



# What IS risk assessment?

## OBSERVATIONS & RUMINATIONS

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## 9th Annual ABSANZ Biosafety and Biocontainment Conference

Crown Conference Centre, Melbourne  
Monday 28 October – Friday 1 November 2019



### Introduction

- Caveats and *mea culpas*
- Why am I here?

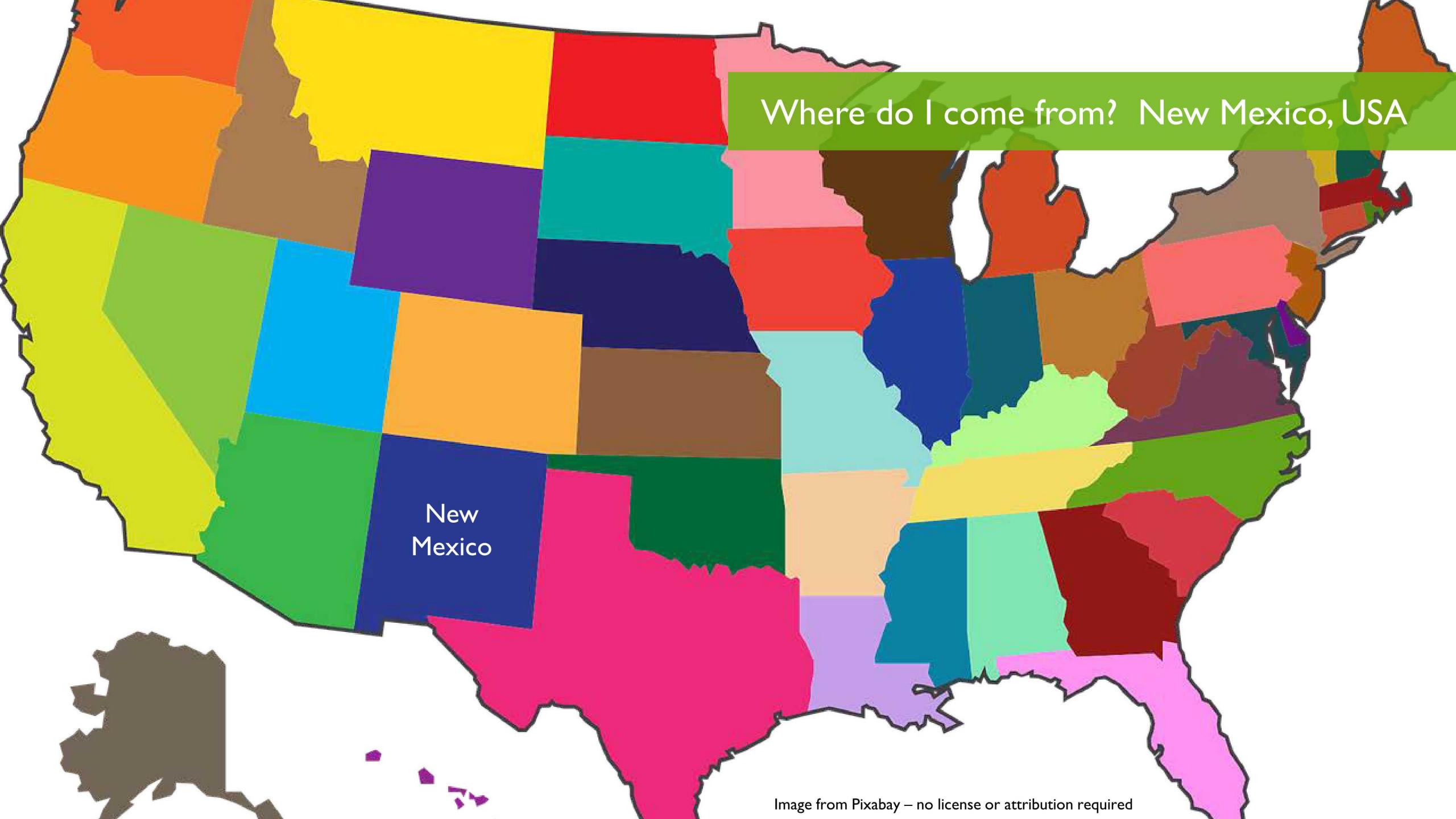
### Risk Assessment

- Studies
- Observations & Ruminations

### Invitation for Ongoing Discussion



Global Chemical and  
Biological Security



