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The Role of Clinical Laboratories During a Radiological Event

Statement of

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Good morning Mr. Chairman and Members of the Subcommittee.

My name is Dr. Robert Jones, and I am Acting Chief of the Inorganic Radiation and Analytical Toxicology Branch in the Division of Laboratory Sciences of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC).

Thank you for the opportunity to be here today to discuss the role of clinical laboratories, and in particular, the role of CDC's radiation laboratory, in protecting the health of the American people in response to an event involving radioactive materials.

I will first discuss the essential laboratory information that is needed to respond to these events, focusing on the assessment of internal contamination with radioactive materials. Then I will describe the current estimate of the national laboratory capability for such a response and potential methods to improve our ability across the nation to respond to an event. I also will address CDC's efforts to monitor and assess the potential exposure of U.S. citizens during an incident in the United Kingdom that resulted in the death of a former Russian KGB agent from polonium-210. I also will describe briefly CDC's capabilities and readiness to meet emergency response needs under the Nuclear/Radiological Annex of the National Response Plan; and finally, I will touch briefly on our laboratory's role in the just-completed TOPOFF 4 counterterrorism exercise.

Laboratory Public Health Response

Information Needed Following a Radiation Event**:** Following an event with uncontrolled radioactive material, such as a dirty bomb or terrorist nuclear attack, public health officials need to answer three questions to guide their response: what were people exposed to or contaminated with, who was exposed or contaminated, how much exposure or contamination did each person have, and did it enter the body? Contamination can be primarily internal (that is, inside the body), primarily external (outside the body), or a combination of both. Handheld radiation detectors, like Geiger counters, generally are used for assessing externally deposited contamination by certain radioactive materials and are useful for prioritizing people for external decontamination. These detectors can be used to assess internal contamination in some specific cases.

Internal contamination cannot be reliably quantified by clinical assessment of early symptoms. The decision to medically treat people will depend on our ability to rapidly and accurately identify and quantify internal contamination. To direct appropriate medical treatment to the truly affected, we need a method to rapidly and accurately assess internal contamination for a broad array of radionuclides. The new methods for measurement of radionuclides in urine are being developed to meet this need for internal contamination and dose assessment.

Current Laboratory Capabilities for Internal Contamination**:** In the event of a radiological incident, our ability to effectively respond to the health needs of our citizens will depend on the methods we have in place to measure radionuclides in urine. These methods must have four essential characteristics: first, they must be fast, with results available in a day or so; second, they must be able to process large numbers of samples per day to handle urine samples from the many people involved; third, they need to use a small amount of urine available from collecting a sample at one point in time; and fourth, they must be able to identify and quantify the various radionuclides likely to be used by terrorists.

Nationwide, the current laboratory capability for measuring radionuclides in people in response to an emergency is limited. Currently available methods for measuring radionuclides in urine, and our national capacity to do so, are limited. Right now, the methods are slow; it typically takes 5 to 30 days to obtain a urine radionuclide measurement. The number of samples that can be processed per day is low—the few labs that can measure urinary radionuclides typically process fewer than 20 samples per day. Urine volume requirements are high--about half a gallon of urine, usually comprising a patient's entire urine output for a 24-hour period. Finally, we currently have validated analytic methods to measure only a few of the radionuclides of concern.

CDC recognized this gap a few years ago and took steps to begin developing a state-of-the-art Urine Radionuclide Screen. To date, CDC has developed the

scientific approach for the Urine Radionuclide Screen using a combination of radiation-detection instruments that detect the three types of radiation, alpha, beta, and gamma, and a specialized technique in mass spectrometry. CDC currently has some limited capacity to measure five radionuclides in urine. Although our scientific approach is working well, considerable applied method development remains to be done.

A radiological event is one of many threats for which the Nation must prepare. At CDC, our all hazards approach to preparedness also includes preparation for chemical and biological events, as well as natural disasters. The challenges I have cited in our current lab capacity to respond to a radiological event must be balanced with the need to prepare for other public health emergencies.

