made in writing. OSHA does encourage the use of the latest technology.
The option to post exposure monitoring results is a feature of many of OSHA's substance-specific standards. *See,* e.g., 29 CFR 1910.1053(d)(6) (Respirable Crystalline Silica); 29 CFR 1910.1024(d)(6) (Beryllium); 29 CFR 1910.1025(d)(6) (Lead). However, posting is not required and employers are permitted to notify employees individually.

B. The commenter's second concern stated, "The written notification required by the EtO standard shall contain the corrective action being taken by the employer to reduce employee exposure to or below the Time Weighted Average (TWA) and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit has been exceeded. BD believes the requirement to include corrective action in the notification to be redundant; these corrective actions are already required to be a part of the written compliance program according to paragraph (f)(2) of the standard. The standard specifies that the written compliance program requires where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce exposure to or below the TWA and to or below the excursion limit by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. BD proposes using this written compliance program as a means to advise associates in lieu of including it in the employee monitoring results to reduce regulatory burden to comply with the EtO standard."

The requirement to include corrective measures in the exposure monitoring notification reinforces the written compliance program required by paragraph (f)(1) of the standard. It provides affected employees the necessary context to understand the consequences of the exposure monitoring results and provides immediate knowledge of the corrective actions that must be taken to reduce exposure. This requirement is also common to many of OSHA's substance-specific standards. *See,* e.g., 29 CFR 1910.1053(d)(6) (Respirable Crystalline Silica); 29 CFR 1910.1024(d)(6) (Beryllium); 29 CFR 1910.1025(d)(6) (Lead).

C. Commenter's concern three states that, "OSHA provides both an 8-hour time weighted average (TWA) and an excursion limit for ethylene oxide in the standard. The standard list the Excursion Limit as an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes. The term Excursion Limit may create confusion when compared to other definitions commonly used in the practice of industrial hygiene. The National Institute of Safety and Health (NIOSH) has set a Short-Term Exposure Limit (STEL) for ethylene oxide which is defined as a 15-minute TWA exposure that should not be exceeded at any time during a workday. California OSHA also has set a STEL limit for ethylene oxide and does not use the terminology 'excursion limit'. NIOSH is the authoritative Federal agency with providing recommendations, established according to the legislative mandate, to recommend standards to OSHA. BD suggests for clarity's sake of updating the terminology of 'excursion limit' to instead 'short term exposure limit'. This would help prevent any confusion when training staff in the different terminology which varies based on where the associates work (California versus federal OSHA jurisdictions, for example). In fact, the OSHA Z-1 Table showing annotated version uses the abbreviation terminology (ST) in place of the ethylene oxide term 'excursions limit' defined as ST = Short Term Exposure Limit and therefore establishing consistency across all agencies and the American Conference of Governmental Industrial Hygienists (ACGIH)."

The term "excursion limit" is used in the standard for Ethylene Oxide to denote the requirement that "the employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes" (29 CFR §1910.1047(c)). This term was included in the standard when it was issued in 1984. OSHA recognizes that other organizations use different terms to describe comparable exposure limits. OSHA appreciates your concerns regarding revising the standard to avoid confusion in the workplace, however, this is outside of the scope of this notice.

D. In the commentor's fourth concern stated that, "BD would like to share its input regarding Table 1 "Number of Facilities by Industry Sector". BD believes the number of Ethoxylators appears to be low, and likely does not include all applicable industry sectors such as glycol manufacturing, plastics manufacturing, and soap products manufacturing. Additionally, the number of Medical-Product Manufacturers likely does not correlate to

the number of facilities with EtO Sterilizers and the number of Contract Sterilizers does not reflect the number of EtO sterilization sites that do work within the United States.

BD also believes the wage hour estimates in Table 2 are low. The Mean Hour Wage Rate for each class of worker listed does not correlate to current wage scales. They are, at best, in line with entry-level positions in the listed fields. Wage rates for safety professionals should also reflect that the person performing all the activities required by the standard requires training, skill, and competence in Industrial Hygiene.

Reviewing Table 3 "Exposure Monitoring Burden Hour and Cost Estimates", BD suggests the number of facilities should be adjusted reflecting the Table 1 comments above. We believe the Burden Hours used does not account for any of the time to observe monitoring in progress, calibrate sampling pumps, post calibrate, etc. The values used appear to be an order of magnitude low.

The number of samples listed in Table 3 "Exposure Monitoring Burden Hour and Cost Es mates" appears to include only on-going routine samples, and does not include monitoring when changes are made, exposure sampling for special tasks with potential for higher exposures and does not include samples as a direct result of staff turnover since the standard specifically calls out monitoring for new employees. Analysis of monitoring results and report preparation time also appear not to have been included in the burden hours. In Table 3, the wage rate utilize should reflect average wages for a person with Industrial Hygiene Training/Knowledge/Skills.

When estimating the burden hours for the compliance plan, BD believes the time required to develop a meaningful Compliance Plan, including implementation time would be two orders of magnitude greater (not including cost of implementation). The wage burden used must reflect a person with not only the Industrial Hygiene training/skill/knowledge but also a person with Engineering training and ability in designing modifications to the operation.

When estimating the cost and burden of additional medical exams, cost calculations do not appear to account for the administrative time involved nor the paid time for workers to travel to and from the medical exam.

