

collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden is the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to respond to a collection of information, search data sources, and complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR 73) (OMB Control No. 0920-0576, exp. 12/31/2018)—Revision—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Subtitle A of the *Public Health Security and Bioterrorism Preparedness*

and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (which may be cited as the *Agricultural Bioterrorism Protection Act of 2002*), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). The HHS Secretary delegated the responsibility for promulgating and implementing select agent regulations found at 42 CFR part 73 to CDC Division of Select Agents and Toxins (DSAT). The Animal and Plant Health Inspection Service (APHIS)/Agriculture Select Agent Services (AgSAS) was delegated responsibility by USDA for select agent regulations (7 CFR part 331, and 9 CFR part 121). The Federal Select Agent Program (FSAP) is the collaboration of the DSAT and AgSAS to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. Accordingly, CDC and APHIS have

adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to revise the collected information under the select agent regulations through the use of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins). The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a),(b)) must be completed by an individual or an entity whenever the individual or entity experiences a theft, loss, or release of a select agent or toxin.

CDC is proposing to revise the form to further clarify what needs to be reported as a “release” and “loss” and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness. Estimated average time to complete this form is one hour.

The total estimated annualized burden for this collection was calculated using data obtained from the FSAP database and is estimated as 430 hours. Information will be collected via fax, email and hard copy mail from respondents. Upon OMB approval, CDC will continue use of the revised form through November 2018. There is no cost to the respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
73.19 Section	Report of Theft, Loss, or Release of Select Agents and Toxins.	215	1	2	430
Total	430

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

[60Day-17-1074; Docket No. CDC-2016-0123]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the revision of the information collection entitled “Colorectal Cancer Control Program (CRCCP) Monitoring Activities.” The change to the collection will include a

redesigned survey and a redesigned clinic-level data collection template.

DATES: Written comments must be received on or before February 28, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0123 by any of the following methods:

- *Federal eRulemaking Portal:*

Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Colorectal Cancer Control Program (CRCCP) Monitoring Activities—(OMB Control No. 0920-1074, exp. 6/30/2018)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision of the information collection approved under OMB Control Number 0920-1074. Based on feedback from grantees and internal subject matter experts, CDC proposes use of a revised annual grantee survey instrument, as well as a revised clinic-level data collection template. The number of respondents will also decrease from 31 to 30 grantees. Total estimated annualized burden will decrease. OMB approval is requested for three years.

Colorectal cancer (CRC) is the second leading cause of death from cancer in the United States among cancers that affect both men and women. CRC screening has been shown to reduce incidence of and death from the disease. Screening for CRC can detect disease early when treatment is more effective and prevent cancer by finding and removing precancerous polyps. Of individuals diagnosed with early stage CRC, more than 90% live five or more years. Despite strong evidence supporting screening, only 65% of adults currently report being up-to-date with CRC screening as recommended by the U.S. Preventive Services Task Force,

with more than 22 million age-eligible adults estimated to be untested. To reduce CRC morbidity, mortality, and associated costs, use of CRC screening tests must be increased among age-eligible adults with the lowest CRC screening rates.

CDC's Colorectal Cancer Control Program (CRCCP) currently provides funding to 30 grantees under "Organized Approaches to Increase Colorectal Cancer Screening" (CDC-RFA-DP15-1502). CRCCP grantees include state governments or bona-fide agents, universities, and tribal organizations. The purpose of the cooperative agreement program is to increase CRC screening rates among an applicant defined target population of persons 50-75 years of age within a partner health system serving a defined geographical area or disparate population. The CDC significantly redesigned the CRCCP in 2015. The CRCCP has two components.

Component 1: Funding for component 1 is limited to partnerships with health systems to implement up to four priority evidence-based interventions (EBIs) described in the Guide to Community Preventive Services as well as other supporting strategies. Grantees must implement at least two EBIs in each partnering health system. All 30 CRCCP grantees received Component 1 funding.

Component 2: Funding for component 2 is used by grantees to provide direct screening and follow-up clinical services for a limited number of individuals aged 50-64 in the program's priority population who are asymptomatic, at average risk for CRC, have inadequate or no health insurance for CRC screening, and are low income. Six of the 30 CRCCP grantees received Component 2 funding.

