

THE CURRENT STATUS OF NAMP EFFORTS TO ACQUIRE CLIA CERTIFICATION OF DOE LABORATORIES

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In 1988, the U.S. Congress passed the Clinical Laboratory Improvement Amendments (CLIA), establishing quality standards for laboratory testing to ensure uniform accuracy, reliability and timeliness of patient test results, regardless of where the tests were performed. Title 42 Code of Federal Regulations 493, Laboratory Requirements, was issued by the Center for Medicare and Medicaid Services and provides certification standards for laboratories engaged in testing specimens derived from humans for the assessment of human health, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Any laboratory participating in performance testing of either waived or nonwaived tests on samples derived from the human body to provide diagnosis or guidance on treatment must abide by CLIA requirements. These requirements are dependent on the complexity of the tests being conducted and the type of certification that is of interest.

The National Analytical Management Program (NAMP) was reestablished by the Department of Energy Office of Environmental Management with the intent of coordinating U.S. national laboratory services and capabilities. NAMP CLIA subcommittee efforts are directed toward CLIA certification of laboratories at Sandia National Laboratories, the Savannah River Site, the Y-12 Weapons Security Complex, the Oak Ridge Associated University, and the Waste Isolation Pilot Plant. Achievement of CLIA certification by these participating laboratories will enhance the nation's response capabilities in assisting the Centers for Disease Control and Prevention (CDC) in the event of a radiological incident, such as activation of a radiological dispersion device. CLIA certification will enable NAMP laboratories to assist CDC in bioassay analyses in a surge capacity.

The approach to CLIA certification includes the coordination of performance testing by all participating laboratories to meet compliance requirements, and the appointment of a qualified laboratory director to represent NAMP's four laboratories. This presentation describes NAMP's path forward to CLIA certification and the obstacles it has encountered along the way.