Efforts to Improve Capabilities for Internal Dose Assessment: CDC efforts to improve lab capacity to respond to a radiological event include:

1) The development of a validated Urine Radionuclide Screen, which would provide results within 24 hours of receiving the sample. The CDC Urine Radionuclide Screen, which is currently under development, would require only a point-in-time, small-volume urine sample—no need for 24-hour collections—and the Screen would identify and quantify 13 different priority radionuclides.

2) When the Urine Radionuclide Screen is ready for distribution, the CDC will consider how to build on the existing Laboratory Response Network (LRN), a

national network of local, state and federal public health laboratories that provide the infrastructure and capacity to respond to public health emergencies, to establish surge capacity in public health laboratories for measuring people's exposure to a variety of radionuclides.

Lessons Learned from UK Polonium-210 Event

The recent incident in London involving the death of a former Russian KGB agent from exposure to polonium-210 underscores the importance of having laboratory capability that can provide human exposure information.

Shortly after the incident, CDC became the U.S. Public Health Point of Contact for the U.K. Health Protection Agency. The CDC radiation laboratory was asked to identify laboratories in the United States that could analyze polonium-210 in urine because it was thought that some U.S. citizens had been exposed to the radionuclide during the incident. We contacted more than 12 federal or commercial laboratories in the United States to determine which could do the analysis. We found that only one laboratory—a commercial laboratory—could analyze polonium-210 and had certification under the Clinical Laboratory Improvement Amendments (CLIA–certified). This laboratory needed 24-hour urine samples, and its usual time for sample analysis is 30 days. For this emergency, the laboratory completed the analyses in 7 days.

In an effort to identify U.S. citizens who may have been exposed to polonium-210, CDC began contacting these citizens directly by telephone, e-mail, or letter.

In a few cases, CDC contacted the state or local health department and provided lists of citizens within their jurisdiction to contact. CDC provided state and local health departments with telephone interview scripts for this process. If the individuals or their physicians who were contacted wished to have urine testing performed, CDC referred them to a private laboratory capable of performing this analysis.

Thirty-one individuals who were tested requested that their laboratory urine results be interpreted by CDC. CDC's Health Physics staff calculated individual dose assessments based on internationally recognized and accepted methods similar to dose assessments that were used by the UK Health Protection Agency and communicated these results to the individuals or their physicians.

Communication played a key role in CDC's efforts to monitor U.S. citizens potentially exposed to polonium-210. CDC provided citizens, their private physicians, and the state and local health department with communication and educational materials about the incident and laboratory testing. Direct communication via telephone and mail were the primary channels for communicating with the citizens and physicians involved; however, CDC also used its public Web site and secure network notification systems to communicate information and updates.

During the response, contact with citizens initially was delayed in large part by a lack of complete contact information for U.S. citizens. At the outset, CDC had to rely on contact information provided by the UK Health Protection Agency, which obtained telephone and address information obtained from hotel registers or credit card receipts in places of interest. Therefore, neither CDC nor the UK Health Protection Agency can be certain that all potentially exposed people were contacted or whether other people who may have been exposed (e.g., those paying bills in cash) will ever be identified.

Communications with state and local health agencies were hampered because of limited awareness or understanding about the state and local health department responsibilities in an event involving radioactive materials. In some cases, state and local health departments did not know their Radiation Control Program contact even when this contact resided in their own organizational structure. CDC did provide this information to the requesting health departments but cannot be certain that other health departments made the correct connections to their local Radiation Control Program.

Finally, the private laboratory conducting the testing did not provide results of analyses directly to CDC, citing privacy issues. In all cases, the private laboratory would not provide results directly to CDC without the express permission of their clients. Therefore, CDC cannot be sure that it has received the results of all of the analyses conducted for U.S. citizens.

The Nation has a limited laboratory capability necessary to identify people who were exposed occurring during an event involving radioactive materials. This leads to a limited capability to provide patients, their doctors, and health departments with exposure information.

