OSHA-ETO

TO: Sid Pitts

FROM: T. G. Grumbles
DATE: April 22, 1988

Interoffice Communication

SUBJ: FINAL ETO EXCURSION LIMIT STANDARD

VISTA

Attached is a copy of the preamble and standard revisions for EtO. The final is substantially unchanged from the proposal we saw in January. The EL is a 5.0 ppm 15-minute average limit with corresponding additions to the monitoring, labeling, regulated area, respiratory protection, and other ancillary requirement areas. The standard is effective June 6, with compliance required September 6.

The regulated area and product labeling, or product exemption, sections have been "fine-tuned" to clarify OSHA's intent. I've noted the sections in the preamble where these changes are discussed. I believe them to be responsive to our concerns.

My thoughts on action items necessary to respond to the promulgation of the standard are below.

1. Inform employees of the standard.

2. Assure an adequate assessment of short-term exposures in the plant. This should be documented.

3. Proceed with sampling at Southcoast terminals in Houston to help document our product exemption determination. Southcoast has agreed to this. Please contact me to discuss logistics.

4. Other compliance items indicated by the results of Item 2.

5. Notification of customers regarding the Standard and our determination on product exemptions. I'll do this with marketing after Item 3 is done.

Please give me a call to discuss these items.

T. G. Grumbles

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Attachments

cc W. L. McClain, J. R. Drumwright, J. Friend, J. A. DeBernardi, R. B. Martin,

cc w/o att: C. F. Putnik, B. E. A. Larsen

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-200B]

Occupational Exposure to Ethylene Oxide

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final standard.

SUMMARY: By this notice, the Occupational Safety and Health Administration (OSHA) amends its existing standard that regulates occupational exposure to ethylene oxide (29 CFR 1910.1047) by adopting an excursion limit for ethylene oxide (EtO) of 5 parts of EtO per million parts of air (5 ppm) averaged over a sampling period of 15 minutes.

Where the excursion limit is exceeded, employers are obligated to reduce exposure through implementation of feasible engineering controls and work practices. s[illegible]emented by the use of respirators v[illegible] necessary. In addition, employers are required to establish and implement a written compliance program to achieve the excursion limit, establish exposure monitoring and training programs for employees subjected to EtO exposure above the excursion limit, identify as regulated areas any locations where airborne concentrations of EtO normally exceed the excursion limit, and affix warning labels on products capable of releasing EtO to the extent that an employee's exposure would foreseeably exceed the excursion limit.

DATES: For the purposes of 29 CFR 1911.18(d), this document will be officially filed in the Office of the Federal Register at 12:00 p.m. on Monday, April 4, 1988.

This final standard shall become effective June 6, 1988, except the following paragraphs which contain information collection requirements pertinent to the excursion limit which are under review at OMB: § 1910.1047 (a)(2), (d), (f)(2), (g)(3), and (j).

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Occupational Safety and Health Administration, Office of Public Affairs, Room N-3649, U.S. Department of Labor, 200 [illegible]onstitution Avenue, NW., Washington, C 20210. Telephone (202) 523-8151.

For additional copies of this notice, contact: OSHA, Office of Publications, U.S. Department of Labor, Room N-3101, Washington, DC 20210, Telephone 202-523-8576.

SUPPLEMENTARY INFORMATION:

I. Events Leading to This Action

On January 28, 1982, OSHA published an Advance Notice of Proposed Rulemaking (47 FR 3566) announcing its intention to reevaluate its existing EtO standard of 50 ppm as an 8-hour TWA. In addition to a request for public comment on the adequacy of 50 ppm as a TWA, comment was also solicited on the question of the necessity of a short-term limit as follows:

> Is a short-term or ceiling limit for EtO exposures necessary and why, and what would be the technological and economic feasibility of complying with that limit? (48 FR 3566)

On April 21, 1983, OSHA published a Notice of Proposed Rulemaking for EtO that proposed to reduce the permissible 8-hour TWA from 50 ppm to 1 ppm (48 FR 17284). Although a specific short-term limit for EtO was not included in the proposed regulatory text, public comment on that issue was solicited by the following questions:

> Is a short-term or ceiling exposure limit for EtO exposure necessary for the PEL or action level in view of recent information regarding increased spontaneous abortions and chromosome changes in workers exposed to EtO? What monitoring methods and control technology are available to meet such a short-term limit and what would be the economic burdens, if any, of such a limit? (48 FR 17284)

and,

> What are the most suitable methods for determining compliance with EtO permissible exposure limits (PEL's) of 0.5 and 1 ppm as 8-hour time-weighted averages and for ceilings ranging from 5 to 50 ppm for 30 minutes or less? What are the problems associated with such monitoring methods? Do they require special training or experience? Are there serious limitations as to the accuracy or precision of the available sampling techniques? (48 FR 17284)

Numerous comments and data were received by OSHA in response to the short-term limit questions set forth in the ANPR and NPRM (Ex. 168). However, the final EtO rule published on June 22, 1984, which lowered the permissible 8-hour TWA from 50 ppm to 1 ppm (49 FR 25734) reserved decision on the question of whether the standard should contain a short-term limit (Ex. 167A). In the June 22, 1984 final rule, OSHA stated that upon its review of comments submitted by the Office of Management and Budget (OMB) pursuant to Executive Order 12291 (Ex. 162), OSHA determined that certain issues relating to a short-term limit were important and merited further consideration. To develop the fullest possible administrative record, all exhibits in the docket relating to the short-term limit (compiled as Ex. 168), were submitted to a number of scientifically qualified peer reviewers for comment, analysis, and criticism. The peer reviewers filed statements that were placed in the public docket. Public comments on the statements filed by the peer reviewers on the issues raised by OMB on the June 14, 1984 draft standard were solicited by a Federal Register notice published September 19, 1984 (49 FR 36659).

After a review of the rulemaking record pertaining to the short-term limit, OSHA published a Federal Register notice on January 3, 1985 (50 FR 64) announcing its determination that the available health data did not necessitate the establishment of a short-term limit to supplement the 8-hour TWA of 1 ppm. OSHA's decision not to issue a short-term limit for EtO centered on three findings: First, the available health data did not demonstrate the risks from EtO exposure to be dose rate-dependent. In other words, the studies did not indicate that the risk from exposure to a given dose of EtO are greater when that dose is distributed at high concentrations over a short period of exposure during a workday rather than at a lower concentration during a longer period of time. Second, since the effects of EtO are assumed to be *dose* dependent rather than dose-*rate* dependent, OSHA concluded that reduction of the total dose was the critical factor in dealing with the significant risks of EtO exposure. Therefore, the Agency believed that the 1 ppm TWA was sufficient to minimize significant risk, within the bounds of feasibility. Third, in terms of industrial hygiene and methods of controlling EtO, it was felt that compliance with the TWA would in itself necessitate the control of short-term exposures, particularly for employees whose exposure consists primarily of short-term bursts.

Petition for review of OSHA's decision not to adopt a short-term limit for EtO subsequently was filed by the Public Citizen Health Research Group, pursuant to section 6(f) of the OSH Act (29 U.S.C. 655(f)).

On July 25, 1986, the U.S. Court of Appeals for the District of Columbia Circuit issued a decision on the ethylene oxide standard (*Public Citizen Health Research Group* v. *Tyson*, 796 F. 2d 1479) in response to the petition from Public Citizen. In that decision, the Court upheld OSHA's permissible exposure limit of 1 ppm as an 8-hour time-weighted average, finding that OSHA had "complied with the relevant legal standards in promulgating the 1

ppm PEL." 796 F. 2d at 1503. In addition, the Court upheld OSHA's determination that the evidence in the rulemaking record did not establish the existence of a dose-rate relationship for the health effects of EtO. However, the Court rejected OSHA's argument that the lack of such an established dose-rate effect rendered it unnecessary for the Agency to promulgate a short-term limit for EtO. The Court noted:

> The agency recognized that EtO exposures at 1 ppm still allowed a significant health risk * * *. If in fact a STEL would further reduce a significant health risk and is feasible to implement, then the OSH Act *compels* the agency to adopt it (barring alternative avenues to the same result). 796 F. 2d at 1505.

Therefore, the Court said, in order for OSHA to avoid issuing a short-term limit for EtO, the Agency must find either that a short-term limit would have no effect on the significant risk which is still present at 1 ppm TWA, or that a short-term limit is not feasible. If the Agency cannot make either of these two findings, then a short-term limit must be issued. The Court proceeded to remand the EtO standard to the Agency for further proceedings on these issues, specifically directing OSHA to "either adopt a short-term limit or explain why empirical or expert evidence on exposure patterns makes a short-term limit irrelevant to controlling long-term exposures". 796 F. 2d at 1507.

On July 21, 1987 the Court of Appeals for the District of Columbia Circuit issued a further decision on the ethylene oxide rulemaking, in *Public Citizen Health Research Group* v. *Brock*, 823 F. 2d 626. In that decision, the Court clarified its mandate to OSHA by ordering that "OSHA's final decision on the EtO short-term exposure limit is to issue no later than March 1988." 823 F. 2d at 629.

Pursuant to the Court decision, OSHA's proposed rule on EtO was published January 21, 1988 (53 FR 1724). The proposal limited short-term exposures to EtO to 5 ppm averaged over a 15 minute period and contained additional provisions which OSHA believed appropriate. In the preamble to the proposal, OSHA requested public comments, information, and evidence on all issues raised. A public comment period was established running through February 22, 1988. Hearing requests were also to be submitted by February 22, 1988.

An informal public hearing was convened by Administrative Law Judge Stuart Levin on March 3, 1988 pursuant to notice and section 6(b) of the Act (29 U.S.C. 655(b)(3)). The hearing concluded on that date. Post-hearing submissions of data requested by parties at the hearing were received through March 10, 1988; post-hearing comments and briefs from participants in the hearing were received through March 17, 1988.

The entire record was certified by Judge Levin on March 18, 1988 in accordance with 29 CFR 1911.17. Copies of materials contained in the record may be obtained from the Docket Office, Room N-3670, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210. The final amendment to OSHA's standard on occupational exposure to ethylene oxide is based on full consideration of the entire record of this proceeding, including materials discussed or relied upon in the proposal, the record of the informal hearing, and all written comments and exhibits received.

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (the Act) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and the concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically directed that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards, and experience gained under this and other health and safety laws. [Section 6(b)(5)].

Where appropriate, the standards are required to include provisions for labels or other appropriate forms of warning to appraise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and training and education. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for the development of information regarding occupational accidents and illnesses [section 8(c)].

In vacating OSHA's 1978 revision to its benzene standard, the Supreme Court required in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 601, 64 L. Ed. 2d 1010, 100 S. Ct. 2844 (1980), that before the issuance of a new or revised standard pursuant to section 6(b)(5) of the Act, OSHA must make two theshold findings that: A significant risk exists under the current standard, and that the issuance of a revised standard would reduce or eliminate the risk.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the regulatory action, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employees will suffer material impairment of health * * *" (Section 6(b)(5) of the Act). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981).

Authority for this action is also found in section 8(c)(3) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6."

The Secretary's authority to issue this amendment is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under the Act"—in this case as part of or ancillary to a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

> Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1);

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce (29 U.S.C. 651 (b)(3);

Building upon advances already made through employer and employee initiative for providing safe and health working conditions (29 U.S.C. 651(b)(4));

Providing for the development and promulgation of occupational safety and health standards; (29 U.S.C. 651 (b)(9));

Providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem (29 U.S.C. 651(b)(12));

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * * (29 U.S.C. 651 (b)(6);

Encouraging joint labor-management efforts to reduce injuries and disease arising out of employment (29 U.S.C. 651(b)(13)), and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (29 U.S.C. 651(b)(5)).

Because this amendment to the ethylene oxide standard is reasonably related to these statutory goals, the Secretary finds that this action is necessary to carry out his responsibilities under the Act.

In addition, section 4(b)(2) of the Act provides that standards issued under OSHA apply to construction and maritime employment where the Secretary determines these standards to be more effective than existing standards which otherwise apply to that employment. (As set forth in 29 CFR 1910.19(h), the current EtO standard applies to construction and maritime employment, in addition to its coverage of general industry).

III. Justification for the Adoption of an Excursion Limit

Section 6(b)(5) of the OSH Act requires the Agency to set health standards which most adequately assure protection against significant risks of material health impairment, to the extent feasible. OSHA established its 8-hour TWA of 1 ppm for EtO (49 FR 25734) based upon considerations of feasibility, and determined that a significant cancer risk would persist at that level. As discussed above, the U.S. Court of Appeals has directed that OSHA reconsider further means of reducing that risk and "either adopt a STEL or explain why empirical or expert evidence on exposure patterns makes a STEL irrelevant to controlling long-term average exposures." 796 F.2d at 1507. The Agency believes that additional protection against continuing significant risk will be provided by a limitation on short-term exposures of 5 ppm over a 15 minute period. This additional protection has been determined to be feasible in the affected industries (see discussion under "Regulatory Flexibility and Impact Analysis"). The rulemaking record indicates that for industry sectors whose exposure patterns involve periods of intermittent, burst-type exposures to EtO, the excursion limit in certain instances will result in TWA exposures below those being experienced now.

In developing the final rule, OSHA has evaluated EtO exposure patterns to determine which employees are currently being exposed above the 5 ppm excursion limit. Of particular concern are those employees whose 8-hour TWA exposures are below the current 1 ppm permissible exposure limit but incorporate one or more short-term bursts which would exceed 5 ppm averaged over 15 minutes. It is these employees who would benefit the most from an excursion limit, because a reduction in short-term bursts would serve to reduce their total EtO dose, and thus would reduce their cancer risks. The Court in *Tyson* directed OSHA to issue an excursion limit if it would further reduce the significant risk attributable to total EtO dose; OSHA has determined that there are employees whose total EtO does would, in fact, be reduced by the imposition of an excursion limit, in accordance with the *Tyson* decision.

Based upon their site visits and a review of reports provided to the record by the National Institute for Occupational Safety and Health (Ex. 205–17), Meridian Research estimates that approximately six percent of all EtO-using facilities have at least one employee who is currently exposed below the 8-hour TWA of 1 ppm but above the proposed 5 ppm excursion limit. Therefore, OSHA has determined that the proposed excursion limit is, in fact, reasonably necessary to provide additional reduction of the significant risk which persists under the current standard. Further, OSHA has determined that such an excursion limit is generally feasible for the affected industry as a whole.

OSHA previously concluded that a short-term limit was not needed since "the compliance program designed to maintain exposure at or below the 1 ppm * * * limit * * *will also substantially reduce the magnitude of short-term exposures" (50 FR 64). The Agency also argued to the Court in *Public Citizen*, that "the record clearly indicates that for a number of reasons the benefits that would be achieved by a short-term limit will be almost entirely achieved by the PEL". Repondent's brief at 55. The Court disagreed with these assertions. In the opinion of the Court, the Agency's conclusions were not supportable since it had not been demonstrated that "in attempting to meet the 1 ppm PEL, employers will *in every case* reduce short-term exposures * * *" 796 F. 2nd at 1505.

The Court concluded that:

> The evidence in this record * * * does not demonstrate that employers will necessarily reduce short-term exposures below 10 ppm in order to meet the PEL. For example, an employer might measure a very low background level of EtO exposure, a level significantly below the 1 ppm PEL. Conceivably, such an employer could allow short-term exposures to exceed 10 ppm over a fifteen-minute period but still have cumulative exposure fall below the 1 ppm PEL, which is an eight-hour average. 796 F 2d at 1505.

The 8-hour TWA for EtO of 1 ppm was established because OSHA believed that this new exposure limit would substantially reduce the significant risk associated with EtO exposures at the previous TWA of 50 ppm, and that the 1 ppm level would be feasible for most operations in most workplaces that use EtO. However, as OSHA's quantitative risk assessment shows, an excess EtO-related cancer mortality risk of 12 to 23 deaths per 10,000 workers persists even at the 1 ppm 8-hour TWA level. Congress has mandated that reducing significant occupational health risks to the lowest feasible level clearly lies within OSHA's authority under the Act. The Court of Appeals remand on this issue in the EtO context further supports this position. OSHA believes that promulgation of a 5 ppm excursion limit for EtO is consonant with the intent of the Act. The available data on current exposure patterns and control measures indicate that compliance with a 5 ppm, 15-minute excursion limit will augment the employee protection provided by the 8-hour TWA in many cases. Because implementation of the 5 ppm excursion limit will further reduce the residual risk which persists at the current 1 ppm TWA, OSHA has determined that the Act compels its adoption, in accordance with the *Tyson* decision.

