

Supporting Statement A
U.S. National Authority for Containment of Poliovirus Data Collection Tools
(OMB Control No. 0920-xxx)
New

Centers for Disease Control and Prevention
Office of Readiness and Response
U.S. National Authority for Containment of Poliovirus (NAC)

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Supporting Statement A

Goal of the project: The goal of the project is to collect data in the event of a poliovirus breach of containment - as well as to understand the biosafety practices of facilities working on poliovirus and mitigations strategies in place to reduce risks. These goals are in line with World Health Organization's Global Action Plan (GAP) for Poliovirus containment efforts.

Intended use of the resulting data: Intended use of the six different tools encompassed in this project is as follows:

- Data captured on the *Facility Incident Reporting Form for Poliovirus Release and Potential Exposure* will be used in the U.S. NAC risk assessments and guide federal emergency response efforts.
- Data captured on the *Facility Incident Reporting Form for Poliovirus Theft and Loss* will be used in the U.S. NAC risk assessments and guide federal emergency response efforts.
- The information collected in the *Personal Protective Equipment Survey for Laboratories* will assist the Centers for Disease Control and Prevention (CDC), U.S. NAC and National Institute for Occupational Safety and Health (NIOSH) with developing guidance and recommendations for PPE selection and use in support of poliovirus containment as well as identify laboratory PPE commonly used to evaluate laboratory PPE performance characteristics in testing studies.
- Information collected in the *Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist* will aid U.S. facilities in preparing for an audit to obtain a poliovirus certificate of containment.
- Data collected from the *Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire* will collect additional information on poliovirus materials held by a U.S. facility, their work activities, and facility features.
- The *Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF)* in the United States will collect information to assess poliovirus essential facility's wastewater system, the primary safeguards to reduce and control the release of poliovirus from the facility. In addition, it will verify the safeguards of local wastewater utilities that receive wastewater from the PEF.

Methods to be used to collect: The *Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure and Theft and Loss*, the *Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist*, the *Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire*, and the *Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States* will be in a fillable form and include a paper and electronic based format. The NAC-NIOSH *Personal Protective Equipment Survey for Laboratories* will be a web based electronic survey using an anonymous REDCap survey.

The subpopulation to be studied: U.S. facilities possessing infectious or potentially

Goal of the project: The goal of the project is to collect data in the event of a poliovirus breach of containment - as well as to understand the biosafety practices of facilities working on poliovirus and mitigations strategies in place to reduce risks. These goals are in line with World Health Organization's Global Action Plan (GAP) for Poliovirus containment efforts.

infectious poliovirus material.

How the data will be analyzed: The data collected through the six U.S. NAC tools described in this document are typically analyzed by using Microsoft Excel, Power BI, and Access software. Simple calculations, summarizations, dashboard visualizations will be achieved using Microsoft Excel and Power BI while more complex data queries will be performed using Microsoft Access.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection request is new and the length of time requested is 3 years.

The Public Health Service Act, Section 2102 (42 U.S.C. 300a-2) and the Federal Information Policy, 44 USC Sect. 3501 are legal authorizing statutes for the *Facility Incident Reporting Form for Poliovirus Release or Potential Exposure*, the *Facility Incident Reporting Form for Poliovirus Theft or Loss*, the *GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire*, the *GAP Facility Assessment Checklist*, and the *Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States*. Data collection for the *Personal Protective Equipment Survey* is authorized under the OSH Act of 1977 (29 USC 669 Section 20(a)(1)).

In 2018, HHS designated the Centers for Disease Control and Prevention (CDC) as the National Authority for Containment of Poliovirus (U.S. NAC) for the United States. The U.S. NAC is located in the Center for Preparedness and Response (CPR). The role of the U.S. NAC is to ensure that the requirements established in the World Health Organization (WHO) Global Action Plan (GAP) III and IV standards are effectively implemented and maintained in poliovirus-essential facilities. Part of this standard includes emergency planning, the implementation of surveillance following an incident, and the reporting of facility-associated poliovirus events to the U.S. NAC. Risk assessments following an incident are a critical component for adequate application of the GAPIII/GAPIV standard and efficient emergency response. To support these activities, fillable forms were created to allow facilities to capture and submit information concerning a poliovirus release, exposure, loss, or theft incident to the U.S. NAC. The forms address the biosafety and biosecurity containment emergency elements of the GAPIV standard creating a normalized dataset and inform the U.S. NAC risk assessments, thereby, guiding CDC's determination of the emergency response level and direction. The other tools aim to

gather information on current conditions and practices of facilities working with poliovirus and its infrastructure related to its capacity to maintain containment. Collectively, these tools are critical in ensuring facilities that continue work with poliovirus have programs in place that align with global poliovirus eradication initiative.