In the Recordkeeping burden cost, the wage cost used in the calculations reflects wages of an entry level clerical person. Although some of the work could be done by a person at that level, the bulk of the information would need to be generated by a person with the level of an EHS Technician or above. The calculated number of records needs to be adjusted to reflect actual numbers of individuals subject to the requirements in the standard, not just those who were monitored in an individual exposure monitoring activity. The numbers must also be adjusted to reflect needed changes noted above. Based on the above suggested corrections to Table 1 "Number of Facilities by Industry

> Sector", these changes should also be reflected in Table 7, "Total Number of Employees Hired Annually'. The wages used in this calculation are based on the assumption that recordkeeping could be done by a clerical person, and although some of the work could be done by a person at that level, the bulk of the information would need to be generated by a person with the level of an EHS Technician or above.
>
> In the Exposure Monitoring assumptions, BD feels the cost per sample is low when comparing with actual sampling and analysis costs. Additionally, the assumptions used may only reflect the simpler methodology using passive collection with passive dosimetry badges. The time and complexity needed for active sampling using sampling pumps and sorbent tubes would be higher and needs to include the time and equipment for pump calibration as well as the technical expertise needed to set up and collect active samples. Companies may choose either method and may prefer the active sampling method to achieve a lower limit of quantification or for other technical reasons. BD suggests an increase in this estimated cost based on these factors.
>
> In the Medical Surveillance burden cost, BD believes the estimated cost of medical exams does not reflect current healthcare costs when the exam includes all the items required for effective medical screening.
>
> In summary, BD feels the estimated overall Program Changes or adjustments. In light of comments above, the overall burden hours and costs are underestimated and should be increased significantly, not reduced."

The wage rates used in the supporting statement for EtO are taken from the US Bureau of Labor Statistics (BLS) website. The mean hourly wage rates from the May 2022 National Occupational Employment and Wage Estimates are used with the fringe benefit mark up to derive the loaded wage contained in the supporting statement. The BLS wage rates can vary depending on the area and location of employment. These rates generally are higher in the Mid Atlantic/Northeast than the Midwest or South.

OSHA used pre-existing methods to develop estimates of ethoxylates and medical product manufacturers. For ethoxylators and medical product manufacturers, OSHA used counts of establishments in the 2005 Regulatory Review of its Ethylene Oxide Standard (29 CFR 1910.1047) and adjusted to account for changes in these industry sectors as described below. The number of contract sterilizers is estimated directly from an industry list of companies providing this service, also described in more detail below.
In the 2023 EtO Standard ICR, OSHA estimated the number of ethoxylator establishments following the method used in the 2016 and 2020 EtO Standard ICRs. This method scales the latest available total number of establishments from Census County Business Patterns in NAICS codes 325613, 325110, 325120, 325180, 325194, 325193, 325199, 325998 by the ratio of ethoxylators to total establishments found in OSHA's 2005 "Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard (29 CFR 1910.1047).

In OSHA's 2005 regulatory review, OSHA defined ethoxylators as any manufacturing firm that uses EtO as a chemical feedstock to make other chemical products. These products include ethylene glycol, glycol ethers, ethanolamines, surfactants (including those used to manufacture shampoos, dish detergents, and specialty cleansers), and other specialty compounds. The number of ethoxylators used in the ratio of ethoxylators to total establishments therefore includes a range of sectors that use EtO as a chemical feedstock.

To estimate the number of medical product manufacturers in the 2023 EtO Standard ICR, OSHA followed the methodology used in the 2016 and 2020 EtO Standard ICRs. In the 2005 "Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard (29 CFR 1910.1047)," OSHA references EPA's estimate of affected medical product manufacturers in EPA's 1996 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations standard. Because EPA has since updated its estimate of total facilities in its EtO NESHAP ICRs, OSHA calculated the ratio of the affected medical manufacturers to total facilities in EPA's 1996 standard and has applied this ratio to EPA's estimate of total facilities. OSHA followed this method for its 2016, 2020 and 2023 ICRs.

OSHA used ThomasNet (formerly Thomas' Registry of American Manufacturers) to estimate the number of contract sterilizers in its 2023 ICR. This method deviates from the 2016 and 2020 ICRs. In 2016, OSHA used the same scaling method as was used to estimate medical-product manufacturers. In 2020, OSHA based its estimates of contract sterilizers on counts of these establishments in the American Chemistry Council's 2019 report "The Economic Benefit of Ethylene Oxide and the potential cost of deselection." The American Chemistry Council has not updated this report or its estimate of contract sterilizers. For 2023, OSHA again used an industry list (ThomasNet) of companies providing ethylene oxide contract sterilization services, which when compared to the method used in 2016 resulted in similar establishment counts.

OSHA concludes that an appropriate wage rate has been used for this ICR. While some companies may choose to involve safety professionals in the complete process, others will delegate duties to First Line Supervisors, Secretaries & Administrative Assistants (Clerical). A supervisor documents the exposure levels and posts the results. The supervisor will update and review the written compliance plan while an administrative professional documents and posts the results. The supervisor would document the exposure results and post them while the administrative professional documents and posts the test results. OSHA estimates that Occupational Health and Safety Specialists and Technicians would only be used to review and update the written compliance plan. OSHA considers their respective wage rates to represent a rough average among the wages for various possible job categories. If some employers choose to utilize employees in very high wage categories to complete these tasks, that is not an incremental cost of this rule.

