



March 29, 2024

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, Investigation of *Burkholderia multivorans* infections in acute care hospital settings following potential exposure to nonsterile ice and water from ice machines, United States, 2022-2024, hereinafter referred to as the *B. multivorans* Ice Machine Multistate Investigation, be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to the continued and uninterrupted operation of the *B. multivorans* Ice Machine Multistate Investigation. The *B. multivorans* Ice Machine Multistate Investigation is part of the public health response efforts of a federal public health agency, as specified in the Code of Federal Regulations [45 CFR 46.102(I)(2)], to stop the transmission of a bacterial pathogen and protect the public from further harm; in order to keep in compliance with the statute, this information collection request (ICR) needs to go forward as an Emergency to avoid a lapse in the public health response-related collection activities.

This request includes a new data collection instrument, hereinafter referred as a case report form. Approval is requested for 180 days from the date of approval.

By way of background, CDC has been assisting state and local jurisdictions investigate clusters of *B. multivorans* infections among patients admitted across four hospitals in two non-contiguous states. The outbreak strain of the bacteria has been identified in environmental samples from ice machines. Molecular analysis has shown that the bacterial strain identified in ice machines is genetically highly similar to the patient isolates. Further investigation revealed that the same brand of ice machine and the same filters, descaling/cleaning, and sanitizing products were used by the four hospitals. Epidemiologic and laboratory evidence suggest the possibility of contaminated nonsterile ice and water from the same brand of ice machines as a common source of exposure.

Further investigation is needed to identify the scope of the outbreak and the source of the ice machine contamination. CDC is issuing a national call for cases requesting that public health authorities report cases and clusters of *B. multivorans*. A case report form was developed by CDC to assist jurisdictions in this effort. Jurisdictions will gather information using this case report form to assist in determining epidemiologic characteristics and risk factors of patients with *B. multivorans* as well as potential



source(s) of *B. multivorans*, including ice machines and ice machine-related products (e.g., cleaning solutions). CDC will use this information to inform additional measures that could stop transmission and implement mitigation measures to prevent further spread. These public health response activities, which require the use of a new data collection instrument, are specified in 45 CFR 46.102(I)(2).

CDC cannot reasonably comply with the normal clearance given the fact that this outbreak response activity is addressing a potential public health emergency, normal clearance processing time will prevent the rapid response that is warranted during an outbreak investigation. Therefore, the ICR needs to be go forward as an emergency to prevent a lapse in collection activities.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business 4/05/2024.

Respectfully,

A handwritten signature in black ink, reading "Daniel B. Jernigan". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Daniel B. Jernigan, MD MPH
Director, National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention