



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-24HP; Docket No. CDC-2024-0056]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Compliance Attestation Statement for the Framework for Nucleic Acid Synthesis Screening. The project aims to assist providers and manufacturers of synthetic nucleic acids and benchtop nucleic acid synthesis equipment (providers) in making an attestation that they have instituted a process to screen nucleic acid sequences of concern and verify customer legitimacy, in accordance with the requirements outlined in the OSTP Framework for Nucleic Acid Synthesis Screening.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2024-0056 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Compliance Attestation Statement for the Framework for Nucleic Acid Synthesis Screening - New – Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection form was developed pursuant to the Framework for Nucleic Acid Synthesis Screening, which was released by the Office of Science and Technology Policy (OSTP) in April of 2024. This framework was directed by the *Executive Order on the Safe, Secure, and Trustworthy Development of Artificial Intelligence*, and recommends that providers and manufacturers of synthetic nucleic acids screen their sequences and customers before fulfilling orders to prevent potential misuse.

The Attestation Form will collect basic organizational information and an attestation of compliance from providers and manufacturers of synthetic nucleic acids and benchtop nucleic acid synthesis equipment. Data collected includes organization name, location, website, and type of organization. The form also includes primary and secondary contact information such as name, location, phone number and email address to ensure there is a point of contact with the company in case of questions regarding compliance and record keeping. This data is needed to ensure the self-attestation form can be filed and logged correctly, and to ensure the government can reach out to the correct contact if clarification is necessary.

CDC requests OMB approval for an estimated 20 annual burden hours. There is no cost to respondents other than their time to participate.

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 (in hours)
Providers and manufacturers of synthetic nucleic acids and bench top nucleic acid synthesis equipment	Annual Provider and Manufacturer Self-Attestation Statement	60	1	20/60	20
Total					20

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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