2. Purpose and Use of Information Collection

This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

The Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure and Theft and Loss, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire, and the Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States will be in a fillable form and include a paper and electronic based format. The NAC-NIOSH Personal Protective Equipment Survey for Laboratories will be a web based electronic survey using an anonymous REDCap survey. This data will be collected by CDC as needed as incidents occur or once per year.

Intended use of the resulting data: Intended use of the six different tools encompassed in this project is as follows:

- **Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure (Attachment 3)** will be used in the U.S. NAC risk assessments and guide federal emergency response efforts.
- **Facility Incident Reporting Form for Poliovirus Theft and Loss (Attachment 4)** will be used in the U.S. NAC risk assessments and guide federal emergency response efforts.
- **Personal Protective Equipment Survey for Laboratories (Attachment 5)** will assist the Centers for Disease Control and Prevention (CDC), U.S. NAC and National Institute for Occupational Safety and Health (NIOSH) with developing guidance and recommendations for PPE selection and use in support of poliovirus containment as well as identify commonly used laboratory PPE to evaluate performance characteristics in testing studies.
- **Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist (Attachment 6)** will aid U.S. facilities in preparing for an audit to obtain a poliovirus certificate of containment.
- **Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire (Attachment 7)** will collect additional information on poliovirus materials held by a U.S. facility, their work activities, and facility features.
- **Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States (Attachment 8)** will collect information to assess poliovirus-essential facility's wastewater system, the primary safeguards to reduce and control the release of poliovirus from the facility. In addition, it will verify the safeguards of local wastewater utilities that receive wastewater from the PEF.

3. Use of Improved Technology and Burden Reduction

The Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure and Theft and Loss, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire, and the Poliovirus Containment Sampling Plan and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States will be in a fillable form and include a paper and electronic based format. The NAC-NIOSH Personal Protective Equipment Survey for Laboratories will be a web based electronic survey using an anonymous REDCap survey.

4. Efforts to Identify Duplication and Use of Similar Information

U.S. NAC's research and collaboration extends to the National Institute for Occupational Safety and Health (NIOSH), National Center for Immunization and Respiratory Diseases (NCIRD), National Center for Environmental Health (NCEH), and the Federal Select Agent Program/Office of Readiness and Response Division of Select Agents and Toxins (DSAT). However, only the DSAT Theft, Loss, & Release Reporting Form (form 3) was similar in nature to the needs of the U.S. NAC but was determined to be insufficient due to the general nature of its data collection and lack of poliovirus specific data elements. The new U.S. NAC incident reporting form for release/potential exposure and loss/theft will specifically collect information related to a poliovirus-associated containment breach.

NIOSH conducted surveys on personal protective equipment use and practices for multiple sectors, such as firefighters. However, these surveys lack specific information that applies to the laboratory workers working with poliovirus, their PPE needs, selection and use practices. U.S. NAC collaborates with NIOSH's National Personal Protective Technology Laboratory (NPPTL) and its Institute-wide Personal Protective Technology (PPT) Program ensures that no duplication of work across government agencies occurs as it relates to PPE. NPPTL was established by NIOSH at the request of Congress in 2001 and serves as the nation's laboratory for personal protective technologies which includes PPE. NPPTL was established to advance PPE knowledge and application. NPPTL also administers NIOSH's Respirator Approval Program and maintains a Standing Committee on PPE for Workplace Safety and Health that is administered by the National Academies of Sciences, Engineering, and Medicine. NIOSH's NPPTL and PPE Program confirm that they have no plans to conduct similar work as what is described here.

