1 Becton Drive
Franklin Lakes, NJ 07417
Tel.: +1 201 847 6800
www.BD.com

October 2, 2023

Occupational Safety and Health Administration

[Docket No. OSHA-2009-0035]

Comments on the Ethylene Oxide Standard Extension of the Office of Management and Budget's Approval of Information Collection (Paperwork) Requirements

On behalf of Becton, Dickinson and Company ("BD" or "Company"), I am submitting the following comments on the Information Collection Request (ICR) for the Ethylene Oxide (EtO) Standard (29 CFR 1910.1047) Office of Management and Budget (OMB) Control NO. 1218-0108 (August 2023).

A. Employee notification of monitoring results

The current standard requires employee notification of ethylene oxide (EtO) exposures within 15 working days after the receipt of the results of any monitoring performed, either individually in writing or by posting the results in an appropriate location that is accessible to employees. BD recommends a change to the standard to ease the burden on notifying employees of their ethylene oxide (EtO) exposures to allow for electronic notification rather than notification to each person in writing. With current technology and use of electronic communication commonplace, BD believes revising the standard to allow for electronic notification to each individual would be more efficient cutting down on the time required to perform the notification while still meeting the notification requirement. In light of the fact that BD performs routine and regular exposure monitoring of EtO exposures, this time savings from this change to electronic notification would be sizeable.

BD also believes that posting of exposure monitoring results can be construed to violate Privacy Laws. Personnel exposure monitoring data could be considered a medical record and therefore posting is not the preferred route of employee notification.

B. Including corrective action in the notification of monitoring results

The written notification required by the EtO standard shall contain the corrective action being taken by the employer to reduce employee exposure to or below the Time Weighted Average (TWA) and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit has been exceeded. BD believes the requirement to include corrective action in the notification to be redundant; these corrective actions are already required to be a part of the written compliance program according to paragraph (f)(2) of the standard. The standard specifies that the written compliance program requires where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce exposure to

or below the TWA and to or below the excursion limit by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. BD proposes using this written compliance program as a means to advise associates in lieu of including it in the employee monitoring results to reduce regulatory burden to comply with the EtO standard.

C. Comments on the quality, utility and clarity of the information collected

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

D. Comments on the accuracy of the Agency's estimate of the burden (time and costs) of the information-collection requirements, including the validity of the methodology and assumptions used

BD would like to share it's input regarding Table 1 "Number of Facilities by Industry Sector". BD believes the number of Ethoxylators appears to be low, and likely does not include all applicable industry sectors such as glycol manufacturing, plastics manufacturing, and soap products manufacturing. Additionally, the number of Medical-Product Manufacturers likely does not correlate to the number of facilities with EtO Sterilizers and the number of Contract Sterilizers does not reflect the number of EtO sterilization sites that do work within the United States.

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

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

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

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

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

In the Recordkeeping burden cost, the wage cost used in the calculations reflects wages of an entry level clerical person. Although some of the work could be done by a person at that level, the bulk of the information would need to be generated by a person with the level of an EHS Technician or above. The calculated number of records needs to be adjusted to reflect actual numbers of individuals subject to the requirements in the standard, not just those who were monitored in an individual exposure monitoring activity. The numbers must also be adjusted to reflect needed changes noted above. Based on the above suggested corrections to Table 1 “Number of Facilities by Industry Sector”, these changes should also be reflected in Table 7, “Total Number of Employees Hired Annually’. The wages used in this calculation are based on the assumption that recordkeeping could be done by a clerical person, and although some of the work could be done by a person at that level, the bulk of the information would need to be generated by a person with the level of an EHS Technician or above.

In the Exposure Monitoring assumptions, BD feels the cost per sample is low when comparing with actual sampling and analysis costs. Additionally, the assumptions used may only reflect the simpler methodology using passive collection with passive dosimetry badges. The time and complexity needed for active sampling using sampling pumps and sorbent tubes would be higher and needs to include the time and equipment for pump calibration as well as the technical expertise needed to set up and collect active samples. Companies may choose either method, and may prefer the active sampling method to achieve a lower limit of quantification or for other technical reasons. BD suggests an increase in this estimated cost based on these factors.

