SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS IN THE ETHYLENE OXIDE (EtO) STANDARD (29 CFR 1910.1047)[1,2] (OFFICE OF MANAGEMENT AND BUDGET (OMB) CONTROL NO. 1218-0108(September 2010))

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 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. Items 2 and 12 below list and describe the specific information collection requirements of the Standard.

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[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, and 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.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The following are the collection of information requirements 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 employee 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.

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)(1))***

§1910.1047(j)(1)(i)

The employer shall post and maintain legible signs demarcating regulated areas and entrances or accessways to regulated areas that bear the following legend:

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)(1)(ii)

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)(1)(ii)(A):

DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD;

and

> §1910.1047(j)(1)(ii)(B) - A warning statement against breathing airborne concentrations of EtO.

§1910.1047(j)(1)(iii)

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.

L. Material safety data sheets (§1910.1047(j)(2))

Employers who are manufacturers or importers of EtO shall comply with the requirements regarding development of material safety data sheets as specified in 29 CFR 1910.1200(g) of OSHA's Hazard Communication standard.

Purpose: MSDSs serves as the main source of information to workers and downstream employers who must be provided with a MSDS if EtO is produced and shipped out of a plant. In addition, the MSDS serves as the basic source of information on the hazards of EtO essential to the training provisions required in the Standard.

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

§1910.1047(j)(3)(i)

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; and

§1910.1047(k)(2)(ii)(F) - Name, social security number 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 and social security number 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))

§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: The OSHA compliance officer uses these records to assess employer compliance with the major requirements of the Standard. 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))

§1910.1047(k)(5)(i)

The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

§1910.1047(k)(5)(ii)

Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least 90 days prior to disposal and transmit them to the Director.

Purpose: NIOSH may serve as a repository for exposure monitoring and medical-surveillance records, workers have access to their records if needed.

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 burden.

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 purpose(s) described in Item 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, as well as any technical or legal obstacles to reducing the 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 date 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 those 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 3 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.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), OSHA published a notice in the *Federal Register* on November 4, 2009 (74 FR 57198, Docket No. OSHA-2009-0035) soliciting comments from the public and other interested parties on the information collection requirements contained in the Standard on Ethylene Oxide (29 CFR 1910.1047). The notice was part of a preclearance consultation program that provides the general public and government agencies with an opportunity to comment on OSHA's request for an extension by OMB of a previous approval of the information collection requirements found in the EtO Standard. The Agency received one comment from P. Richard Warburton, PhD, Chief Technology Officer and General Counsel of the ChemDAQ Corporation.

Dr. Warburton provided no comment on the burden hours or cost estimates associated with the Standard's collection of information requirements. Rather, Dr. Warburton, raised the question of whether the current methods of measurement are sufficient to satisfy §1910.1047(c)(1) and (2), (PEL and STEL), and Section 6(b)(5) of OSH Act. Secondly, Dr.Warburton raised the question of whether the current methods and measurement protocols, specifically leak detection and other methods of compliance, are sufficient to satisfy §1910.1047(f) (2)(ii), Methods of Compliance. Lastly, Dr. Warburton expressed concern that the current methods of sampling and other means of compliance fail to satisfy the requirement of §1910.1047(h)(2), which states, "Where there is a possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly."

Dr. Warburton suggests that these EtO provisions do not protect workers should there be a leak in a system or a sterilizer that uses EtO. Dr. Warburton contends that 24-hour daily sampling is necessary because of the high volatility and reactivity of EtO. He further contends that the employer will need moment-to-moment exposure profiles to ensure the safety of employees, claiming that the exposure protocols required by OSHA are not sufficiently protective because the protocols do not explicitly require continuous EtO monitoring. Based on these comments, Dr. Warburton recommends to the Office of Management and Budget not approve these collection of information requirements since they fail to provide adequate protection to employees.

Dr. Warburton contends that exposure monitoring conducted under paragraph (d) does not fulfill the obligations stated under paragraph (c). Paragraph (c) requires the employer to *ensure* that no worker is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an (8)-hour time-weighted average. Dr. Warburton argues further that employers must use continuous monitoring systems to ensure employee protection against unexpected leaks, and that paragraph (d) does not protect against unforeseen leaks or releases of EtO.

The purpose of the exposure-monitoring provisions under paragraphs (d)(1) through (4) is to identify and determine *employee* exposure levels during their actual working operations; not area exposures. Paragraph (d)(5), additional monitoring, specifies "whenever there has been a change in 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;" this provision, therefore, requires additional monitoring when working conditions change. This provision also would require monitoring after an emergency situation. These paragraphs do not regulate how an employer must protect workers in the event of a leak or accidental release of EtO. Using the area monitors, as recommend by Dr. Warburton, would not identify specific employee exposures while they are performing their job tasks, and, thus, would not meet the requirements of paragraph (d). Other provisions of the standard keep the number of emergencies to a minimum, and also provide protection to workers during and after such emergencies. In addition to paragraph (d), paragraphs (e) (demarcating regulated areas), (f)(2)(ii) (schedule for leak detection), (g)(2) (use of respirators in emergencies). (h) (emergency situations), and (j)(3) (training) provide protection to workers during emergencies, and would ensure their exposures are below the standard's PELs. OSHA concurs with Dr. Warburton that a continuous-monitoring system could alert employees to potential leaks and accidental releases of EtO. However, OSHA does not believe that such systems are the only means to protect employees during a leak or accidental release of EtO.

OSHA maintains that the EtO standard sufficient protects workers, and believes that preventing emergencies and leaks is critical to protecting employees. Accordingly, the EtO preamble, standard, and Appendix A of the Standard provide compliance mechanisms involving comprehensive engineering and administrative controls (supplemented by respirators, as necessary) which is evaluated by personal air sampling and leak-detection devices. OSHA concedes that EtO is a highly reactive chemical and can deteriorate rubber gaskets and seals. Both OSHA and the Environmental Protection Agency (EPA) require/recommend that employers provide a method to detect leaks in sterilizers and EtO gas-cylinder delivery systems. OSHA requirements are performance based, while EPA recommends using a chlorofluorocarbon detector on a two-week interval. The Agency's performance-based requirements allow employers to adopt the latest technology to meet the monitoring requirements. The standard does not prohibit the use of 24-hour EtO monitoring, but it does not promote or require its use. The EPA recommendations also make no mention of 24-hour EtO monitoring at fixed sites. Appendix A, a non-mandatory appendix in the standard, sets forth EPA's recommendations for workplace design and work practices for hospitals and healthcare facilities that use sterilizers. The standard's provisions, and EPA's recommendations, ensure that accidental-release situations do not occur, thereby limiting employee overexposure. Therefore, employers can attain a safe workplace without using continuous-monitoring devices.

EPA recommended design criteria are:

- Install gas-line hand valves to minimize leakage during cylinder change.
- Install capture boxes at EtO gas/water discharge points, or an isolated room that is well ventilated and is infrequently illustrated.

- Position existing and newly installed aeration units or rooms as close as possible to the sterilizer, and provide exhaust ventilation to a dedicated, non-circulating air system.
- Provide exhaust ventilation during EtO cylinder change. [Note: Three alternatives provided, with no mention of continuous monitoring or an alarm system.]
- Provide exhaust ventilation near the sterilizer door area by placing the sterilizer in a laboratory fume hood or a metal canopy hood above the sterilizer's door opening. [Note: Opening the door at the end of the purge cycle is a major source of potential worker exposure.] Hood design and dedicated, non-circulating ventilated air should be sufficiently robust to keep the sterilizer operator exposure below the 5 ppm, 15-minute excursion limit required by the standard.
- Provide exhaust ventilation of sterilizer relief valves.
- Install audio and visual alarm systems that provide a warning when the ventilation system motor is not working. [Note: No reference made of direct-reading instruments based on area measurements of ETO.]

EPA recommended work practices are:

- Change supply-line filters. When using a mixture consisting of 12% EtO and 88% chlorofluorocarbon, use a fluorocarbon leak detector for hoses, valves, and filters.
- Designate a restricted access area (or "regulated area" in OSHA terminology) that is limited to essential personal doing potentially high-exposure activities.
- Develop specific work procedures for unloading sterilizers.
- Have operators visually inspect sterilizer-door gaskets daily for cracks and debris so as to ensure the integrity of the door seal. Every two weeks, maintenance personnel should inspect sterilizer door gaskets, cylinder and vacuum piping, hoses, filters, and solenoid and other valves under pressurized conditions using a fluorocarbon leak detector when using 12%/88% gas-cylinder systems. Replace all leaky or compromised parts and equipment as necessary.

Other provisions of the standard provide sufficient protection to employees without using continuous monitoring. These provisions include:

- Paragraph (d) *Permissible Exposure Limits*. Peak exposures are associated with many EtO processes. These include, opening a sterilizer door after the completion of the sterilization cycle, entering a large aeration room or chamber, and changing or repairing EtO gas cylinders and lines. The standard establishes a STEL of 5 ppm for EtO during any 15-minute exposure period. This provision addresses both routine and accidental-release situations.
- Paragraph (e) R*egulated areas.* In the preamble to the standard, OSHA specifically redefined a regulated area based on employee exposure. These areas have temporary high exposures, but workers were generally not present would not be treated as a regulated area, which triggers a series of monitoring and administrative procedures. EPA has a similar concept which they call restricted access.

- Paragraph (f), *Methods of Compliance*. This paragraph establishes the following key points:

– The need for a written work plan to control EtO hazards, and sharing the plan with key management personnel and those operating and maintenance employees directly affected by EtO exposures and/or involved in methods of control.
– Similar to the EPA activities described above, the need for enhanced maintenance leak detection, coupled with a program of effective equipment repair and part replacement.

Dr. Warburton also commented that paragraph (h)(2), which addresses means of alerting potentially affected employees of emergency occurrences promptly, should require that employers use continuous monitoring for ethylene oxide. Paragraph (h)(2) of the standard is a performance requirement that specifies that employers must have a means of alerting potentially affected employees of emergencies in a prompt manner. The standard does not specify any particular means of warning employees, but instead gives employers the flexibility to use any approach that will achieve the provision's goal. As stated in the preamble to the 1984 final rule, OSHA determined that "[t]he performance language of the emergency situation paragraph of the final standard will give employers the flexibility to choose any effective method of alerting employees, including communications systems, voice communication or a bell or other alarm" (49 FR 25783). For example employers may use continuous, real-time EtO alarms as one method of complying with this requirement. In 1987, OSHA also issued a compliance interpretation letter stating that "a sophisticated alarm system might be unnecessary for some facilities such as small hospitals with only one EtO sterilizer." In addition, ethylene oxide sterilizers are designed to ensure worker using the sterilizer are protected from the hazards associated with EtO. For example, sterilization chambers generally have indicators to alert workers to changes in pressure and possible release of EtO, and pressure-release valve to prevent over-pressurization of sterilizers (and the release of EtO into the ambient atmosphere). Sterilizers also incorporate a means to ensure that sterilizing conditions are achieved and maintained within the sterilizer chamber by detecting problem conditions and preventing continuation of the phase timer or the cycle time until the conditions are again within specification.

Thus, OSHA does not agree that the standard should be modified to require continuous exposure monitoring to meet the requirement to alert employees in emergency-release requirement. OSHA continues to believe that employers are in the best position to identify an effective method of complying with this requirement based on the circumstances of their particular workplaces.

Paragraph (k)(2) of the standard requires employers to develop and maintain employee exposure records. These records must include: date of exposure measurement; operation involving exposure to EtO which is being monitored; sampling and analytical methods used and evidence of their accuracy; number, duration, results of samples taken; types of protective devices worn, if any; and name, Social Security number, and exposure of the employee whose exposures are represented. In addition, employers must maintain these records must for at least 30 years (per 29 CFR 1910.1020). These records are generated when employers conduct initial, periodic, and

additional monitoring under paragraph (d). Mr. Warburton argues that continuous monitoring would reduce the burden hours and costs associated with exposure monitoring records. However, these records would still need to be generated, and documentation from a continuous monitoring system would not provide the required information.

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

The Agency will not 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.

As medical records contain personal information, OSHA and NIOSH have taken steps to assure that the medical data in these records are kept confidential. Agency practices and procedures governing access to worker medical records are contained in 29 CFR 1913.10.

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.

There are no provisions in the Standard requiring sensitive information.

