

**Non-Substantive Change Request
National Disease Surveillance Program – II. Disease Summaries, OMB 0920-0004
National Respiratory and Enteric Virus Surveillance System (NREVSS)
NREVSS Laboratory Assessment**

Expiration Date: 8/31/2014

Submission Date: 12/19/2013

Explanation of Form Changes or Adjustments:

The information collection, “National Disease Surveillance Program - II. Disease Summaries,” is an ongoing surveillance activity at the Centers for Disease Control and Prevention (CDC). The National Respiratory and Enteric Virus Surveillance System (NREVSS) is an ongoing laboratory-based system that monitors laboratory detections of respiratory and enteric viruses such as respiratory syncytial virus, influenza virus, human parainfluenza viruses, human metapneumovirus, and rotavirus. This surveillance system plays an important role in determining seasonal and geographic trends of the leading causes of respiratory viral infections in children. OMB 0920-0004 covers a range of data surveillance that spans approximately 36 different forms and 17 different pathogens/conditions. The NREVSS surveillance system includes 4 data collection forms NREVSS 55.83 A-D. This non-substantive change request refers specifically to NREVSS 55.83C. NREVSS 55.83 A, B and D remain current and in use.

The CDC surveillance program is based on the premise that diseases cannot be diagnosed, prevented or controlled until existing knowledge is expanded and new ideas developed and implemented. These data are essential on Local, State, and Federal levels for measuring trends in diseases, evaluating the effectiveness of current preventive strategies and determining the need for modifying current preventive measures.

OMB 0920-0004, Current Form NREVSS 55.83C (NREVSS EM Worksheet) has become obsolete and CDC requests a non-substantive change request to use the proposed form attached, NREVSS Laboratory Assessment FORM , in place of Form NREVSS 55.83C. Again, use of forms A, B, and D continue.

Proposed Changes:

Due to the constant evolution of technology, laboratory testing practices and data management practices have changed substantially over the past several years. The current Form NREVSS 55.83C was used by participating laboratories to report, on a weekly basis, the number of Electron Microscopy tests performed and the number of times that certain pathogens were detected. Included on the form is an open ended comment field associated with each weekly report that allows the laboratories to describe their testing practices and explain the results. However, CDC finds that, particularly for clinical purposes, few laboratories still utilize electron microscopy, thus rendering form 55.83C outdated.

An accurate understanding of current laboratory practices and diagnostics remains essential to maintaining the quality of data received through the NREVSS system and informs the interpretation of the data used for analysis. For instance, it helps answer questions such as: how representative are the reported results, how accurate are the tests being utilized, and do testing protocols change between the typical peak times of respiratory illness to the off-season. One important example of the way testing practices influence disease prevention is illustrated by the fact that prophylactic treatments to prevent severe illness and hospitalizations due to RSV infections are only medically recommended (and therefore reimbursed by insurance companies) for high risk infants of a certain age during the months that RSV circulates in a community. The CDC has historically used only antigen detection data to identify RSV season onset and offset for specific geographic regions. It has become apparent that many laboratories are switching from antigen tests to PCR methods to detect RSV, so the current approach to defining RSV season onset and offset will need to be evaluated and adjusted accordingly. Therefore, the new assessment proposes to better understand 1) current laboratory practices as well as 2) monitor the changes of these laboratory practices and diagnostics.

Similarities of the form include asking the number and type of tests done weekly and in which geographic locations. The proposed data collection, done by CDC personnel via telephone or sent via email, instead of through a computer system, will allow current participating laboratories to describe their current testing practices in a more thorough and systematic fashion. In addition, the CDC personnel will ask laboratory managers to describe standard laboratory protocols, general testing guidelines, data management, and reporting practices. CDC personnel estimate each response will require 15-20 minutes to complete and questions are designed for respondents to readily answer without the need to collect further information. NREVSS Laboratory Assessment FORM differs slightly from the current NREVSS 55.83C as it focuses on the way in which the data is collected versus the laboratory providing the actual test result data via a computer system.

Another differentiation includes the addition of more questions (both open and closed-ended), and the NREVSS Laboratory Assessment FORM will be used one time per year per laboratory and all responses will be made on a voluntary basis. The requested new form will collect information on an annual basis versus a weekly collection associated with the current form. In addition, information obtained will be used to better interpret the NREVSS surveillance data and as a tool for reviewing changes in testing trends and reporting practices and understanding the multiple factors which influence these changes. Furthermore, it will help to determine the logical way to collect the data, based upon the available results and the way the information is managed within the laboratories.

As mentioned, these data are essential on the Local, State, and Federal levels for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need for modifying current surveillance methods and preventive measures.

To better understand current practices and to monitor changes in practices, CDC requests the use of NREVSS Laboratory Assessment FORM to conduct an assessment of participating laboratories within the United States.