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(2006))

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 employee 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 employee exposure to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further requires that employers notify employees 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 employee 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 employee
exposure monitoring and medical surveillance. Items 2 and 12 below list and describe the

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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.

specific information-collection requirements of the Standard.

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)(2))

§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 employees 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 employee exposures to EtO. Periodic exposure monitoring also enables employees 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 employee exposure levels. Additional monitoring is necessary so that the employer may take action to protect employees, 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 employee 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 employee 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) 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 employee exposure and establishing an organized and comprehensive program for reducing employee 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 respirators that comply with the requirements of this paragraph. Respirators must be used during:

> *§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 29 CFR 1910.134 (b) through (d) (except (d)(1)(iii)), and (f) through (m).

Purpose: The Respiratory Protection Standard assists employers in protecting the health of employees exposed to airborne contaminants and biological agents. The respiratory protection collections of information are contained the Respiratory Protection 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 employees 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 provide a continuous record of employee health. Physicians use these records to determine the extent to which employees, since their last examination, experience health effects related to their EtO exposure. Further, the physician often needs information about an employee'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 employees 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 employee'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 an employee's previous medical conditions to make an accurate diagnosis of the new condition, it's apparent cause, and the course of treatment required. Medical records also ensure that employees 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 employees, and to assess the employee's ability to use protective clothing and equipment. The physician's written opinion will also provide information to the employer about whether the employee 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 employees 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 employees 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 employees 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 employees 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 employees 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 employees and downstream employers who must be provided with an 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;
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> §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.);
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> §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 employees 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 employees that enables 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 employees on warning signs, labels, and MSDSs. This warning information will be successful and relevant only if employees 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 employees 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 employees 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 employees 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 employees 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 employees 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 employees and their physicians in determining the need for treatment or other interventions as a result of the employees' exposure to EtO. This information also will alert employers when employee 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, while NIOSH may compile these records for research purposes. Employees and employee representatives use exposure-monitoring and medical-surveillance records to assess employee medical status over the course of employment, to evaluate the effectiveness of the employee'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 use these records for research purposes (e.g., assessing the medical effects of long-term EtO exposure). In addition, with NIOSH serving as a repository for exposure-monitoring and medical-surveillance records, employees 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 purposes described in Item 2 above.

The information required to be collected and maintained is specific to each employer and employee 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 (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

The information collection does 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 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 employees 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 employee, in writing, of their exposure-monitoring results within 15 working days after receiving the results. If the results show that an employee's exposures 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 potentially 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 employee 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 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 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 October 16, 2006, (71 FR 60769, Docket Number ICR-1218-0108(2006)) requesting public comment on its proposed extension of the information collection requirements specified by the Standard. This notice is part of a preclearance consultation program to provide those interested parties the 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 Standard. The Agency received no comments in response to this notice.

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

No payments or gifts will be provided 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 employee 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 reason 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 and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage-rate categories.**

The following table provides information on the number of facilities in industry sectors covered by the Standard:

Table 1
Number of Facilities by Industry Sector

Industry Sector	No. of Facilities
EtO Producers	13[3]
EtO Ethoxylators	38[4]

3This figure is from the Chemical Resource Handbook, SRI International, 2001.
4

Hospitals Using EtO Sterilizers	5,303[5]
Medical-Product Manufacturers	95[6]
Spice Manufacturers	25[7]
Total	5,474

Wage Rates: The Agency adopted the following mean wage rates from the Occupational Employment Statistics, May 2005 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325100 – Basic Chemical Manufacturing (published by BLS in 2006). Total compensation for these occupational categories includes an adjustment of 29.6 percent for fringe benefits; this figure represents the average level of fringe benefits in the private sector. 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 employee time. These hourly wages are:

- First-Line Supervisor/Manager of Production and Operating Workers 51-1011: $42.43
- Occupational Health and Safety Specialist and Technician 29-9012: $26.52
- Secretary 43-6014. $18.38

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

Table 2
Summary of Burden Hours and Cost Estimates

Information-Collection Requirement	Current Burden Hours	Requested Burden Hours	Change	Estimated Cost
Exposure monitoring				
Initial monitoring	0	0	0	0
Periodic and additional monitoring	2,003	1,937	-66	$82,187

[?]This figure is from the Meridian Research Inc. submission to this Informal Rulemaking Hearing for an Excursion Limit for EtO, Docket H-200B, March 10, 1988.