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 14.**

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.[3] 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[4]	12
EtO Ethoxylators[5]	64
Hospitals Using EtO Sterilizers[6]	3,823
Medical-Product Manufacturers[7]	86
Contract Sterilizers[8]	16
Total	**4,001**

Wage Rates: The Agency adopted the following mean wage rates from the *Occupational Employment Statistics, May 2008 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325100 – Basic Chemical Manufacturing* (published by BLS in 2008). Total compensation for these occupational categories includes an adjustment of 30.2 percent for fringe benefits; this figure represents the average level of fringe benefits in the private sector

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

[4]This figure is from the OSHA Regulatory Impact Analysis for the Ethylene Oxide Standard, 2003.

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

[6]This figure is from the County Business Patterns (for the year 2007), U.S. Department of Commerce, 2009. OSHA multiplied the total number of hospitals (7,352) identified from this source by 52% because several studies in the mid-90's estimated that 52% of hospitals use EtO; therefore, the total number of hospitals used in determining burden hours and cost in this ICR is 3,823 (i.e., 7,352 x 0.52 =3,823).

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

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

2008.[9] The costs of labor used in this analysis are; therefore, estimates of total hourly compensation.

The Agency determined average wage rates using average hourly earnings, including benefits, to represent the cost of worker time. These hourly wages are:

- First-Line Supervisor/Manager of Production and Operating Workers (51-1011): $41.61
- Occupational Health and Safety Specialist and Technician (29-9012): $30.34
- Secretary (43-6014): $20.57

The following table summarizes the burden hours and costs associated with each provision of the Standard that contains a paperwork requirement:

[9]Based on benefit statistic for "Civilian, All workers, Total Benefits," Employer Cost for Employee Compensation, Bureau of Labor Statistics, October 1, 2009.

Table 2
Summary of Burden Hours and Cost Estimates

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Change	Estimated Cost
Exposure monitoring	0	0	0	0
Initial monitoring	0	0	0	0
Periodic and additional monitoring	1,937	1,414	-523	$58,836
Employee notification of monitoring Results	281	205	-76	$4,217
Compliance program	821	600	-221	$24,966
Respirator program	0	0	0	$0
Emergency situations	0	0	0	$0
Medical surveillance	0	0	0	0
General requirements and medical examinations and consultations	27,730	28,345	615	$859,987
Information provided to the physician	3,527	3,226	-301	$66,359
Physician's written opinion	3,527	3,226	-301	$66,359
Communication of EtO hazards to employees	0	0	0	0
Signs and labels	0	0	0	$0
Material safety and data sheets	0	0	0	$0
Information and training	0	0	0	$0
Recordkeeping	0	0	0	0
Objective data for exempted operations	0	0	0	$0
Exposure measurements	911	666	-245	$13,700
Medical records	3,527	3,226	-301	$66,359
Availability	468	576	108	$11,932
Transfer of records	3	3	0	$62
Totals	**42,732**	**41,487**	**-1,245**	**$1,172,777**

Burden Hour and Cost Determinations

The following sections provide the number of burden hours and costs resulting from the information collection requirements of 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 (.17 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. While there is an overall decrease in the number of establishments, OSHA notes increases in the number of establishments for two individual sectors. These sectors are EtO Ethoxylators and Contract Sterilizers. OSHA believes that these are newly identified for the analysis, but not new establishments.

The Agency did not identify any new establishments in Table 1, "Number of facilities in Industry Sectors." In fact, the number of hospitals using ethylene oxide sterilizers has decreased over the last 3 years. Also, there are a smaller number of medical product manufacturers and no spice manufacturers were included in the facilities by industry sector. The EtO Ethoxylators facility was the only type of facility that saw an increase in their number. This may be due to the capturing of these businesses and not necessarily new facilities.

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 360) 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 360) of all facilities will have worker exposures above the TWA; and 6% of all facilities (240) will have exposures above the EL.[10] OSHA also assumes that 10% of the total facilities (400) require

[10]As 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.

additional monitoring. 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	Sampling Frequency per Year	Sampling Time (Hours)	Burden Hours per Requirement	Professional Wage Rate	Cost per Requirement
Above TWA	360	3	4	0.17	734	$41.61	$30,542
At/Above AL & At/Below TWA	360	3	2	0.17	367	$41.61	$15,271
Above EL	240	6	1	0.17	245	$41.61	$10,194
Additional	400	1	1	0.17	68	$41.61	$2,829
Totals	**1,360**				**1,414**		**$58,836**

