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U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) EXPERIENCE IN THE JOINT EXTERNAL EVALUATION PROCESS – RADIATION EMERGENCIES TECHNICAL AREA

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Abstract

In 2015–2016, the U.S. Department of Health and Human Services led 23 U.S. Government (USG) agencies including the Centers for Disease Control and Prevention (CDC), and more than 120 subject matter experts in conducting an in-depth review of the U.S. core public health capacities and evaluation of the country's compliance with the International Health Regulations using the Joint External Evaluation (JEE) methodology. This two-part process began with a detailed "self-assessment" followed by a comprehensive independent, external evaluation conducted by 15 foreign assessors. In the Radiation Emergencies Technical Area, on a scale from 1-lowest to 5-highest, the assessors concurred with the USG self-assessed score of 3 in both of the relevant indicators. The report identified 5 priority actions recommended to improve the USG capacity to handle large-scale radiation emergencies. CDC is working to implement a post-JEE roadmap to address these priority actions in partnership with national and international partners.

INTRODUCTION

In 2015–2016, the U.S. Department of Health and Human Services led 23 U.S. Government (USG) agencies including the Centers for Disease Control and Prevention (CDC), and more than 120 subject matter experts in conducting an in-depth review of the U.S. core public health capacities and evaluation of the country's compliance with the International Health Regulations using the Joint External Evaluation (JEE) methodology. The objective of the USG JEE was to assess USG capacities and capabilities relevant for the 19 technical areas of the JEE tool in order to provide baseline data to support USG's efforts to reform and improve its public health security.

The JEE uses a peer-to-peer process, and as such, is a collaborative effort between host country experts and JEE team members. The entire external evaluation, including discussions around the scores, the strengths, the areas that need strengthening, best practices, challenges and the priority actions should be collaborative, with JEE team members and host country experts seeking full agreement on all aspects of the final report findings and

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recommendations. This two-part process began with a detailed “self-assessment” followed by a comprehensive independent, external evaluation conducted by 15 foreign assessors.

The U.S. Government has a robust approach to prepare for and respond to radiological and nuclear emergencies. The USG provides assistance and support to state and local governments as needed on the premise that events would be handled at the local level until they exceed the capability of the local jurisdiction.

The National Response Framework [(1)] contains the Nuclear/Radiological Incident Annex to the Response and Recovery Federal Interagency Operational Plans (NRIA) [(2)], which outlines the roles, responsibilities and authorities for the federal agencies during a radiological emergency response. The capabilities/capacities of state and local governments vary widely across the USA, with the greatest resources found in states that have nuclear power plants. The overall coordination of response to any significant radiological/nuclear emergency would be carried out by the Department of Homeland Security (DHS) and the Federal Emergency Management Agency (FEMA), in close coordination with the White House National Security Council. The Federal Bureau of Investigations (FBI) would also take lead actions if the incident were the result of terrorism or other federal crimes. The USG is a signatory to the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency of the International Atomic Energy Agency.

The USG, like most other nations, would be challenged to respond to a large-scale, catastrophic nuclear emergency. Evaluation and testing of the identified roles and responsibilities of authorities as described in the NRIA, and its regular updating would be of value. Mechanisms can be established for systematic information exchange between radiological competent authorities and human health service units. Management of radiological and nuclear waste with the development of a long-term repository mechanism and appropriate monitoring systems is crucial for radiation safety. Finally, there is a trend in the decreasing number of radiation and radiobiology professionals.

CDC is a primary partner with the World Health Organization (WHO) in the development and implementation of Joint External Evaluations (JEEs) and post-JEE national action planning. CDC, working with numerous federal partners conducted the JEE process in two stages; (1) an initial self-evaluation using the JEE tool [(3)] and (2) an in-country evaluation and review conducted by a Joint External Evaluation Team of subject matter experts [(4)].

Indicators and scores

The JEE tool is comprised of 19 capacity elements or technical areas grouped into the following categories: “Prevent” (P), “Detect” (D), and “Respond” (R). Other International Health Regulations (IHR)-Related Hazards and Points of Entry indicators were labeled as “Points of Entry” (PoE), “Chemical Events” (CE) and “Radiation Emergencies” (RE). Table 1 4 shows the indicators and scores for the technical areas within “Other IHR hazards and points of entry”, where the scores for the Radiation Emergencies category are listed.