Where do I come from? New Mexico, USA

New  
Mexico



Where do I come from? Albuquerque, New Mexico, USA

# Albuquerque International Balloon Fiesta

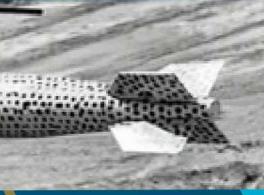
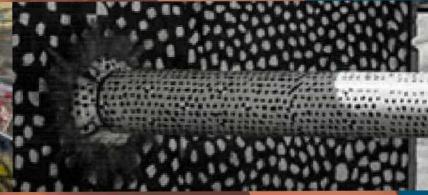
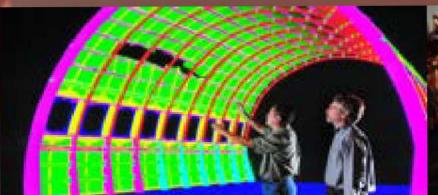


Albuquerque (and Sandia National Laboratories)  
are found at the foot of the Sandia Mountains

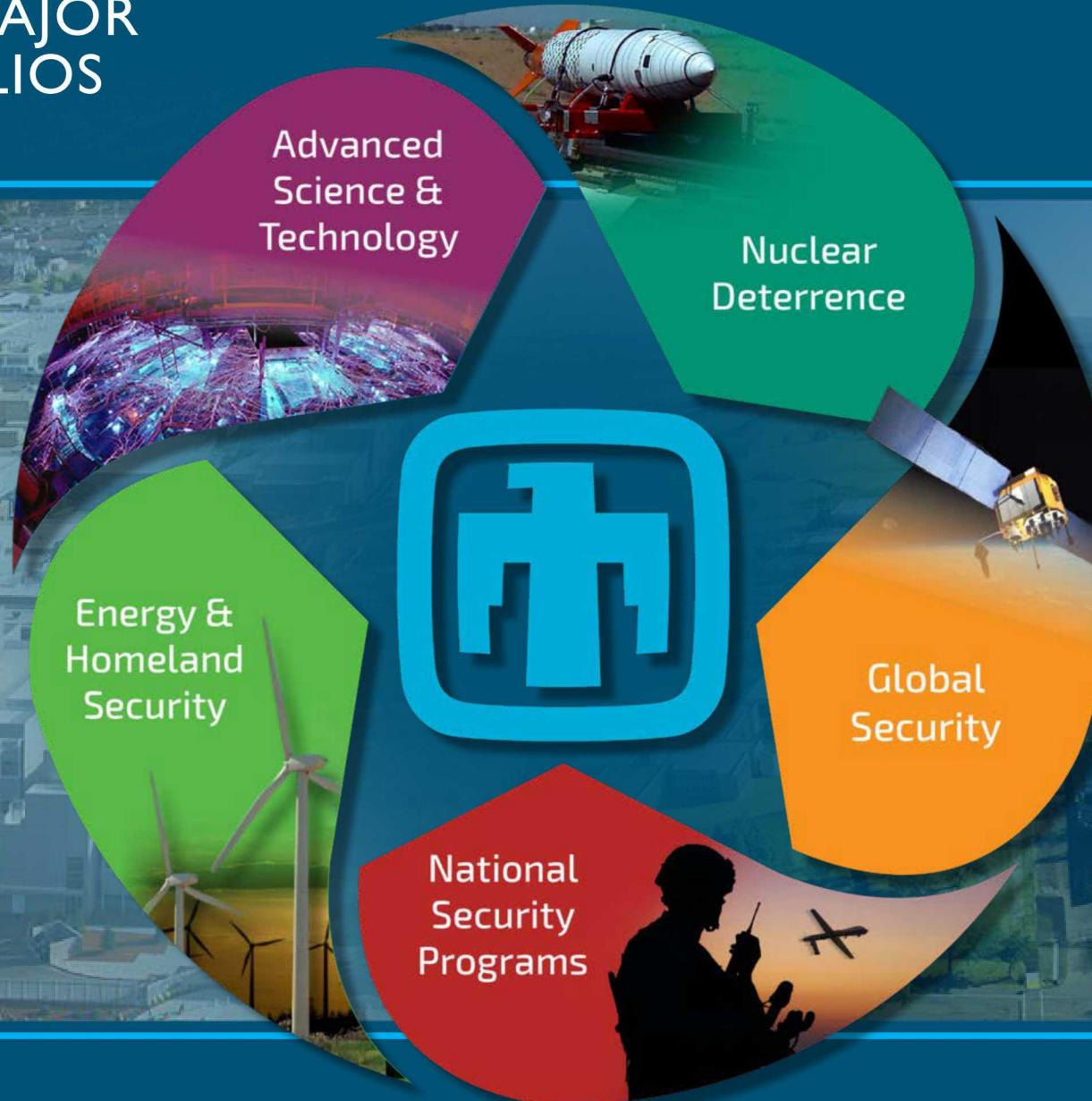


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Exceptional service in the national interest