As noted in section V of this preamble below, OSHA estimates that approximately 8 percent of EtO facilities have at least one employee whose 8 hr. TWA exposures are below the current 1 ppm PEL, but who continue to be exposed to short-term levels exceeding 5 ppm as averaged over any 15 minute period during the workday. Based on OSHA's risk assessment, an employee

To illustrate its contention that promulgation of an EL will not affect (and may even increase rather than decrease) long-term exposures, OMB described the following hypothetical situation: An employer, finding that general dilution ventilation has reduced his employees' total EtO dose to levels below the action level of 0.5 ppm, chooses to purchase controls to achieve compliance with the newly promulgated excursion limit. To purchase these controls, he uses the money he saved as a result of cutting back on the general dilution ventilation that achieved the reduction in total dose in the first place. OSHA finds this scenario implausible, for several reasons.

First, the Agency believes that there are no (or very few) workplaces where the 8-hour TWA PEL is being achieved solely with general dilution ventilation. Such an approach would involve uncontrolled emission sources emitting EtO into the atmosphere continuously (i.e., from a slowly leaking canister) or intermittently (i.e., whenever a sterilizer or canister was opened) while the employer attempted to control the resulting ambient EtO concentrations by exchanging the air in the workplace at a high rate. In such an environment, ambient concentrations would be likely to be very high and to increase as the work week progressed. Thus an EtO-using workplace controlled only by means of general dilution ventilation would have ambient levels that are increased, while one using point source controls would be characterized by decreased levels.

Second, OSHA believes that employers will select that mix of controls that will most efficiently reduce exposures to the levels necessary to comply with both limits (the PEL and the EL) most cost-effectively. This mix will almost certainly consist of general dilution ventilation and point source controls. Even if it is true, as OMB states, that requiring employers to implement effective point source controls will divert resources away from maintaining general dilution ventilation systems, OMB is not accurate when it states that such a reduction in dilution ventilation is likley to increase the ambient EtO level. The ambient concentation would not increase in such a case because the operation of the point source controls will eliminate (or nearly eliminate) any contribution to ambient EtO levels generated by these emission sources. Thus, the ambient EtO level would decrease after point source controls were implemented.

Third, OSHA finds the scenario presented by OMB highly improbable because the likelihood is vanishingly small that EtO-using facilities exist that are (1) maintaining their employees' 8-hour TWA exposures below the action level solely by means of general dilution ventilation, and (2) have short-term exposures above 5 ppm. As discussed above, the Agency is aware only of a small percentage of facilities where the 1 ppm TWA is being met but the 5 ppm EL is being exceeded, and OSHA is aware of no instances where the 8-hour PEL has been achieved by means of general dilution ventilation alone.

Methods of Compliance

OMB [Ex. 205–27, pp. 9–11] commented at length on OSHA's proposed requirement that employers must implement feasible engineering and work practice controls to achieve the 5 ppm excursion limit. The comment addresses two main points. First, OMB states that many of the criticisms against primary reliance on respirators (i.e., that they are uncomfortable and cause irritation) are less relevant when respirators are used for short periods of time. OMB's second point is that, since the least protective respirator permitted under the EtO standard reduces exposure by a factor of 50, respirators may be more effective than engineering and work practice controls in reducing short-term exposure. OMB states that OSHA should permit employers to rely on respiratory protection to comply with the 5 ppm excursion limit as long as the employer is complying with the 8-hour TWA by means of feasible engineering and work practice controls.

Because of the difficulties associated with relying on respiratory protection as a first line of defense against exposure to toxic substances, OSHA has traditionally required that employers use feasible engineering controls and work practices to comply with the Agency's exposure limits. This policy has been applied consistently in all of OSHA's previous health rulemakings. Although it may be the case that, as OMB argues, discomfort and facial irritation are less of a problem during short periods of respirator use, these problems are not entirely eliminated with short-term use and the safety hazards associated with respirator use, such as reduced vision and communication, are present whenever respirators are worn.

Furthermore, for respirators to be effective in reducing exposures, employers must implement a comprehensive respirator program, including adequate fit-gesting, training of employees, and proper respirator maintenance. If these programs are not in place, respirators will not be nearly as effective as their protection factors would suggest. Moreover, as OMB itself acknowledges (Ex. 205–27, p. 10), adequate respiratory protection programs were not in place at some of the facilities visited by Meridian [Ex. 204]. Thus, OSHA is not persuaded that employees will receive equal or greater protection against high short-term exposures to EtO if they use respirators during these excursions. Accordingly, the final rule requires employers to achieve compliance with the excursion limit by using feasible engineering and work practice controls. (OSHA notes, however, that the issue of engineering controls is moot for all but the 6 percent of facilities in which the 8-hour TWA is being achieved but the EL is being exceeded.)

The issue of whether to apply different methods of compliance principles to short-term or excursion limits was raised in OSHA's recent rulemakings for benzene (52 FR 34460) and formaldehyde (52 FR 46168). In both cases, the rulemaking record did not offer specific comments on this issue, and OSHA determined that applying the traditional methods of compliance requirements to the short-term limits for benzene and formaldehyde was a protective and cost-effective approach. This issue is expected to arise in the proceeding on OSHA's methods of compliance rulemaking (see the 1987 Regulatory Program of the United States Government). As is the case with both the benzene and formaldehyde standards, if appropriate evidence is submitted in the methods of compliance rulemaking, OSHA will consider making appropriate changes to the EtO standard.

Proposed Monitoring Requirements

OMB [Ex. 205–27] also commented on OSHA's proposed amendments to the final rule's monitoring requirements, stating that they "do not appear to be the least burdensome necessary to identify accurately those workers exposed above the * * * [excursion limit]" [Ex. 205–27, p. 12]. Specifically, OMB compared the proposed short-term monitoring requirements for EtO with the short-term monitoring requirements in OSHA's final benzene standard. OMB points out that, instead of requiring the employer to conduct representative sampling on each shift, for each job, and for each work area, the final benzene standard requires short-term monitoring "only where there is reason to believe exposures are high" [Ex. 205–27, p. 12], and also permits employers to conduct sampling on the one shift where exposures are highest. OMB also took

have exposure limits ranging from instantaneous peaks to 8-hour TWAs, suggests that the line drawn by OMB between long-term and short-term controls is not, in fact, reflected in the compliance strategies followed by employers in real-world workplaces. The traditional hierarchy of controls, which has been the underlying tenet of industrial hygiene since the 1950s, emphasizes that certain general types of control, i.e., engineering controls, are to be preferred over others, i.e., personal protective equipment, but nowhere makes a distinction between long-term and short-term controls. Within the category of engineering controls, certain control methods, such as those that eliminate or substantially reduce emissions at their source, are ordinarily preferred and considered to be more effective than other controls, such as general dilution ventilation, which simply dilute rather than eliminate the amount of the hazardous substance in the air.

OSHA believes that, when confronted with hazardous exposures in their workplaces, the overwhelming majority of employers will analyze their workplaces to identify and locate specific sources of emission and that they will then design an integrated control strategy to reduce these emissions. Such an integrated control approach in a medical products sterilization facility would generally include, for example, local exhaust ventilation; general dilution ventilation; the use of T-valves, hoods, and/or isolation to control exposures from EtO canisters; and observance of the work practice of cracking the sterilizer door for several minutes before unloading. In the facilities in all sectors that were in compliance with the PEL, Meridian found that employers were using a combination of the following controls: General dilution ventilation, local exhaust ventilation, isolation, and work practices [Ex. 204].

Further, no site visited by Meridian had attempted only to implement a general dilution ventilation system to achieve the 8-hour TWA PEL. In every case where employers had implemented engineering controls, they were using an integrated approach that focused on removing EtO at the source of emission and were supplementing these controls with general dilution ventilation.

OSHA finds that EtO-using or producing facilities will (1) be in compliance with both the 1 ppm PEL and the 5 ppm EL at the present time; (2) be out of compliance with both the PEL and the EL at the present time; or (3) in fewer than 6 percent of all cases, be in compliance with the 8-hour TWA and be exceeding the 15-minute EL. In the first instance, employers will already be in full compliance, and will incur no costs to comply with the EL. Employers in the second category will, OSHA believes, implement an integrated control strategy to address their EtO exposure problems. This control strategy will undoubtedly adopt the surest, most direct, and most cost-effective control approach: elimination of emissions at their source. Employers in this group may also choose to supplement these point source controls with general dilution ventilation.

Workplaces falling into the third category, i.e., that have employee exposures at or below the 8-hour TWA but short-term exposures above the 5 ppm level, will need to analyze their situation carefully to identify the source of their exposure problem. This emission source inventory and industrial hygiene task analysis will help employers to locate the problem and to address it most cost-effectively. The following theoretical example illustrates this approach to the management of workplace exposures. A medical product company's sterilizer operator has a short-term exposure above 5 ppm (15 minutes), although her 8-hour TWA exposure is within the full-shift limit. A source inventory and task analysis would help to determine whether this operator's work practices were poor (e.g., she was not cracking the door before removing freshly sterilized product or was bending too closely over the product to remove biological indicators), whether inadequate isolation of offgassing product was responsible for the elevated exposure, or whether a particular product mix was the source of the problem. The control strategy adopted by the employer to address each of these problems would be quite different, and could range from re-training of the sterilizer operator to walling off a product quarantine area to scheduling the most difficult loads for times when longer aeration periods are available. Each of these hypothetical control solutions would involve minimal or no additional costs.

Thus, OSHA reaffirms its findings that achieving the 8-hour TWA PEL and the short-term limit are linked in all but a small percentage of cases, and that compliance with one limit will simultaneously achieve compliance with the other in the great majority of workplaces. The Agency also finds that effective industrial hygiene control of both short-term and long-term exposures requires the control of point source emissions at their point of origin, and that controlling these emissions sources has a direct impact on the total dose or overall exposures of affected employees. Because control of the workplace depends on control of emissions at their source, and because this control approach is essential to achieve either EtO exposure limit, OSHA concludes that the control involved in complying with either limit are the same and will impose no additional EL-related costs on employers. Thus, with the exception of the small minority firms discussed above, no additional costs will be incurred to achieve compliance with the final rule's excursion limit.

Effect on Long-Term Exposures

OMB's comment states that, before OSHA can promulgate a short-term limit for EtO, the Agency must "establish that adoption of a STEL is 'relevant' to average long-term exposures" [Ex. 205–27, p. 5]. According to OMB, "a PEL controls total dose, which is the only relevant exposure measure when timing and duration [i.e., a dose-rate effect] do not affect the risk" [Ex. 205–27, p. 6]. The argument put forward by OMB is that an 8-hour limit "directly" reduces risk, while a STEL is only a "means * * * to reach the [desired] end [changing the total dose]" [Ex. 205–27, p. 6]. OMB appears to be saying that the imposition of an EL will serve only to redistribute the *pattern* by which the total dose is administered and will not actually reduce total dose.

OSHA does not agree with this view of the function of a short-term exposure limit. The record contains evidence (Company D, Ex. 204; Hospital E, NIOSH 1988, Ex. 205–17) that as many as 6 percent of affected facilities are currently in compliance with the final rule's 1 ppm 8-hour TWA but are achieving a 5 ppm 15-minute excursion limit. In these two real-world instances, controlling the excursions of these employees will reduce their total EtO dose to a level below the exposures they are currently experiencing.

To illustrate the interaction between the 8-hour TWA and the EL, the preamble to the proposal described a hypothetical example where an employee is exposed to 24 ppm for a single 15-minute interval and to no other exposure during the day. In this example, the employee's 8-hour TWA exposure would be 0.75 ppm. After controlling the short-term peak to 5 ppm, this employee's 8-hour TWA would fall to 0.16 ppm. In these and other instances cited in the record, OSHA finds that control of short-term exposures will have a direct impact on employees' long-term exposures (total dose) of EtO.

IV. Regulatory Flexibility and Impact Analysis

Introduction

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) similarly requires OSHA to consider the impact of the proposed regulation on small entities.

The Secretary has determined that this action would not be "major" as defined by Section 1(b) of Executive Order 12291. The Secretary also certifies that this action would not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. This determination is based upon cost and feasibility data provided to OSHA in a report prepared by Meridian Research, Inc. (Ex. 204, *Assessment of Short-Term Exposures to Ethylene Oxide*).

On March 31, 1983, the Office of Management and Budget (OMB) published a new 5 CFR Part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (48 FR 13666). Part 1320, which became effective on April 30, 1983, sets forth procedures for agencies to follow in obtaining OMB clearance for collection of information requirements in proposed and final rules. In particular § 1320.13 requires agencies to submit information requirements contained in proposed rules to OMB not later than the date of publication of the proposal in the **Federal Register**. It also requires agencies to include a statement in the notice of proposed rulemaking, indicating that such information requirements have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act.

In accordance with the above mentioned provisions of both the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it has submitted the information collection requirements contained in its rule on occupational exposure to ethylene oxide to OMB for review under section 3504(h) of that Act.

Summary of Exposure, Technological Feasibility, and Cost Data

In repsonse to the Court's remand discussed above, OSHA has evaluated short-term employee exposures to EtO in the sectors which would principally be affected by promulgation of an excursion limit, assessed the technological feasibility of achieving compliance with the excursion limit alternatives under consideration, and developed cost-of-compliance data for firms in the affected sectors. In particular, OSHA has made a determination as to the portion of an employee's full-shift exposure that is accounted for by short-term peaks.

For this effort, OSHA contracted with Meridian Research, Inc., to gather the information specified above and to conduct a total of nine site visits to selected facilities in four industry sectors: EtO producers, EtO ethoxylators (i.e., facilities using EtO as a chemical feedstock), hospitals, and firms that use EtO to sterilize medical and other products and devices. Meridian was unable to arrange a site visit to a facility in the fifth potentially affected sector, spice manufacturing, because no spice manufacturing frim was willing to permit a site visit. Meridian's final report appears in the docket as Exhibit 204. For the purposes of this analysis, OSHA considered two regulatory alternatives: A 10 ppm excursion limit (15 minutes) and a 5 ppm excursion limit (15 minutes). OSHA's principal findings are discussed below.

The five sectors listed above were identified for further study by OSHA based on the information available in the rulemaking record (see the Regulatory Impact Assessment for the final rule for ethylene oxide, Ex. 164, and the report entitled *Economic and Environmental Impact Study of Ethylene Oxide*, written by JRB Associates, 1984, Ex. 6-22). In two of these sectors—chemical production and ethoxylation—a total of approximately 50 U.S. firms produce or use EtO as a chemical feedstock in closed systems in an outdoor environment. In the three other sectors—hospitals, spice manufacturing, and medical products sterilizing—EtO is used as a sterilant gas to sterilize medical equipment and devices, paper and other products, and spices. OSHA estimated (49 FR 25767, June 22, 1984) that there were as many as 6,300 hospitals, 125 medical products sterilizers, and fewer than 30 spice manufacturers in the United States. Medical and other product sterilization firms can be divided into two groups of companies: Those that have a sterilization department within a larger facility that produces the medical devices or other products to be sterilized, and small firms that provide sterilization services exclusively, generally on a contract basis. At the time of the 1984 rulemaking, OSHA estimated that a total of 71,196 directly exposed employees and 69,175 incidentally exposed employees were exposed to EtO in these five sectors (49 FR 25767, June 22, 1984). Meridian has recently estimated the total number of exposed workers to be 67,728 as of 1988. (See Table A taken from Ex. 223.)

TABLE A.—EXPOSED EMPLOYEES BY INDUSTRY SECTOR

Number of sector	Exposed employees [1]
EtO Producers	[2] 1,048
Ethoxylators	[2] 1,436
Medical Products Sterilizers	[3] 1,814
EtO-Sterilizer-Using Hospitals	[4] 63,000
Spice Manufacturers	[5] 432
Total	67,728

Source: Meridian Research, 1988.