In response to the comment on the "Medical Surveillance burden cost, BD believes the estimated cost of medical exams does not reflect current healthcare costs when the exam includes all the items required for effective medical screening." In the 2023 EtO Standard ICR, OSHA estimated the cost of a medical examination by inflating a previously established cost estimate to 2022 dollars. This established cost includes the costs associated with all requirements in section 1910.1047(i)(2)(ii), "Content" of the EtO Standard and was inflated using the Consumer Price

Index for medical care to reflect inflation in the medical care industry.

E. BD states in lastly that, "The FIFRA EtO PID includes a number of requirements directly intended to regulate worker health and safety within OSHA-regulated workplaces. For example, the FIFRA EtO PID states that "uses of EtO pose inhalation risks to workers inside commercial sterilization facilities [and] healthcare facilities . . . Therefore, EPA is proposing mitigation to address inhalation risk concerns . . ." PID at 3. The regulation of worker safety within a workplace was entrusted by Congress to OSHA pursuant the OSH Act. As OSHA states on its website: "With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for workers by setting and enforcing standards and by providing training, outreach, education and assistance." *See* 29 U.S. Code § 651 ("The Congress declares it to be its purpose and policy . . . to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources . . . by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses . . ."). OSHA's ethylene oxide standard is intended to be comprehensive and applies to all occupational exposures to ethylene oxide (EtO)" above OSHA's action level of 0.5 ppm. 29 C.F.R. 1910.1047(a)(1).

   While EPA may have authority that impacts workplaces in some cases, the FIFRA EtO PID goes much further and is explicitly designed to bypass limitations in OSHA's statutory authority and revise OSHA PEL:

   In April 2023, EPA issued three proposals that together will reduce risk in communities and for workers: . . . Reducing Risk to Workers in the Sterilization Industry: On April 11, 2023, EPA proposed a broad set of new protections under the Federal Insecticide, Fungicide, and Rodenticide Act that will reduce risk for all workers who use EtO to sterilize things and for others who work, live, or go to school near sterilization facilities. In fact, the FIFRA EtO PID states that because OSHA "health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible," this limitation "often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers." PID at 35. Similarly, EPA states that OSHA's authority to ensure a work environment "free from recognized hazards that are causing or are likely to cause death or serious physical harm" under the "General Duty Clause," is not often enforced and places a "heavy evidentiary burden on OSHA to establish violations." PID at 36. Based on these limitations, EPA concludes "it is appropriate that EPA conduct risk assessments and, where it finds risks of concern to workers, develop risk mitigation measures to address risks from the pesticidal uses of chemicals that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's." PID at 36.

> While OSHA's ethylene oxide standard (29 C.F.R. § 1910.1047)—which has proven effective in ensuring workplace safety—will remain in force, much of it will be functionally replaced by EPA's regulations ill. EPA is clearly stepping beyond its area of expertise and is not following the standard, accepted methods for settng occupational health standards. This issue is not cured by EPA's consultaton with OSHA or even OSHA's cooperation At the very least, EPA must respect how Congress intended worker safety to be implemented: i.e., taking into account technological and economic feasibility. EPA has some authority to ensure that these factors can be considered through the "economic, social, and environmental" cost/benefits analysis that EPA must conduct under FIFRA. *See* 40 C.F.R.§ 155.56);7 U.S. Code § 136(bb). And any mi ga on measure that effectively regulates workplace safety should utilize the recognized methods, standards, and protocols utilized by worker safety experts, such as TWA-and breathing zone-based limits and respiratory PPE requirements based on facility-specific air sampling."

OSHA appreciates your concerns on implementing safe work practices, but this is outside the scope of this notice, concerns the regulatory authority of a different agency, and is not an issue related to this ICR.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

The Agency will <u>not</u> provide payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Since medical records contain information that may be considered private, OSHA has taken steps to ensure that the data are kept private to the extent allowed by law. Rules of Agency practice and procedure governing OSHA access to worker medical records are contained in 29 CFR 1913.10. The legal authority for these procedural regulations is found in sections 8(c)(1) and 8(g)(2) of the Occupational Safety and Health Act, 29 U.S.C. 657.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Perceived questions of a sensitive nature may be included in medical questionnaires. Information

from medical questionnaires is necessary for the PLHCP or physician, or employer, to determine what protections an employer must take to ensure that the employee will have minimal occupational exposure to hazards such as, insufficient oxygen environments, harmful dusts, fogs, smokes, mists, gases, vapors, and sprays.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.**

The Agency updated the number of facilities affected by the Ethylene Oxide Standard based on findings from the regulatory review of the Standard conducted in 2005.[4] The updated numbers of affected facilities are shown in Table 1.

Table 1 - Number of Facilities by Industry Sector

Industry Sector	No. of Facilities
EtO Producers [1]	14
EtO Ethoxylators [2]	105
Hospitals Using EtO Sterilizers [3]	1,839
Medical-Product Manufacturers [4]	57
Contract Sterilizers [5]	11
Total	**2,026**

4 "Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard," [29 CFR 1910.1047], OSHA, March 2005.