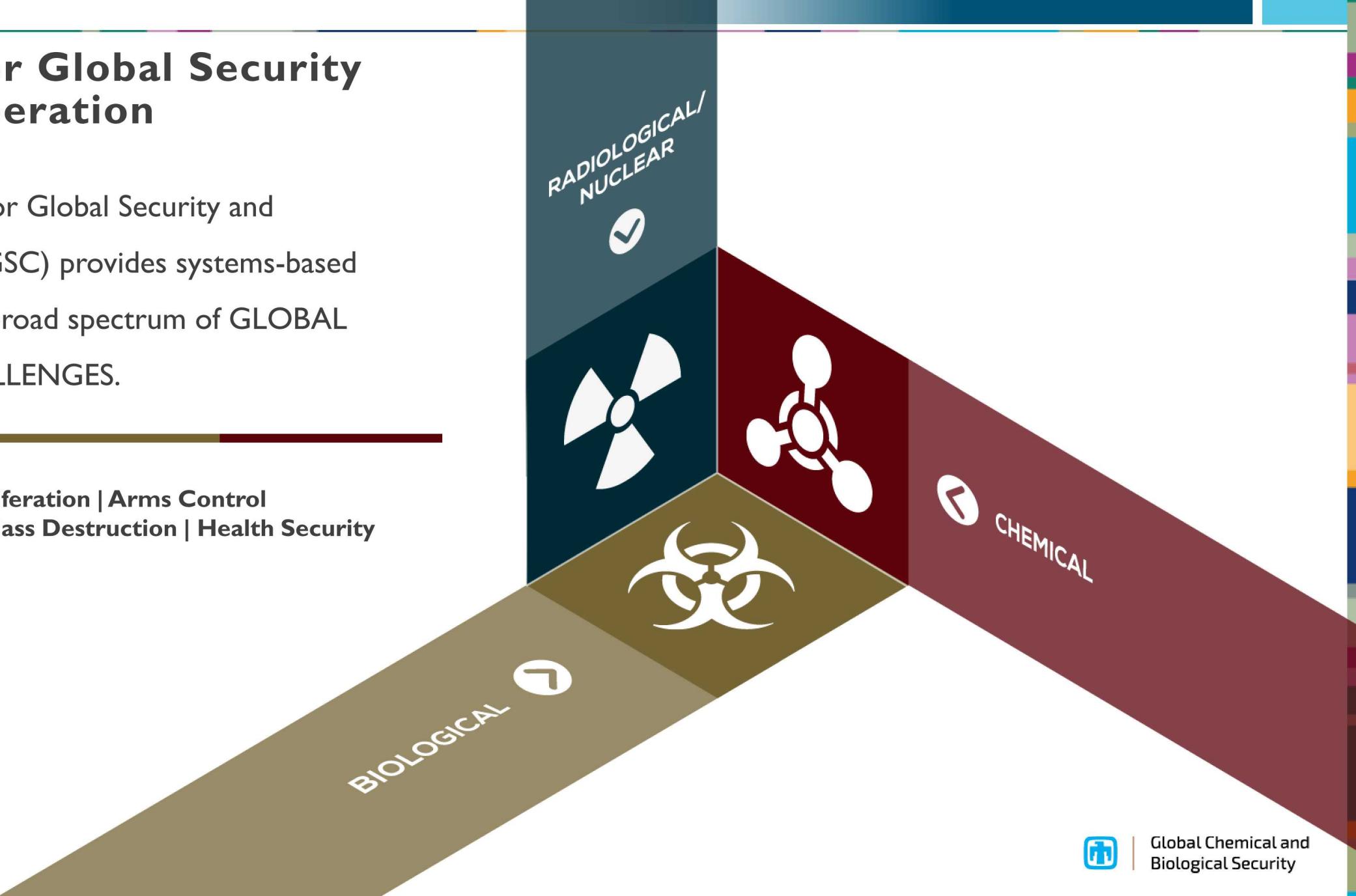
# SANDIA HAS FIVE MAJOR PROGRAM PORTFOLIOS



# Center for Global Security and Cooperation

Sandia's Center for Global Security and Cooperation (CGSC) provides systems-based solutions to the broad spectrum of GLOBAL SECURITY CHALLENGES.