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 (.08 hour) documenting exposure levels (including representative exposure levels) and posting the results. As stated in footnote 9, 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 Requirement	No. of Facilities	Sampling Frequency per Year	Time to Post (Hours)	Burden Hours per Requirement	Secretary Wage Rate	Cost Per Requirement
Above TWA; Above EL	360	4	0.08	115	$20.57	$2,366
At/Above AL & At/Below TWA; Above EL	360	2	0.08	58	$20.57	$1,193
Additional	400	1	0.08	32	$20.57	$658
Totals	1,120			205		$4,217

(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 600 existing facilities (360 facilities with workers who exceed the TWA + 240 facilities with workers who are above the EL) must review their written compliance programs annually. OSHA assumes from the RIA for the final Standard that, on average, a professional spends 1 hour reviewing and updating a written compliance program. OSHA assumes that there are new facilities, but that more facilities are included in the ICR, but were not included before.

Burden hours: 600 facilities x 1 hour = 600 hours
Cost: 600 hours x $41.61 = $24,966

(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 final 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 final 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 final Standard as the "pre-Standard compliance rate." Accordingly, after multiplying the number of exposed workers by the turnover rate for each industry sector, the Agency multiplied the resulting product by the pre-Standard compliance rate, and then subtracted this latter product from the first product (i.e., the product obtained from multiplying the number of exposed workers by the turnover rate) to obtain the number of exposed workers in each sector who must receive the initial medical examinations required by the Standard.

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 .50 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 per facility[11]	No. of Exposed Employees	Turnover Rate (%)[12]	Pre-Standard Compliance Rate	Lost Time (Hours)	Burden Hours	Employee Wage Rate	Cost per Sector
EtO Producers	89	1,068	32%	100%	0	0	$30.34	0
EtO Ethoxylators	60	3,840	32%	94%	2	148	$30.34	$4,490
Hospitals Using EtO Sterilizers	12	45,876	36%	100%	0	0	$30.34	0
Medical-Product Manufacturers	19	1,634	32%	66%	2	356	$30.34	$10,801
Contract Sterilizers	19	304	36%	100%	2	0	$30.34	0
Totals		**52,722**				**504**		**$15,291**

The Agency also used the RIA for the final 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.

[11]EtO exposed employee figures are taken from *Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard*, [29 CFR 1910.1047], OSHA, March 2005.

[12] Turnover rates are taken from *Job Openings and Labor Turnover Survey (JOLTS)*, Bureau of Labor Statistics, 2008.

Table 6
Periodic Employee Medical Examinations
Burden Hour and Cost Estimates

Industry Sector	No. of Exposed Employees	Pre-Standard Compliance Rate	Lost Time (Hours)	Burden Hours	Employee Wage Rate	Cost per Sector
EtO Producers	1,068	25%	2	1,602	$30.34	$48,605
EtO Ethoxylators	3,840	25%	2	5,760	$30.34	$174,758
Hospitals Using EtO Sterilizers	45,876	25%	0.5	17,204	$30.34	$521,969
Medical-Product Manufacturers	1,634	25%	2	2,451	$30.34	$74,363
Contract Sterilizers	304	25%	2	456	$30.34	$13,835
Totals	**52,722**			**27,473**		**$833,530**

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 52,722 exposed workers will require an additional medical examination each year. Hospitals using EtO sterilizers employ 45,876 of these workers, while the other industry sectors covered by the Standard employ the remaining 6,846 workers; 1% of the workers in the hospital and non-hospital sectors would be 459 and 69 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 0.5 hour for hospital workers).

Burden hours: (69 medical examinations x 2 hours) + (459 medical examinations x .5 hours) = 368 hours

Cost: 368 hours x $30.34 = $11,165

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 = 504
Periodic medical examinations = 27,473
Additional medical examinations = 368
Total: 28,345

Cost: Initial medical examinations = $15,291
Periodic medical examinations = $833,531
Additional medical examinations = $11,165
Total: $859,987

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 4,001 facilities covered by the Standard must administer a total of 40,322 medical examinations to their workers each year (i.e., 252 initial medical examinations[13] + 39,542 periodic medical examinations[14] + 528 additional medical examinations[15]). The Agency assumes that, for each medical examination administered to a worker, a secretary requires 5 minutes (.08 hour) to compile the information and provide it to the physician.