[1] Thomas Register of American Manufacturers, Thomas Publishing Co., NY, NY. Retrieved 6/9/2023, from https://www.thomasnet.com
[2] The SIC codes for ethoxylators in OSHA's (2005) Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard (29 CFR 1910.1047), SIC 2843, SIC 2869, were converted to NAICS to obtain the number of establishments in the U.S. Census's County Business Patterns for the years 2000 and 2021. The ratio of the number of ethoxylators in the OSHA (2005) Regulatory Review document (64) to the total number of establishments in the Census County Business Patterns data for the relevant SIC codes in the year 2000 (2,242) was multiplied by the total number of number of establishments in 2021 (3,667) to update the estimated number of ethoxylators.
[3] According to the American Hospital Association's Fast Facts on U.S. Hospitals, 2023, there were 6,129 hospitals in the U.S. in 2021. We estimate that 30 percent of these hospitals conduct EtO sterilization based on EPA's (2007) National Emission Standards for Hospital Ethylene Oxide Sterilizers Proposed Rule (71 FR 64907). In that rule, EPA estimated that there were 5,800 hospitals in 2002, and used permits and inventory data to estimate that 1,600 to 1,900 of these were confirmed to conduct EtO sterilization. Taking the midpoint of this range (1,750) and rounding to zero decimal places, 30 percent of the 5,800 hospitals conduct EtO sterilization. We thus multiply the number of hospitals by 30 percent to obtain the estimate of 1,839 shown here (6,129 x 30 percent = 1,839).
[4] OSHA's (2005) Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard (29 CFR 1910.1047) used a background information document from EPA's (1994) National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations. That document estimated there were a total of 187 affected facilities, including 86 medical-product manufacturers. EPA's (2016) Information Collection Request for this rule (ICR Number 201606-2060-010) estimated a total of 125 commercial ethylene oxide sterilization and fumigation facilities, but did not include a breakdown of facilities by type. OSHA thus updated the estimate of 86 medical-product manufacturers using the ratio of total commercial ethylene oxide sterilization and fumigation facilities in the 2005 Regulatory Review document (187) to the number in the 2016 EPA ICR (125), resulting in a total of 57 medical-products manufacturers. (125 *(86/187)). For this (2023) ICR, OSHA carries forward the number of medical product manufacturers estimated in the agency's 2017 ICR due to no changes in the EPA 2020 ICR from the EPA 2016 ICR: https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=201606-2060-010 ("Extension without change of a currently approved collection").
[5] Thomas Register of American Manufacturers, Thomas Publishing Co., NY, NY. Retrieved 6/9/2023, from https://www.thomasnet.com

BURDEN HOUR AND COST DETERMINATIONS

The agency determined the wage rate from mean hourly wage earnings to represent the cost of employee time. For the relevant standard occupational classification category, OSHA used the wage rates reported in the Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Wage Statistics (OEWS), May 2022 accessed: June 20, 2023. (OEWS data is available at List of SOC Occupations (bls.gov) To access a wage rate, select the year, "Occupation profiles," and the Standard Occupational Classification (SOC) code.)

To account for fringe benefits, the agency used the *Occupational Employment Wage Statistics (OEWS)*. Fringe markup is from the following BLS release: *Employer Costs for Employee Compensation* news release text; For release, June 16, 2023 Employer Costs for Employee Compensation – December 2022 (bls.gov). BLS reported that civilian workers, fringe benefits accounted for accounted for 29.5 percent of total compensation and wages accounted for the remaining 70.5 percent.

Table 2 WAGE HOUR ESTIMATES (2023)				
Occupational Title	**Standard Occupation Code**	**Mean Hour Wage Rate (A)**	**Fringe Benefits (B)**	**Loaded Hourly Wage Rate (C) = (A)/((1-(B)))**
First Line Supervisor	51-1011	$33.22	.295	$47.12
Secretaries & Administrative Assistants (Clerical)	43-6014	$20.87	.295	$29.60
Occupational Health and Safety Specialist and Technician	19-5012	$30.40	.295	$43.12

Burden Hour and Cost Determinations

The following sections provide the number of burden hours and costs resulting from the collection of information in the Standard.

(A) Exposure monitoring (§1910.1047(d))

The provisions under paragraph (d) of the Standard specify the conditions under which employers must perform initial, periodic, and additional monitoring for workers exposed to EtO. The number of samples required per facility depends on EtO exposure levels, the number of affected job categories, and the number of shifts per day. OSHA assumes that a professional will take 10 minutes (10/60 hour) using a passive dosimeter to collect a TWA sample or an excursion limit (EL) sample; this time includes preparing the required documentation.

Initial monitoring (§1910.1047(d)(2))

The number of hospitals using ethylene oxide sterilizers has decreased over the years. There are less medical product manufacturers also, and no spice manufacturers were identified as using EtO. There is an overall decrease in the number of establishments, due primarily to the number of hospitals using Ethylene Oxide.

