

required by the CSTHEA to submit ingredient reports to HHS on an annual basis. The legislation also authorizes HHS to undertake research, and to report to Congress, as deemed appropriate, about the health effects of these ingredients.

Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently

required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. The information collection is

subject to strict confidentiality provisions and electronic mail submissions are not accepted. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

OMB approval is requested for three years. There are no changes to information collection procedures, the estimated burden per response, or the estimated number of respondents. The total estimated annualized burden hours are 22,269. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers.	SLT Nicotine and Ingredient and Report .....	13	1	1,713

**Leroy A. Richardson,**

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC-2014-0003]

**Draft Guideline—Centers for Disease Control and Prevention Draft Guideline for the Prevention of Surgical Site Infections**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Notice of availability and request for public comment.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) requests public comment on the Draft Guideline for the Prevention of Surgical Site Infections (SSIs) (draft Guideline). The Draft Guideline addresses new and updated strategies for the prevention of SSI in healthcare settings. This draft Guideline can be found at <http://www.regulations.gov> Docket No. CDC-2014-0003. CDC is also publishing the supporting appendices that include primary evidence, study evaluation, and

data evaluation tables that were used in developing the draft Guideline recommendations at <http://www.regulations.gov>.

The draft Guideline is designed for use by infection prevention staff, healthcare epidemiologists, administrators, nurses, and personnel responsible for developing, implementing, and evaluating infection prevention and control programs for healthcare settings across the continuum of care. The recommendations contained in the draft Guideline are based on a targeted systematic review of the best available evidence for specific topics related to the prevention of surgical site infections (SSI).

**DATES:** Comments must be received on or before February 28, 2014.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2014-0003, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Attn: Guideline for the Prevention of Surgical Site Infections, Docket No. CDC-2014-0003, 1600 Clifton Road NE., Mailstop A07, Atlanta, Georgia 30333.

**Instructions:** All submissions received must include the agency name and docket number or RIN. All relevant public comments received will be posted publicly to [www.regulations.gov](http://www.regulations.gov) without change, including any personal

or proprietary information provided. To download an electronic version of the draft Guideline and appendices, access <http://www.regulations.gov>.

Written materials identified by Docket No. CDC-2014-0003 will be available during the comment period for public inspection Monday through Friday, except for legal holidays, 9 a.m. until 4:30 p.m. Eastern Standard Time, at CDC Library, 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to (404) 639-1717 and request a Library representative schedule your visit. All public comments will be reviewed and considered prior to finalizing the draft Guideline.

**FOR FURTHER INFORMATION CONTACT:** Erin Stone, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A-31, Atlanta, Georgia 30333; Telephone: (404) 639-4000.

**SUPPLEMENTARY INFORMATION:** Since 2010 CDC has collaborated with national partners, academicians, public and private health professionals, and other partners to create this draft Guideline. Additionally, CDC sought input in each phase of development from subject matter experts in surgery, infectious diseases, and orthopedics through a Guideline Expert Panel formed to develop the new draft Guideline. CDC also received input from the Healthcare Infection Control Practices Advisory Committee (HICPAC) throughout the development of the draft Guideline. HICPAC includes representatives from public health,

infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders. This new draft Guideline will not be a federal rule or regulation.

Dated: January 22, 2014.

**Stacey Hoffman,**

*Acting Director, Division of Executive Secretariat Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Influenza Diagnostic Testing and Reporting

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** General notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is seeking to assess new technologies that improve rapid influenza diagnostic testing and supplement national laboratory-based surveillance for human influenza infections. In particular, the Influenza Division within the National Center for Immunization and Respiratory Diseases (NCIRD) at HHS/CDC proposes to evaluate new or improved point of care diagnostic tests for influenza virus detection that incorporate the capability to transmit influenza diagnostic test results electronically, such as through wireless communication technology, for more timely diagnosis of human influenza and/or other respiratory pathogen infections in outpatient/ambulatory and emergency room healthcare practices.

