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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Inventory for Poliovirus Containment: Minimizing Risk of Poliovirus Release from Laboratories in the United States; Availability

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

ACTION: Notice.

SUMMARY: The United States National Authority for Containment of Poliovirus (NAC), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), announces the availability of the National Inventory for Poliovirus Containment survey. This survey is designed to collect relevant laboratory inventory data to ensure facilities throughout the United States are in compliance with requirements established in the World Health Organization (WHO) Global Action Plan (GAPIII), as adapted for the WHO Region of the Americas. Per GAPIII, each country is required to complete a national inventory of poliovirus-containing materials, including poliovirus potentially infectious materials (PIM).

DATES: The deadline for completion of the survey is December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Lia Haynes Smith,
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SUPPLEMENTARY INFORMATION:

The survey should be completed by laboratories, storage sites, or other facilities that test, extract, handle, or store biological samples from humans, experimentally infected animals, sewage, or environmental waters. The survey questions are intended to identify facilities that possess any materials that may contain poliovirus. The questions seek to distinguish between potentially infectious materials (PIM) containing wild poliovirus (WPV), circulating vaccine-derived poliovirus (cVDPV), and oral poliovirus vaccine (OPV). PIM includes historical domestic and international specimens, human respiratory secretions, fecal specimens and environmental samples collected for non-polio related work in a time and place where wild poliovirus (WPV) or vaccine-derived poliovirus (cVDPV) was circulating or where oral polio vaccine (OPV) was in use. A table of country-specific poliovirus data can be found at <http://polioeradication.org/wp->

<content/uploads/2018/11/PIM-Annex-2-16-Nov-18.pdf>.

Additionally, PIM cultured in some common cell lines in order to isolate other viruses of interest may have unintentionally amplified poliovirus, so respiratory or enteric viral isolates obtained from PIM specimens using these cell lines are also considered PIM. With the release of the WHO PIM guidance in April 2018, nucleic acid extracted using a validated method and specimens that potentially contain only OPV (OPV PIM), are no longer subject to containment under WHO GAP III. However, they are still considered part of the US inventory and should be reported.

For the purpose of this survey, PIM should be identified based on where and when the specimens were collected, not based on any test results.

If a facility intends to destroy any of the potentially infectious poliovirus material or infectious material it possesses, it must submit material destruction attestation to the NAC. The NAC will send this attestation form to the facility once the completed survey is received.

Although the U.S. no longer immunizes with OPV, poliovirus materials are still present within a limited number of U.S. facilities for public health and virologic research, as well as diagnostic and manufacturing-related

purposes. In these essential facilities [poliovirus-essential facilities; PEFs], poliovirus materials will continue to be retained, post-eradication, to serve critical national and international functions. It is crucial that poliovirus materials are appropriately contained under strict biosafety and biosecurity handling and storage conditions to ensure that the virus is not released into the environment, either accidentally or intentionally, to cause outbreaks of the disease in susceptible populations. The risk from a poliovirus reintroduction can be minimized, in part, by ensuring that facilities retaining poliovirus are located in areas with high levels of vaccination coverage. The data collected from this survey will be used to identify facilities with poliovirus materials, to inform poliovirus immunization activities at PEFs including the potential need to immunize particular facility staff, and to identify vaccination coverage estimates for communities surrounding these facilities.

Survey Overview

An overview of the survey questions can be found at https://www.cdc.gov/cpr/polioviruscontainment/00_docs/SurveyGuidance.pdf. This overview document is provided to help facilities prepare their survey responses and is not

intended to be completed as a paper-based format. The survey must be completed online.

Access to the survey, including appendices and other references, can be found at

<https://www.cdc.gov/cpr/polioviruscontainment/NIPC.htm>

The time needed to complete the online survey will vary depending on the complexity of a facility and the availability of needed information.

Paperwork Reduction Act

CDC has determined that the information collection activities conducted under this project are exempt from the requirements of the Paperwork Reduction Act (PRA) as they fall under the activities authorized under the National Childhood Vaccine Injury Act (NCVIA) at section 2102(a)(6)-(a)(7) of the Public Health Service Act (42 USC 300aa-2(a)(6)-(a)(7)).

Dated: October 2, 2019.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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