In the Radiation Emergencies Technical Area, on a scale from 1-lowest to 5-highest, the assessors concurred with the USG self-assessed score of 3 in both of the relevant indicators. For Indicator #1 (RE.1), the USG offered the following remarks for its self-assessed score: "There are numerous guidelines, internal plans and protocols. However, there is not "systematic information exchange between radiological competent authorities and human health surveillance units" required for higher score of 4." For Indicator #2 (RE.2), the USG offered the following remarks for its self-assessed score: "There are explicit indicators, plans, communication protocols, and participates in frequent radiation-related drills and exercises, etc. However, there have not been realistic drills to evaluate its ability to assist and support state and local Community Reception Center and associated Population Monitoring activities in its response to a RDD or IND." A discussion of strengths and best practices as well as areas that need strengthening/challenges for those indicators where USG scored 3 is provided below.

Strengths/best practices for Indicator #1

- Radiation detection exists in the USG with defined responsibilities of various authorities – The Environmental Protection Agency (EPA) is responsible for radiation contamination assessment and monitoring in the environment; DHS is responsible for the BioWatch system[3], multiple agencies like the Food and Drug Administration (FDA), and the US Department of Agriculture (USDA) monitor consumer products with laboratory support; the Department of Energy (DOE) and the EPA monitor the radiation resulting from the incident and measure environmental radiation through aerial measuring system.

- There is a comprehensive system of protection in place for radiological and nuclear hazards with scalable national response plans.

- The capacity for conducting public health risk assessments and mechanisms for exposure assessments are in place (CDC provides assistance and support to state and local governments for monitoring of the exposed population and post-incident health surveillance. DOE led Federal Radiological Monitoring and Assessment Center (FRMAC) coordinates the collection and assessment of environmental radiological data immediately after an emergency).

- Regular exercises allow federal, state and local agencies, as well as nuclear power operators, to test both national and local plans, and maintain a level of readiness through integrated communication and capabilities across all levels and sectors.

- Mechanisms have been developed for mitigation and treatment following radiation incidents (such as various guidance documents published by FDA; and the Radiation Injury Treatment Network (RITN) to care for patients during radiation events with guidance on various possible incidents).

- Radiation Emergency Assistance Center/Training Site (REAC/TS) and the Department of Defense's (DoD) Armed Forces Radiobiology Research Institute serve as medical resources.

- The DHS FEMA RadResponder network[(4)]enables organizations to rapidly and securely record, share and aggregate large quantities of data while managing their equipment, personnel, interagency partnerships and multijurisdictional event spaces.

Areas that need strengthening/challenges for Indicator #1

- There is a need to assess human health risk by characterizing the impact of radiation emergencies on humans.
- There is a very limited capacity of laboratories to conduct bioassays for internal radioactive contamination or biodosimetry for the assessment of external radiation exposure.
- A system for information exchange is required between radiological competent authorities and human health surveillance units.

Strengths/best practices for Indicator #2

- The NRIA outlines the roles, responsibilities and authorities for federal agencies during radiation emergencies (federal government provides assistance and support to state and local government as needed).
- Various stakeholders play a crucial role in the management of radiation emergencies (such as FRMAC, which is coordinated by National Nuclear Security Administration in the DOE and supported by other federal, state and local agencies; the Advisory Team for the Environment, Food and Health [(5)], comprising technical representatives from EPA, FDA, CDC and USDA; state and local response agencies including radiation control programs).
- A well-developed network of assets and plans exists for sampling, monitoring and assessing risks to the food supply and the environment.
- The USG has used lessons learned from regular exercises and various incidents to refine strategies and set up priorities (lessons learnt from the Fukushima incident particularly on radiation detection equipment and the risk communication to the public are essential).
- The CDC National Center for Environmental Health (Division of Environmental Hazards and Health Effects/Radiation Studies Branch) and the DOE REAC/TS are collaborating centers for radiation emergencies with the WHO Radiation Emergency Medical Preparedness and Assistance Network.

Areas that need strengthening/challenges for Indicator #2

- Evaluate and test the identified roles and responsibilities of authorities as described in the NRIA, and where appropriate, update them.
- Improve the availability and sustainability of experienced radiation and radiobiology professionals.

- Conduct realistic wide-scale drills that test the ability of state and local communities to assist and support during a radiological or nuclear emergency.

RECOMMENDATIONS TO ADDRESS SIGNIFICANT CHALLENGES

There were five priority actions recommended to improve the United States' capacity to handle large-scale radiation emergencies. Those include:

1. Establish mechanisms for systematic information exchange between authorities of the radiological competent and human health service surveillance units,
2. Develop a long-term waste management repository following the cleanup of a radiological spill,
3. Research, develop and implement systems to create novel, high-throughput systems that are capable of performing biodosimetry and bioassay in both mass casualty and large-scale radionuclide dispersion situations,
4. Implement the recommendations in the report "Where are the radiation professionals?" (Statement No. 12) issued by the National Council on Radiation Protection and Measurements in 2015 [6] and
5. Integrate triage systems and population monitoring guidance with the existing national public health and clinical systems in order to provide a national capacity for continuity of assessment, care and treatment.