**DATES:** HHS/CDC will accept inquiries/proposals until December 31, 2015.

**ADDRESSES:** You may submit your inquiry/proposal by email: [FluDiagnosticTests@cdc.gov](mailto:FluDiagnosticTests@cdc.gov).

All information submitted to HHS/CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905). Responses are preferred in electronic format. CDC does not intend to publish the results of these evaluations.

**FOR FURTHER INFORMATION CONTACT:** Influenza Division, Centers for Disease Control and Prevention. Email: [FluDiagnosticTests@cdc.gov](mailto:FluDiagnosticTests@cdc.gov).

**SUPPLEMENTARY INFORMATION:** HHS/CDC uses epidemiologic, laboratory, clinical, and biostatistical sciences to prevent and control vaccine preventable infectious diseases. HHS/CDC also conducts applied research in a variety of settings, and translates the findings of this research into public health practice. HHS/CDC/NCIRD Influenza Division has lead technical responsibility for research, development, and evaluation of diagnostic tools for influenza and application of these to national surveillance and epidemiologic studies of influenza. Improving influenza diagnostic testing is part of HHS/CDC/NCIRD Influenza Division's strategic plan and includes support of the development of expanded respiratory pathogen tests on existing test platforms; development of advanced sequence detection methods for identifying novel influenza strains with pandemic potential; rapid identification of antiviral resistant influenza strains; rapid identification of influenza immunological response to determine the presence or absence of circulating antibodies specific for influenza viruses; and the development and characterization of stable diagnostic reagents or reference material and controls, for application with existing diagnostic test systems on established platforms.

HHS/CDC/NCIRD Influenza Division seeks to collaborate on evaluations of any new or improved diagnostic tests for the detection of human influenza viruses. The tests may range from high complexity molecular assays providing genetic sequence information to point of care type tests that facilitate more timely diagnosis of human influenza infections and/or other respiratory pathogen infections in ambulatory and emergency room healthcare practices. Assays should present sensitivity and specificity higher than currently available products.

For commercial products with approval for use by the US Food and Drug Administration (FDA), HHS/CDC/NCIRD Influenza Division is seeking to evaluate the potential supplementation of current national laboratory-based influenza surveillance data with influenza test result data that can be transmitted directly to a public health entity (state, local, or CDC) from the test platform electronically, such as through wireless technology. Direct test platform-based reporting capability has been newly established. Current surveillance incorporates data from healthcare provider offices and laboratories through manual or automated reporting functions; however, most of the current testing

platforms do not have the capacity to directly transmit reports. Such reports represent a new data source and thus require evaluation and determination of appropriate data use agreements.

HHS/CDC/NCIRD Influenza Division is also interested in collaborating with organizations working on validation of novel and improved respiratory specimen collection materials and methods that can enable reliable and consistent self-collection or collection by non-expert personnel. Data obtained from the evaluation can be compared through analytical assessments and be used by HHS/CDC in making recommendations and decisions for diagnosis of influenza in the health setting. Products may be evaluated at HHS/CDC and/or at collaborating laboratories and if appropriate, may be used in epidemiologic validation studies.

Interested organizations that have candidate products are invited to approach the HHS/CDC/NCIRD Influenza Division to assess whether the available product(s) are at a sufficient stage of development and how HHS/CDC can collaborate on evaluations and comparative analysis.

#### Information To Submit

At a minimum, submitted information should include the following for each candidate product: (a) Product package insert or detailed instructions for use; (b) Detailed information to determine if the product is calibrated to a recognized standard; (c) Preliminary data demonstrating suitability for validation studies and clinical trial data on sensitivity and specificity; (d) Whether the product is FDA approved; and (e) Statement of how HHS/CDC/NCIRD Influenza Division could collaborate on product evaluation or further development.

Dated: January 22, 2014.

**Stacey Hoffman,**

*Acting Director, Division of Executive Secretariat Centers for Disease Control and Prevention.*

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