Radiological Response:
Assessing Environmental and Clinical Laboratory Capabilities

Staff Report to Chairman Bart Gordon and
Subcommittee Chairman Brad Miller
By the Staff of the
Subcommittee on Investigations and Oversight
House Science and Technology Committee

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Summary

To prepare the nation for potential catastrophic events, including terrorist attacks, the White House's Homeland Security Council has developed fifteen planning scenarios for use by Federal, State, and local homeland security officials in order to help them prepare for, respond to and effectively recover from these potential incidents.[1] National Planning Scenario #11, developed under this inter-agency process, envisions the detonation of a Radiological Dispersal Device (RDD) or "dirty bomb" in a major downtown urban area. That scenario was just played out in a national counterterrorism exercise called TOPOFF, mandated by Congress and conducted every two years.

This year, TOPOFF IV (T4) took place from October 14-24, 2007. In the exercise, involving thousands of federal, state and local officials and sponsored by the Department of Homeland Security (DHS), terrorists detonated an RDD in Guam, Portland, Oregon and Phoenix, Arizona. The exercise tested the handling and flow of operational and time-critical intelligence between agencies and the existing procedures and policies for domestic incident management of a major radiological event.

One of the key assumptions in National Planning Scenario #11 is that all potentially exposed individuals (an estimated 100,000 people, including 20,000 victims with detectible contamination) will be tested for radiological exposure and/or contamination and that a valid method exists for testing these clinical specimens. Yet, today validated methods to test clinical specimens in a radiological emergency exist for only six of the 13 highest priority radioisotopes most likely to be used in a terrorist scenario. For those isotopes for which "validated" methods do exist screening 100,000 individual clinical specimens in the wake of a radiological attack could take more than *four years* to complete due to the current shortfall in radiochemistry laboratories, personnel and equipment. Environmental sampling could take as long as *six years* to complete given the current capacity and capabilities of the U.S. radiochemistry laboratory infrastructure.

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[1] See National Planning Scenarios, Version 20.1 DRAFT, Created for Use in National, Federal, State, and Local Homeland Security Preparedness Activities accessed here: http://media.washingtonpost.com/wp-srv/nation/nationalsecurity/earlywarning/NationalPlanningScenariosApril2005.pdf

The analytical requirements for responding to a potential radiological emergency are in stark contrast to the nation's existing capabilities. This drastic shortfall in current radiochemistry laboratory capacity, capability and competency is magnified by bureaucratic inertia in addressing this critical issue and the lack of clear lines of authority and responsibility for responding to a radiological event. A 2005 Department of Homeland Security report on radiological response needs highlighted the potential public health implications of these weaknesses. "Individual dose assessment is essential for predicting the clinical severity, treatment, and survivability of exposed individuals and identifying those with minimal or no exposure," it said.[2] But, despite the best efforts of many of the radiological experts in the trenches at agencies throughout the federal government the overall government effort to close these gaps have been slow, meek and cumbersome.

Purpose

Although not a focus of the TOPOFF IV exercise, in any real world event the critical lack of a sufficient laboratory capacity will delay appropriate public health care actions and plans, increase public panic, degrade public trust in government officials and increase the economic losses due to delays in assessment and cleanup.[3] The subcommittee hearing on radiological response will review what steps are underway to address this critical need, what technologies or resources would help tackle this capacity gap and what federal agencies responsible for addressing this need have learned from actual radiological emergencies, such as the recent Polonium-210 poisoning in London that killed former Russian KGB agent Vladimir Litvinenko last November and the 1987 (accidental) radiological release in Goiania, Brazil, that killed four people and injured hundreds. It will also examine why this crucial public health ability has received limited attention and what more needs to be done to improve the U.S. radiochemistry laboratory infrastructure.

