

Guidance for Laboratories Testing for Radiologic Threats

*Additional Information for the Public Health Emergency Preparedness (PHEP)
Cooperative Agreement Grantees*

The Division of Laboratory Sciences (DLS) at CDC's National Center for Environmental Health has received inquiries from state public health laboratories about radiation laboratory capabilities and how to address them in their applications. At this time, CDC has no funds to directly support state public health laboratory response to radiologic terrorism. Moreover, CDC's radiation laboratory response plans, capacities, and capabilities are still under development.

For example, of the more than 20 priority radionuclides for which methods must be developed and validated, CDC currently has developed and validated analytical methods for only seven radionuclides. Further, DLS currently does not have the staff or other resources for technology transfer to state laboratories. State laboratories involved in measuring these radionuclides in clinical (human) samples would be considered surge capacity laboratories.

CDC has not yet established a Radiologic Laboratory Response Network (LRN-R) but expects to be able to develop this capacity if resources become available in the future. CDC plans for the structure of the LRN-R to be similar to that of the Chemical Laboratory Response Network (LRN-C) and will use the infrastructure of the LRN-C as much as possible to have a common access point for both chemical and radiologic laboratory issues. However, the number of laboratories in each level of the LRN-R would be different from that of the LRN-C.

Although the LRN-R has yet to be established, CDC can provide the following written information to guide state laboratories at this time:

- CDC's general plan for assessing population exposure to radionuclides (below).
- Information on properly collecting, packaging, shipping, and storing human samples as well as ensuring chain-of-custody of these samples. With some exceptions, this information is the same as that used for chemical terrorism response.
- Clinical Laboratory Improvement Amendments (CLIA)-certified methods for analyzing seven priority radionuclides.
- Information about the quantity and type of stock materials and supplies needed to analyze as many as 500 to 1,000 samples.

CDC's general plan for assessing the population's internal exposure to radionuclides for an effective response to an act of terrorism consists of three essential steps: 1) early and accurate detection and diagnosis, 2) early and correct treatment, and 3) early and effective actions to prevent additional exposure. The laboratory plays a major role in each of these steps.

- 1) **Early and accurate detection and diagnosis** – Clinical laboratory methods to measure radionuclides in urine are critical for the accurate identification of the radionuclide that has entered the individual's body.

- 2) **Early and correct treatment** - Accurate laboratory identification of the radionuclide is then the basis for correct treatment. When urine levels of radionuclides can be quantified, this information can prioritize treatment to most affected individuals.
- 3) **Early and effective actions to prevent additional exposure** - Laboratory data typically are very helpful in determining the source of exposure (e.g., radionuclides in ingestion pathways) and routes of exposure so that early and effective steps can be taken to prevent additional exposure.

To support these three essential steps effectively, laboratory methods must meet performance requirements adequate for their intended use. The main requirements are as follows:

- 1) Accuracy – the correct identification of the radionuclide and, if possible, the correct quantification of the amount of radionuclide present. Accuracy includes high specificity, or the ability to distinguish the radionuclide from interfering substances.
- 2) Sensitivity – the ability to measure small amounts of the radionuclide in clinical samples. Higher sensitivity is almost always desirable because it permits the measurement of clinically relevant low levels in smaller sample sizes.
- 3) Adequate sample analysis rate – a high throughput sample-analysis rate is commonly needed to handle clinical specimens from large numbers of affected or possibly affected individuals. The sampling rate for analyzing urine samples for radionuclides should be at least several hundred samples per day.
- 4) Precision, ruggedness, and the cost of the method are also important factors related to the method used.

DLS is currently developing CDC's Urine Radionuclide Screen (URS), which will include 12 to 15 analytic methods that will identify and quantify priority radionuclides in human samples. In the URS, many radionuclides are identified first by a screening method followed by a confirmatory method that also quantifies the amount of the radionuclide. The URS will have the following features:

- 1) Detection and quantification of gamma-emitting radionuclides.
 - A NaI gamma spectroscopy system for rapidly screening urine samples for gamma-emitting radionuclides.
 - A HPGe gamma spectroscopy system for identifying and quantifying gamma-emitting radionuclides.
- 2) Detection and quantification of alpha- and beta-emitting radionuclides.
 - A low-background Liquid Scintillation Counter (LSC) for screening radionuclides that are either alpha or beta emitters (Gross alpha/beta method).
 - A low-background Liquid Scintillation Counter (LSC) for quantifying some beta-emitting radionuclides.
 - An alpha spectrometry system for identifying and quantifying alpha-emitting radionuclides.
- 3) Detection of long half-life radionuclides (actinides) by inductively coupled plasma mass spectrometry (ICP-MS).

- A rapid screening method for screening long half-life radionuclides by HPLC-ICP-MS.
- A rapid quantification of some long half-life radionuclides by quadrupole ICP-MS.
- A rapid quantification of some long half-life radionuclides by high-resolution ICP-MS.

CDC can provide additional details of the URS for state laboratories that wish to have detailed information about CDC's URS for planning purposes. CDC also can provide the CLIA analytical method write-ups for radioanalytical methods that have been developed and validated at CDC.

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