There are a number of challenges and opportunities to improve the United States capacity to handle a large-scale radiation emergency. Currently, very few laboratories can conduct large-scale Public Health rapid bioassays for internal radioactive contamination or biodosimetry for the assessment of external radiation exposure of the general public. Without those capabilities, it would be very difficult in a large-scale incident to determine an appropriate initial course of medical management as well as to make optimal use of limited medical resources. Research and development are needed to create novel, high-throughput systems that are capable of performing biodosimetry in mass casualty situations, as well as novel medical countermeasures that can be manufactured and stored in large quantities. In addition, new triage systems should be networked with the existing public health and clinical systems in order to provide a national capacity for continuity of care and treatment. On the environmental side, there are some laboratory capabilities for the detection of radiological contamination in food, water, and other environmental media, but those are not widespread and their combined capacity may not be sufficient to address the overwhelming demand.

Another previously identified challenge for the United States is a decline in the availability of radiation and radiobiology professionals similar to that observed in the rest of the world. In a large-scale response situation, incident managers at various levels and operational teams may not have immediate access to people with the training and experience to accurately assess a dynamic situation and make recommendations. Additionally, there are not enough scientists in the "development pipeline" to replace those who have retired or will retire soon. Such a shortfall foreshadows a significant gap in the U.S. research and development sector. To address the gaps in the availability of qualified radiation professionals, the National

Council on Radiation Protection and Measurements [6] suggested the need for a national effort to increase research funding for low-dose radiation research to spur interest in advanced degrees among baccalaureates. The Council also suggested that existing radiation science laboratories could look for opportunities to support a larger number of trainees earlier in the educational cycle, such as through internships and fellowships, to provide radiation-degree candidates with opportunities to gain hands-on experience.

Under the NRIA of the NRF [2], monitoring of people for potential radionuclide contamination is primarily a state and local responsibility. In 2007, CDC issued comprehensive guidance to public health departments on how to organize a population-monitoring program [7]. This guidance was revised in 2014 [8]. However, a 2010 survey by the Council of State and Territorial Epidemiologists (CSTE) revealed that only three of 37 responding states (8%) reported adequate resources to conduct population-based exposure/contamination monitoring and most states reported insufficient equipment and health physics expertise to assess exposure and to interpret monitoring data [9]. In addition, the Association of Public Health Laboratories 2014 survey of Public Health laboratories [10] found that of the 21 state labs that test for environmental samples and 16 state labs that test for food samples, only one tests clinical samples with limited sample throughput and no Clinical Laboratory Improvement Amendments (CLIA - https://wwwn.cdc.gov/clia/) compliant methods for a few of the priority threat radionuclides.

INITIATIVES TO FILL IDENTIFIED GAPS

CDC has a multi-year research and development plan to address the need to create and disseminate radiobioassay and radiobiodosimetry systems, as well as medical countermeasures for radiation exposure, that can be deployed across the country for rapid responses to exposures. The plan includes development of bioassay tests for the remaining priority radionuclides as well as a plan to disseminate the tests to surge labs once funding is identified to create a network of bioassay surge capacity laboratories.

To address the goal to develop a “National systems” approach to radiation event management that links medical triage, diagnostic/prognostic data, treatment plans, and long-term follow-up, CDC is working with partners to develop a plan to identify radiological data elements that need to be incorporated in an all-hazards patient management, tracking and reporting system for human health surveillance.

Conclusion

The JEE process provided a candid and open opportunity for the U.S. government to carefully consider public health capability and capacity gaps in response to radiation emergencies. The CDC Radiation Studies Branch became the focal point and led the CDC effort in the self-assessment process. On a scale from 1-lowest to 5-highest, the CDC gave the USG a score of 3 in both of the indicators relevant to the human health aspects of preparedness for radiation emergencies. The Joint External Evaluation Team agreed with the self-assessment and provided some clear recommendations for filling the identified gaps. CDC is working to implement a post-JEE roadmap to address these priority actions in partnership with national and international partners to fill these gaps to improve its radiation emergency preparedness posture.

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Table 1.

Technical areas within the OTHER IHR HAZARDS AND POINTS OF ENTRY section of the JEE Tool.

Capacities	Indicators	Score
Points of entry	PoE.1 Routine capacities are established at points of entry	4
	PoE.2 Effective public health response at points of entry	5
Chemical events	CE.1 Mechanisms are established and functioning for detecting and responding to chemical events or emergencies	4
	CE.2 Enabling environment is in place for management of chemical events	5
Radiation emergencies	RE.1 Mechanisms are established and functioning for detecting and responding to radiological and nuclear emergencies	3
	RE.2 Enabling environment is in place for management of radiation emergencies	3