Background

A Radiological Dispersal Device (RDD) releases radioactive material through the use of a conventional explosive, but does not result in a nuclear explosion. Although an RDD does not result in a mushroom cloud or the massive destruction of buildings it can release considerable amounts of radioactive material contaminating large downtown urban areas, for instance, resulting in major economic consequences for the city, state and nation. Most experts agree that a radiological attack of this kind is not likely to cause massive casualties or physical destruction. Few people are likely to die as a result. Yet, tens of

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2 "Radiological and Nuclear Countermeasures Program: Technology Assessment and Roadmap for the Emergency Radiation Dose Assessment Program (ERDAP)," Department of Homeland Security, Science and Technology, June 2005, p.10.
http://www.dhs.gov/xlibrary/assets/S_T_TechAssess_ERDAP_June05.pdf

3 "Creation of a National Radioanalytical Laboratory Response Network," developed by the Integrated Consortium of Laboratory Networks' (ICLN) Network Coordinating Group (NCG) Radiological Laboratory Workgroup, Presented by John Griggs, EPA and Robert Jones, CDC, August 16, 2006, p. 7.

thousands of individuals may be exposed to small traces of radioactive materials, more than half of them may suffer from internal contamination requiring medical treatment and all of those exposed may be at higher risk of developing cancers and may need to undergo periodic medical monitoring for the rest of their lives.

While the human health consequences from an RDD attack are likely to be small, the public outcry for detailed clinical health assessments confirming their *lack* of radiological contamination is likely to be tremendous. The need to provide these individuals – expected to number in the tens of thousands – with a clean bill of health will help to reassure them psychologically and emotionally that they have not suffered harm and will enhance their trust in the government's ability to effectively recover from the incident.

In the event of a major radiological emergency, stationary, mobile and hand held radiation detectors will help to identify the specific radioisotopes present and the amount of material released. Sophisticated computer "plume models" can help ascertain the most likely path of the radiation and possible "hot zones" that should be avoided by the public. Handheld Geiger counters can begin to help sort those that have been "exposed" to radiation from those that have not. Yet the only current method for determining internal contamination is through laborious laboratory analysis, often involving a 24-hour urine collection, days to process the results and still more time to interpret them accurately. This will be necessary for the thousands of "exposed" individuals to determine whether they suffer from internal contamination and to identify appropriate medical treatment. Clinical analysis may also be demanded by those medically unaffected, but fearful of contamination nonetheless.

The ability to conduct this analysis currently exists. But the time consuming nature of the process to analyze samples and the limited number of laboratories available to conduct this analysis will drastically hinder any response to a large scale radiological emergency today. There are several research and development efforts that are attempting to create "high-throughput" environmental and clinical radiochemistry devices that would be capable of quickly and efficiently processing thousands of samples per day. The CDC has been developing a Urine Radionuclide Screen that would permit them to take a "spot" sample of urine, as opposed to a normal and tedious 24-hour urine collection, run the analysis in hours not days and process up to two thousand samples per day screening for 13 of the highest priority radioisotopes simultaneously. But this effort and almost all others are years away from being fully developed, vetted and fielded.

Still, National Preparedness Guidelines released last month by the Department of Homeland Security call for the nation's public health laboratory infrastructure to be able to rapidly detect and accurately identify chemical, radiological and biological agents and "produce timely and accurate data to support ongoing public health investigations and the implementation of appropriate preventative or curative countermeasures."[4] In the event of a radiological attack, timely, reliable and quantifiable clinical health data regarding the

[4] "National Preparedness Guidelines," Department of Homeland Security, September 2007, p. 7. http://www.dhs.gov/xlibrary/assets/National_Preparedness_Guidelines.pdf

degree of individual contamination will be critical for determining appropriate medical interventions and response, as well as for identifying the "worried well" of individuals who have not been exposed and do not require medical attention. Public policy decisions regarding evacuation, resettlement and/or destruction of buildings and cleanup recommendations will also be predicated upon the results of environmental samples from the scene. Yet, today the ability of the U.S. to meet these challenges is negligible.