Periodic and additional monitoring (§1910.1047(d)(3) and (d)(5))

Employers must perform additional exposure monitoring if any changes occur in EtO production, process, control equipment, personnel, or work practices that may result in new or increased worker exposure to EtO, or the employer reasonably suspects that any other condition

could result in such exposures. For this ICR, the Agency used the assumptions specified in the previous ICR in determining the burden hours and costs for these provisions; this procedure was necessary because no current exposure-monitoring data for the affected industries are available. Accordingly, OSHA assumes that: 9% (or 182) of the total facilities listed in Table 1 will have exposures at or above the AL and at or below the TWA; an additional 9% (or 182) of all facilities will have worker exposures above the TWA; and 6% of all facilities (122) will have exposures above the EL.[5] OSHA also assumes that 10% of the total facilities (203) require additional monitoring. OSHA assumes a Supervisor spends 10 minutes (10/60 hour) documenting exposure levels (including representative exposure levels) and posting the results. Table 3 summarizes the burden hour and cost determinations for these exposure monitoring requirements:

Table 3: Exposure Monitoring Burden Hour and Cost Estimates

Monitoring Requirement	No. of Facilities	No. of Samples	Frequency per Year	Total Samples	Sampling Time (Hours)	Burden Hours	Loaded Wage Rate	Burden Costs
Above TWA	182	3	4	2,184	10/60	364	$47.12	$17,152
At/Above AL & At/Below TWA	182	3	2	1,092	10/60	182	$47.12	$8,576
Above EL	122	6	1	732	10/60	122	$47.12	$5,749
Additional	203	1	1	203	10/60	34	$47.12	$1,602
Totals	**689**			**4,211**		**702**		**$33,079**

Employee notification (§1910.1047(d)(7))

Employers must provide written notification to each worker of their exposure-monitoring results, either individually or by posting their exposure-monitoring results in an appropriate location that is accessible to the affected workers. OSHA assumes a secretary spends 5 minutes (5/60 hour) documenting exposure levels (including representative exposure levels) and posting the results. OSHA assumes that worker exposures above the EL occur only in facilities that have airborne EtO concentrations at or above the AL; therefore, employers would post their TWA and EL monitoring results simultaneously (i.e., employee notification of elevated TWAs and ELs can occur in a single posting). Table 4 summarizes the burden hour and cost determinations for this employee-notification requirement:

Table 4: Employee Exposure Notification Burden Hour and Cost Estimates Samples and Cost

Monitoring	No. of	Frequency	Total	Sampling	Burden	Loaded	Cost

5As stated in Table 3, each facility collects 6 samples in determining ELs. In addition, OSHA assumes that employee exposures above the EL occur only in facilities that have EtO concentrations at or above the AL.

Requirement	Facilities	per Year	Samples	Time (Hours)	Hours	Wage Rate	
Above TWA; Above EL	182	4	728	5/60	**61**	$29.60	**$1,806**
At/Above AL & At/Below TWA; Above EL	182	2	364	5/60	**30**	$29.60	**$888**
Additional	203	1	203	5/60	**17**	$29.60	**$503**
Totals			**1,295**		**108**		**$3,197**

(B) Compliance program (§1910.1047(f)(2))

If any worker EtO exposures exceed the TWA or EL, the employer must establish and implement a written program to reduce the worker's exposure to or below the TWA or EL; the employer must do so using primarily engineering controls and work practices, and then respirators as permitted by the Standard. The written compliance program must also include a schedule for periodic leak detection surveys, as well as a plan for emergency situations as specified in paragraph (h)(i). Employers must review their written compliance programs at least annually and update them as necessary to account for significant program changes.

This provision requires existing facilities to review their written compliance program at least annually if the facility has worker exposures above the TWA or EL. Based on the analysis conducted above under "Periodic and Additional Monitoring," if 9% and 6% of the existing facilities have worker exposures above the TWA or EL, respectively, then a total of 304 existing facilities (182 facilities with workers who exceed the TWA + 122 facilities with workers who are above the EL) must review their written compliance programs annually. OSHA assumes from the RIA for the Standard that, on average, a professional spends 1 hour reviewing and updating a written compliance program.

Burden hours: 304 facilities x 1 hour = 304 hours
Cost: 304 hours x $ 47.12 = $ 14,324

(C) Respirator protection (§1910.1047(g)(2))

The Standard requires employers to implement a respiratory-protection program in accordance with the provisions of OSHA's Respiratory Protection Standard (29 CFR 1910.134). OSHA takes the burden for this requirement under the ICR for the Respiratory Protection Standard for General Industry (29 CFR 1910.134), OMB Control Number 1218-0099.

(D) Emergency situations (§1910.1047(h)(1)(i))

Employers must develop a written plan for emergency situations for each workplace where there is a possibility of an emergency. The plan must provide workers engaged in correcting

emergency conditions with respiratory protection specified by paragraph (g) of the Standard. The plan must also include the elements required by 29 CFR 1910.38 and 29 CFR 1910.39, "Emergency action plans" and "Fire prevention plans," respectively.

(E) Medical surveillance (§1910.1047(i))

General requirements and medical examinations and consultations (§1910.1047(i)(1) and (i)(2))

Employers must provide workers with an initial medical examination prior to their assignment to an area where EtO exposures may be at or above the AL for 30 or more days a year, and an annual medical examination to any worker who has EtO exposures at or above the AL for 30 or more days a year. The Standard requires additional medical examinations for workers who: terminate employment or receive a reassignment to an area where exposure to EtO is not at or above the AL for at least 30 days per year; have EtO exposures that occurred during an emergency situation; notify the employer that they have signs or symptoms indicating possible overexposure to EtO; or desire medical advice concerning the effects of current or past exposure to EtO on their ability to produce a healthy child. The employer must also increase the frequency of medical examinations if so advised by the examining physician.