There are no similar data/information for the Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) (Attachment 8)

There are no similar data /information for the GAP Facility Assessment Checklist and GAP Poliovirus Containment Poliovirus Essential Facility Questionnaire (Attachment 6 and 7)

5. Impact on Small Businesses or Other Small Entities

Collection of information may involve some small businesses or other small entities, but the burden has been limited to providing minimal information on forms, verifying information by telephone, and emailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

6. Consequences of Collecting the Information Less Frequently

There are legal obstacles to reducing the burden by collecting this information less frequently.

The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for CDC to carry out its commitments to protect the public health as mandated by these regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8A. A “60 Day Federal Register Notice” was published in the Federal Register on December 12, 2022, Vol. 87, No. 237, Pages 76052-76053 (**Attachment 2**). One comment was received regarding this notice and CDC responded accordingly. (**Attachment 2a**)

A8B. Consultation Outside the Agency

The “Personal protective equipment survey for laboratories” survey tool was piloted with 5 PEFs as a way to obtain their views on clarity of instructions, format of questions and also as means to estimate burden time to complete the survey. Data provided by PEFs also allowed the U.S. NAC to analyze it and determine if questions in the survey were beneficial to inform decisions on best practices for personal protective equipment. As information and feedback was collected from PEFs and there are sensitivities surrounding facilities holding this virus, any identifying information about the PEFs cannot be disclosed by the U.S.NAC.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Assurance of Confidentiality Provided to Respondents

The Office of Readiness and Response has determined that the Privacy Act does not apply to this information collection. The data collection does not involve collection of sensitive or identifiable personal information. Although contact information is obtained for, the contact person provides information about the organization, not personal information. No system of records will be created under the Privacy Act.

Information will be kept secure in a permission-based folder (restricted access) on the CDC server. Only authorized CDC personnel will have access to the system using their network/password or personal identity verification (PIV) card credentials. No IIF will be distributed. Data will be kept private to the extent allowed by law.

11. Justification of Sensitive Questions

This activity has been determined to be a non-research activity. (Attachment 9). No sensitive questions will be asked.

Sensitive Questions

This data collection does not include personal questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

It is expected that one individual from a facility where a breach of containment occurs will complete the Facility Incident Reporting Form for Poliovirus Release and Potential Exposure (Attachment 3) or the Facility Incident Reporting Form for Poliovirus Theft or Loss Form (Attachment 4) after a breach occurs. The total number of respondents completing the form will vary annually based on the number of incidents that occur but is expected to be less than ten per year nationally. The form has been estimated to take 45 minutes to complete but may vary depending on the awareness and availability of information needed to complete the form questions and prepare a full incident narrative. Average time burden was determined through in-house testing during final development of the form. Associated cost factors include the rate of pay of the individual completing the form and transmitting it to the U.S. NAC.

The Personal Protective Equipment Survey for laboratories (Attachment 5), GAP Facility Assessment Checklist (Attachment 6), GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire (Attachment 7) and the Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems (Attachment 8) will be completed by individuals from facilities possessing and actively working on poliovirus. These tools have been piloted previously with fewer than 10 respondents and the estimated burden hours are shown in the table below. On average, the forms have been estimated to take 1.5 hours to complete per respondent per survey. There are no costs to respondents other than their time.

Table A12A. Estimate of 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)
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Release/Potential Exposure Att 3	10	1	45/60	8
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Theft/Loss Att 4	10	1	45/60	8
Facility Staff/Leadership	Personal Protective Equipment Survey for Laboratories Att 7	20	1	1.5	30
Facility Staff/Leadership	GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire Att 6	20	1	1.5	30
Facility Staff/Leadership	GAP Facility Assessment Checklist Att 5	20	1	1.0	20
Facility Staff/Leadership	The Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States Att 8	20	1	1.5	30
Total	-----	-----	-----	-----	125

Table A12B. Estimate of Annualized Cost to Respondent

When estimating the annualized burden costs, CDC assumes that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an average hourly respondent labor rate of \$ 38.81. These rates were obtained from the Bureau of Labor Statistics, from the 2021 Occupational Employment Statistics Survey by Occupation (<http://www.bls.gov/oes/>). The total estimate of the annualized costs to the respondents is \$3,686.95.