The potential adverse human health effects from radiation exposure are dependent upon the length of time a person is exposed and the amount of radiation absorbed by the body. There are also tremendous variables in responding to radiological or nuclear scenarios, depending on the radioisotopes used, the amount of radioactivity dispersed, and where and how the release occurs. An Improvised Nuclear Device (IND), essentially a "home-made" nuclear weapon, for instance, would be magnitudes more devastating than the detonation of a RDD and the laboratory analysis needed would be amplified significantly. But, in virtually all potential major radiological emergency scenarios the nation's current capacity to respond effectively is extraordinarily limited. Under the National Response Plan the Environmental Protection Agency (EPA) has a lead role for collecting and assessing environmental samples, decontaminating buildings, neighborhoods and other areas impacted by a radiological event and determining when it is safe to return to the area.[5] The Centers for Disease Control and Prevention (CDC) is tasked with monitoring, assessing and coordinating follow up medical monitoring on people's health as a result of exposure to or contamination with radiological materials in a national emergency.

Yet, at present neither agency has the capability to carry out these formidable tasks. The CDC, for instance, currently has *no capacity* to analyze seven of thirteen of the most likely radioisotopes that would be present in a radiological or nuclear incident, according to information provided to the Subcommittee. For some of the most likely "dirty bomb" or RDD scenarios the CDC is currently capable of processing only 65 human samples per day. At that rate it would take more than *four years* to process 100,000 clinical samples as called for in National Planning Scenario #11. A recent report prepared for the Department of Homeland Security's Science & Technology Directorate found that responding to that scenario "dramatically demonstrates major shortfalls in environmental and clinical laboratory radiological/nuclear capacity in the response to and mitigation of such an event."[6]

A primary reason for these shortfalls is the dwindling radiochemistry laboratory infrastructure that has occurred over the past decade due to the drawdown in production of nuclear weapons and the completion of many of the environmental cleanup projects throughout the nuclear weapons complex. As a result, the need for radiation health physicists and the capacity and need to monitor workers for radiation exposure has been greatly reduced. "In addition to capacity

[5] National Response Plan, includes the Nuclear/Radiological Incident Annex, December 2004, p. NUC-28. http://www.dhs.gov/xlibrary/assets/NRP_FullText.pdf

[6] "Integrated Consortium of Laboratory Networks (ICLN) Capability Assessment," Final Report, 30 April 2007, Prepared for Dr. S. Randolph Long of the Department of Homeland Security's Science and Technology Directorate by the Homeland Security Institute, p. 11.

gap," noted an August 2006 joint CDC/EPA presentation, "competency gap at many environmental radioanalytical laboratories due to loss of expertise, lack of training programs, inadequate funding for many state laboratories elimination of federal environmental proficiency testing (PT) programs, etc. will further hinder response efforts."[7]

Polonium-210 Poisoning

The lack of domestic radiochemistry laboratory capabilities was driven home last November when former Russian KGB agent Vladimir Litvinenko was poisoned with the radioisotope Polonium-210 (Po-210) in London. The CDC identified 160 U.S. citizens who were potentially exposed to the isotope while staying at the same hotel(s) or eating in the same restaurant(s) as Litvinenko. In its search to find a lab that could determine if these individuals had been exposed, the CDC found a *single* U.S.-based laboratory capable and qualified to conduct a clinical analysis for potential exposure to Po-210.[8] To run the clinical analysis a 24-hour urine specimen must first be collected. The results of the analysis are then normally processed within 30-days, but the commercial laboratory expedited the testing and the results were available in 7-days. Only 31 of the 160 people contacted by the CDC choose to participate in the test and none of them showed exposures to Po-210 that was deemed a health risk, although two individuals showed slight elevations of the isotope in their urine.