[1] Exposed workers are those who do at least some work in the vicinity of EtO units.

[2] As reported in Heiden Associates, Inc., *An Estimate of Industry Costs for Compliance with Two Ethylene Oxide Workplace STEL Scenarios: Ethylene Oxide Production and Ethoxylation Plants*, 1988, p. ii.

[3] As reported in Heiden Associates, Inc., *A Medical Products Industry Profile for Evaluating Compliance with Two Ethylene Oxide Workplace STEL Scenarios*: 10 ppm STEL and 5 ppm STEL, 1988, p. ii.

[4] Calculated by multiplying the estimated number of facilities (see footnote k of Exhibit 1) (4,500) by the number of exposed employees per facility (14), as reported in JRB Associates, *Economic and Environmental Impact Study of Ethylene Oxide*, 1983, pp. 3-5.

[5] JRB Associates, *Economic and Environmental Impact Study of Ethylene Oxide*, 1983, pp. 3-11

Short-term Exposure Data

On the site visits conducted in connection with this analysis, Meridian took 8-hour TWA personal samples on all potentially exposed employees at eight of the sites visited. Using passive dosimeters, these long-term breathing zone samples were taken over the full shift of the employees sampled. In addition, whenever these employees initiated an activity having the potential for a short-term peak exposure, Meridian's Certified Industrial Hygienist took short-term (15-minute) breathing zone samples using hydrogen-bromine-treated charcoal tubes, as specified by OSHA's Method 50. Short-term samples were taken during all activities during the working day that were associated with episodic exposures. The specific activities characterized by such short-term peaks varied according to sector. For example, in production and ethoxylation facilities, peaks were associated with activities such as quality control sampling and railcar unloading, while high, short-duration exposures occurred in the sectors that use EtO as a sterilant during such activities as sterilizer loading and unloading and removal of biological indicators from freshly sterilized goods.

issue with OSHA's proposed requirement that the employer repeat short-term EtO monitoring every 6 months as long as short-term exposures exceed the excursion limit; the Budget Office argued that OSHA's benzene standard requires periodic short-term monitoring only as necessary to evaluate employee exposures. OMB believes that OSHA's short-term monitoring requirements for benzene are more flexible and less burdensome than the proposed short-term monitoring requirements for EtO, and states that OSHA should "completely justify" any short-term monitoring requirement for EtO that goes beyond the same requirements in the Agency's recent benzene standard.

In formulating the proposed short-term monitoring requirements for EtO, OSHA's intent was to ensure that employers monitor the short-term exposures of those employees who are performing tasks that may result in high short-term exposures. OSHA did not intend that employers measure the short-term exposures of employees whose work activities were not associated with a potential for elevated short-term exposures to EtO. Thus, OSHA expects employers to monitor short-term exposures of employees engaged in activities such as sterilizer loading and unloading, changing EtO tanks on sterilizer equipment, taking process quality control samples, or disconnecting a loading arm from a railcar; these activities carry a potential for elevated short-term exposures to EtO. On the other hand, OSHA would not expect an employer to measure the short-term exposures of employees who, for example, work in an enclosed control room where there is no potential for elevated short-term exposures to EtO. OSHA's intent is reflected in the language contained in proposed paragraph (d)(1)(ii), which states that the employer shall collect samples "representing 15-minute exposures *associated with operations that are most likely to produce exposures above the excursion limit* for each shift for each job classification in each work area" (emphasis added). Thus, OSHA believes that the final rule's short-term monitoring requirements for EtO are consistent with those of OSHA's benzene standard: both standards require short-term monitoring only where there is a potential for elevated short-term exposure.

OMB [Ex. 205–27, p. 12] also pointed out that the proposed monitoring requirements for EtO would require that employers conduct short-term monitoring on each shift. In contrast to OSHA's benzene standard, which permits the employer to conduct short-term monitoring only on the shift where the highest exposures occur. First, the requirement in the benzene standard referred to by OMB does not apply in the case of initial monitoring, where the benzene standard requires employers initially to monitor on every shift. Second, once the employer has made these initial determinations, the employer may restrict periodic monitoring to include one shift only if the employer can demonstrate that employee exposures on the remaining shifts are similar or lower. Thus, the benzene standard permits employers to conduct monitoring on one shift only after the employer has adequately determined that exposure measurements taken during one shift are representative of employee exposures that occur during other shifts. Since benzene is most frequently encountered in closed, controlled chemical process or storage systems (i.e., petroleum refining, petrochemical production, bulk motor fuel storage, and fuel transport), OSHA believes that an employer in a benzene-using facility can have some degree of confidence that exposures encountered during one shift are representative of employee exposures during other shifts.

However, in the case of EtO, OSHA believes that a number of factors may cause employee exposures during one shift to differ from those on other shifts, particularly during sterilization operations. For example, many companies sterilize a variety of different products that offgas EtO at different rates; this can lead to very different short-term exposures among employees working on different shifts. Additionally, short-term exposures to EtO are highly dependent on work practices, which may vary markedly among different employees. The importance of collecting short-term samples of EtO on each shift was demonstrated during a visit to a medical products sterilizing facility conducted by Meridian Research, Inc. [Ex. 204]. At this facility (Company D), the daytime sterilizer operator had short-term exposures below the 5 ppm excursion limit, but the night shift operator had two short-term exposure measurements exceeding 5 ppm. The difference in exposure measurements obtained during the two shifts was attributed to the different periods of time that the product was allowed to offgas in the sterilizer after the end of the sterilizer cycle. Clearly, in this particular case, the daytime operator's exposure would not have been representative of the short-term exposure of the nightshift operator. Therefore, OSHA concludes that the nature of the particular operations in which EtO is used makes it necessary for employers to characterize the short-term exposures of employees on each of their shifts.

OMB's final point concerns OSHA's proposed monitoring frequency requirements for short-term exposures to EtO. OMB stated that—

> The more flexible benzene approach [which requires that employers monitor short-term exposures "as necessary] seems particularly sensible with regard to a STEL because the separate annual monitoring required for the action level and twice-a-year monitoring required for the PEL would be useful in determining when exposures had changed sufficiently to trigger additional STEL monitoring * * *. Since the agency already requires periodic monitoring for total dose, periodic monitoring for the STEL in the absence of changes in total dose would be of little benefit. [Ex. 205–27, pp. 12–13]

OSHA believes that the situation with regard to EtO is unique in that, for many operations such as EtO sterilization, employee exposures are characterized predominently by periodic peak exposures to relatively high levels of EtO. Because employees are exposed to EtO in this manner, OSHA believes that it is particularly important that the employer continue monitoring short-term exposures when prior monitoring results indicate that employee exposures exceed the excursion limit. It is only by periodic monitoring of short-term exposures that employers can fully understand how their operations are contributing to such exposures, and what steps may be effective in reducing short-term exposures. Periodic monitoring of short-term exposures will also direct the employee's attention to those work operations that present a potential for high short-term exposure to EtO, and will reinforce the need to use good work practices during those operations. Thus, OSHA does not agree that monitoring short-term exposures to EtO provides no benefit, even if TWA exposures remain fairly constant. In addition, OSHA does not believe that the proposed periodic short-term monitoring requirements are unduly burdensome, since OSHA is only requiring such monitoring if short-term exposures exceed the excursion limit; that is, unlike the monitoring requirements for the 1 ppm TWA PEL, there is no corresponding action level below the excursion limit that would trigger periodic monitoring.

OSHA's employee sampling results showed that implementation of engineering and work practice controls have reduced employee exposure to below that anticipated by OSHA when promulgating the final standard in June 1984. In addition, almost without exception, where employers had achieved compliance with the final rule's 1 ppm 8-hour permissible exposure limit (PEL), controlling short-term employee exposures to either 10 ppm or 5 ppm would neither be difficult nor expensive. OSHA therefore believes that a 5 ppm excursion limit is feasible.

The results of OSHA's data gathering on short-term exposures were as follows: In the EtO-producing sector, 8-hour employee exposures ranged from 0.21 to 0.78 (TWA), while 15-minute short-term exposures did not exceed 2.2 ppm. (In this sector, no samples were taken by Meridian because of inclement weather during the site visit; these results were given to Meridian by the EtO-producing company itself.) In the ethoxylator sector, 8-hour TWAs were non-dectectable, while 15-minute short-term exposures ranged from non-detectable to 1.07 ppm.

In the sterilant-using sectors, short-term exposures tend to be higher because of the episodic exposure pattern characteristic of these sectors. Samples taken by Meridian at three hospitals showed that the 8-hour TWA exposures of sterilizer operators in these facilities ranged from 0.14 to 0.34 ppm, while their 15-minute short-term exposures never exceeded 0.95 ppm. The hospitals selected for this analysis included a large, private-sector facility, a small rural hospital, and a large public-sector institution.

EtO exposures in the medical products sterilization sector appear to be strikingly dependent on the size of the facility in question. In large sterilization facilities owned by firms that manufacture medical products and sterilize them before shipping them off site, employee exposures in the facilities studied by Meridian have been reduced to levels well below the 1 ppm TWA, and short-term exposures are correspondingly low. The full-shift samples taken at two large facilities in this sector ranged from 0.08 to 0.38 ppm, and the 15-minute short-term exposures at these plants ranged from 0.24 to 4.1 ppm. At two small sterilization facilities in this sector, however, full-shift exposure levels were measured that were considerably above the 1 ppm PEL promulgated in the final rule. At one of these small facilities, the sterilizer operator had an 8-hour TWA of 3.97 ppm, and at the other small contract-sterilization plant, the sterilizer's full-shift exposure was 2.84 ppm, while that of the laboratory technician was 2.27 ppm. The short-term exposures of these employees were correspondingly high. At the first small facility, the short-term exposures (approximately 15 minutes) of the sterilizer operator ranged from 2.15 to 7.89 ppm, while the sterilizer operator's short-term exposures at the second facility ranged as high as 32.2 ppm (15 minutes) and those of the laboratory technician were as high as 7.21 ppm.

As stated earlier, no spice manufacturing firm was willing to permit Meridian to visit a spice facility; consequently, OSHA was unable to obtain any current data on short-term exposures of employees in this sector. However, information obtained during the rulemaking for the final EtO standard shows that the sterilization technology used in the spice manufacturing industry is similar to the technologies used in the sterilization of medical products (JRB Associates, Ex. 8–22). Short-term exposures in the spice sterilization operation may occur during the unloading of sterilized spices from the sterilizer, the handling of newly sterilized product, and the changing of EtO cylinders. OSHA has no data to suggest that short-term exposures in the spice manufacturing industry are substantially different from those in other EtO sterilant-using industry sectors. Therefore, by analogy to the exposure data obtained from medical product sterilizer facilities, OSHA believes that it will be possible to control the short-term exposures of employees in the spice manufacturing sector at or below 5 ppm.

The pattern that emerged at all the sites visited was thus consistent across sectors: Where employers have achieved compliance with the 1 ppm PEL, their facilities would already be in compliance with either a 5- or a 10-ppm short-term limit or could feasibly achieve these levels with minor changes in work practices. There was only a single exception to this finding among all sites visited by Meridian: At one facility, the evening-shift sterilizer operator's short-term (approximately 15 minutes) exposures were 3.56, 10.97, 8.49, and 0.39 ppm; no full-shift measurement was taken on this operator, and thus it is possible that his 8-hour TWA exceeded 1 ppm. However, because 87 percent of the 8-hour TWA exposure level of the day-shift operator at the same facility was accounted for by his four short-term exposures, OSHA considers it unlikely that the evening shift operator's 8-hour TWA actually exceeded 1 ppm. (As described below, OSHA believes that this employee's short-term exposure could be reduced to 5 ppm by a modification in work practices.) OSHA therefore believes that firms that have achieved compliance with the 1 ppm TWA promulgated in the final rule in 1984 should be able to lower employee exposures to a 10- or 5-ppm short-term level, at minimal cost.

TABLE B.—ESTIMATED COSTS FOR INITIAL ETO EXCURSION LIMIT MONITORING AND RECORDKEEPING IN THE AFFECTED INDUSTRY SECTORS

Number of Hours Needed To Conduct Sampling [1]	Costs For Conduction	Number of Short-Term Samples To Be Air Sampling [2]	Sample Collected Per Facility [1]	Number of Hours Needed for Analysis Costs [3]	Recordkeeping [4]	Cost for Recordkeeping [4]	Cost Per Facility [5]	Total Number of Burden-Hours for Number of Facilities in Sector	Initial Monitoring and Recordkeeping [6]	Total Estimated Cost for Initial Monitoring and Recordkeeping [7]
EtO Producers	8	$320	6	$210	1	$10.75	$540.75	[8]13	117	$7,030
Exthoxylators	8	320	6	210	1	10.75	540.75	[9]38	342	20,549
Medical Products Sterilizers	8	320	6	210	1	10.75	540.75	[10]95	855	51,371
EtO Sterilizer-using Hospitals	8	320	6	210	1	10.75	540.75	[11]4,500	40,500	2,433,375
Spice Manufacturers	8	320	6	210	1	10.75	$540.75	[12]27	243	14,600
TOTAL								4,673	42,057	$2,526,925

SOURCE: Meridian Research, 1988.

[1] Median estimate, based on 1986–87 site visits.

[2] The cost for conducting air monitoring is based on hiring an industrial hygiene consultant at a cost of $40 per hour, or $320 per day. The cost of an industrial hygiene consultant includes the costs of pumps, sampling tubes, and packaging and mailing of samples for analysis. (SKC, Inc. sells 50 tubes suitable for measuring EtO excursions using OSHA Method 50 for $79, according to their 1988 comprehensive catalog and guide (p.6)).

[3] The sample analysis cost is based on the number of short-term samples to be collected multiplied by an analytical cost of $35 per sample (American Medical Laboratory Inc., Fairfax, Virginia, 1987 estimate). Two additional labs contacted in 1988 quote analysis costs of $28 and $45 per sample, respectively; thus $35 appears to be a reasonable estimate.

[4] Recordkeeping costs are estimated by multiplying the number of hours needed by the average hourly wage of clerical personnel in 1988. This wage estimate ($10.75 hour) was calculated by compounding the 1986 average hourly wage of $9.75 for secretaries (source: March 9, 1988 telephone conversation between R. Gering, Meridian Research, Inc., and P. Doyle, Bureau of Labor Statistics, U.S. Department of Labor) by five percent annually over two years.

[5] Cost per facility is estimated as the sum of costs for air sampling, sample analysis, and recordkeeping.

[6] The estimated total number of burden-hours is calculated by multiplying the number of facilities in each industry sector by the sum of the number of hours needed to conduct sampling and the number of hours needed for recordkeeping.

[7] The total estimated cost for initial monitoring and recordkeeping was calculated by multiplying the number of facilities in each industry sector by the sum of the costs of conducting air sampling, the cost of sample analysis, and the cost of recordkeeping.

[8] Sources: 49 FR 25767, June 22, 1984; and Heiden Associates, Inc., *An Estimate of Industry Costs for Compliance with Two Ethylene Oxide Workplace STEL Scenarios: Ethylene Oxide Production and Ethoxylation Plants* (Final Report), p. ii, prepared for the Ethylene Oxide Industry Council of the Chemical Manufacturers Association, February 5, 1988.

[9] Source: Heiden Associates, Inc., *An Estimate of Industry Costs for Compliance with Two Ethylene Oxide Workplace STEL Scenarios: Ethylene Oxide Production and Ethoxylation Plants* (Final Report), p. ii, prepared for the Ethylene Oxide Industry Council of the Chemical Manufacturers Association, February 5, 1988.

[10] Source: Estimate made by Heiden Associates, Inc., in *A Medical Products Industry Profile for Evaluating Compliance with Two Ethylene Oxide Workplace STEL Scenarios: 10 ppm STEL and 5 ppm STEL* (Final Report), p. i, prepared for the health industry Manufacturers *Association*, February 22, 1988.