Type of Respondents	Form Name	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Release/Potential Exposure	8	\$38.81	\$310.48
Facility Staff/Leadership	Facility Incident Reporting Form for Poliovirus Theft/Loss	8	\$38.81	\$310.48
Facility Staff/Leadership	Personal Protective Equipment Survey for Laboratories	30	\$38.81	\$1,164.30
Facility Staff/Leadership	GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire	30	\$38.81	\$1,164.3
Facility Staff/Leadership	GAP Facility Assessment Checklist	20	\$38.81	\$776.20
Facility Staff/Leadership	The Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States	30	\$38.81	\$1,164.30
Total	-----	----- ----	----- ----	\$3,686.95

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with completing forms. All these costs are part of normal business expenses.

14. Annualized Cost to the Government

The total estimated cost for implementing these regulatory activities for upcoming fiscal year 2024 is \$7,681.28. This estimate includes 5 full-time Federal Employees (FTE) currently working in the U.S. NAC within the Office of Readiness and Response; and 2 from Division of Environmental Health Sciences and Practice at NCEH. We are using an average hourly respondent general schedule pay scale rate of \$ 56.48. These rates were obtained from the U.S. Office of Personnel Management ([SALARY TABLE 2023-ATL \(opm.gov\)](https://www.opm.gov/policy-data-oversight/salary/)). Administrative costs incurred are minimal because the survey and forms are primarily sent to respondents via email.

FY 2024 Annualized Government Cost (Itemized by Survey Tool)

Form Name	Total hours	Hourly Wage Rate	Total Respondent Costs
Facility Incident Reporting Form for Poliovirus Release/Potential Exposure	8	\$56.48	\$451.84
Facility Incident Reporting Form for Poliovirus Theft/Loss	8	\$56.48	\$451.84
Personal Protective Equipment Survey for Laboratories	30	\$56.48	\$1,694.40
GAP Poliovirus Containment Poliovirus-Essential Facility Questionnaire	30	\$56.48	\$ 1,694.40
GAP Facility Assessment Checklist	20	\$56.48	\$ 1,129.60
The Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States	30	\$56.48	\$ 1,694.40
Total			\$ 7,681.28

15. Explanation for Program Changes or

Adjustments

“This is a new data/information collection.”.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for publication of data collected from both Facility Incident Reporting forms (Release or Potential Exposure, and Theft or Loss), GAP Poliovirus Containment PEF Assessment Checklist and GAP Poliovirus Containment PEF Facility Questionnaire. Facility Incident Reporting forms (Release or Potential Exposure, and Theft or Loss) and GAP Poliovirus Containment PEF Facility Questionnaire may be analyzed through simple tabulations and summarization followed by visualization using Microsoft Excel. The data collection is used solely to carry out the provisions of the regulation.

Data collected from “Personal protective equipment survey for laboratories” and “Poliovirus containment sampling form for wastewater systems supporting a PEF in the US”, will be analyzed through simple tabulations and summarization followed by visualization using Microsoft Excel. These data, which will not have identifying data of facilities, will be prepared for publication to help inform best practices and develop mitigation strategies to reduce risk of poliovirus breach of containment. This data will also be prepared for presentation as posters at forums related to Biosafety. Shown in Table 1.16.A, is the projected time schedule for the collection and preparation of data for publication and presentation.

Table 1.16A

Project Time Schedule	
Activity	Time Schedule
Emails sent to respondents	1-2 months after OMB approval
Information/Data collection	3-8 months after OMB approval
Complete field work	8-9 months after OMB approval
Validation	10-12 months after OMB approval
Analyses	12-18 months after OMB approval
Publication	18-24 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments:

Attachment 1- Authorizing Legislation - Public Health Service Act, Section 2102 (42 U.S.C. 300a-2)

Attachment 1a - Authorizing Legislation - Federal Information Policy, 44 USC Sect. 3501

Attachment 1b - Authorizing Legislation -OSHA Act of 1977 (29 USC 669 Section 20(a)(1))

Attachment 2 – 60-Day Federal Register Notice

Attachment 2a – 60-Day Comment and CDC Response

Attachment 3- Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure

Attachment 4 – Facility Incident Reporting Form for Poliovirus Theft and Loss

Attachment 5 – Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist

Attachment6 – Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire

Attachment 7 – Personal Protective Equipment Survey for Laboratories

Attachment 8 – Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States

Attachment 9 – Non-research determination