Although Polonium-210 is a unique isotope and is unlikely to be used or effective in a Radiological Dispersal Device, the incident highlighted the extraordinarily weak U.S. radiochemistry infrastructure. It also emphasized some problems regarding inter-agency emergency response issues. Although the Department of Energy (DOE) has the ability to conduct analysis of Po-210 and has done so on DOE workers, it is not CLIA (Clinical Laboratory Improvement Amendments) certified. Congress passed CLIA in 1988 establishing quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. But this does not apply to DOE, since the testing they conduct is for "occupational" exposure. As a result, CDC officials were reluctant to rely on DOE's clinical analysis of the Po-210 specimens and turned down the agency's offer to conduct the analysis, instead turning to a private lab. It is unclear how these issues would be resolved in a national radiological emergency even though the Nuclear/Radiological Incident Annex identifies DOE's role responding to a radiological event as providing consultation and support to other Federal agencies in the areas of radiological assessments, population monitoring and medical expertise and advice.

The response to the Polonium incident may be emblematic of other interagency issues. A recent interagency (draft) report on responding to a radiological attack found that the specific roles and responsibilities of federal agencies tasked with responding to a

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[7] "Creation of a National Radioanalytical Laboratory Response Network," developed by the Integrated Consortium of Laboratory Networks' (ICLN) Network Coordinating Group (NCG) Radiological Laboratory Workgroup, Presented by John Griggs, EPA and Robert Jones, CDC, August 16, 2006, p. 7.

[8] GEL Laboratories, LLC based in Charleston, South Carolina. http://gel.com/services/env_lab/polonium210.html

radiological event have not been clearly defined in the National Nuclear/Radiological Incident Annex, upon which these agencies rely.[9] "This is a weakness of the Rad Annex as agencies are not given a specific scope or mandated to allocate specific resources and funding to fulfill a need during preparedness or response to a radiological incident," the report noted. In addition, the report found that both standards for radiological emergency response and "specific guidelines for performing both external and internal monitoring and decontamination of potentially exposed members of the general public have not yet been developed," the report says. "Following a radiological disaster it is of extreme importance to screen the public in as timely a fashion as possible. However, current federal assets are ill-equipped to undertake such an endeavor," the report concluded.

The U.S. ability to evaluate potential radiological contamination on the environmental side also lacks the resources to effectively respond to a radiological emergency. White House National Planning Scenario #11 demands that the EPA be capable of analyzing more than 350,000 environmental samples in the 12 month period following a radiological attack. Depending on the radioisotope used in the attack, however, it would take *two to six years* to complete that task given the current available laboratory facilities today, according to a March 2007 draft EPA report.[10] "Currently, there is insufficient capacity for radiochemical laboratories in the United States to process samples generated as a result of an RDD event," the report concluded. "There is some certainty that the numbers of samples calculated in this report are really *underestimates* of the total numbers that would be generated." In addition, the numbers prepared in the report looked at a single radiological event. However, the scenario exercised in TOPOFF IV predicts three nearly simultaneous radiological attacks in three separate cities. According to National Planning Scenario #11, that scenario could demand an analysis of more than one million environmental samples in the first year and more than 300,000 human clinical samples in the first few days of an actual radiological emergency.

TOPOFF IV

During TOPOFF IV the CDC dispatched one of its aircraft to retrieve 100 urine samples from Portland, Oregon and brought them back to the CDC radionuclide lab in Atlanta. The samples were then "spiked" with actual radioisotopes in order to test the lab's ability to properly and swiftly analyze the samples. This is the type of testing that is critical to assess and evaluate the U.S. radiochemistry laboratory infrastructure to identify gaps and needs. But the exercise also confirmed that the current capacity of these labs would be incapable of responding to the actual onslaught of samples they would be requested to process. In the TOPOFF exercise the state of Oregon wanted to send the CDC 65,000 clinical samples.

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[9] "Mission Analysis – Volume One – Revision 1; Emergency (Early) Phase," Federal Radiological Monitoring and Assessment Center, An Interagency Document for Implementing the National Response Plan Nuclear/Radiological Incident Annex, June 2007 – DRAFT, p. A-1.