To estimate the burden hours and costs of initial medical examinations for this ICR, OSHA multiplied, for each industry sector, the number of exposed workers by the turnover rate specified for the sector in the RIA of the Standard. However, the RIA found that many employers in each industry sector provided newly hired workers with initial medical examinations prior to publication of the Standard (i.e., as a usual and customary practice); the Agency refers to the proportion of employers in each sector who administered initial medical examinations to their newly hired workers prior to publication of the Standard as the "pre-Standard compliance rate." Accordingly, after multiplying the number of exposed workers by the turnover rate for each industry sector, then the Agency multiplied the resulting product by the non-compliance rate to get the number of responses to be multiplied by the time per response.

The RIA also assumed that a worker would be away from the job for 2 hours while taking the medical examination (i.e., "lost time"), except for workers in hospitals that use EtO sterilizers, who would be away from their jobs for only 30 minutes (30/60 hour) because they do not have to travel to a medical facility for the medical examination.

The following chart summarizes the burden hour and cost determinations for the initial medical-examination requirement.

Table 5: Initial Employee Medical Examinations Burden Hour and Cost Estimates

Industry Sector	No. of Exposed Employees	Turnover Rate (%) [2]	Non-Compliance Rate	Total Exposed Employees	Lost Time (Hours)	Total Burden Hours	Loaded Wage Rate	Total Cost
EtO Producers	1,246	43.1%	0%	0	2	0	$43.12	$0
EtO Ethoxylators	6,300	43.1%	6%	163	2	326	$43.12	$14,057
Hospitals Using EtO Sterilizers	22,068	44.0%	0%	0	30/60	0	$43.12	$0
Medical-Product Manufacturers	1,083	43.1%	34%	159	2	318	$43.12	$13,712
Contract Sterilizers	209	44.0%	0%	0	2	0	$43.12	$0
Total				**322**		**644**		**27,769**

[1] This represents the hires rate for the Manufacturing (43.1%) and Health Care and Social Assistance (44.0%) sectors taken from Job Openings and Labor Turnover Survey (JOLTS), Bureau of Labor Statistics, 2023.

The Agency also used the RIA for the Standard to estimate the burden hours and cost of periodic medical examinations. According to the RIA, 25% of the employers in each industry sector provided periodic medical examinations as a usual and customary practice prior to publication of the final Standard (i.e., the "pre-Standard compliance rate"). The Agency, therefore, estimated burden hours and costs by multiplying the number of exposed workers by the pre-standard compliance rate, and then subtracting this product from the number of exposed workers to obtain the number of exposed workers who must receive the periodic medical examinations required by the Standard. Additionally, OSHA used the same "lost time" estimates for these medical examinations that it used for the initial medical examinations. The following chart summarizes the burden hour and cost determinations for the periodic medical-examination requirement.

Table 6: Periodic Employee Medical Examinations Burden Hour and Cost Estimates

Industry Sector	No. of Exposed Employees	Non-Compliance Rate	Total Exposed Employees	Lost Time (Hours)	Total Burden Hours	Loaded Wage Rate	Total Cost
EtO Producers	1,246	75%	935	2	1,870	$43.12	$80,634
EtO Ethoxylators	6,300	75%	4,725	2	9,450	$43.12	$407,484
Hospitals Using EtO Sterilizers	22,068	75%	16,551	30/60	8,276	$43.12	$356,861
Medical-Product Manufacturers	1,083	75%	812	2	1,624	$43.12	$70,027
Contract Sterilizers	209	75%	157	2	314	$43.12	$13,540
Totals			**23,180**		**21,534**		**$928,546**

Additional Medical Examinations

Employers must also provide workers with the following additional medical examinations: After exposure to an emergency situation; on termination of employment or reassignment to a work area with EtO exposures below the AL; after developing signs or symptoms of possible EtO exposure; if they desire medical advice concerning their reproductive ability; or as indicated by the examining physician. For the purposes of this ICR, OSHA assumes that 1 percent of the 30,906 exposed workers will require an additional medical examination each year. Hospitals using EtO sterilizers employ 22,026 of these workers, while the other industry sectors covered by the Standard employ the remaining 8,838 workers; 1% of the workers in the hospital and non-hospital sectors would be 221 and 88 workers, respectively. OSHA used the same "lost time" estimates for these medical examinations that it used for the initial and periodic medical examinations (i.e., 2 hours for non-hospital workers and 30 minutes (30/60 hours) for hospital workers).

Burden hours: (88 medical examinations x 2 hours) + (221 medical examinations x 30/60 hours) = 287 hours

Cost: 287 hours x $43.12= $ 12,375

Note total responses = 309

In summary, the total burden hours and cost for the lost time accrued by workers who take the various medical examinations required by the Standard are:

Burden hours:	Initial medical examinations =	643
	Periodic medical examinations =	21,533
	Additional medical examinations =	287
	Total:	22,463
Cost:	Initial medical examinations =	$27,737
	Periodic medical examinations =	$ 928,546
	Additional medical examinations =	$12,375
	Total:	$ 968,658

Information provided to the physician (§1910.1047(i)(3))

Employers must provide the examining physicians with specific information on each worker who receives a medical examination. Accordingly, the 2,026 facilities covered by the Standard must administer a total of 23,811 medical examinations to their workers each year (i.e., 322 initial medical examinations[6] + 23,180 periodic medical examinations[7] + 309 additional medical

6 Sum of total exposed employees multiplied by turnover rate multiplied by one minus the pre-standard compliance rate from each row of Table 5 Initial Exams.