In the Medical Surveillance burden cost, BD believes the estimated cost of medical exams does not reflect current healthcare costs when the exam includes all the items required for effective medical screening.

In summary, BD feels the estimated overall Program Changes or adjustments. In light of comments above, the overall burden hours and costs are underestimated and should be increased significantly, not reduced.

E. U.S. Environmental Protection Agency's ("EPA") Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") Proposed Interim Registration Review Decision ("PID") for ethylene oxide ("EtO") ("FIFRA EtO PID")

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

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

In April 2023, EPA issued three proposals that together will reduce risk in communities and for workers: . . . Reducing Risk to Workers in the Sterilization Industry: On April 11, 2023, EPA proposed a broad set of new protections under the Federal Insecticide, Fungicide, and Rodenticide Act that will reduce risk for all workers who use EtO to sterilize things and for others who work, live, or go to school near sterilization facilities.[2]

In fact, the FIFRA EtO PID states that because OSHA "health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible," this limitation "often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers." PID at 35. Similarly, EPA states that OSHA's authority to ensure a work environment "free from recognized hazards that are causing or are likely to cause death or serious physical harm" under the "General Duty Clause," is not often enforced and places a "heavy evidentiary burden on OSHA to establish violations." PID at 36. Based on these limitations, EPA concludes "it is appropriate that EPA conduct risk assessments and, where it finds risks of concern to workers, develop risk mitigation measures to address risks from the pesticidal uses of chemicals that OSHA also regulates, and it

[1] About OSHA, OSHA.Gov., https://www.osha.gov/aboutosha#:~:text=OSHA's%20Mission,%2C%20outreach%2C%20education%20and%20assistance (last visited, May 24, 2023).

[2] *See* Actions to Protect Workers and Communities from Ethylene Oxide (EtO) Risk, EPA.Gov, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/actions-protect-workers-and-communities-ethylene-oxide-eto (last visited May 24, 2023).

is expected that EPA's findings and requirements may sometimes diverge from OSHA's." PID at 36.[3]

While OSHA's ethylene oxide standard (29 C.F.R. § 1910.1047)—which has proven effective in ensuring workplace safety—will remain in force, much of it will be functionally replaced by EPA's regulations. EPA is clearly stepping beyond its area of expertise and is not following the standard, accepted methods for setting occupational health standards. This issue is not cured by EPA's consultation with OSHA or even OSHA's cooperation. At the very least, EPA must respect how Congress intended worker safety to be implemented: i.e., taking into account technological and economic feasibility. EPA has some authority to ensure that these factors can be considered through the "economic, social, and environmental" cost/benefits analysis that EPA must conduct under FIFRA. *See* 40 C.F.R. § 155.56); 7 U.S. Code § 136(bb). And any mitigation measure that effectively regulates workplace safety should utilize the recognized methods, standards, and protocols utilized by worker safety experts, such as TWA- and breathing zone-based limits and respiratory PPE requirements based on facility-specific air sampling.[4]

Submitted by: Matthew Garamone

Becton, Dickinson and Company (BD)
1 Becton Drive, Mail Code 089
Franklin Lakes, NJ 07417
Matthew.Garamon@bd.com

Matthew Garamone

[3] *See also* PID at 37 ("Therefore, in lieu of revising the EtO PEL of 1 ppm, EPA will work with OSHA to revise the following parts of OSHA standard 29 CFR 1910.1047 Ethylene Oxide to align more with updated scientific assessments on EtO. . . . EPA will also work with OSHA to revise the OSHA Safety and Health Topics Webpage for Ethylene Oxide to acknowledge EPA's publications."

[4] Notably, EtO sterilization workers are only a small percentage of the total workforce that works in jobs involving EtO exposure. EPA should also recognize that in setting its own PEL for EtO sterilization facilities, it is creating a dichotomy between these workers and workers in other EtO industries. The OSHA ethylene oxide standard in 29 C.F.R. 1910.1047 was intended to apply to all industries and is the more suitable means for regulating EtO workplace exposures.