[10] "Assessment of National Environmental Radiological Laboratory Capacity Gap," DRAFT report prepared for Dr. John Griggs, U.S. Environmental Protection Agency, Office of Air and Radiation, National Air and Radiation Environmental Laboratory, Montgomery, Alabama, March 2007. Prepared by Environmental Management Support, Inc., 8601 Georgia Ave., Suite 500, Silver Spring, MD 20910.

Goiania, Brazil

The response capability demanded in a radiological attack in the U.S. is based on large part on the response to a major accidental radiological release of cesium-137 in Goiania, Brazil.[11] In 1987 two individuals found and removed a shielded radioactive "source assembly" from a teletherapy unit containing cesium-137 from an abandoned health clinic in Goiania. The scavengers took the assembly home and attempted to dismantle it rupturing the source which resulted in radiological contamination. They then sold the assembly for scrap to a junkyard. Fascinated by the blue glow of the material several individuals took small fragments of the assembly, the size of a grain of rice, home spreading the radioactive contamination even further.

Eventually, four people died within four weeks of exposure, including a 6-year-old girl who had rubbed the shiny blue material on her body. In the end, 28 people suffered radiation burns, 20 people were hospitalized, 129 people had internal contamination and were referred for medical care, 249 people suffered external contamination and 112,000 individuals were monitored for radiation exposure. Contamination was tracked over an area equivalent to 40 city blocks. A total of 85 houses were found to have significant contamination, some were demolished and contamination was removed from 45 different public places, including pavements, squares, shops, bars and about 50 vehicles. The Goiania incident resulted in the highest levels of cesium-137 clinical contamination ever recorded. The consequences of an intentional radiological attack in a large downturn urban arena in the U.S. are likely to be far worse.

In a positive step, the TOPOFF exercise will include a Long-Term Recovery Tabletop Exercise in December that will examine some of the key issues impacting potential recovery, including our current laboratory capacity. In addition, by the end of the year, the EPA plans to issue two five-year grants to state radiochemistry laboratories worth a total of $1.3 million that will include equipment and training to help respond to a radiological or nuclear emergency. But considering the stated threat and known gaps in the U.S. radiochemistry infrastructure these steps are helpful but not sufficient.

Despite the threat of a domestic radiological attack in the U.S. cited by government officials since the 9/11 terrorist attacks attempts to close the gap in U.S. radiological emergency response efforts have only just begun. Homeland Security Presidential Directive/HSPD-18 was issued last January which addressed "Medical Countermeasures against Weapons of Mass Destruction." The Presidential Directive warned: "Threats posed by fissile and other radiological material will persist," and argued that "[o]ur Nation must improve its biodosimetry capabilities.…" Just last week, another Homeland Security Presidential Directive (HSPD-21) on "Public Health and Medical Preparedness" was issued which addressed naturally occurring and intentional "catastrophic health" events. The directive did not specifically address the laboratory capacity gap, but said

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[11] "The Radiological Accident in Goiania," International Atomic Energy Agency, Vienna, Austria, September 1988. http://www-pub.iaea.org/MTCD/publications/PDF/Pub815_web.pdf

"[i]t is the policy of the United States to plan and enable provision for the public health and medical needs of the American people in the case of a catastrophic health event."

Proficiency Testing

But the efforts to close the critical radiochemistry laboratory gap have – at times – taken one step forward and two steps back. In 2005, for instance, at the same time the Department of Homeland Security was initiating a new Integrated Consortium of Laboratory Networks (ICLN) to help enhance the nation's laboratory response capabilities it was inexplicably dismantling the Quality Assessment Program (QAP), an environmental performance evaluation program run by the Environmental Measurements Laboratory (EML), a DHS lab based in Manhattan. The QAP had been in existence since the 1970s and provided independent quality assurance testing to more than 150 environmental laboratories throughout the country. The program and the lab were the subject of a hearing held by the Subcommittee last May.[12] Today, the critical need for a nearly identical program geared towards the emergency response community has been cited as a clear need by EPA and a report by the Federal Radiological Monitoring and Assessment Center, an interagency group run by DOE that includes DHS.[13] The manager of Oregon's state radiation laboratory, which used to participate in the EML QAP program, told Subcommittee staff that QAP was a critical program for his lab and that proficiency testing program's provide the public with confidence that the degree of environmental contamination being reported by labs that participate are accurate.