Burden hours: 40,322 medical examinations x .08 hour = 3,226 hours
Cost: 3,226 hours x $20.57 = $66,359

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 (.08 hour) 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 40,322 medical examinations annually, each of which results in an opinion written by the examining physician.

Burden hours: 40,322 medical examinations x .08 hour = 3,226 hours
Cost: 3,226 hours x $20.57 = $66,359

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

Signs and Labels (§1910.1047(j)(1))

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

[13]Sum of total exposed employees multiplied by turnover rate multiplied by one minus the pre-standard compliance rate from each row of Table 5.

[14]Sum of total exposed employees multiplied by one minus the pre-standard compliance rate from each row of Table 6.

[15]1% of total exposed employees from Table 5.

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 final rule entitled "Controlling Paperwork Burden on the Public," 5 CFR 1320.3(c)(2).)

Material Safety Data Sheets (§1910.1047(j)(2))

This paragraph of the Standard notes that employers who are manufacturers or importers of EtO must comply with OSHA's Hazard Communication Standard (29 CFR 1910.1200(g)). The Agency takes the burden hours and costs for this provision in the ICR for the Hazard Communication Standard (OMB Control Number 1218-0072).

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

The Standard's information and training requirements are performance oriented. Therefore, OSHA takes no burden hours and costs for this requirement.

(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))

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 (.08 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 1,360 facilities covered by the Standard will generate a total of 8,320[16] periodic and additional exposure-monitoring records for determining either TWAs or ELs.

Burden hours: 8,320 records x .08 hour = 666 hours
Cost: 666 hours x $20.57 = $13,700

Medical records (§1910.1047(k)(3))

Under this provision, employers must establish and maintain a record of each medical

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

examination. As noted in the analysis conducted above under "Information provided to the physician," the 1,360 facilities covered by the Standard administer a total of 40,347 medical examinations to exposed workers each year. OSHA estimates that a secretary will require 5 minutes (.08 hour) to establish, maintain, and update each of these records.

Burden hours: 40,322 records x .08 hour = 3,226 hours
Cost: 3,226 hours x $20.57 = $66,359

Availability (§1910.1047(k)(4))

On request, employers must provide all records required by the Standard, including written compliance programs specified in paragraph (f)(2) of the Standard, to OSHA compliance officers and NIOSH for examination and copying. In addition, 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.

The Agency estimates that, among the 4,001 facilities covered by the Standard, its compliance officers make a request for EtO-related records during 56 facility inspections annually, and that a professional at the facility will spend 5 minutes (.08 hour) informing an OSHA compliance officer of the location of the requested records during the inspection.

In addition, the Agency assumes that 10% of exposed workers 7,144 (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 (.08 hour) to make these records available to the workers and their designated worker representatives.

Table 7 – Number of New Workers Hires (Turnover Rate)

Sector	Exposed Employees	Turnover Rate	Annual Employment
Producers	1,068	32%	1,409.76
Ethoxylators	3,840	32%	5,068.8
Hospitals	45,876	36%	62,391.36
Medical- Product Manufacturers	1,634	32%	2,156.88
Contract Sterilizers	304	36%	413.44
Totals	52,722		71,440

Burden hours: (56 inspections x .08 hour) + (7,144 workers/representatives x .08 hour) = 576 hours

Cost: (4 hours for inspections x $41.61 (professional)) + (576 hours for workers/representatives x $20.57 (secretary)) = $11,932

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

Employers who cease to do business within the period specified for retaining exposure monitoring and medical surveillance records, and who have no successor employer, must notify NIOSH of any impending record disposal at least 90 days before disposing of the records. They may transmit the records to NIOSH.

In the past, NIOSH received EtO-related exposure monitoring or medical surveillance records from one employer during the last 3 years. To account for possible future transfers, OSHA assumes that employers covered by the Standard will transfer 3 sets of records to NIOSH, and that an employer's secretary will spend 1 hour preparing and sending each set of records to NIOSH.

Burden hours: 3 sets of records x 1 hour = 3 hours
Cost: 3 hours x $20.57 = $62

13. Provide an estimate for 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 service 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 respondent (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 $6,636,501which consists of $507,520 for collecting exposure monitoring samples, $6,128,944 to administer medical examinations and questionnaires, and $37 to transfer records to NIOSH via United States Postal Service.