[11] Based on the following: Estimate of 3,600 EtO using facilities (out of 6,300 hospitals) may be Charles R. Manning of Assay Technology, Inc., in "Analytical Chemistry Testimony Regarding Rulemaking on Employee Exposure to Ethylene Oxide," p. 2, presented to U.S. Department of Labor, Occupational Safety and Health Administration, February 20, 1988; and estimate of 4,500 facilities made by Charles O. Hancock, Manager, Process and Power Equipment RD&E, of MDT Corporation, in p. 1 of letter dated February 19, 1988 to Docket Officer, Docket No. H-200, U.S. Department of Labor, Occupational Safety and Health Administration. The estimate of 4,500 facilities was used because it represents the upper bound.

[12] Based on the number of facilities reported in 40 FR 25767, June 22, 1984.

Representativeness and Reliability of the Meridian and Heiden Approaches

In its Proposal (53 FR 1724), OSHA stated Meridian's belief that the sites visited represented the "better" firms in their respective sectors (*i.e.* firms that have active safety and health programs and/or have expended considerable time and effort to attempt to achieve the 1 ppm PEL). The Health Industry Manufacturers Association (HIMA) has contended that Meridian "went into the tail of the curve looking for worst case examples in the noncompliant tail of the curve" (Tr. p. 82). However, in response to questioning at the hearing, Meridian indicated that it chose, for its observations of procedures at small medical product sterilizers two companies which had indicated in earlier rule making that they would have great difficulty in meeting a PEL of 1 ppm or any STEL (Tr. p. 55). This was done so OSHA would not overlook the possible problems of HIMA members in meeting the standard. It is the opinion of OSHA that Meridian's selections of "better" and "worst case" sites added to the broad representativeness of its observations.

HIMA also maintained that Meridian did not visit any companies with large sterilizing facilities (Tr. p. 83). HIMA and the Ethylene Oxide Industry Council (EOIC) criticized the small number of facilities in Meridian's study, compared to the large number of facilities which submitted information sheets to Heiden Associates for the HIMA and EOIC surveys. OSHA believes that the independent review and analysis of workplace conditions performed by Meridian's professional industrial hygiene team provided the Agency with the best available information on the impacts of implementing the excursions limit in actual workplace settings.

Heiden's studies were commissioned directly by the industry groups and were surveys developed with the assistance of members of industry. The "Heiden A" report stated that incremental costs of "STEL compliance measures are 'hypothetical' in the sense that survey-participating firms may not have had experience with measuring short-term exposure levels and/or administering STEL's for ethylene oxide as past or current voluntary company workplace policy of the absence of regulations" (Ex. 205–6, App. A, p. 4).

Although "Heiden A" presented data for 71 facilities (extrapolated to represent 95 total facilities potentially subject to OSHA EtO short-term limit regulations), only four separate companies, operating nine separate facilities, currenty had EtO short-term exposure limits (*Ibid.* p. 12). "Heiden B" was based upon samples from nine companies. The report did not indicate how representative they might be of the universe of sterilizer facilities and chambers (Ex. 205–6, p. 26).

Heiden Associates made no visits to the facilities in its surveys. Although Heiden made follow-up calls by telephone, its staff included no engineers. Heiden's principal investigator testified that "we are economists, so we are not qualified to make judgments as to the feasibility or reliability or quality of the engineering estimates * * *" (Tr. p. 93). Heiden accepted the respondents' estimates of which items they needed, on checklists printed on the survey forms, and merely costed out the engineering control methods. Heiden also included work practice changes in the category of engineering controls and did not analyze or list them separately.

The derivation of cost estimates in Heiden's reports involved methodology which is not convincing to OSHA. For example, Heiden converted all data which were reported as "less than" or "greater than" a specific value to "equal to" that value for the purpose of computer analysis. A further bias entered from the use of the arithmetic mean to represent per-facility costs, which were than multiplied by the number of facilities. This allowed extreme estimates by a few respondents to distort results. For example, Exhibit 7 of the "Heiden A" shows that 17 respondents estimated incremental costs (without respirators) of equipment operation under a 5 ppm STEL to range from $0 to $2,249,520 per facility. The median cost was $0. Yet the arithmetic mean of $188,416 was taken to represent all 17 respondents. OSHA appreciates the willingness of HIMA and EOIC to submit the types of information contained in the Heiden surveys. However, OSHA has determined that the lack of independent engineering or industrial hygiene verification of any of the costs or compliance methods submitted to Heiden, together with the lack of actual site visits by the contractor, leaves the results of the surveys open to considerable question. Accordingly, the Agency does not believe that it can rely upon the estimates contained in the Heiden surveys.

Technological Feasibility

Site visit observations, exposure data, and reports from the trade literature have shown that, in the producer, ethoxylator, hospital, and medical product sterilizer sectors (and, by analogy, the spice manufacturing sector), achieving compliance with 5 or

10 ppm EL is feasible with the use of the same engineering and work practice controls determined by OSHA at the time of the final rule to be feasible to achieve the 1 ppm PEL. The engineering controls implemented by those employers who had achieved compliance with the 1 ppm PEL were standard and widely available controls: local exhaust and general dilution ventilation, the use of closed-loop sampling devices, vapor recovery systems at railcar loading racks, and enclosure/ventilation of aeration and quarantine areas.

HIMA has objected that Meridian did not try any of the controls which it said would work at the sites where it found high exposures (Tr. p. 39). However, Meridian actually observed these controls in use at other facilities, where they had proven effective in achieving the desired exposure levels (Tr. p. 46).

At least one spice manufacturing firm is planning to adopt a substitute for EtO, thus eliminating employee exposures (Meridian Research personal communication, spice company representative, November 21, 1988). OSHA believes it likely that other spice manufacturers will also be able to use a substitute sterilant.

Work practice controls used by employers at the sites visited to reduce exposures include: Opening ("cracking") sterilizer doors for 15 minutes before unloading the sterilizer, pulling rather than pushing carts containing offgassing goods, and performing manual leak detection.

The use of respiratory protection was observed during a few short-term activities: During railcar loading at the EtO producer facility and when entering walk-in sterilizers at medical product sterilization facilities.

In addition to exposure data obtained from site visits, a number of submissions to the EtO docket (Exs. 4–13, 11–132, 139, 179, 198A) indicate that a 5 ppm excursion limit can be achieved during operation of EtO sterilizers in hospitals. Several articles submitted by T. Joel Loving of the University of Virginia's Environmental Health and Safety Office show that the use of vacuum purge systems and exhaust hoods can reduce the 8-hour TWA to or below 1 ppm and the short-term limit to or below 5 ppm for 15 minutes.

The major engineering controls in use at the sites visited to achieve the excursion limits are the same controls that OSHA determined in the Regulatory Impact Assessment (Ex. 163) and JRB Associates' report (Ex. 8–22) to be necessary to achieve compliance with the current 1 ppm PEL. OSHA's analysis shows that, in some instances, employers may need to implement additional work practice controls, such as extending the period of offgassing in the sterilizer, to achieve compliance with a 5 ppm excursion limit. OSHA's findings thus demonstrate that it is feasible to comply with a 5 ppm excursion limit.

Summary of Costs

To assess the magnitude of the costs that might be incurred by employers to comply with a short-term limit, OSHA estimated the costs potentially associated with achieving a 5 ppm short-term limit at each of the nine facilities visited by Meridian Research. OSHA's analysis shows that the 5 ppm short-term limit was already being achieved at the EtO producer site, the ethoxylator site, one large medical product sterilizer facility, and three hospital sites. Therefore, no significant additional costs would be incurred at any of these sites to comply with a 5 ppm excursion limit.

At the remaining large medical product sterilizer site visited by Meridian, exposure data collected on the day-shift sterilizer operator show that both the 10 ppm and 5 ppm short-term limits, were achieved. However, samples taken on the night-shift operator at this site showed that his 15 minute short-term exposures exceeded 5 and 10 ppm. OSHA believes that this operator's short-term exposure could be reduced by allowing the sterilizer load to offgas inside the sterilizer for four hours before the sterilized product is removed by the operator. This practice would not interfere with the work schedule currently being used at this site and would thus be unlikely to result in an increase in costs. If allowing the load to offgas for 4 hours did not reduce this operator's short-term exposures to below 5 ppm, OSHA believes that the sterilization unit's work schedule could be adjusted so that the load could offgas for 8 hours before the operator unloaded the sterilizer.

Neither of the two small medical product sterilizer facilities was currently achieving the 5 ppm excursion limit, and one short-term sample taken at one site (Company F, Ex. 204) exceeded 10 ppm for a sterilizer operator. However, at both of these sites, sterilizer operators and a laboratory technician also had 8-hour TWA exposures that exceeded the current 1 ppm PEL. Area samples taken at these sites indicate that high ambient levels of EtO were present as a result of the offgassing of sterilized product. OSHA believes that installing ventilated, enclosed, quarantine areas and modifying existing ventilation systems are necessary in order to comply with the existing 1 ppm PEL and that these changes would substantially aid in achieving compliance with a 5 ppm excursion limit.

OSHA's findings thus demonstrate that employers are not likely to incur significant costs to comply with an excursion limit. These findings reflect site visit observations and evidence in the record (Ex. 11–132) that the engineering controls that are necessary to achieve the 1 ppm 8-hour TWA also can be implemented to reduce short-term exposures to 5 ppm, although some minor work practice changes may be necessary in some activities. In addition, in those limited situations in which changes in work practices and engineering controls are not feasible, some respirator use may be necessary in for certain sterilization operations, as discussed below.

The 5 ppm excursion limit will be associated with an increased cost burden primarily in connection with the provision dealing with exposure monitoring. The requirement for the monitoring of excursion levels will increase the burden of affected employers because the type of sampling required to evaluate short-term exposures is different from the type of monitoring required to monitor the final standard's 8-hour TWA PEL or the action level. Because some methods for monitoring short-term exposures to EtO have only recently been developed and become commercially available, the cost analysis assumes that employers in the affected sectors will not yet have been able to perform short-term employee monitoring and thus, that all affected firms will need to perform initial excursion limit monitoring. It is clear that this assumption is a worst-case analysis, in that some firms in the principally affected sectors have already performed some short-term sampling and thus will be able to submit previous monitoring results as long as they meet the accuracy requirements of the standard. Further, OSHA has used the cost of its own validated method (OSHA Method 50) as the basis of its monitoring cost estimates. To the extent that other available methods are less costly, these cost estimates will overstate the true monitoring costs under the excursion limit.

OSHA has based the cost estimate for initial monitoring on the assumption that each firm will conduct such monitoring in accordance with the OSHA 50 method. This is assumed to require the retention of the services of an industrial hygiene consultant for 8 hours, at a cost of $40.00 per hour, to collect the necessary short-term samples. The

effect of using this assumption is also to overstate costs somewhat, because many facilities have in-house industrial hygiene personnel and laboratory facilities available to collect and analyze their monitoring samples at a lower cost. This will also substantially overstate costs since data in the record now strongly suggests that passive dosimeters can adequately measure for the excursion limit.

OSHA's original estimate of a cost of $35 per hour for an industrial hygienist (53 FR 1729) was criticized as too low by the Association of Ethylene Oxide Users (Ex. 205–3, p. 8), EOIC (Ex. 205–15A, p. 27), the American Hospital Association (AHA) (Hearings, p. 130), and Kem Medical Corp. (Ex. 206–6, p. 4). These comments apparently based their comments on the need for a *certified* industrial hygienist. The standard does not require the person performing the monitoring to be certified. In response to the comments, Meridian Research reexamined the hourly rate of an industrial hygienist and indicated that a more accurate figure is $40 per hour. This cost includes the costs of pumps, sampling tubes, and packaging and mailing of samples for analysis (Ex. 223). AHA has objected that the sampling tubes cost approximately $100 each, according to "a basic phone survey to the industry itself" (Tr. pp. 130, 140). For the purpose of analysis, OSHA accepts Meridian's estimate, which includes material costs for sampling tubes based upon a supplier's catalog (Ex. 223).

The sectors principally affected by OSHA's EtO standard are: EtO producers; EtO ethoxylaters (*i.e.*, firms which use EtO as a feedstock chemical); sterilizers of heat- and moisture-sensitive medical products and devices; hospitals; and spice manufacturers. The number of short-term samples to be collected will depend on the number and pattern of activities occurring during the day that may cause elevated short-term exposures to EtO. The pattern of exposure varies from sector to sector: for example, sterilizer operators using EtO to sterilize medical devices are generally exposed to elevated short-term exposures four or five times per shift, while the unit operator in an ethoxylation facility performs activities having the potential for short-term exposures two or three times in a working day.

To estimate the average number of short-term samples that employers in each of these sectors would collect to comply with an initial excursion limit monitoring requirement, OSHA relied on the feasibility study conducted by Meridian Research, Inc. (Ex. 204). While conducting site visits to facilities in the affected sectors, Meridian collected from 3 to 10 short-term (15 minute) samples at each facility. In order to estimate monitoring costs, OSHA thus assumes that employers at each facility will need to collect an average of six short-term samples to fulfill their initial EL monitoring obligation. EOIC claimed that this assumption was "off by an order of magnitude" (Ex. 205–15A, p. 22). Kem Medical Products asserted that collecting only five or six samples "gives you no statistical validity" (Tr. p. 195). However, insufficient evidence has been submitted to persuade OSHA to change its assumption.

OSHA estimates that, under a worst-case scenario, employers in the five principally affected EtO sectors will incur a total cost of $2,526,925 for initial monitoring to comply with the excursion limit. Individual sector costs are: $7,030 for EtO producers; $20,549 for ethoxylators, $51,371 for medical products sterilizers; $2,433,375 for hospitals; and $14,600 for spice manufacturers. This estimate has been revised downward from the $3,161,480 in OSHA's original Proposal (53 FR 1730), primarily because of a drop in the estimated number of EtO-using facilities. (See Table B, below, taken from Ex. 223.)

OSHA has recognized the need to add to the estimated costs of initial monitoring per facility (which includes $320 for eight hours of hygienists' time, $210 for laboratory analysis for six samples, and $10.75 for one hour of clerical time to set up record keeping) an allowance for costs of periodic monitoring. On the basis of their site visits and their review of National Institute for Occupational Safety and Health reports, Meridian has estimated that approximately six percent of EtO-using facilities have at least one employee who is currently exposed below the 8-hour PEL of 1 ppm but above the proposed EL of 5 ppm. It is possible that promulgation of the EL would induce some facilities to change work practices at little or no cost and that employees who had been exposed over the EL would be under it by the time of initial monitoring. As a "worst case," six percent of all facilities would discover upon initial monitoring that they had to continue monitoring until two successive periodic measurements indicated that all employees were under the EL. Thus OSHA is adding an allowance for periodic monitoring costs of 6%, times two, times the total of $530 for conducting sampling and analyzing samples, times the number of facilities. Total costs for the EL standard thus increase to $2,824,128 under this revised worst-case scenario for employers in the five principally affected EtO sectors.

The cost estimates presented above assumed the use of charcoal tubes and OSHA Method 50. Costs would be even lower with the use of dosimeters. According to Assay Technology, Inc., more than 95% of personal monitoring tests for the 8-hour PEL are being done with some type of diffusional badge. (Ex. 206–2, p. 3). Similar dosimeters have been developed for personal monitoring tests for the 15-minute EL, using the same readers. Assay Technology's "EtO STEL BADGE" system which requires the same electronic badge reader as their 8-hour badge, has a list price of $14.00 per test, down to $7.50 per test with large quantity discounts. Establishments that do not have Assay Technology's Electronic Badge Reader may purchase it separately for $950, or at a discount with yearly badge orders (Ex. 206–2, p. 3). Kem Medical Products can collect 24 samples, including analysis, samples for a retail list price of $688.

OSHA believes that in general the only significant incremental costs of the 5 ppm EL involve initial monitoring, record keeping, and (for 6% of facilities) periodic monitoring. HIMA and EOIC have insisted that "ancillary costs" estimated by respondents to Heiden surveys should also be accounted for. OSHA has examined these categories. Leak detection, hazard communication and training, and medical surveillance for meeting the EL do not logically involve any significant incremental cost. There might be incremental administrative respirator program costs—*if* imposing an EL required putting respirators on employees who are now working without them. However, it should be noted that HIMA's "Heiden A" report, hearing testimony, and post-hearing comments (Ex. 222, pp. 4, 12) estimate that of 36 workers (two percent of all "potentially" exposed workers in the medical products industry) who are under the PEL and over 5 ppm short-term exposure. It is unclear how many are currently using respirators. Heiden's principal investigator testified (Tr. p. 87) that Heiden "didn't ask the specific details" of the administrative costs of respirators. Heiden's final "ancillary requirement, "other costs (e.g., "consulting", lab fees, administrative, etc.)" provides insufficient information to enable OSHA to evaluate or incorporate it into this analysis. Under EtO assumption that the number of employees in this group (greater than 5 ppm EL but below 1 ppm TWA) in the

affected industry is 406, these "other costs" cannot be determining and would probably be minimal.

