



Monday, October 26, 2015

Submitted via regulations.gov

**Re: Comments on the Notice, Docket no. FDA-2015-N-2372: FDA/CDC/NLM Promoting Semantic Interoperability of Laboratory Data Public Workshop**

On behalf of the Association of Public Health Laboratories (APHL), please accept the following comments from the National User Group (NUG) concerning the notice and request for comments, docket number FDA-2015-N-2372, on the Promoting Semantic Interoperability of Laboratory Data Public Workshop.

As a body that represents many State laboratories that report to numerous State and Federal agencies, the NUG has advocated the widespread adoption of vocabulary and messaging standards. We are in favor of promoting interoperability by enabling consistent reporting of diagnostic device results by using standard code response sets. Moreover, we strongly support the adoption of LOINC, SNOMED CT and UCUM by FDA, CDC, NLM and other agencies to facilitate data exchange with laboratories and other messaging partners.

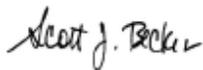
By necessity, all local entities configure their systems according to their requirements, and even laboratories that use the same version of an information management system will face challenges to interoperable communication. The industry-wide use of standards such as LOINC, SNOMED CT and UCUM is therefore an important step in the right direction. Consistent coding of laboratory testing and results is a critical element for the meaningful synthesis of multi-jurisdiction data in a national database like eLEXNET.

While food safety and other public health programs have been slow to adopt messaging and vocabulary standards, LOINC, SNOMED CT and UCUM are widely used in clinical settings and for public health reporting. It should be noted that food and feed testing laboratories and public health laboratories have multiple messaging partners and perform a variety of testing. Indeed, some laboratories report results to seven or more agencies, as well as to the original submitter. With different reporting protocols, acceptance criteria, required data elements, and message formats for each agency or program, these obligations translate into a substantial burden for the laboratory. With broader acceptance of these standards, laboratories would be able to leverage previous mapping work to format reports for multiple messaging partners. Moreover, an agency can use the value sets associated with specific diagnostic devices as the basis to map from the standard codes that it receives from the laboratory to whatever local codes they may use in their internal systems. Key to this gain in efficiency is the assumption that data exchange solutions with all messaging partners should allow labs to use the data that is already in their LIMS with no need for additional data entry or manipulation. As an additional measure, labs and

agencies may receive support for electronic messaging and the use of standards through the APHL Informatics Messaging Services or the Public Health Community Platform.

For regulatory and surveillance programs at the state and federal level, the benefits of standardized data exchange are clear. Arduous manual processes discourage routine reporting and lead to incomplete and often untimely data of suspect quality. The use of vocabulary standards enables computer-to-computer data exchange, reducing the level of effort for both parties to maintain the data flow and reconcile errors. The agency receives timely, accurate and more complete data.

Sincerely,



Scott J. Becker, MS  
Executive Director  
Association of Public Health Laboratories

### **The National User Group**

*The National User Group (NUG) was formed in 2013 under a cooperative agreement between the Food and Drug Administration (FDA), the Association of Public Health Laboratories (APHL), the Association of American Feed Control Officials (AAFCO) and the Association of Food and Drug Officials (AFDO). This multi-tiered initiative strives to enhance data exchange between FDA and state laboratories and ensure that high-quality, timely data are available to investigators during outbreaks and for long-term surveillance. Within this context, the NUG serves as a resource for FDA on issues of concern to food and feed-testing laboratories, specifically with regard to information management, vocabulary and messaging standards and data exchange. FDA has particularly sought the NUG's feedback on plans for updating the FDA Electronic Laboratory Network (eLEXNET), which is a secure network that allows health officials from multiple government agencies to access and analyze food testing results from State and Federal laboratories. The ultimate aim of this collaboration is to integrate food and feed testing laboratories and strengthen the partnership between FDA and State laboratories.*

### **APHL**

*APHL works to strengthen laboratory systems serving the public's health in the U.S. and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.*