uploaded to a secure network or entered into a secure website. All case notifications that are faxed or emailed are done so in the form of an aggregate weekly or annual report, not individual cases. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or condition. Jurisdictions remove most personally identifiable information (PII) before data are submitted to CDC, but some data elements (*e.g.,* date of birth, date of diagnosis, county of residence) could potentially be combined with other information to identify individuals. Private information is not disclosed unless otherwise compelled by law. All data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA) and the 2010 National Institute of Standards and Technology (NIST) Recommended Security Controls for Federal Information Systems and Organizations. Weekly tables of nationally notifiable diseases are available through CDC WONDER and *data.cdc.gov.* Annual summaries of finalized nationally notifiable disease data are published on CDC WONDER and *data.cdc.gov* and disease-specific data are published by individual CDC programs.

The burden estimates include the number of hours that the public health department uses to process and send case notification data from their jurisdiction to CDC. Specifically, the burden estimates include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred for modernizing surveillance systems as part of CDC's Data Modernization Initiative (DMI) implementation, separate burden hours incurred for annual data reconciliation and submission, and separate one-time burden hours incurred for the addition of new diseases and data elements. The burden estimates for the one-time burden for reporting jurisdictions are for the addition of case notification data for the addition of case notification data for Chagas disease, yersiniosis (non-pestis), and injuries related to firearms, new conditions under standardized surveillance; and the addition of new disease-specific data elements for toxoplasmosis and congenital toxoplasmosis. The estimated annual burden for the 257 respondents is 18,354 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-automated)	10	52	2	1,040
States	Weekly (DMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements.	50	1	2	100
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93
Territories	Weekly (DMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements.	5	1	4	20
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements.	3	1	2	6
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (DMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements.	2	1	2	4
Total					18,354

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2274]

Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices.'' This guidance provides information regarding FDA recommendations and general principles to be referenced by holders of premarket approval applications (PMAs) and humanitarian device exemptions (HDE) for class III devices sterilized by

ethylene oxide (EtO) whose products are affected by the potential, actual, or temporary stop or reduction of operations at a sterilization facility, if they wish to have FDA consider whether the exercise of enforcement discretion relating to the implementation of certain types of sterilization site changes is appropriate. FDA is issuing this guidance to provide an enforcement discretion policy to help proactively address manufacturing limitations or supply chain issues due to disruptions caused by closures or potential closures of sterilization facilities that use EtO as a medical device sterilant during the time in which manufacturers are transitioning to compliance with certain new requirements. FDA believes that the enforcement discretion policy described in this guidance may help address concerns during this time related to potential sterile medical device impacts affecting certain devices sterilized by EtO, help mitigate possible interruptions in sterile device processing, and help maintain adequate supplies of finished sterile medical devices. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on November 26, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2274 for ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993–0002, 301–796–6476; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry and FDA staff entitled ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices.'' FDA plays a critical role in helping to protect the medical device supply chain and to prevent and mitigate potential medical product impacts. As part of this work, FDA closely monitors the supply chain effects of closures and potential closures of sterilization facilities that use EtO gas to sterilize medical devices prior to their use. For many medical devices, sterilization with EtO may be the only method that effectively sterilizes and does not damage the device during the sterilization process. To help maintain patient access to

sterile medical devices and mitigate risks to the sterile device supply chain, FDA has been developing solutions to avoid potential device impacts during the time in which manufacturers are transitioning to compliance with certain new requirements for the use of EtO as a sterilant.

FDA believes that the temporary enforcement discretion policy set forth in this guidance may help address urgent public health concerns related to potential sterile medical device impacts affecting certain devices sterilized by EtO. Specifically, this guidance is intended to provide information regarding what guiding principles FDA will consider and what types of information submitted by industry would be helpful to FDA to determine, on a case-by-case basis, whether to not object to sterilization site changes geared specifically to PMA and HDE holders of approved class III devices sterilized by EtO prior to the approval of a PMA or HDE supplement. This approach is intended to help firms more quickly and proactively manage the possible timeframes associated with implementing changes in the manufacturing site and any processes, methods, procedures, qualifications, and validations to help minimize impacts to the supply chain for EtO-sterilized class III devices. Further, this document is intended to be considered alongside other applicable FDA guidance documents, such as ''Manufacturing Site Change Supplements: Content and Submission,'' (hereafter ''Site Change Supplement Guidance'') issued December 17, 2018.

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). The immediate implementation of this guidance document is necessary to help protect the sterile device supply chain and is in the interest of proposing a less burdensome policy consistent with public health. FDA believes that the enforcement discretion policy described in this guidance may mitigate possible interruptions in sterile device processing and help maintain adequate supplies of finished sterile medical devices. Expedited sterilization site changes may be needed due to ongoing changes in the medical device sterilization landscape to reduce the likelihood of impact for certain EtO sterilized devices due to a potential, actual, or temporary stop or reduction of operations at a sterilization facility that sterilizes those devices. Although this policy is being implemented immediately without prior comment, it remains subject to comment in accordance with FDA's good guidance practices regulation (21 CFR 10.115(g)(3)(D)). FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007027 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing.	0910–0625

Dated: November 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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