EOIC has objected that the EL standard would impose significant "downstream" costs for products which are capable of releasing EtO in excess of the EL (Hearings, pp. 148–150, 155–163). EOIC was unable to indicate the extent of this potential problem. OSHA considers that, if a manufacturer had reason to believe that a product was capable of significant emissions the manufacturer could monitor for 8-hour exposures (as required under the current standard) and for 15-minute exposures at the same time.

OSHA does not foresee nor do data in the record indicate that there will be any incremental cost in extending the current requirement for precautionary labelling to cover containers whose contents are capable of causing employee exposures above the EL. It is likely that containers of EtO products that could result in exposures above the excursion limit, also could result in exposures above the action level of 0.5 ppm as an 8-hour TWA. Products which may release EtO in concentrations above the action level are already required to be labelled under the 1984 EtO standard. Thus, there are likely to be few products, if any, that require labelling because the excursion limit may be exceeded while the action level may not be. OSHA believes that the possibility of such a situation arising is extremely remote. Moreover, EOIC has submitted no evidence of the extent of this purported problem.

Economic Impact and Regulatory Flexibility Analyses

Based on the proceeding cost analysis, OSHA has determined that the additional costs of complying with the proposed 5 ppm excursion limit are likely to be negligible for employers that are in compliance with the existing 1 ppm PEL. Thus the promulgation of a 5 ppm excursion limit is not likely to have a significant economic impact on typical firms, in each sector or cause adverse differential impacts on small entities in each sector.

Total estimated incremental cost of the 5 ppm EL is less than three million dollars. Total hospital care expenditures (the revenues of the hospital sector, where most EtO users are located) were nearly 180 *billion* dollars in 1986. OSHA agrees with Gas Monitoring and Analysis, Inc. that for hospitals which are in compliance with the PEL, there is no significant economic impact caused by the pending excursion limit" (Ex. 205–25, p. 3). In the industrial sterilizer sector, OSHA notes that Meridian was told by the two small facilities which it visited that these companies' clients "insisted on full compliance with OSHA regulations and were willing to absorb any compliance costs necessary"* * * (Tr. pp. 37–38).

Relationship Between Short-Term and 8-Hour TWA Exposures to EtO

To address the Court's request that OSHA examine the impact of controlling short-term employee exposures on the residual health risks that remain at the 1 ppm TWA PEL, OSHA assessed the contribution of employees' short-term exposures to their 8-hour TWA exposures. To accomplish this analysis, Meridian obtained concurrent personal 8-hour TWA and short-term air samples during visits to sites in several sectors. Meridian then calculated each employee's total EtO exposure from short-term activities (in ppm-minutes) and each employee's total full-shift exposure in ppm-minutes (determined from the 8-hour TWA). This analysis permitted OSHA to determine the extent to which an employee's 8-hour TWA would be reduced by controlling that employee's short-term exposures.

For example, exposure data were obtained at one ethoxylator facility. The top operator had a non-detectable 8-hour TWA exposure and a single 15-minute exposure of 1.07 ppm that occurred while the operator was collecting a quality control sample from a railcar. Even assuming that this employee's 8-hour TWA was 0.05 ppm (i.e., the limit of detection), the exposure to EtO that occurred during railcar sampling contributed 67 percent of the operator's total exposure for the day. These results show that controlling the operator's 15-minute exposure during this activity (i.e. close loop sampling system) had a significant impact on reducing the employee's 8-hour TWA to well below 1 ppm (see Site Visit Report for Company A, Ex. 204). In addition, short-term and 8-hour TWA exposure data collected at three medical product sterilizer facilities show that reducing the short-term exposures of sterilizer operators and forklift drivers contributed significantly to reducing their 8-hour TWA exposures to below 1 ppm (see Site Visit Reports for Companies C, D, and F, Ex. 204).

This analysis of the contribution of exposures experienced during short-duration, high-exposure activities has shown that controlling short-term exposures has had a substantial impact on reducing employees' 8-hour exposures to EtO. Although most of the sites visited by Meridian will not need to implement additional controls to achieve compliance with an excursion limit of 5 ppm, one site may need to change its work schedule to extend the amount of offgassing time before removal of the load from the sterilizer or of biological indicators from sterilized product. OSHA believes other firms in the affected sectors may also need to implement additional work practices or alter their work schedules to accommodate longer offgassing times, and there may be some limited use of respirators where those controls are not effective or feasible.

OSHA has examine comments by HIMA on the existence of sterilization operations which take place in large industrial sterilizers continuously at full capacity over the full 24-hour day, seven day days a week, and which would not allow time for extended offgassing of sterilized materials. HIMA stated at the hearing that "most large sterilizers are already running continuous cycles." (Ex. 222). However, the Association did not provide additional information on the number of such facilities or the extent to which full capacity is being utilized. OSHA has evaluated HIMA's submittals and acknowledges that there may be some limited situations involving employee entry into large industrial sterilizers, under conditions of full capacity utilization and continuous sterilization cycles, in which there may not be adequate time for offgassing of the sterilized materials in the sterilizer before employees are exposed. In these situations, as is the case with the current 1 ppm TWA, employees would need to be protected by respirators during their entry into and exit from the sterilizer. However, based on its review of the record, including Meridian's site visits, OSHA does not believe that a general exclusion of "sterilizer unloading" is warranted. The Agency has determined that for most sterilizer unloading, a combination of engineering controls and work practices will enable employers to comply with the 5 ppm excursion limit.

Summary of Benefits

To the extent an excursion limit reduces average long-term exposures, then the cancer deaths prevented by adoption of an excursion limit represent the primary benefit derived from this action. As discussed previously in this preamble, it is not possible to quantify the number of deaths prevented by compliance with the excursion limit since data do not reveal the precise incremental EtO dose reduction that will result from limiting 15-minute short-term exposures to 5 ppm. However, OSHA has estimated the risk from a lifetime exposure, assuming exposure only once

a day to a 5 ppm short-term limit, with no other exposure or background levels of EtO, to be approximately 2 to 4 excess deaths per 10,000 workers. The calculated risks, 2 per 10,000 to 4 per 10,000 probably understate the overall risk because it has been established that short-term exposures often occur more than once per day and that background EtO concentration during the day is above zero, additionally contributing to worker exposure. Thus, OSHA believes that the risk from 5 ppm short term exposures will not be insignificant, even if such exposure constituted the employees' only EtO exposure during the workday (*See Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980)).

OSHA believes that implementation of this amendment will act to reduce the number of EtO-related cancer cases, although the number of additional lives saved cannot be quantified.

Environmental Assessment-Finding of No Significant Impact

During OSHA's previous rulemaking on EtO, information was solicited from the public on a variety of issues including possible environmental impacts of a revised standard which might contain both a TWA and short-term limit. The information and comments submitted have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq*), the regulations of the Council on Environmental Quality (40 CFR Part 1500), and OSHA's DOL NEPA Procedures (29 CFR Part 11). As a result of this review, the Assistant Secretary has determined that this proposed action will not have a significant impact on the external environment.

EtO is used primarily as an intermediate in the production of several industrial products, such as antifreeze, polyester fibers, films, and bottles. EtO is also used as a pesticide, fumigant, and antimicrobial sterilant for medical products and spices, and in limited applications for items such as cosmetics, books, railcars, etc.

Adoption of an excursion limit is not anticipated to affect the external environment because: (1) The process equipment containing EtO generally consists of tightly closed and highly automated systems: (2) any emissions that occur to the external atmosphere would dissipate and disperse rapidly; and (3) no solid waste is directly associated what EtO fumigation and sterilization.

Although the removal of increased amounts of EtO from the workplace air might seem to contribute to the pollution of ambient air surrounding EtO operations and applications, this is not anticipated because direct exhaust to the external environment is regulated under EPA air quality standards. In cases where worker exposure is reduced by the use of improved control methods such as chamber ventilation and purge systems, atmospheric emissions of EtO would remain constant, having an insignificant impact on the external environment.

Only minimal amounts of EtO are released from manufacturing processes as wastewater effluents. Treatment of EtO containing wastes usually involves degradation in water (producing ethylene glycol). Wastewater treatment must comply with the requirements of the Clean Water Act of 1977, and under this standard, conventional biological wastewater treatment would effectively remove EtO from water effluents.

In cases where liquid EtO is transported or stored, there may be some potential for spills or leaks. Because of the nature of EtO, however, such occurrences are not anticipated to impact on the environment, since EtO quickly volatilizes and dissipates. Although instances of waste disposal have not been presented to the record, such disposal would be covered by EPA regulations and transportation would be regulated by the Department of Transportation. The requirements of the proposed standard will not alter present methods for waste disposal or transportation of EtO.

Based on this discussion, OSHA concludes that there will be no significant impact on the general quality of the human environment outside the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal.

V. Summary and Explanation

The requirements set forth in this notice are those which, based on currently available data, OSHA believes are necessary and appropriate to provide additional protection to employees who are now exposed to airborne concentrations of EtO at levels that pose a significant risk of material impairment to their health. OSHA has considered all data and recommendations on the short-term limit issue contained in the EtO docket (H-200).

The following sections discuss new individual requirements of the EtO standard. The sections include an analysis of the record evidence and the reasons underlying the adoption of the various provisions of the standard. The final standard adopts an additional permissible exposure limit of 5 ppm excursion limit averaged over a sampling period of 15 minutes. Engineering controls, work practices, and respirators are required where necessary to reach the excursion limit, and written compliance plans must be developed where the excursion limit is exceeded. Engineering controls must be completed within 6 months from the effective date of the standard. Several proposed provisions of the standard, including those on exposure limits, exposure monitoring, labels, regulated areas, and recordkeeping have been revised and clarified as described in detail below.

Scope and Application, Paragraph (a)(2)

This paragraph currently specifies that the EtO standard does not apply to products containing EtO where data demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the 8-hour TWA action level of 0.5 ppm. This provision provides for such materials to be excluded from coverage, regardless of their potential for short-term high exposures. Because employers will now be required to comply with an excursion limit as well as an 8-hour TWA, it is no longer appropriate for EtO-containing products to be excluded automatically from the standard if they are capable of exposing employees to EtO concentrations above the EL. Therefore, the product exclusion provision is being revised, as proposed, to incorporate the EL. Briefly, in order for a product containing EtO to be exempted from all provisions of this standard, it must be incapable of releasing EtO above both the 8-hour TWA action level and the 15-minute excursion limit. If a material is capable of exposing employees above any of the levels which would trigger protections under the standard, it is not appropriate to provide an automatic exclusion for such material. To illustrate the potential for dose reduction attributable to this provision it can be calculated that under the present standard a product is exempt if emitted dose remains below 240 ppm/minutes (0.5 ppm × 480 minutes). Thus, for products which may by nature initially emit relatively high EtO concentrations over a short time span, the current standard would exempt such products only if they are not capable of releasing 16 ppm EtO over a 15 minute period (16 ppm × 15 min = 240 ppm-minutes). Imposition of the excursion limit would not allow exemption in this example (e.g. for product exemption emitted dose could not exceed 75 ppm-minutes [5 ppm × 15 minutes], rather than 240 ppm-

minutes). Thus, incorporation of the excursion limit, under worst case exposure conditions, into the product exemption, will reduce the allowable release of EtO for products to be exempted from the standard.

The impact of this provision is felt primarily in the area of labeling. Some participants opposed the extension of the product exemption criteria to include the EL, based primarily on the potential burden of having to label products which do not currently require labeling, i.e., products which release EtO below the action level over 8 hours, but which could release EtO in concentrations exceeding the 15-minute excursion limit (Ex. 205–6, 205–11, 205–14). These commenters suggested that OSHA's generic Hazard Communication Standard (§ 1910.1200) adequately addresses issues associated with product labelling and warning of potential hazards to downstream users. In response, the Agency notes that the current labeling provisions for EtO, which were upheld by the Court in *Tyson*, as consistent with those set forth in § 1910.1200. In particular, § 1910.1200(d)(5)(iv) provides that a component in a chemical mixture is "hazardous" (and therefore the mixture must be labeled) if that component "could be released in concentrations which would exceed an established OSHA permissible exposure limit * * *" Permissible exposure limits in Subpart Z of Part 1910 take various forms, ranging from 8-hour time-weighted averages to "ceilings" to "peaks." Under the revised EtO standard, there will be two permissible exposure limits: The 1ppm 8-hour TWA, and the 5 ppm 15-minute EL. Thus, under § 1910.1200, an EtO chemical mixture which could release EtO in excess of either of these permissible exposure limits would require labeling. This is no different from the criteria contained in the revised EtO standard itself.

In testimony at the hearing and in their post-hearing comments (Ex. 225), EOIC contended that there would be an additional burden on manufacturers and formulators of EtO-containing products to provide data to downstream users, in order to enable those users to take advantage of the product exclusion under the standard. However, no data were provided to indicate how the burden would be increased over that of the existing provision, nor was there evidence as to products which currently qualify for exclusion but which would not qualify under the revised rule. OSHA believes that the testing procedures which determine a product's capability of releasing EtO over an 8-hour period can also be used to determine the maximum releases during 15 minute segments within that period.

The intent of the product exemption (paragraph (a)(2)) and labelling requirement (paragraph (j)(1)) is not to encompass products which under extremely unusual instances may unexpectedly or unpredictably release EtO above the excursion limit. OSHA's proposed language that products are within the scope of the rule and must be labelled if they are "capable of releasing" EtO above the excursion limit has caused confusion regarding OSHA's intended practical application of those provisions. OSHA agrees with the suggestion by the EOIC that product exemption and labelling would be more clearly defined by predicating exemption where objective data demonstrate it is "not reasonably foreseeable" that the product will release EtO above the excursion limit (Ex. 225). Thus, as EOIC suggests, OSHA amends paragraph (a)(2) to indicate that this section does not apply to EtO products where objective data demonstrate that the product "may not reasonably be foreseen to release EtO in excess of the excursion limit" * * *. Also as suggested by EOIC, OSHA amends the labelling requirement in paragraph (j) to require labelling of containers of EtO * * * "where contents may reasonably be foreseen to cause employee exposure above the excursion limit." (Labelling is discussed further below).

Permissible Exposure Limit, Paragraph (c)(2)

In the final amendment, OSHA establishes a 5 ppm excursion limit for EtO and revises proposed paragraph (c)(2) to clarify that the excursion limit is to be determined as a time weighted average over a sampling time of 15 minutes. The proposal required that the excursion limit was to be "* * * determined over a maximum sampling period of fifteen (15) minutes." The word "maximum" appears to have led to the misconception that 5 ppm was to be treated as a ceiling limit rather than a time weighted excursion limit. (Exs. 205–8, 205–16). OSHA has no data to support the adoption of a health related ceiling limit for EtO and did not intend to propose the adoption of such a limit. Therefore, for purposes of clarification, paragraph (c)(2) is revised to read: "The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as determined over a sampling period of fifteen (15) minutes."

OSHA proposed a 5 ppm EL as being both effective and feasible at lowering total EtO dose below that achievable through the 1 ppm 8 hour TWA alone. Other limits were suggested by several parties, ranging from Public Citizen's & AFSCME's recommendation of 3 ppm (Exs. 205–2, 205–9) to EOIC & HIMA's (Exs. 205–3, 205–6) OSHA has determined that, based on the Meridian data and other evidence in the record, a 5 ppm 15 minute EL is feasible and can be reliably and consistently monitored, using available monitoring methodology. There is insufficient evidence on the feasibility of monitoring and attaining lower short-term exposures. Further, the record indicates that no monitoring method has been thoroughly validated for use in monitoring 3 ppm over a 15 minute sampling period. By contrast the record reflects that a 10 ppm EL, while clearly feasible and measurable would not provide adequate reduction total dose, and that a 5 ppm EL is both achievable and effective.