7 Sum of total exposed employees multiplied by one minus the pre-standard compliance rate from each row of Table 6 Periodic Exams.

examinations[8]). The Agency assumes that, for each medical examination administered to a worker, a secretary requires 5 minutes (5/60 hour) to compile the information and provide it to the physician.

Burden hours: 23,811 medical examinations x 5/60 hour = 1,984 hours
Cost: 1,984 hours x $ 29.60 = $58,726

Physician's written opinion (§1910.1047(i)(4))

Employers must provide a copy of the physician's written opinion to each worker who receives a medical examination. OSHA assumes that a secretary will take 5 minutes (5/60 hours) to deliver a copy of the physician's written opinion to each worker receiving an examination. Based on the analysis performed under "information provided to the examining physician" above, workers received 23,811 medical examinations annually, each of which results in an opinion written by the examining physician.

Burden hours: 23,811 medical examinations x 5/60 hour = 1,984 hours
Cost: 1,984 hours x $29.60 = $58,726

(F) Communication of EtO hazards to employees (§1910.1047(j))

Signs and Labels (§1910.1047(j)(2)

"See item 2, above."

Information and Training (§1910.1047(j)(3))

"See item 2, above."

(G) Recordkeeping (§1910.1047(k))

Objective data for exempted operations (§1910.1047(k)(1))

Employers must keep a record of the objective data. OSHA believes that employers have previously developed required objective data and now must maintain the objective-data records. The regulatory burden for maintaining objective data is negligible; therefore, the Agency is taking no burden hours or costs for this requirement.

Exposure measurements (§1910.1047(k)(2))

8 1% of total exposed employees from Table 5 Initial Exams.

The Standard requires each employer to establish and maintain an accurate record of all measurements taken to monitor worker exposure to EtO. OSHA estimates that a secretary will spend 5 minutes (5/60 hour) to establish, maintain, and update each exposure-monitoring record according to the requirements of this provision. Based on analysis above under "Exposure monitoring," the 689 facilities with additional exposure monitoring will generate a total of 4,211[9] periodic and additional exposure-monitoring records for determining either TWAs or ELs.

Burden hours: 4,211 records x 5/60 hour = 351 hours
Cost: 351 hours x $29.60 = $10,390

Medical records (§1910.1047(k)(3))

Under this provision, employers must establish and maintain a record of each medical examination. As noted in the analysis conducted above under "Information provided to the physician," the 2,026 facilities covered by the Standard administer a total of 23,811 medical examinations to exposed workers each year. OSHA estimates that a secretary will require 5 minutes (5/60 hour) to establish, maintain, and update each of these records.

Burden hours: 23,811 records x 5/60 hour = 1,984 hours
Cost: 1,984 hours x $29.60 = $ 58,726

Availability (§1910.1047(k)(4))[10]

Employers must provide, on request, objective data, worker exposure-monitoring records, and written compliance programs to affected workers, former workers, and designated worker representatives, as well as a worker's medical surveillance records to the worker and to anyone having the worker's specific written consent.

Table 7 – Total Number of Employees Hired Annually

Sector	Exposed Employees	Turnover Rate	Annual Employment
Producers	1,246	43.1%	1,783
Ethoxylators	6,300	43.1%	9,015
Hospitals	22,068	44.0%	31,778

9 The total number of exposure monitoring records is based on the total number of samples taken by employers (see Table 3).

10 The Agency has determined that the requirement for employers to make records available upon request to the Assistant Secretary is no longer considered a collection of information. OSHA typically requests access to records during an inspection, and information collected by the Agency during the investigation is not subject to the PRA under 5 CFR 1320.4(a)(2).

Medical- Product Manufacturers	1,083	43.1%	1,550
Contract Sterilizers	209	44.0%	301
Totals	**30,906**		**44,427**

The agency assumes that 10% of exposed workers (4,443) (see Table 7 below), including designated worker representatives, will request access to exposure-monitoring and medical-surveillance records, or written compliance programs, each year. OSHA estimates that it will take a secretary 5 minutes (5/60 hour) to make these records available to the workers and their designated worker representatives.

Burden hours: 4,443 workers/representatives x 5/60 hour = 370 hours
Cost: 370 hours for workers/representatives x $29.60 (secretary) = $10,952

THE ETHYLENE OXIDE (EtO) STANDARD (29 CFR 1910.1047)
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The following table summarizes the burden hours and costs associated with each provision of the Standard that contains a collection of information:

TABLE 8 - RESPONDENTS, RESPONSES, BURDEN HOURS AND ANNUAL BURDEN COST FOR PRIVATE SECTOR

Collection of Information	Type of Respondent*	No. of Respon-dents	No. of Responses per Respondent	Total Responses	Time per Response (Hrs.)	Total Burden Hours (rounded)	Loaded Hourly Wage Rate	Total Burden Costs (rounded)
(A) Exposure monitoring (§1910.1047(d))								
Exposure Monitoring (§1910.1047(d))	First Line Supervisor	2,026	2.0785	4,211	10/60	702	$47.12	$33,079
Exposure Notification (§1910.1047(d)(7))	Secretaries and Administrative Assistants	2,026	0.6402	1,295	5/60	108	$29.60	$3,197
(B) Compliance program (§1910.1047(f)(2))								
Compliance Program (§1910.1047(f)(2))	First Line Supervisor	2,026	0.1500	304	1	304	$47.12	$14,324
(E) Medical surveillance (§1910.1047(i))								
Initial Medical Examinations (§1910.1047(d)(1) & (d)(2))	Occupational Health and Safety Specialist and Technician	2,026	0.1589	322	2	644	$43.12	$27,769
Periodic Medical Examinations (§1910.1047(d)(3))	Occupational Health and Safety Specialist and	2,026	3.27196	6,629	2	13,258	$43.12	$571,685