5This figure is from County Business Patters (for the year 2003), U.S. Department of Commerce, 2005. OSHA multiplied the total number of hospitals (6,887) identified from this source by 77% because the RIA for the final Standard estimated that 77% of hospitals use EtO; therefore, the total number of hospitals used in determining burden hours and cost in this ICR is 5,303 (i.e., 0.77 x 6,887 =5,303).

6This figure is from the Meridian Research Inc. submission to the Information Rulemaking Hearing for an Excursion Limit for EtO, Docket H-200B, March 10, 1988.

7The American Spice Trade Association (ASTA) could not verify this number, although the point-of-contact at ASTA believed the number of Spice Manufacturers using EtO is less than 25.

Employee notification of monitoring results	290	281	-9	$5,165
Compliance program	850	821	-29	$34,835
Respirator program	0	0	0	$0
Emergency situations	0	0	0	$0
Medical surveillance				
General requirements and medical examinations and consultations	28,464	27,730	-734	$735,401
Information provided to the physician	3,645	3,527	-118	$64,826
Physician's written opinion	3,645	3,527	-118	$64,826
Communication of EtO hazards to employees				
Signs and labels	0	0	0	$0
Material safety and data sheets	0	0	0	$0
Information and training	0	0	0	$0
Recordkeeping				
Objective data for exempted operations	0	0	0	$0
Exposure measurements	943	911	-32	$16,744
Medical records	3,645	3,527	-118	$64,826
Availability	484	468	-16	$8,746
Transfer of records	3	3	0	$55
Totals	**43,972**	**42,732**	**-1,240**	**1,077,611**

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 employees 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 Agency did not identify any new establishments in Table 1, "Number of facilities in Industry Sectors." In fact, the number of hospitals has decreased over the last 3 years. Therefore, the Agency is assuming that no new facilities will conduct initial monitoring.

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 employee 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 493) 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 493) of all facilities will have employee exposures above the TWA; and 6% of all facilities (328) will have exposures above the EL.[8] OSHA also assumes that 10% of the total facilities (547) require 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	493	3	4	.17	1,006	$42.43	$42,685
At/Above AL & At/Below	493	3	2	.17	503	$42.43	$21,342

8As 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.

TWA							
Above EL	328	6	1	.17	335	$42.43	$14,214
Additional	547	1	1	.17	93	$42.43	$3,946
Totals					**1,937**		**$82,187**

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

Employers must provide written notification to each employee of their exposure-monitoring results, either individually or by posting their exposure-monitoring results in an appropriate location that is accessible to the affected employees. 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 employee 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

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	493	4	.08	158	$18.38	$2,904
At/Above AL & At/Below						

TWA; Above EL	493	2	.08	79	$18.38	$1,452
Additional	547	1	.08	44	$18.38	$809
Totals				**281**		**$5,165**

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

If any employee EtO exposures exceed the TWA or EL, the employer must establish and implement a written program to reduce the employee'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 employee 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 employee exposures above the TWA or EL, respectively, then a total of 821 existing facilities (493 facilities with employees who exceed the TWA + 328 facilities with employees 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.

Burden hours: 821 facilities x 1 hour = 821 hours
Cost: 821 hours x $42.43 = $34,835

(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 employees 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. No burden hours or costs

are attributed to this collection of information since no new establishments have been identified.

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

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

Employers must provide employees 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 employee who has EtO exposures at or above the AL for 30 or more days a year. The Standard requires additional medical examinations for employees 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 employees 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 employees 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 employees prior to publication of the final Standard as the "pre-Standard compliance rate." Accordingly, after multiplying the number of exposed employees 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 employees by the turnover rate) to obtain the number of exposed employees in each sector who must receive the initial medical examinations required by the Standard.