With respect to the length of the permitted sampling period, OSHA believes that collection of EtO over 15 minutes is necessary to ensure that a sufficient amount of EtO is collected for accurate analysis.

Data in the record on available exposure monitoring devices and methods (discussed below under *Exposure Monitoring*) suggest that a reasonable adequate representation of typical short term exposures in the EtO industry can be obtained by performing sampling for a period of 15 minutes. While one commenter (Ex. 205–17) suggested reducing the permitted sampling period to 10 minutes, OSHA retains the proposed 15 minute period based on data in the record that indicates that a variety of devices have undergone validation testing over 15 minute periods and have been reported to exhibit an acceptable degree of accuracy under those test conditions. Equivalent validation test data for sampling over a 10 minute period are not in the record.

Other commentors suggested that the excursion limit sampling period should be related to the length of the short-term task being performed (Exs. 225, 205–6). EOIC (Tr. 157) pointed out that sterilizer loading and unloading can take up to 30 minutes in the medical products sector and that sampling should be averaged over the entire task period. EOIC stated that "The goal of short term exposure monitoring is observation, not interaction" (Tr. 157), and therefore, the length of the short-term task should dictate the length of the monitoring period. OSHA disagrees with these

arguments. The 15 minute monitoring period was chosen based on the length of time believed necessary to collect a sufficient amount of EtO for reliable analysis. It has been shown by data submitted to the record that 5 ppm can be feasibly measured by performing sampling for 15 minutes. More lengthy sampling is not necessary to collect enough EtO for analysis. To permit more lengthy monitoring periods over which the amount of EtO collected could be time-weighted would permit higher doses to occur for operations that take less than 15 minutes. HIMA in the Heiden report (Ex. 205–6) only 36 employees in the EtO medical products sector are exposed above the excursion limit during OSHA does not believe that a 30-minute period for determining the 5 ppm EL is appropriate, for several reasons. First, most employees exposed to short-term bursts of EtO receive those exposures in periods of 15 minutes or less. For example, based on the figure of 3600 to 4500 health care facilities performing EtO sterilization (Exs. 206–2, 205–22), OSHA estimates that 7,200 to 9,000 employees are exposed to short-term EtO bursts in these facilities, lasting 15 minutes or less. By contrast, HIMA's Heiden report indicates that only 36 employees have short term peak exposures 30 minutes in the health care manufacturing sector (Ex. 205–6). For an employee whose actual exposures are 15 minutes or less in duration, a 30-minute EL sampling period would result in an increased total dose of EtO as compared to the 15 minute EL. The employee would be allowed to have 150 ppm-minutes of exposure (5 ppm times 30 minutes) as opposed to 75 ppm-minutes (5 ppm times 15 minutes) under the 15 minute period. In essence, for employees exposed for 15 minutes, averaged over 30 minutes would double the total allowable short-term dose as compared with a 5 ppm 15-minute EL, and would not produce the desired reduction in total dose which this standard is directed at achieving.

OSHA has determined that exposure to EtO under the present standard still presents a significant risk of material impairment to employees. Based on the current record, OSHA believes that compliance with the excursion limit as set-forth in this paragraph will further reduce such significant risk.

As required, OSHA has given consideration to the economic and technological feasibility of the proposed and final excursion limit during the EtO rulemaking. In order to obtain the information necessary to allow the Agency to perform such feasibility analyses, OSHA contracted for the services of Meridian Research, Inc. of Silver Spring, Maryland, to perform site visits and exposure monitoring in representative EtO-using facilities prior to publication of the proposal (Ex. 204). In addition, Meridian staff provided testimony on feasibility at the hearing and provided an analysis of the feasibility issues and data provided to the record during the rulemaking proceeding. Based on these data, and data previously provided to the EtO record, OSHA believes that compliance with the excursion limit is both technologically and economically feasible (see "Regulatory Flexibility and Impact Analysis" section).

Exposure Monitoring, Paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(ii), (d)(3)(iv), (d)(4)(iii), (d)(4)(iv), and (d)(7)(ii)

Section 6(b)(7) of the Act (29 U.S.C. 655) mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposures at such locations and intervals, and in such a manner as may be necessary for the protection of employees." The primary purpose of monitoring is to determine the extent of employee exposures to EtO.

Exposure monitoring informs the employer whether the employer is meeting the obligation to keep employee exposures below the established permissible exposure limits. Exposure monitoring also permits the employer to evaluate the effectiveness of engineering and work practice controls and informs the employer whether additional controls need to be installed. In addition, section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)) requires employers to notify promptly any employee who has been or is being exposed to toxic materials or harmful physical agents at levels that exceed those prescribed by an applicable occupational safety or health standard. Finally, the results of exposure monitoring are part of the information that must be supplied to the physician, and these results may contribute information on the causes and prevention of occupational illness.

One of the more significant issues raised during this stage of the EtO rulemaking involved the availability of monitoring methods and equipment which could be used for an excursion limit. OSHA notes that many of the same arguments about monitoring were raised in the earlier stages of this rulemaking, as well. As was discussed in the preamble to the 1984 final rule, there are many methods available for monitoring EtO in the workplace. Although these methods varied considerably in accuracy and precision, OSHA was at that time confident that they would be refined within a short period of time after the final rule was issued. The record of this rulemaking indicates that such refinement has, in fact, occurred. Data submitted by several manufacturers of monitoring equipment indicates that monitoring of 8-hour TWA exposures is a routine matter today. Further, the available data also indicate that extending many of the existing monitoring methods, including those utilizing passive dosimeters, to incorporate 15-minute periods of exposure will not be a significant problem, either technologically or economically (Exs. 205–5, 205–20, 205–25). OSHA itself has modified and refined its monitoring technology, as reflected in its revised OSHA method 50 (Ex. 203). This method which no longer requires refrigeration of samples, has been validated by OSHA's Salt Lake City Laboratory for concentrations well below the 5 ppm excursion limit over a 15-minute sampling period. Although it was suggested by one commenter that only the OSHA laboratory would either be capable or willing to perform the analysis, (Ex. 206–3) the record indicates that such is not the case. A cursory set of telephone contacts of analytical laboratories by Meridian research revealed that other laboratories are available to do this work. Two such laboratories contacted by Meridian were Galston Technical Services in New York City and Analytics, Inc., in Richmond, Virginia.

It should also be noted that EOIC has submitted a revised monitoring method to ASTM for evaluation of its use at concentrations of less than 5 ppm over 15 minutes (Ex. 205–15). It is clear to OSHA that there are and will be methods available to monitor the excursion limit accurately to determine employee short-term exposures.

Further, the OSHA 50 is far from the only method available for monitoring the 5 ppm excursion limit. As noted above, the most promising development in the EtO monitoring area is the wide use and acceptability of passive diffusion monitors. These monitors, which involve the use of relatively-unobtrusive badges which are affixed to the employee's clothing, use different means of absorbing EtO from the employee's breathing zone. At the end of the sampling period, the badge is removed and analyzed. Data submitted to the record indicate that several dosimeters are now commercially available for use by the EtO industry. For example, as Laurence Locker of Kem Medical Products stated at the hearing with respect to the EO–TRAK device

manufactured by Kem Medical. "There is no difficulty in using this * * * badge to measure this short-term exposure limit" (Tr. 188). Assay Technology (Ex. 206–2) provided written testimony indicating that their "* * * EtO STEL Badge is specially designed to monitor 15-minute exposures in the range of 0–20 ppm * * *" and is "* * * fully available to the EtO industry in a convenient format which is easy to use."

Bacharach, Inc. (Ex. 205–20) also provided technical data with respect to their "AirScan" diffusion monitor. From their test data, Bacharach concluded that "* * * the Bacharach AirScan technology is capable of precisely determining compliance with a 5 ppm 15 minute STEL."

The standard does not specify which method of monitoring is used by the employer to monitor the excursion limit, just as it does not specify the method for monitoring either the action level or 8-hour TWA. The employer has considerable flexibility in determining the monitoring method or methods which best suit the type of work being done, the configuration of the workplace, and other factors.

A number of the specific monitoring provisions that were set forth in the Notice of Proposed Rulemaking have been modified in this final rule, based on data in the record. These provisions pertain to the use of prior results for initial monitoring determination, frequency of excursion limit monitoring, and required accuracy of monitoring methodology. The basis for these revised requirements and for retention of other proposed paragraphs is discussed below.

The final amendment to paragraph (d)(1)(i), as proposed, requires that the employer perform breathing zone sampling that is representative of the 15-minute short-term exposure of each employee. Paragraph (d)(1)(ii) is retained as proposed and requires that representative 15-minute short-term employee exposures be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

While these exposure monitoring provisions require that the employer determine the short-term exposure for each employee exposed to EtO, it does not necessarily require separate measurements for each employee. If a number of employees perform essentially the same job under the same conditions, it may be sufficient to monitor a fraction of such employees. Representative personal sampling for employees engaged in similar work and exposed to similar short-term EtO levels can be achieved by measuring the exposure of that member of the exposed group who can reasonably be expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

In many specific work situations, the representative monitoring approach can be more cost-effective in identifying the exposures of affected employees. However, employers may use any monitoring strategy that correctly identifies the extent to which their employees are exposed.

Existing paragraph (d)(2)(i) applies to the excursion limit, and requires employers to perform initial monitoring to determine accurately the short-term airborne concentrations of EtO to which employees are exposed. However, proposed paragraph (d)(2)(iii), which is modified in the final rule as discussed below, contains a provision designed to eliminate unnecessary and redundant exposure monitoring. As proposed, it would permit employers who have monitored short-term employee exposures to EtO within a one-year period immediately preceding publication of a final rule in the Federal Register to forego the initial monitoring required by paragraph (d)(2)(i) if the results of monitoring within this period have shown that their employees are not exposed to EtO levels above the excursion limit.

This provision was designed to make clear that OSHA does not intend to require employers who have voluntarily performed employee monitoring to repeat such monitoring if they have reliable and objective data showing that their employees are not exposed to EtO above the excursion limit. There were no substantive comments with respect to the monitoring provisions discussed above with the exception that several parties suggested that monitoring results taken more than over a year prior to publication of the standard should be acceptable in lieu of performing initial monitoring (Ex. 205–6, 205–16). OSHA agrees that a 1 year limitation on acceptable monitoring results may be unnecessarily arbitrary in the instance of EtO excursion limit monitoring. The issue with respect to an EtO short-term exposure limit was initially raised by the Agency in its 1982 ANPR. Data received during the ensuing rulemaking reveals that it has been feasible to monitor short-term elevated exposure for a number of years. In fact, the record reveals that a number of EtO facilities have been conducting monitoring for a voluntarily established short-term limit since at least 1984 (Exs. 11–68, 11–113). OSHA believes that the results of any prior monitoring designed to determine an employer short-term exposure, should be acceptable if such sampling was conducted in accordance with the monitoring provisions prescribed for excursion limit monitoring in this standard. That is, additional initial excursion limit monitoring is not required under this new revision if: prior exposures (paragraph (d)(1)(ii)); if such from breathing zone air samples that are representative of 15 minute short-term exposures (paragraph (d)(1)(ii)); if such determinations were associated with operations that are most likely to produce exposures above the excursion limit (paragraph (d)(1)(ii)); and if the monitoring method was accurate, to a confidence level of 95 percent, within plus or minus 35 percent for airborne concentrations of EtO at the excursion limit of 5 ppm (paragraph (d)(6)(ii)). It is noted here that recognition of the fact that employers have been able to monitor for short-term exposures and have been doing so for many years, further supports OSHA's determination that such monitoring is clearly feasible under the new standard.

Based on the discussion above, final paragraphs (d)(1)(i) and (d)(1)(ii) are adopted as proposed, and proposed paragraph (d)(2)(iii) is modified in the final standard to permit the use of any prior monitoring results to fulfill the initial monitoring requirements prescribed under paragraph (d), as long as such monitoring satisfies all other requirements of the new monitoring provisions.

The final frequency of monitoring and termination of monitoring requirements regarding the excursion limit are found in paragraphs (d)(3)(iv), (d)(4)(iii) and (d)(4)(iv) and, with the exception of frequency of periodic monitoring, carry the same provisions as proposed. The excursion limit itself would not change the current frequency and termination of monitoring provisions as they apply to the TWA.

With the adoption of an excursion limit the final rule would contain a TWA, an excursion limit, and an action level. The interrelationship among these three exposure levels would determine the frequency at which employers are obligated to monitor employee exposures. There would be six possible exposure scenarios, or combinations of TWA and short-term exposures, that would determine the frequency of required monitoring if an excursion limit were promulgated. The table below lists these six exposure scenarios, along with the monitoring frequency for each. As indicated previously, the frequency of

monitoring dictated by the action level and TWA would not be changed by adoption of the excursion limit. However, these levels are included in the Table below to clarify what the overall monitoring obligations would be if all three triggering levels existed. (Note: "EL" means "excursion limit" in the table below).

Exposure scenario	Required monitoring activity
Below the action level and at or below the EL.	No monitoring required.
Below the action level and above the EL.	No TWA monitoring required; monitor short-term exposures 4 times per year.
At or above the action level, at or below the TWA, and at or below the EL.	Monitor TWA exposures 2 times per year.
At or above the action level, at or below the TWA, and above the EL.	Monitor TWA exposures 2 times per year and monitor short-term exposures 4 times per year.
Above the TWA and at or below the EL.	Monitoring TWA exposures 4 times per year.
Above the TWA and above the EL.	Monitor TWA exposures 4 times per year; monitor excursion limit exposures 4 times per year.

As is shown by the table above, the action level trigger largely determines whether employers must monitor employee exposure to EtO; the only exception would be the scenario in which 8-hour TWA exposures are below the action level and short-term exposures are above the excursion limit. In this particular case, the existence of an excursion limit would obligate employers to monitor short-term exposures 4 times per year at those job locations where the excursion limit is exceeded, but employers would not be obligated to monitor 8-hour TWA exposures at those job locations. Although OSHA proposed that excursion limit monitoring the performed semiannually where overexposure is found, comment was solicited on the adequacy of this monitoring frequency. The Agency sought comment on whether quarterly or even more frequent periodic monitoring where the excursion limit is exceeded was necessary due to the potential variability in burst type exposure levels from day to day, week to week, or month to month. Views were requested on whether semiannual monitoring of employees who are likely to receive short-term exposures above the excursion limit is sufficiently representative of expected exposures throughout the year.

Data submitted to the record suggest that OSHA's proposed semiannual period requirement may provide an adequate indication as to what an employeee's expected excursion limit exposure profile may be. Operations that cannot be controlled to below 5 ppm on a short-term basis by engineering controls may be subject to widely fluctuating excursion exposures. For example, field investigations conducted by NIOSH (Ex. 205–17) revealed that short-term exposures in 2 poorly controlled hospital sterilization operations ranged from 0.2 ppm to 17.6 ppm. Triodyne, Inc. provided hospital sampling data they collected that revealed 8-hour TWA exposure ranging from 0.1 to 0.6 ppm, while short term exposures during door opening ranged up to 10 ppm (Ex. 205–1). Assay Technology stated that high exposure variations require frequent monitoring (Ex. 2062). AFSCME commented that monitoring should be quarterly and preferably monthly (Ex. 205–9). MDT asserted that continuous monitoring of excursion levels in the only real protection for workers (Ex. 205–22). Gas Monitoring and Analysis, Inc. recommended that continuous documentation of exposure variations is necessary to allow employers to focus on control of short-term exposures (Ex. 205–25). This commenter also stated that monitoring only for the 8-hour TWA leads to workability problems in complying with the excursion limit. Kem Medical stated that continuous monitoring should be performed due to the potential for leaks, spills, and equipment malfunction, and that periodic diagnostic monitoring for the excursion limit is essential (Ex. 206–6). Kem Medical further testified that at least quarterly monitoring should be prescribed. HIMA supported OSHA's proposed semiannual periodic monitoring provision (Ex. 206–1), as did Professional Medical Products (Ex. 205–16). These two commenters further suggested that excursion limit monitoring frequency should be permitted as necessary as determined by professional judgment. Assay Technology (Ex. 206–2) suggested adopting the short-term sampling strategy recommended by Leidel and Busch (Ex. 205–17) that "* * * the employer should monitor each employee in such a fashion that there is a high dose of confidence that each employee has a high percentage of daily exposures below the standard. OMB (Ex. 205–27) urged that OSHA require EtO excursion limit monitoring "as necessary" as prescribed in the recently promulgated benzene standard (52 FR 34460).