A robust quality assurance program also helps re-assure government officials that the data they receive in order to make critical public policy decisions regarding evacuation, re-occupation or clean-up are based on solid scientific methods. In order to validate the number of national labs capable of reliably conducting environmental analysis, for instance, the draft March 2007 EPA report (cited above) on the national environmental radiological laboratory capacity gap relied upon data generated by the EML QAP and a similar program at the DOE's Radiological and Environmental Services Laboratory (RESL) in Idaho called the Mixed Analyte Performance Evaluation Program (MAPEP). But DHS terminated the QAP program in 2005 and the Department of Energy is seeking to make a decision regarding the privatization of the RESL laboratory in December.

Without the data provided by these programs administration officials and other government decision makers will have no way to validate or quantify the performance capabilities of environmental laboratories based on independent analysis. Contracting out the MAPEP program at RESL has been described by some government officials as short-sighted. They fear that the government will be inadvertently giving away a critical

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[12] See: "Transitioning the Environmental Measurements Laboratory at the Department of Homeland Security," House Science and Technology Committee, Subcommittee on Investigations and Oversight, May 3, 2007 hearing. http://science.house.gov/press/PRArticle.aspx?NewsID=1806

[13] "Mission Analysis – Volume One – Revision 1; Emergency (Early) Phase," Federal Radiological Monitoring and Assessment Center – An Interagency Document for Implementing the National Response Plan Nuclear/Radiological Incident Annex, June 2007 – DRAFT, p. 45.

oversight function to ensure that the radiological data government officials receive is accurate. If a radiological emergency erupts five years from now, for instance, policy makers may be forced to utilize the services of labs without any valid means of knowing whether or not the results of their tests can be or should be trusted.

In order to close the radiochemistry laboratory gap and ensure that the government is capable of effectively responding to a potential radiological emergency, the EPA is proposing a five-year $36.5 million plan to build a National Environmental Radioanalytical Laboratory Response Network that would include creation of a national proficiency testing and audit program. The EPA estimates that once fully established the network would decrease the average capacity shortfall for environmental samples for the RDD scenario envisioned in National Planning Scenario #11 by approximately 80%.

The CDC hopes to establish a Clinical (Bioassay) Radioanalytical Laboratory Response Network as well. A fully functional CDC network would include five state radioanalytical (bioassay) labs to augment the federal response and cost $20.6 million over the next five years. If implemented, this network which would include equipment, personnel, training and its own proficiency testing program, would reduce the time to analyze the 100,000 clinical samples envisioned in the National Planning Scenario from two years to less than three weeks.

Unfortunately, both networks exist only on paper today despite the fact that various federal agencies have highlighted the need to establish these sorts of laboratory networks for years. A June 2007 interagency (draft) document concludes that major gaps in the radiochemistry laboratory infrastructure remain.[14] This report listed many recommended proposals that it believes need to be addressed quickly, including providing clarity to the roles and responsibilities of federal agencies charged with responding to radiological emergencies. "These proposals need to be quickly implemented and will have an immediate impact on our ability to protect the health and safety of the American public in the event of a nuclear/radiological disaster," it warned. Until that is done, this mix of problems may be a recipe for creating the ingredients for a radiological Katrina if the U.S. government is forced to respond to a real-world radiological emergency today.

[14] "Mission Analysis – Volume One – Revision 1; Emergency (Early) Phase," Federal Radiological Monitoring and Assessment Center, An Interagency Document for Implementing the National Response Plan Nuclear/Radiological Incident Annex, June 2007 – DRAFT, p. xvi.