STATEMENT FOR THE RECORD

of

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Regarding a Hearing Entitled

"Radiological Response: Assessing Environmental and Clinical Laboratory Capabilities"

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INTRODUCTION

Good morning, Chairman Miller and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the Nation's critical need for improved radiological laboratory capabilities and capacities to respond to an accidental or intentional release of radiological material. Insofar as the panel assembled here has the technical depth and responsibility for addressing the functional needs, I will restrict my comments to the Integrated Consortium of Laboratory Networks and the role it plays in highlighting and supporting laboratory analytical requirement across the all-hazards landscape.

THE ROLE OF LABORATORIES IN RESPONSE TO A RADIOLOGICAL INCIDENT

Assessment of contamination due to any hazard in the chemical, biological, or radiological realm requires the services of highly technical laboratory services. These services support both the determination of exposures to population, to determine who has been exposed to how much of the hazard, and the determination of the environment or physical space that remains a hazard until remediation and restoration has occurred. In both cases, decisions affecting application of medical countermeasures and evacuation from potentially contaminated spaces are effectively determined through risk assessments that rely upon quality information from laboratory systems. Expeditious decisions that may affect large numbers of people and key assets of commerce or government critically depend on a system of quality laboratory service that is sufficiently robust to provide the data needs for such decisions.

The need to develop such a system of quality laboratory service across all hazards provided the impetus for the establishment of the Integrated Consortium of Laboratory Networks.

INTEGRATED CONSORTIUM OF LABORATORY NETWORKS (ICLN)

In response to the threat posed by terrorist use of WMD threat agents, a number of laboratory networks have been established over the past several years to provide the Nation the capability to characterize, contain, and recover from such attacks on our people and our essential commodities. During the fall of 2004, the Homeland Security Council and multiple Agency stakeholders worked together to develop an organizational framework that links existing and future laboratory networks under a single interagency umbrella. The goal of the effort is to create the basis for a system of laboratory networks capable of integrated and coordinated response and consequence management of acts of terrorism and other major incidents requiring laboratory response. Establishing a laboratory network system to strengthen early detection and consequence management is consistent with Homeland Security Presidential Directives 9 and 10.

The Memorandum of Agreement establishing the Integrated Consortium of Laboratory Networks (ICLN) was signed in June of 2005. Senior officials of agencies with primary responsibility for current and emerging networks as well as those with a strong supporting role joined together to endorse the laboratory organizational framework. Signatory agencies to this agreement include the Department of Agriculture (Food Safety Inspection Service [FSIS], Cooperative State Research, Education, and Extension Service [CSREES], and Animal and Plant Health Inspection Service [APHIS]), Department of Commerce, Department of Energy, Department of Health and Human Services (Food and Drug Administration [FDA], and Centers for Disease Control and Prevention [CDC]), Department of Defense, Department of Homeland Security, Department of Interior, Department of Justice (Federal Bureau Investigation), Department of State, and the Environmental Protection Agency.

As outlined by the MOA, the primary functions and motivations of the ICLN include:

- Agreement by signatories to work cooperatively to optimize national laboratory preparedness by improving coordination of laboratory response to incidents;
- Recognizing Responsible Federal Agencies' role in assuring capability of networks;
- Promoting common standards of performance across all lab response assets to ensure data supporting homeland security decisions is best quality and defensible;
- Assessing and filling gaps in coverage across multiple sample types, potential victim groups (human, animal, plant), all WMD weapons, and all response phases;
- Rationalizing and enhancing relevant interagency budgets.

Established networks included in the ICLN are the Laboratory Response Network (LRN), Food Emergency Response Network (FERN), National Animal Health Laboratory Network (NAHLN), and National Plant Diagnostic Network (NPDN). A network under development in the consortium is EPA's Environmental Laboratory Response Network (eLRN).

The managers of the networks mentioned above, along with designated representatives of other signatory agencies, comprise the Network Coordinating Group (NCG) of the ICLN, which meets on a monthly basis. A senior-level oversight group, the Joint Leadership Council, oversees their work. DHS serves to coordinate activities through chairmanship of the JLC and the NCG.

To support the efforts of the primary representatives of the NCG, the NCG established a number of technical sub-groups, addressing issues of Scenarios and Threat Prioritization, Methods Development, Quality Assurance, Training, and Information Technology and Communications. In addition, three technical working groups address specific areas of concern. These include the Environmental Anthrax Sampling Validation Working Group,

the Environmental Chemical Laboratory Response Working Group, and the Radiological Laboratory Response Working Group.

In its short history, the ICLN has accomplished two major objectives relevant to the subject of this hearing: the assignment of Responsible Federal Agencies across the CBR response spectrum, and a first assessment of the Nation's laboratory capability across this same spectrum.

Assignment of Responsible Federal Agencies

In order to ensure a basis for organization and maintenance of the Nation's laboratory response infrastructure against chemical, biological, and radiological, the ICLN first considered the types of samples which might require analysis and the phase of response during which such analysis would be required. The principal analytical matrices that would be encountered include human clinical, environmental, food, drinking water, animal, and plant samples. Phases of response common to each hazard area include monitoring and surveillance, incident response, remediation, and forensics. The assignment of Responsible Federal Agencies gave consideration to existing Department obligations and authorities, a history of already working toward or having established capability, and applicable Executive Branch directives or logical extensions thereof.

These assignments are not ratified among the signatory agencies by a separate formal Memorandum of Agreement, but rather serve as a basis for development and sustainment of an effective all-hazards laboratory response capability. Accordingly, if prevailing guidance or organizational environment shifts, the assignments could, in principle, change. Separate MOAs do need to be developed to outline the shift in operational responsibility from one agency to another during response to a crisis to enhance overall orderly process. Finally, the level of attention given to a specific analytical area is expected to be guided by consideration of risk relative to other requirements.