The record on EtO indicates that short-term exposures to EtO occur, for the most part, at predictible times during recognized operations (sterilized unloading, tank changing, sterilizer entry etc.) and that the magnitude of such excursions can be great in those instances where the excursion limit is exceeded due to lack of effective controls. It is during periods when the excursion limit is exceeded poorly controlled operations, therefore, that monitoring is justified. This is based on the assumption that exposures which will exceed the excursion limit, as determined by initial monitoring, will continue to exceed the excursion limit whenever that particular activity is performed. Thus, such instances should be closely observed, especially in view of the potentially wide fluctuation in the magnitude of such exposures.

Excursions are experienced predictably in the EtO industry, as opposed to the types of short-term exposures encountered in operations in the benzene industry. In the benzene industry, most short-term bursts are encountered unpredictably. Thus, a requirement to monitor "as necessary" may be appropriate for benzene excursion determinations since it is not clearly defined when short-term benzene exposures will occur. For EtO, however, most burst exposures occur during recognized activities and can fluctuate widely in magnitude. Thus, periodic monitoring for EtO at a minimum frequency is appropriate because it can be performed during periods known to be present potential exposure problems. Based on EtO exposure patterns, OSHA believes that semiannual periodic monitoring, as proposed, is inadequate. It was pointed out by one commenter that semiannual monitoring is "statistically useless" (Ex. 205–26). OSHA agrees and, therefore, requires at least quarterly excursion limit monitoring in the final rule. OSHA also requires additional periodic exposure monitoring where necessary to determine the extent to which an employee exposure exceeds the excursion limit, as suggested by commenters cited above.

Paragraph (d)(4)(iii), permits termination of excursion limit monitoring where initial monitoring required under paragraph (d)(2)(i) reveals employee exposure to be at or below the excursion limit. Likewise, paragraph (d)(4)(iv) permits termination of the periodic excursion limit monitoring under paragraph (d)(3), if at least two consecutive excursion limit measurements taken at least 7 days apart, are at or below the excursion limit. These are the same termination of monitoring requirements that were

proposed and are also the same requirements applicable to the existing action level (i.e. TWA monitoring not required where exposures are below the action level). OSHA believes that incorporating some monitoring termination mechanisms with respect to the excursion limit is reasonable and appropriate as proposed. Comment was requested on these proposed amendments. Comment was particularly requested on the degree of confidence that could be placed in assuming that short-term exposures would remain below the excursion limit, if initial monitoring or two specific periodic measurements indicated such. The Agency requested data on whether short-term EtO exposures in industry could be expected to consistently remain below a given limit, or whether the magnitude of short-term exposures fluctuates so frequently and widely that more stringent demonstration of short-term exposure stabilization was necessary prior to permitting the termination of excursion limit monitoring.

Data were submitted to the record that reveal that relatively large fluctuations in short-term exposure levels can occur during sterilizer unloading operations for which adequate engineering and work practice controls have not been instituted (Ex. 205–17, 206–1, 206–2). Other data reveal, however, that exposures below the excursion limit can be consistently maintained through effective implementation of engineering controls such as local exhaust ventilaton at the sterilizer door and vacuum pump discharge, sterilizer cycle modification, and work practices such as leaving the sterilization area after door opening (Ex. 205–17, 205–22, 205–25). As stated by Meridian Research during testimony at the hearing:

> In the hospital sector, extensive data in the docket, from our site visits, and from NIOSH surveys show that the use of local exhaust ventilation and proper handling of sterilized goods will maintain the short-term exposures of sterile supply technicians to levels below the 5 ppm limit" (TR. 34).

James E. Notarianni of Gas Monitoring and Analysis, Inc., stated:

> I believe that the 5 ppm excursion limit is highly achievable within the hospital gas sterilization environment. In my experience as a consultant to hundreds of hospitals throughout the country, providing real-time EtO exposure measurements as well as breathing zone average exposure measurements, I feel that most hospitals will not experience difficulty maintaining exposure below the 5 ppm excursion limit. The current level of engineering controls generally in use with hospital EtO sterilization equipment, if operating as designed, should be capable of minimizing employee exposure below 5 ppm as a 15 minute average. (Ex. 205–25)

Thus, OSHA believes that employers controlling exposures to within the excursion limit by the engineering controls, and work practices prescribed in this standard are able to maintain such exposures to within that level, mitigating the need for periodic monitoring. As discussed below, however, subsequent exposure determination is required in certain instances. Existing paragraph (d)(5) of OSHA's EtO standard requires additional monitoring for TWA exposures whenever there has been a change in production, process, control equipment, personnel or work practices that may result in new or additional EtO exposures. With the adoption of an excursion limit, revised paragraph (d)(5) will, as proposed also require additional excursion limit monitoring where the employer suspects that workplace changes may increase short-term exposures. The Agency requested comment on this proposed provision. There were no objections to this proposed requirement for additional exposure monitoring. Support for this provision was provided by HIMA in their written testimony as follows: "HIMA agrees that short-term monitoring should be repeated whenever situations arise or workplace changes occur which could possibly increase employe exposure (Ex. 206–1)." OSHA therefore, adopts this provision as proposed.

Paragraph (d)(6) of the current EtO standard requires that monitoring methods be accurate to within plus or minus 25% for EtO concentrations at the 1 ppm TWA, and plus or minus 35% at the action level of 0.5 ppm. These accuracy specifications were based on data in the record that showed that several EtO measurement methods and devices were readily available to employers, and that these methods and devices could meet the specified accuracy requirements for compliance determinations. OSHA believed at the time of the proposal, that a number of measurement methods and devices were also available to employers that could accurately determine compliance with the EtO excursion limit. These included the Qazi-Ketcham Method (Ex. 11–133), direct reading instruments such as infrared detection units, photoionization detection units and gas chromatographs, and the recently developed OSHA method 50 (Ex. 203). Other devices, such as passive dosimeters, were also being developed for use in determining short-term exposures. Data available at the time of the proposal did not indicate, however, that dosimeters were yet capable of accurately measuring short-term EtO levels. Further, because of the wide range of methods and the developmental work being conducted at the time, OSHA did not propose specific accuracy limitations with respect to excursion limit monitoring. The Agency indicated in the Notice of Proposed rulemaking that it believed that additional data were needed to reach an appropriate determination on this issue of accuracy of excursion limit sampling.

Data submitted to the record convinces the Agency that an accuracy requirement for excursion limit monitoring is necessary. For example, the Association for the Advancement of Medical Instrumentation commented that an "* * * issue that concerns us is the absence of accuracy requirements for STEL monitoring. We feel that it is important that OSHA establish accuracy requirements in the final standard's." (Ex. 205–13). Gas Monitoring and Analysis, Inc., comments that they" * * * strongly support the inclusion of an accuracy requirement for short-term exposure monitoring" (Ex. 205–25). Janet Patzman, a Certified Industrial Hygienist employed by a firm that sterilizes packaging components states that:

> OSHA's decision not to propose "specific accuracy limitations with respect to STEL monitoring renders this standard unenforceable. Without defined precision and accuracy requirements for short term monitoring methods, the monitoring becomes a meaningless exercise: there is no recourse or proof that a short term limit has been exceeded. If an employer has conducted short term monitoring by any method indicating compliance, without defined validation parameters OSHA will not be able to "prove" that short term limits are being exceeded and that exposure control measures are required. OSHA must not promulgate a standard without precision and accuracy requirements for an acceptable monitoring method. (Ex. 205–28).

Data in the record further indicate that an accuracy of plus or minus 35 percent, at the 95 percent confidence level, is appropriate and is achievable by a variety of available sampling devices and methods. As discussed previously, several manufacturers of passive diffusion monitors submitted data that suggested that those devices are now suitable for determining 15 minute short term EtO exposures. Included in those submissions were accuracy specifications for those devices. AMSCO provided test data reporting an accuracy of plus or minus 11.4 percent for measurements taken at the excursion limit level by the STELSCAN diffusion monitor (Ex.

205–5). Bacharach reported that their AirScan monitor is capable of measurements in the 3 to 30 ppm range for 15 minutes with an accuracy of plus or minus 10 percent to plus or minus 18 percent (Ex. 205–25). Assay Technology states in their submission that their ChemChip/STELs car has been fully validated at plus or minus 35 percent accuracy at the 5 ppm level (Ex. 208–2. Kem Medical Products Corp. concluded from validated test data on the EO-Trak badge that the accuracy is approximately plus or minus 15 percent. with 95% confidence. for badges exposed to 5 ppm for a period of 15 minutes (Ex. 2056–6). During the informal hearing. Dr. Laurence Locker of Kem Medical Products testified that the accuracy limitation" * * * should not be more stringent than plus or minus 35 percent * * * I would have no trouble * * * meeting that" (Tr. 196).

In conclusion, it is clear to OSHA, based on data in record, that adoption of excursion limit accuracy requirements are necessary to ensure that employees exposures are adequately determined. OSHA also finds that the record supports adoption of accuracy parameters of plus or minus 35 percent at the 95 percent confidence level. As discussed above. the Agency further believes that employers will be able to choose from a variety of exposure monitoring methods that will be in conformance with these requirements.

OSHA, therefore, adopts in final paragraph (d)(6)(ii), the requirement that monitoring to a confidence level of 95 percent, shall be accurate, to within plus or minus 35 percent for airborne concentrations of EtO at the 15 minute excursion limit of 5 ppm.

Final paragraph (d)(7) requires that employers notify employees of the results of excursion limit monitoring performed pursuant to the standard, and inform employees of corrective action being taken by the employer to reduce exposure to or below the excursion limit where the excursion limit has been exceeded. These are the same notification requirements as proposed. Such notification has been determined to be appropriate where TWA monitoring is performed, and is believed to be appropriate where excursion limit monitoring is performed. No objections were received with respect to this proposed requirement. OSHA therefore adopts paragraph (d)(7) as proposed in the final standard.

Regulated Areas, Paragraph (e)(1)

The final provisions of paragraph (e) require employers to identify as regulated areas any locations in their workplaces where occupational exposures to airborne concentrations of EtO exceed the excursion limit or can reasonably be expected to exceed the excursion limit.

The final EtO provision for designating regulated areas conforms to the provision established in the recently promulgated benzene standard (52 FR 34460). Commenters appropriately pointed out that OSHA's proposed regulated areas language for EtO (e.g. that regulated areas be established" * * * wherever * * * exposure * * * may exceed the * * * excursion limit) unreasonably required permanent designation of areas where transient or temporary excess exposures occurred (Exs. 205–11, 205–15, 205–16). OSHA's intention with respect to the provision is to only require designation when excessive exposure occurs.

The language of the final standard therefore has been changed to include language that states that a regulated area is to be established where airborne concentrations of EtO "exceed, or can reasonably be expected to exceed, the excursion for 15 minutes." This also conforms to the comparable provision of the recently promulgated Asbestos Standard (29 CFR 1910.1001). OSHA believes that this new wording more clearly defines the intent of the provision, that, when an employer reasonably expects exposures to be above the excursion limit at a work location or site, he should establish a regulated area in order to prevent employees from unknowingly entering a high exposure area without the proper respiratory protection.

Texaco, Inc. in its submission (Ex. 205–11) stated that areas of a facility that" * * * may be subject to transient or temporary EtO exposures, especially during maintenance activities * * * should be considered "temporarily regulated." OSHA agrees with this assessment.

The intent of OSHA's regulated area requirement is to protect employees from unknowingly entering areas where their exposures would be expected to be above the excursion limit. The final standard, therefore, requires establishment of regulated areas where a reasonable expectation exists that the excursion limit would be exceeded if an employee were to work at that location all day. This both warns employees of the possible need to wear respirators and to keep out if they have no need to be present.

Regulated areas are to be established at all work areas where the excursion limit is exceeded, including maintenance operations. Areas where transient activities such as maintenance operations are being performed and where exposures are temporarily over the excursion limit only need to be temporarily demarcated in the same manner as other areas of overexposure so employees who are not needed in these areas will stay out, and so employees who must enter the areas will put on respirators before entering them. The regulated area provisions of this standard are similar to other OSHA health standards.

Methods of Compliance, Paragraphs (f)(1)(i), (f)(1)(ii), (f)(2)(i) and (f)(2)(ii)

As discussed previously (see section on Summary of Regulatory Flexibility and Impact Analysis) OSHA believes that compliance with the proposed excursion limit can be accomplished by the majority of the EtO industry through implementation of feasible engineering and work practice controls. OSHA, therefore, requires in paragraph (f)(1)(i) of the existing EtO standard, that the employer institute engineering and work practice controls to reduce and maintain employee exposure to or below the excursion limit except to the extent that such controls are not feasible. The final rule further requires, in paragraph (f)(1)(ii), that wherever feasible engineering controls and work practices that can be instituted are not sufficient to reduce employer exposure to or below the excursion limit the employer shall use them to reduce exposure to the lowest levels achievable by those controls, and shall supplement them by the use of respirators. These final provisions are the same as those proposed. Based on available evidence, OSHA believes that the use of engineering and work practices controls will reduce employer exposure to or below the excursion limit for practically all situations. OSHA recognizes in paragraph (f)(1)(iii) of the existing standard, however, that there are some situations where engineering controls are not generally feasible, especially as they pertain to control of short-term exposures. These EtO activities include: Collection of quality assurance samples from sterilized materials; removal of biological indicators from sterilized materials; loading and unloading of tank cars; changing of EtO tanks on sterilizers; and vessel cleaning. These operations generally result in short-term high exposures. Thus, considering that the existing standard permits the use of respirators during these difficult to control activities, OSHA has greater confidence that it is feasible to control virtually all other short-term exposure activities through implementation of engineering and work practice controls. In the Notice of Proposed Rulemaking,

OSHA requested comment on whether employers should be permitted to use respirators to achieve compliance with the excursion limit in other situations.

Industry commenters, primarily from the EtO medical products sterilizing sector, asserted that respirator use should be permitted as the primary excursion limit control means for EtO sterilization operations involving entry into large volume walk-in EtO sterilization chambers for product removal. (Ex. 205–6, 205–14, 205–16, 205–28). These commenters asserted that engineering and work practice controls are economically and technologically infeasible for control of this activity and, therefore, respirator use for excursion limit compliance in this instance should be explicitly permitted under the standard.

OSHA has evaluated the available data on the feasibility of the 5 ppm excursion limit in the affected industry sectors, including and has determined that with few exceptions, noted below, employers should have little difficulty in coming into compliance. As reflected in the EOIC submission (Ex. 205–15) and Meridian's site visits (Ex. 205), the EtO production and ethoxylation sectors are almost totally in compliance with the 5 ppm EL at present. The only employees who would be directly affected by the EL in those sectors are those whose tasks are already recognized under the current standard as being generally infeasible to control by engineering and work practices, namely such operations as tank car loading and unloading. (Paragraph (f)(i)(ii) of the current standard allows for the 1 pm TWA to be met through use of respirators for these operations). Thus, the impact of the EL on EtO production and ethoxylation sectors will be minimal.

Similarly, the record indicates that for most sterilization uses of EtO, namely in hospitals and contract sterilizers, exposures can be controlled to meet the EL through a combination of engineering and work practice controls, with some limited use of respirators in large industrial sterilizing facilities under certain circumstances. As is noted in OSHA's regulatory analysis, and as was reflected in the reports of Meridian's site visits, meeting the EL in sterilization facilities involves the control of EtO from two basic sources: first, from the sterilizer itself, and, second, from the sterilized materials, which continue to offgas after the sterilization process, thus exposing employees who move the materials from the sterilizer to storage areas. As the American Hospital Association (AHA) noted in their testimony, the key to controlling EtO exposure from sterilizers in hospitals, which tend to produce short periods of high exposures and very low background levels, is to install certain sterilizer safety features and implement proper work practices. As Freelove S. Knott, R.N., representing AHA, discussed,

> These work place safety features include continuous or pulsing purges that prevent ethylene oxide build up in the sterilizer chamber before the door is open. Installation of dedicated local exhaust at the door opening to remove residual ethylene oxide present as the door opens. An audible alarm to alert the operator when the cycle is completed and the use of transfer carts or baskets to avoid operator exposure to ethylene oxide through the handling of products transferred from the sterilizer to the aerator. (Tr. 121).