Two forms of data collection have been implemented to assess program processes and outcomes. In Program Year 1, the annual grantee survey monitored grantee program implementation, including (1) program management, (2) implementation of the EBIs and Supporting Activities (SAs) (3) health information technology (IT), (4) partnerships, (5) data use, (6) training and technical assistance (TA), and (7) clinical service delivery (for programs receiving Component 2 funding only). Clinic-level data collection assessed CRCCP's primary outcome of interest—CRC screening rates within partner health systems—by measuring the following components: (1) Partner health system, clinic, and patient population characteristics, (2) reporting period (for screening rates), (3) Chart review screening rate data, (4) Electronic Health Record (EHR)

screening rate, and (5) Priority evidence-based EBIs and SAs. CRCCP grantees collected and reported CRCCP clinic-level information for all partnering health system primary care clinic sites.

For Program Years 2–5, based on feedback from grantees, CDC proposes use of updated data collection instruments. Specifically, CDC plans to implement a revised CRCCP annual grantee survey that eliminates survey items related to implementation of EBIs and SAs as these data are more

accurately reported at the clinic level. Conversely, CDC plans to implement a revised CRCCP clinic-level data collection template that includes additional data variables related to implementation of EBIs and SAs, as well as monitoring and evaluation activities, at the clinic level.

Redesigned data elements will enable CDC to better gauge progress in meeting CRCCP program goals and monitor implementation activities, evaluate outcomes, and identify grantee technical

assistance needs. In addition, data collected will inform program improvement and help identify successful activities that need to be maintained, replicated, or expanded.

OMB approval is requested for three years. The number of grantees decreased from 31 grantees in program year one to 30 grantees in program year two. In addition, the total estimated annualized burden hours have decreased from 210 to 204 hours. There are no costs to respondents other than their time.

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)
CRCCP Grantees	CRCCP Annual Grantee Survey	30	1	24/60	12
	CRCCP Clinic-level Information Collection Template.	30	12	32/60	192
Total	204

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

Electronic Filing of Certain Import Data Into the Document Image System Through the Automated Commercial Environment

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Through publication of this notice, the Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces a new policy and guidance for the electronic submission of data related to the importation of CDC-regulated items in the International Trade Data System (ITDS). Certain data, forms, and documents required to be submitted to HHS/CDC will be submitted through the U.S. Customs and Border Protection (CBP)’s Automated Commercial Environment (ACE) system, using the Document Image System (DIS). This electronic process will replace certain

paper-based processes in keeping with Federal policy and improve operations to further assist HHS/CDC’s mission to protect public health.

DATES: This action is effective December 30, 2016.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice: Ashley A. Marrone, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, GA 30329. For information regarding CDC operations related to this Notice: Kendra Stauffer, D.V.M., Division of Global Migration and Quarantine, Quarantine and Border Health Services Branch, Importations and Animal Contact Team, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E28, Atlanta, GA 30345. Either may also be reached by telephone 404–498–1600 or email CDCAnimalImports@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 19, 2014, the President signed Executive Order 13659, *Streamlining the Export/Import Process for America’s Businesses* (79 FR 10655), that requires the completion and government-wide utilization by December 31, 2016 of the International Trade Data System (ITDS) and establishes a two-tiered governance process to oversee its implementation. Once fully implemented, ITDS, through the Automated Commercial Environment (ACE), will allow importers to submit the data required by

U.S. Customs and Border Protection and its Partner Government Agencies (PGAs) relating to the import or export of cargo through a “single window” concept. CBP has developed ACE as the single window for the trade community to transmit electronically all required cargo-related information.

This notice announces HHS/CDC’s updated policy concerning the electronic transmission of HHS/CDC permits, forms, and documents using CBP’s Document Image System (DIS). This DIS capability will satisfy the HHS/CDC data and electronic document requirements for any entry filed electronically in ACE and enable the trade community to have a CBP-managed single window for the electronic submission of data and documents required by HHS/CDC during the cargo importation and review process. The list of PGA forms and documents, including documents required by HHS/CDC, which may be transmitted using DIS may be found at <http://www.cbp.gov/trade/ace/features> under the DIS tab by clicking on the “ACE PGA Forms List” hyperlink in the “References” column. The HHS/CDC permits, forms, and documents listed in the ACE PGA Forms List are those eligible to be transmitted using DIS.

II. Current HHS/CDC Paper-Based Procedures

Under current applicable HHS/CDC policy and operations, the importation of HHS/CDC-regulated commodities into the customs territory of the United States typically requires the submission