The Nuclear/Radiological Annex of the National Response Plan tasks the Department of Health and Human Services with coordinating Federal assistance for performing population-monitoring activities. Population monitoring is a process that begins soon after a radiation incident is reported and continues until all potentially affected people have been monitored and evaluated for the following:

- Needed medical treatment
- The presence of radioactive contamination on the body or clothing
- The intake of radioactive materials into the body
- The removal of external or internal contamination (decontamination)
- The radiation dose received and the resulting health risk from the internal and external exposure
- Long-term health effects

Assessment of the first five items listed above, and the whole body external dose, should be accomplished as soon as possible following an incident. Long-

term health effects are usually determined through a population registry and an epidemiologic investigation that will likely span several decades.

Under the Nuclear/Radiological Annex of the National Response Plan, population monitoring is the responsibility of state, local, and tribal authorities, assisted and supported by HHS. However, it is likely that in a mass casualty event involving radioactive materials state, local, and tribal authorities will very quickly request assistance from the Federal government.

In the United States, 31 states have operating nuclear power plants. These states already have local plans for responding to an incident at the nuclear power plant in their own state or at one in a neighboring state. These plans include requirements related to population monitoring. However, effective response to a radiological or nuclear terrorism incident requires a broader scope of planning and most likely a different mode of response than those described in these current plans.

Plans need to account for several factors: first, the suddenness of an incident (as opposed to a nuclear power plant failure that would likely unfold over a 24- to 72-hour period); second, the likelihood that the incident would be large in scale, involving a much larger urban population; and third, the unknown aspect of the radionuclide(s) involved. However, the plans and expertise already developed

can be assets in preparing for a radiological or nuclear terrorism incident with mass casualties in these states.

CDC, working with technical staff from a number of other Federal agencies, has developed a planning guide on population monitoring in radiation emergencies for public health officials and emergency preparedness planners at the state, local, and tribal levels. CDC is also developing materials to assist these officials in training personnel to initiate the population- monitoring process before any Federal assets can arrive to assist. However, although most state, local, and tribal authorities have some limited ability to perform external population monitoring and decontamination, their ability to perform internal monitoring and decontamination is much more limited.

For the lab results to be used effectively in managing a radiation event, personnel who are radiation experts in converting radionuclide analyses into dose and risk are required. They can then communicate health risk information to health care providers and decision makers. In every level of Government, the Nation has a limited supply of the radiation health experts who provide these interpretations. CDC plans to leverage the expertise of the radiation protection experts within the Department of Energy and other federal partners. During a national emergency, these experts could be used to help CDC with the surge in needs.

TOPOFF Update

The recent TOPOFF 4 exercise represented the first mass-casualty exercise that included population monitoring as a significant exercise objective. In preparation for TOPOFF 4, I oversaw plans that would exercise CDC's clinical laboratory capabilities. These included sample acquisition, packaging and shipping, sample logistics, analysis, risk assessment, and reporting of final results to state officials. Before the exercise, CDC collaborated with the state public health laboratory in Oregon to pre-position 100 urine samples in Portland.

As the Nation's premier terrorism preparedness exercise, TOPOFF 4 highlighted the essential functions and challenges involved in responding to a national incident involving radioactive materials. It is clear that we have challenges in our laboratory capacity to respond to a radiological event. We are working to complete the Urine Radionuclide Screen and consider plans to transfer the Urine Radionuclide Screen to public health laboratories in the future, At the same time we are supporting improvements in preparedness for biological and chemical events as well, at both the federal and state levels. We continue to strive to maintain a balanced effort across all high priority threats and improve overall public health preparedness.

Closing Remarks

CDC is addressing existing gaps by systematically identifying priorities and working to alleviate these concerns. We have developed a series of goals to

guide capacity improvements in preparedness and other areas. CDC wants to make sure the investments the American People make in public health are having impact.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or Members of the Subcommittee may have.