The types of controls discussed by Ms. Knott are the same types of controls used to control exposures to meet the current 1 ppm TWA, and are clearly feasible.

Data submitted by the National Institute for Occupational Safety and Health (NIOSH) further support the feasibility of a 5 ppm EL in hospitals (Ex. 205–17). NIOSH investigations of sterilizers control systems in 9 hospitals indicated that the following control measures were effective in controlling EtO exposure: Modifications of the sterilizer cycle to reduce end of cycle EtO concentrations inside the sterilizer chamber, local exhaust ventilation at the vacuum pump discharge, and above the sterilizer door. Work practices that helped to reduce employee exposure to EtO included "cracking" the sterilizer door for 15 minutes before opening it and removing sterilized goods, pulling (not pushing) carts containing EtO-sterilized materials, and performance of leak detection.

Many of the same types of controls and procedures which are effective for lowering EtO exposures in hospitals can also be effective in smaller sterilizers used in industry. As noted by Dr. Laurence Hecker of HIMA, "I think it is a matter of scale * * * (Regarding) our R & D units, * * * which tend to be the same size as hospital sterilizers. If one were to remove goods from a small sterilizer the size of a microwave oven it would not be an engineering challenge or very—or extremely costly, I would think, to be able to engineer some type of an activity where you take the goods out and do something with them." (Tr. 105–106).

OSHA is well aware of the greater difficulty involved in controlling EtO exposures in the unloading of larger sterilizers, for both the 1 ppm TWA and the 5 ppm EL. In the preamble to the final rule in 1984, OSHA anticipated that compliance with the PEL might involve some limited use of respirators. As evidenced by the data provided by HIMA in the EL phase of the rulemaking, the Agency's assessment has proven to be accurate. It is true for the EL, as it is with the TWA, that some operations may need to supplement engineering and work practice controls with respirators. However, as was also the case with the 1 ppm TWA, OSHA does not believe that the need to use respirators in unloading sterilizers under certain conditions justifies a wholesale finding that engineering and work practice controls for all unloading of sterilizers are, therefore, infeasible. The record clealy shows that for most operations involving sterilizer unloading, engineering and/or work practice controls are feasible to control employees' exposures below the EL. Meridian's site visits provide graphic evidence of this fact. As Meridian testified at the hearing,

> We paid particular attention to the way we selected small medical product sterilizers because we were aware from the earlier rulemaking that they anticipated great problems. So, what we did was to go into the record and find, thanks to the EOIC, a list of—I think the number was six, it may have been larger, small companies which came into the record in the earlier rule making and said that if they had to comply with the one ppm TWA they would have to go out of business and if they had to do a STEL. I mean well they would leave before we even published. So we went into that worst case group. We selected the companies that really thought they couldn't do anything at all, and of that group we selected two who were willing to host a site visit and those other two we reported on, they ought thus to be really worst case. They were as happy as we were to find that it wasn't going to be quite so awful. (Tr. 55).

Meridian determined that a change in work practices and a longer offgassing time for sterilized materials in the sterilizer were sufficient to control employee exposures in those facilities that they visited. OSHA recognizes that the work practices recommended by Meridian would not work in all sterilization installations under all operating conditions. In particular, OSHA acknowledges that there may be difficulty in one type of sterilization operation: where sterilization of medical products and other materials is performed in large, room-sized sterilizers into which employees must enter to remove those materials after sterilization, and where those facilities are operated in consecutive 8-hour shifts throughout the full 24-hour day, where it is not possible to provide additional

offgassing time for the sterilized materials in the sterilizer without sevrely disrupting the production process and capacity. As noted above, the Agency has long recognized the problems associated with this type of operation. The standard allows for findings of infeasibility of given operations, and the employer making such findings under the standard must provide adequate respiratory protection for his employees. Therefore, while OSHA recognizes some potential for infeasibility in some operations, the Agency does not believe that it justifies a blanket finding of infeasibility for "sterilizer unloading" per se.

OSHA therfore retains the requirement, as proposed in paragraph (f)(1)(i), that employers institute engineering and work practice controls to reduce and maintain employee exposure to or below the excursion limit except to the extent that such controls are not feasible.

Final paragraph (f)(2)(i), as proposed, requries, where the excursion limit is exceeded, that the employer establish and implement a written program to reduce employer exposure to or below the excursion limit, by means of engineering and work practice controls, and by the use of respirators when permitted. There were no objections to this proposed provision.

OSHA therefore adopts this requirement as proposed, based on the determination that the written plan for achieving the excursion limit is as essential as the written plan requirement adopted for achieving the TWA, in ensuring that the employer implement the necessary controls to reduce exposure. The plan also provides the information that would allow OSHA, the employer, and employees to examine the excursion limit control methods chosen and to evaluate the extent to which these planned controls are being implemented. As with the TWA written plan, the excursion limit compliance plan will be accessible to individuals designated in paragraph (f)(2)(iii) for inspection and copying.

Final paragraph (f)(2)(iv), as proposed, prohibits employee rotation as a means of compliance with the excursion limit for the same reasons that employee rotation is not permitted for compliance with the TWA. This prohibition is consistent with OSHA's view that this control strategy is not appropriate in occupational environmetns involving exposure to potential carcinogens. It results in exposure of a large number of employees to levels of EtO which still present a significant risk. There were no objections to this proposed provision and, therefore, for the reasons discussed above, the final standard includes this requirement.

Respiratory Protection and Personal Protective Equipment. Paragraph (g)(1)(iii)

The final standard, with adoption of an excursion limit, provides that respirators be used to limit short-term employee exposure to EtO in the following circumstances:

(i) During the interval necessary to install or implement feasible engineering and work practice controls to achieve the excursion limit;

(ii) In work operations such as maintenance and repair activities or vessel cleaning or other activities for which the employer establishes that engineering and work practice controls are not feasible to achieve the excursion limit; and

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the excursion limit.

These same requirements apply under the current standard with respect to respirator use in complying with the TWA, and are based on OSHA's established policy on compliance methodology (see preamble discussion in the current EtO standard, 49 FR 25734).

Other requirements under this paragraph (g) dealing with "Respirator selection" and "Respirator program," remain unchanged and apply where respirators are used to achieve the excursion limit. There was no substantive objection to these provisions in the record and, therefore, they are adopted as proposed.

Communication of EtO Hazards to Employees. Paragraphs (j)(1)(ii), (j)(3)(i)

The existing EtO standard requires, in paragraph (j)(1)(ii), that employers 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. OSHA also adopts in this paragraph, a requirement for labelling of containers of EtO whose contents can foreseeably be expected to cause employee exposure above the excursion limit. This requirement, as discussed above under *Scope* and *Application*, does not conflict with nor exceed the provisions under the Hazard Communications standard that require labelling of hazardous materials that could give rise to employee exposure above an established exposure limit. Rulemaking participants were in favor of ensuring that the final labelling provisions for EtO conformed to and did not go beyond those in the Hazard Communication Standard. The final EtO labelling requirements satisfy those suggestions.

As discussed previously, various participants objected to expanding the labelling requirement based on the potential burden associated with product evaluation. OSHA notes, however, that employers are required under the 1984 standard to evaluate and label EtO products capable of causing exposure above the action level. OSHA believes that the information the employer has gained in performing product evaluation response to this current requirement will substantially assist them in determining the potential for release of ETO above the excursion limit could be exceeded. In addition, employers are aware that, in general, properly offgassed EtO products retain little EtO that may be released downstream. Peak exposures during offgassing will occur immediately upon conclusion of sterilization and diminish over time. Thus, EtO products that may be removed after sterilization and packaged in tight containers without the benefit of a proper offgassing period, would be candidates for products capable of causing substantial downstream exposures. These products are to be labelled, in accordance with the EtO and Hazard Communication Standard, to warn downstream employees who otherwise would be unaware of the existence of a hazardous situation of the potential for such exposure.

It has been suggested (Ex. 225) that the EtO labelling requirement is more restrictive than that required by Hazard Communication. On the contrary, OSHA believes that requiring that EtO products to be labelled only if they may result in exposure above the action level or the excursion limit, is less restrictive than the requirement under Hazard Communication. By contrast, the Hazard Communication standard requires that warning labels be provided for a substance if it is simply determined to be hazardous. Ethylene oxide is considered a hazardous chemical under the Hazard Communication standard by virtue of it having established permissible exposure limits in Part 1910, Subpart Z and by virtue of it being a human carcinogen. Further, OSHA believes that exposure to EtO at 5 ppm or above for 15 minutes, continues to present a significant risk of adverse health effects to affected employees. Thus, warning employees that exposure to a product may present a significant risk to their health is justified. This warning will alert employers to implement control means to ensure that the material will be used in the

workplace in such a manner that the excursion will not be exceeded, thus, reducing the dose of ETO that employees would otherwise receive.

The intent of this labelling requirement is not to encompass products which under extremely unusual instances may unexpectedly or unpredictably release EtO above the excursion limit. OSHA's proposed language that products be labelled if they are "capable of releasing" EtO above the excursion limit has caused confusion regarding OSHA's intended practical application of the provision. OSHA agrees with the suggestion by the EOIC that product exemption would be more clearly defined by predicating exemption where objective data demonstrate it is "not reasonably foreseeable" that the product will release EtO above the excursion limit (Ex. 225). Thus, as EOIC suggests, OSHA amends the labelling requirement in paragraph (j) to require labeling of containers of EtO * * * "whose contents may reasonably be foreseen to cause employee exposure above the excursion limit.

Existing paragraph (j)(3)(i) requires that information and training on EtO be orovided to employees exposed above he action level. OSHA also adopts in this final rule, as proposed in paragraph (j)(3)(i), a requirement that information and training on EtO be provided to employees exposed above the excursion limit. There were no objections to this requirement.

OSHA is adopting these provisions based on the determination that informing employees through labeling and training that high levels of hazardous materials might be released into the workplace will better enable affected employees to take precautionary measures to protect themselves.

Dates. Paragraph (m) Effective date

As proposed, the final amendments to the EtO standard would become effective sixty (60) days following publication in the **Federal Register**. In order to establish appropriate start-up dates from the effective date, OSHA requested comment on the length of time employers believed would be necessary in order to achieve compliance with the proposed excursion limit, and the time necessary to establish additional exposure monitoring, respirator, and training programs that would be required by adoption of an excursion mit for EtO. The startup dates iscussed below that are established for the various new provisions of the final standard are based on the record and on OSHA's experience with other standards including the 1984 EtO standard, as to the time required for employers to complete exposure monitoring, to obtain necessary equipment such as respirators, to produce written compliance programs, to design, procure, and install engineering controls, to implement training programs, and to evaluate products with respect to required labelling. OSHA believes that the dates set in this standard should be adequate in all but unusual circumstances.

If the time period for meeting any of these startup dates cannot be met because of technical difficulties, employers are entitled to petition the Assistant Secretary for a temporary variance under Section 6(b)(6)(A) of the Act. Based on its evaluation of the feasibility of the standard as discussed above, however, OSHA does not anticipate that many employers will need to use this variance mechanism.

Startup Dates

OSHA believes that expeditious action by employers to achieve compliance with the provision of this standard is warranted. Employees under the current standard are being exposed to EtO at concentrations that present a significant risk of adverse health effects. Compliance with the excursion limit will further reduce total EtO dose, and therefore the risk, to which employees are presently being exposed under the existing rule.

The information provided to OSHA clearly indicates that, with few exceptions, affected employers can be reasonably expected to be able to install feasible engineering controls that would bring their workplaces into compliance with the final standard's excursion limit within 6-months from the effective date of this standard.

Available engineering controls combined with good work practices, such as simply vacating the sterilizer area for 10–15 minutes after opening the sterilizer door after cycle completion, provide a readily available means for employers to comply with this standard in the time-frame specified.

Compliance with the other requirements of the standard within ninety (90) days of the effective date also is believed by OSHA to be appropriate. In response to the requirements set forth in OSHA's 1984 EtO standard, EtO employer have already instituted programs regarding training, compliance plans, respirators, exposure monitoring and work practices, recordkeeping, signs and labels, and regulated areas. Thus, compliance with new burdens imposed by adoption of the excursion limit within the periods specified is believed to be reasonable and appropriate.

VI. State Plan Applicability

Twenty-four states and U.S. territories have their own OSHA-approved occupational safety and health plans. These states and territories are: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. These states and territories are to adopt a standard comparable to that of OSHA's within 6 months of the effective data of the Federal rule.

VII. Authority

This document was prepared under the direction of John A. Pendergrass, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Pursuant to sections 4, 6(b), 8(c) and 8(g)(2) of the Occupational Safety and Health Act (29 U.S.C. 653, 655, 657), 29 CFR 1910.1047 is hereby amended as set forth below.

List of Subjects in 29 CFR Part 1910

Ethylene oxide, Occupational Safety and Health, Chemicals, Cancer, Health, Risk assessment.

Signed at Washington, DC, this 31st day of March, 1988.

John A. Pendergrass,

Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is amended as set forth below:

PART 1910—[AMENDED]

1. The authority citation for Subpart Z of 29 CFR Part 1910 continues, in pertinent part, to read as follows:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

Sections 1910.1045 and 1910.1047 also issued under 29 U.S.C. 653.

2. Paragraphs (a)(2), (c), (d)(1)(i), (d)(1)(ii), (d)(4), (d)(7)(ii), (e)(1), (f)(1)(i), (f)(1)(ii), (f)(2)(i), (f)(2)(iv), (g)(1)(iii), (j)(1)(ii) introductory text, and (j)(3)(i) of § 1910.1047 are revised, (d)(6) and (m)(1) are redesignated as (d)(6)(i) and (m)(1)(i), and new paragraphs (d)(2)(iii), (d)(3)(iv), (d)(6)(ii), (m)(1)(ii) and

(m)(2)(iii) are added to § 1910.1047 to read as follows:

§ 1910.1047 Ethylene oxide.

(a) * * *

(2) This section does not apply to the processing, use, or handling of products containing EtO where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the action level, and may not reasonably be foreseen to release EtO in excess of the excursion limit, under the expected conditions of processing, use, or handling that will cause the greatest possible release.

* * * * *

(c) *Permissible exposure limits*—(1) *8-hour time weighted average (TWA).* The employer shall ensure that no employee 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 (8-hour TWA).

(2) *Excursion limit.* The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.

(d) * * *

(1) * * *

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area. Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

* * * * *

(2) * * *

(iii) Where the employer has previously monitored for the excursion limit and the monitoring satisfies all other requirements of this sections, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(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.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be below the action level, the employer may discontinue TWA monitoring for those employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level, the employer may discontinue TWA monitoring for those employees whose exposures are represented by such monitoring.

(iii) If the initial monitoring required by paragraph (d)(2)(1) of this section reveals employee exposure to be at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by the initial monitoring.

(iv) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by such monitoring.

* * * * *

(6) * * *

(i) * * *

(ii) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 35 percent for airborne concentrations of EtO at the excursion limit.

(7) * * *

(i) * * *

(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.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposure to airborne concentrations of EtO may exceed the TWA or wherever the EtO concentration exceeds or can reasonably be expected to exceed the excursion limit.

* * * * *

(f) * * *

(1) * * *

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and to or below the excursion limit, except to the extent that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA and to or below the excursion limit, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

* * * * *

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

* * * * *

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA or excursion limit.

(g) * * *

(1) * * *

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the TWA or excursion limit; and

* * * * *

(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 purpose 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:

* * * * *

(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.

* * * * *

(m) * * *

(1) * * *

(ii) The requirements in the amended paragraphs in this section which pertain only to or are triggered by the excursion limit shall become effective June 6, 1988.

(2) * * *

(iii) Compliance with the excursion limit requirements in this section shall be by September 6, 1988, except that implementation of engineering controls specified for compliance with the excursion limit shall be by December 6, 1988.

* * * * *

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