The RIA also assumed that an employee would be away from the job for 2 hours while taking the medical examination (i.e., “lost time”), except for employees in hospitals that use EtO sterilizers, who would be away from their jobs for only .5 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 (%)	Pre-Standard Compliance Rate	Lost Time (Hours)	Burden Hours	Employee Wage Rate	Cost per Sector
EtO Producers	1,046	84%	100%	-	-	-	$0
EtO Ethoxylators	1,436	12%	94%	2	21	$26.52	$557
Hospitals Using EtO Sterilizers	53,030	64%	100%	-	-	-	$0
Medical-Product Manufacturers	1,814	22%	66%	2	271	$26.52	$7,187
Spice Manufacturers	432	51%	77%	2	101	$26.52	$2,679
Totals	**57,758**				**393**		**$10,423**

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 employees by the pre-standard compliance rate, and then subtracting this product from the number of exposed employees to obtain the number of exposed employees 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	Pre-Standard Compliance Rate	Lost Time (Hours)	Burden Hours	Employee Wage Rate	Cost per Sector
EtO Producers	1,046	25%	2	1,569	$26.52	$41,610
EtO Ethoxylators	1,436	25%	2	2,154	$26.52	$57,124
Hospitals Using EtO Sterilizers	53,030	25%	.5	19,886	$26.52	$527,377

Medical-Product Manufacturers	1,814	25%	2	2,721	$26.52	$72,161
Spice Manufacturers	432	25%	2	648	$26.52	$17,185
Totals	**57,758**			**26,978**		**$715,457**

Employers must also provide employees 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 57,758 exposed employees will require an additional medical examination each year. Hospitals using EtO sterilizers employ 53,030 of these employees, while the other industry sectors covered by the Standard employ the remaining 4,728 employees; 1% of the employees in the hospital and non-hospital sectors would be 530 and 47 employees, 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 employees and .5 hour for hospital employees).

Burden hours: (47 medical examinations x 2 hours) + (530 medical examinations x .5 hours) = 359 hours
Cost: 359 hours x $26.52 = $9,521

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

Burden hours: Initial medical examinations = 393 hours
Periodic medical examinations = 26,978 hours
Additional medical examinations = 359 hours
Total: 27,730 hours

Cost: Initial medical examinations = $10,423
Periodic medical examinations = $715,457
Additional medical examinations = $9,521
Total: $735,401

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

Employers must provide the examining physicians with specific information on each employee who receives a medical examination. Accordingly, the 5,474 facilities covered by the Standard must administer a total of 44,092 medical examinations to their employees each year (i.e., 197 initial medical examinations + 43,318 periodic medical examinations + 577 additional medical

examinations). The Agency assumes that, for each medical examination administered to an employee, a secretary requires 5 minutes (.08 hour) to compile the information and provide it to the physician.

Burden hours: 44,092 medical examinations x .08 hour = 3,527 hours
Cost: 3,527 hours x $18.38 = $64,826

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

Employers must provide a copy of the physician's written opinion to each employee 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 employee receiving an examination. Based on the analysis performed under "information provided to the examining physician" above, employees receive 44,092 medical examinations annually, each of which results in an opinion written by the examining physician.

Burden hours: 44,092 physician's opinions x .08 hour = 3,527 hours
Cost: 3,527 hours x $18.38 = $64,826

(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 employee 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 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 employee 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 5,474 facilities covered by the Standard will generate a total of 11,389[9] periodic and additional exposure-monitoring records for determining either TWAs and ELs.

Burden hours: 11,389 records x .08 hour = 911 hours
Cost: 911 hours x $18.38 = $16,744

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 5,474 facilities covered by the Standard administered a total of 44,092 medical examinations to exposed employees each year. OSHA estimates that a secretary will require 5 minutes (.08 hour) to establish, maintain, and update each of these records.