It will be noted that, in the areas of response and remediation to radiological contamination, EPA, DOE, and HHS are the major players. When the ICLN NCG considered in 2006 the establishment of a radiological working group to consider laboratory needs and gaps, it charged EPA and HHS with co-chairmanship.

ICLN Capability Assessment Key Findings

The assessment and addressing of gaps in the Nation's laboratory response infrastructure is a key charge to the ICLN under its MOA. The ICLN addressed this charge through a study initiated in early 2006 and finalized as an FOUO report in April 2007. The study considered nine scenarios, generally inspired by the National Planning Scenarios, which explored chemical, biological, and radiological hazards across a variety of targets (i.e., humans, animals, and plants). The Homeland Security Institute mediated the study and

assimilated the report, relying heavily on modeling support and sample throughput data from technicians within the National laboratory response system.

The study is considered a first-order analysis of capabilities, capacities, protocols, and policies of the ICLN laboratory networks in response to the selected homeland security scenarios. It is functionally a self-assessment of the "as-is" operational context of the member networks and provides an "order of magnitude" estimate of gaps that may exist between analytical requirements and existing capability.

In order to assure parity across the range of scenarios and networks examined, certain bounding conditions were set: Funding, reagents, and consumable materials were not considered to be limiting factors. Normal rates of laboratory staffing were assumed. Industry and private laboratories outside Federal oversight were excluded, but laboratories within other Federal agencies were included as analytical assets to the extent they could be accessed. In addition to projected actual sick or injured, "worried well" were included. No assumptions related to policies that might mitigate analytical requirements were made, but prevailing policy was certainly considered. All qualified laboratories within established networks were considered to be accessible analytical resources, regardless of state and local boundaries. An additional exceedingly important reminder is that the assessment is based on agent-specific scenarios. Changes in agent or other key scenario parameters could substantially alter conclusions found in the report.

Specifically for the scenario involving radiological agent dispersal, the study results demonstrate "major shortfalls" in environmental and clinical laboratory capability in the response to and remediation of such an event.

For the specific agent used in the RDD scenario, various sources of data were used to identify laboratories with adequate characteristics to contribute materially to the environmental sampling needs that would support on-the-ground hazard mapping and decontamination. Against the scenario estimate of a large number of environmental samples required during the remediation process, a backlog of samples awaiting analysis would extend some 50 to 100 weeks beyond the event and substantially affect decisions regarding the remediation activity. Similarly, the scenario estimate of clinical samples requiring analysis significantly exceeds the modeled capability for such samples.

The study did not take into consideration the positive benefits of streamlined sampling and analysis, for example, the pooling of samples from multiple sites or individuals that may decrease the overall analytical burden. As such methods are developed and validated, an improvement in our analytical posture may be expected. However, without the benefit of an organized framework and adequate quantitative analytical capability, it seems clear that decisions based on the analysis of both clinical and environmental samples for a substantial RDD event would be compromised.

The testimonies of CDC and EPA will address the clinical and environmental analytical gaps and their implications on response and recovery.

STEPS TAKEN TO BUILD AN EFFECTIVE RADIOLOGICAL ANALYTICAL CAPABILITY

As noted earlier, the ICLN established a Radiological Lab Response Working Group in 2006 to begin to consider the radiological testing gap and what needs to be accomplished to close this gap. EPA and CDC were charged with co-chairing the group, which includes participation also from DOE, DHS, FDA, USDA, National Institute for Standards and Technology, US Geological Survey, and Association of Public Health Laboratories.

An effective radiological lab response network would address capability gaps by establishing acceptance criteria for membership; identifying and enhancing select Federal and state laboratories that have attributes closest to those required to meet acceptance criteria; providing those laboratories with the appropriate tools, resources, and analytical methods; establishing and exercising proficiency testing to ensure readiness and quality; and establishing data management and communication protocols.

The NCG advised the group that, given prevailing funding priorities, a measured approach designed to explore the relationship between analytical power and cost would be the most logical means to establish initial capability while describing the total cost associated with establishing a capability that might be considered "adequate" to meet the needs of an incident of substantial scope.

The initial vision of the Radiological Lab Response Working Group incorporates three "sub-networks," each covering environmental, clinical, and food samples, under the sponsorship of EPA, CDC, and FDA, respectively. Pilot programs have been formulated or proposed within each agency to serve as the genesis of a national radiological capability.

The effort has just begun, with the bulk of the work required to establish an effective radiological analytical capability still ahead.

TOP OFFICIALS 4 EXERCISE

This hearing occurs shortly after the end of the TOPOFF4 exercise. Our information indicates varying levels of play by analytical resources of several government agencies (e.g., DOE, EPA, FBI) in the exercise. The exercise will explore, in various venues, gaps and deficiencies related to short-term medical monitoring, long-term health issues, effects on consumables such as food and water, decontamination, and waste disposal. Laboratory analytical information is a key component to addressing these issues. The actual exercise and associated tabletop exercises, to include the Long-Term Recovery Tabletop Exercise scheduled for early December, offer valuable fora for the consideration of gaps related to radiological laboratory infrastructure.

CONCLUSION

The ICLN exists to design, develop, and promote the use of best practices across the Nation's laboratory response infrastructure to inform critical decisions in the response and recovery from incidents involving chemical, biological, and radiological hazards. We have assessed a significant gap in our radiological laboratory response capability which may compromise important decisions regarding health and environment in key scenarios. We will continue to promote the need to fill this gap among the agencies identified as Responsible Federal Agencies and their partners, and appreciate very much the interest of this Subcommittee in radiological laboratory matters.

SUPPLEMENTAL SHEET – FOLLOW-UP ADDRESS:

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