Exposure Monitoring

The Agency estimated a cost of $61[17] per sample to collect and analyze airborne EtO samples. The determinations made under "Exposure monitoring" above indicate that employers collect 8,320 EtO samples each year. (8,320 x $61 = $507,520)

Medical Surveillance

Consistent with recent ICRs and RIAs for other standards, the Agency estimates that each medical examination costs $152.[18] According to the analysis conducted above under "Information provided to the physician," the 4,001 facilities covered by the Standard administer a total of 40,322 medical examinations each year. (40,322 x $152 = $6,128,944)

Transfer of Records to NIOSH

If an employer ceases to do business and there is no successor employer to receive and retain worker medical and exposure-monitoring records for the specified periods, the employer must transmit the records to NIOSH if so requested. Based on discussions with the U.S. Postal Service, OSHA estimates that it will cost employers about $12.30 to send EtO records via registered mail to NIOSH. Based on the Agency's assumption that 1 employer will send 3 sets of records to NIOSH each year, the total cost to that employer is $37.

TOTAL COST: $507,520 + $6,128,944 + $37 = **$6,636,501**

14. Provide estimates of the 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 may also aggregate cost estimates from Items 12, 13, and 14 into a single table.

Federal Access to Records

OSHA estimates that a compliance officer (GS-12, step 5), with an hourly wage rate of $40.66, spends about 5 minutes (.08 hour) during an inspection reviewing the documents required by the Standard. The Agency determined that its compliance officers will conduct approximately 56

[17]This figure, originally $56, was inflated from 2006 to 2009 using the CPI index of "all items", Bureau of Labor Statistics, July 2009. The ratio of 2009 to 2006 values is: 212.6/195.3.

[18]This figure, originally $130, was inflated from 2006 to 2009 using CPI index of "medical care services ", Bureau of Labor Statistics, July 2009. The ratio of 2009 to 2006 value is 394.7/336.7.

inspections during each year covered by this ICR.[19] OSHA considers other expenses, such as equipment, overhead, and support staff salaries to be normal operating expenses that would occur without the paperwork requirements specified by the Standard. Therefore, the total annual cost of these paperwork requirements to the Federal government is:

Cost: 56 inspections x .08 hour x $40.66 = $182

Transfer of Records to NIOSH

Employers who cease to do business within the period specified for retaining exposure-monitoring and medical-surveillance records, and who have no successor employer, must transmit these records to NIOSH. Employers who remain in business for the entire retention period must, before disposing of these records, notify NIOSH of the impending disposal and transfer the records to NIOSH if it requests the records within 3 months of being so notified.

The cost of this provision to the Federal government consists of NIOSH processing records received from employers covered by this requirement. OSHA estimates that one employer may submit one set of records to NIOSH each year, and that a secretary (GS-6, step 5), earning $20.63 per hour, would spend five minutes (.08 hour) preparing these records.

Burden hours: 1 employer x .08 hour = 1 hour (rounded)
Cost: 1 hour x $20.63 = $21

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

OSHA is requesting a decrease in burden hours for the collections of information contained in the EtO Standard from 42,732 hours to 41,487 hours (a reduction of 1,245 hours) due to a decrease in the number of facilities. There was a small increase in the burden hours and cost for availability, resulting from adding the number of new hires (job turnover rate) to the current number of exposed workers.

Under Item 13, the Agency is requesting an overall increase in the costs of the collections of information contained in the EtO Standard, from $6,369,781 to $6,636,501, an increase of $266,920.

This ICR reduces the total number of exposure monitoring hours from 11,389 samples to 8,320 samples. The reduction in exposure-monitoring samples decreased the total cost from $637,784 to $507,520; a reduction of $130,264.

[19]The Agency estimated the number of inspections by determining the overall inspection rate (1.4%) for facilities covered by the Act (including both Federal OSHA and approved state-plan agencies), and then multiplying the total number of facilities regulated under the Standard (4,001) by this percentage (i.e., 4,001 facilities x 1.4% = 56 facilities inspected per year).

Additionally, there was a reduction in the number of medical examinations from 44,092 to 40,322, resulting in a cost reduction from $6,369,781 to $6,128,944; a decrease of $240,837; although the cost of a medical exam rose from $130 to $152.

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.

No forms are available for the Agency to display the expiration date.

18. Explain each exception to the certification statement.

OSHA is not seeking an exception to the certification statement.