Burden hours: 44,092 records x .08 hour = 3,527 hours
Cost: 3,527 hours x $18.38 = $64,826

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, employee exposure-monitoring records, and written compliance programs to
affected employees, former employees, and designated employee representatives, as well as an employee's medical surveillance records to the employee and to anyone having the employee's specific written consent.

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

The Agency estimates that, among the 5,474 facilities covered by the Standard, its compliance officers make a request for EtO-related records during 77 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% (5,776) of the covered employees (57,758), including designated employee 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 employees and their designated employee representatives.

Burden hours: (77 inspections x .08 hour) + (5,776 employees/representatives x .08 hour) = 468 hours
Cost: (6 hours for inspections x $42.43 (professional)) + (462 hours for employees/representatives x $18.38 (secretary)) = $8,746

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 must transmit the records to NIOSH.

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 $18.38 = $55

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 cost 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 $6,369,781, which consists of $637,784 for collecting exposure-monitoring samples, $5,731,960 to administer medical examinations and questionnaires, and $37 to transfer records to NIOSH via United States Postal Service.

Exposure Monitoring

Based on discussions with consulting firms, the Agency estimated a cost of $56 per sample to collect and analyze airborne EtO samples. The determinations made under "Exposure monitoring" above indicate that employers collect 11,389 EtO samples each year. Therefore, the total annual cost to respondents of this requirement is $637,784 ($56 x 11,389 samples).

Medical Surveillance

Consistent with recent ICRs and RIAs for other standards, the Agency estimates that each medical examination costs $130. According to the analysis conducted above under "Information provided to the physician," the 5,474 facilities covered by the Standard administer a total of 44,092 medical examinations each year. Therefore, the total annual cost to respondents of this requirement is $5,731,960 ($130 x 44,092 medical examinations).

Transfer of Records to NIOSH

If an employer ceases to do business and there is no successor employer to receive and retain employee 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.

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.

Federal Access to Records

Based on the analysis above under "Availability," the Agency determined that employers covered by the Standard undergo 77 OSHA inspections each year. The Agency estimates that a compliance officer (GS-12/5), with an hourly wage rate of $34.15, spends 5 minutes (.08 hour) during each inspection reviewing records maintained by employers covered by the Standard. Other costs, such as equipment, overhead, and support-staff expenses, would occur without these collection-of-information requirements, and OSHA considers these costs to be normal operating expenses.

Burden hours: 77 inspections x .08 hour = 6 hours
Cost: 6 hours x $34.15 = $205

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 one employer may submit one set of records to NIOSH each year, and that a secretary, earning $19.84 per hour, would spend one hour (1.00 hour) preparing these records.

Burden hours: 1 employer x 1 hour = 1 hour (rounded)
Cost: 1 hour x $19.84 = $20

15. Explain the reasons for any program changes or adjustments reported in Items13 or 14 per OMB Form 83-I.

OSHA is requesting a decrease in burden hours for the collections of information contained in the EtO Standard from 43,972 hours to 42,732 hours due to the decrease in the number of hospitals.

Under Item 13, the Agency is requesting an overall reduction in the costs of the collections of information contained in the EtO Standard, from $6,583,000 (rounded from $6,582,872) to $6,369,781; a reduction of $213,219. As a result in the decrease in the number of hospitals, there are decreases in both the number of exposure monitorings being performed and the number of employees receiving medical examinations.

This ICR reduces the total number of exposure monitoring from 18,280 samples to 11,389 samples. The reduction in exposure-monitoring samples decreases the total cost from $660,072 to $637,784; a reduction of $22,288.

This ICR also reduces the number of medical examinations from 46,404 to 44,092. The reduction in the number of medical examinations decreases the total cost from $5,922,800 to $5,731,960; a reduction of $190,840.

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 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 appropriate.

There are no forms on which to display the expiration date.

18. Explain each exception to the certification statement identified in Item 19 per "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

OSHA is not seeking an exception to the certification statement in item 19.