TABLE 8 - RESPONDENTS, RESPONSES, BURDEN HOURS AND ANNUAL BURDEN COST FOR PRIVATE SECTOR

Collection of Information	Type of Respondent*	No. of Respon-dents	No. of Responses per Respondent	Total Responses	Time per Response (Hrs.)	Total Burden Hours (rounded)	Loaded Hourly Wage Rate	Total Burden Costs (rounded)
	Technician							
		2,026	8.169299	16,551	30/60	8,276	$43.12	$356,861
Additional Medical Exams (§1910.1047(d)(5))	Occupational Health and Safety Specialist and Technician	2,026	0.1525	88	2	176	$43.12	$7,589
		2,026	0.10908193	221	30/60	111	$43.12	$4,786
Information provided to the physician (§1910.1047(i)(3))	Secretaries and Administrative Assistants	2,026	11.7527	23,811	5/60	1,984	$29.60	$58,726
Physician Written Opinion (§1910.1047(i)(4))	Secretaries and Administrative Assistants	2,026	11.7527	23,811	5/60	1,984	$29.60	$58,726
(G) Recordkeeping (§1910.1047(k))								
Exposure Measurements (§1910.1047(k)(2))	Secretaries and Administrative Assistants	2,026	2.0785	4,211	5/60	351	$29.60	$10,390
Medical Records (§1910.1047 (k)(3))	Secretaries and Administrative Assistants	2,026	11.7527	23,811	5/60	1,984	$29.60	$58,726

THE ETHYLENE OXIDE (EtO) STANDARD (29 CFR 1910.1047)
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TABLE 8 - RESPONDENTS, RESPONSES, BURDEN HOURS AND ANNUAL BURDEN COST FOR PRIVATE SECTOR

Collection of Information	Type of Respondent*	No. of Respon-dents	No. of Responses per Respondent	Total Responses	Time per Response (Hrs.)	Total Burden Hours (rounded)	Loaded Hourly Wage Rate	Total Burden Costs (rounded)
Availability (§1910.1047(k)(4))	Secretaries and Administrative Assistants	2,026	2.1930	4,443	5/60	370	$29.60	$10,952
Total		**2,026***		**109,708**		**30,252**		**$1,216,810**

*= not cumulative

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government or (4) as part of customary and usual business or private practices.**

OSHA estimates that the total annual cost to respondents is $5,129,858 which consists of $320,036 for collecting exposure monitoring samples and $4,809,822 to administer medical examinations and questionnaires. -

Exposure Monitoring

The Agency estimated a cost of $72[11] per sample to collect and analyze airborne EtO samples.

11The Consumer Price Index (CPI) indicated a 5% increase in the annual average price of professional medical services from 2020 to 2022; the cost of an exposure monitoring sample was assumed to have increased by 5% as well, from $72 to $76.

The determinations made under "Exposure monitoring" above indicate that employers collect 4,211 EtO samples each year. (4,211 x $76= $320,036)

Medical Surveillance

Consistent with recent ICRs and RIAs for other standards, the Agency estimates that each medical examination costs $202.[12] According to the analysis conducted above under "Information provided to the physician," the 2,026 facilities covered by the Standard administer a total of 23,811 medical examinations each year. (23,811 x $202 = $4,809,822).

Table 9 – Total Capitol Cost for Exposure Monitoring and Medical Surveillance

Exposure Monitoring	**Number of EtO Samples Collected**	**Unit Cost**	**Total Cost**
Samples	4,211	$76	$320,036
Medical Surveillance	**Number of Medical Examination**	**Unit Cost**	**Total Cost**
Examinations	23,811	$202	$4,809,822
Total			**$5,129,858**

14. Provide estimates of annualized cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

There is no cost to the Federal Government.

15. Explain the reasons for any program changes or adjustments.

There is an overall adjustment decrease in burden hours for this ICR. The burden hours have decreased a total of 1,005 hours (from 31,257 hours to 30,252 hours). The adjusted decrease is primarily due to the estimated number of establishments covered by the standard.

There is an overall adjusted increase in capital costs of $159,050 (from $4,970,808 to $5,129,858). There was a decrease in the number of medical exams administered, but the cost of exposure monitoring samples and medical examinations increased.

12 The Consumer Price Index (CPI) indicated an 5% increase in the annual average price of professional medical services from 2020 to 2022; the cost of a medical examination was assumed to have increased by 5% as from $192 to $202.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

OSHA will not publish the information collected under the Standard.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

OSHA is not seeking approval to not display the expiration date.

OSHA lists current valid control numbers in §§1910.8, 1915.8, 1917.4, 1918.4, and 1926.5 and publishes the expiration date in the Federal Register notice announcing OMB approval of the information-collection requirement (*see* 5 CFR 1320.3(f)(3)). OSHA believes that this is the most appropriate and accurate mechanism to inform interested parties of these expiration dates.

18. Explain each exception to the certification statement.

OSHA is not seeking an exception to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The supporting statement does not contain any collection of information requirements that employ statistical methods.