Proliferation | Arms Control  
Weapons of Mass Destruction | Health Security



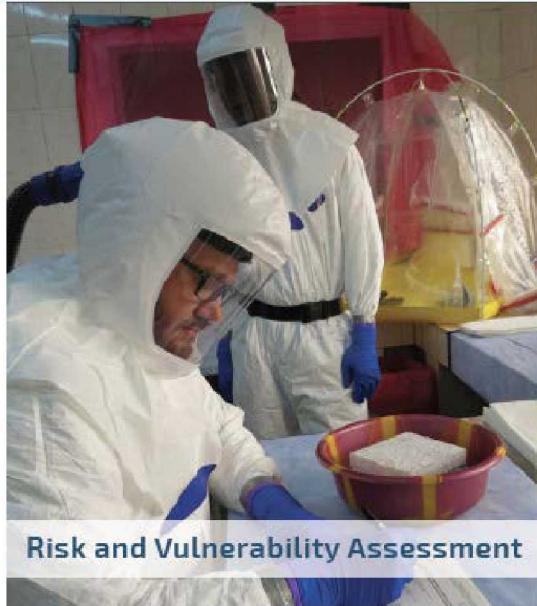
Global Chemical and Biological Security

# Global Chemical and Biological Security

GCBS develops and implements innovative solutions for responding to global biological and chemical threats.

Our team of leading scientists and policy experts is committed to minimize the risk posed by chemical and biological materials and technologies. We create and share new knowledge, tools, and approaches that empower our partners to safely detect, handle, and control dangerous chemical and biological agents anywhere in the world.

## Risk Management



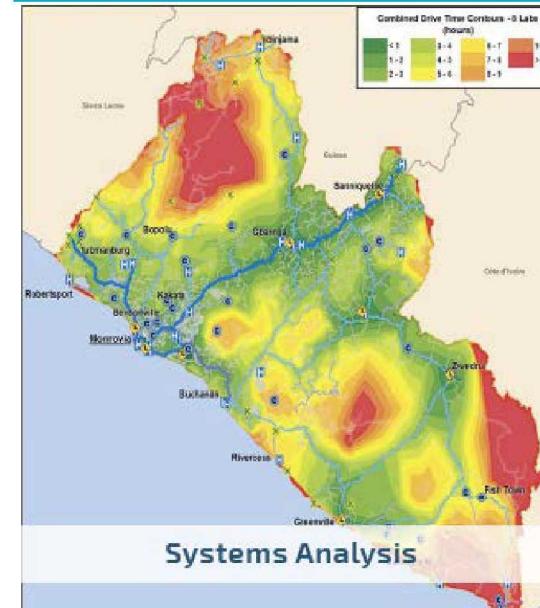
Risk and Vulnerability Assessment

## Human Capacity Development



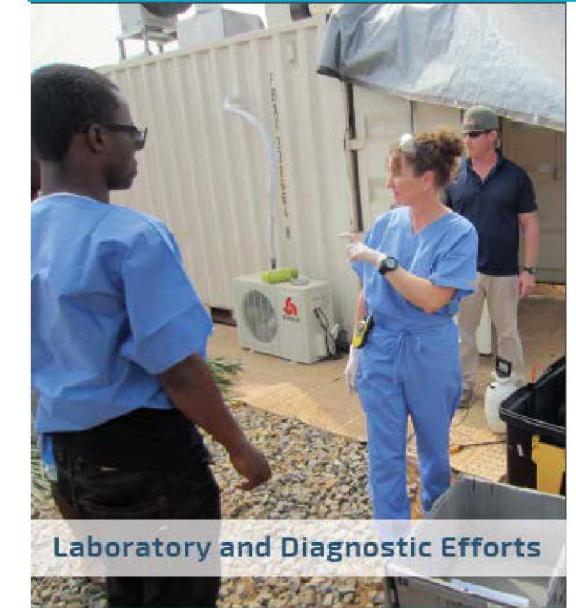
Veterinary Capacity Building

## Analysis



Systems Analysis

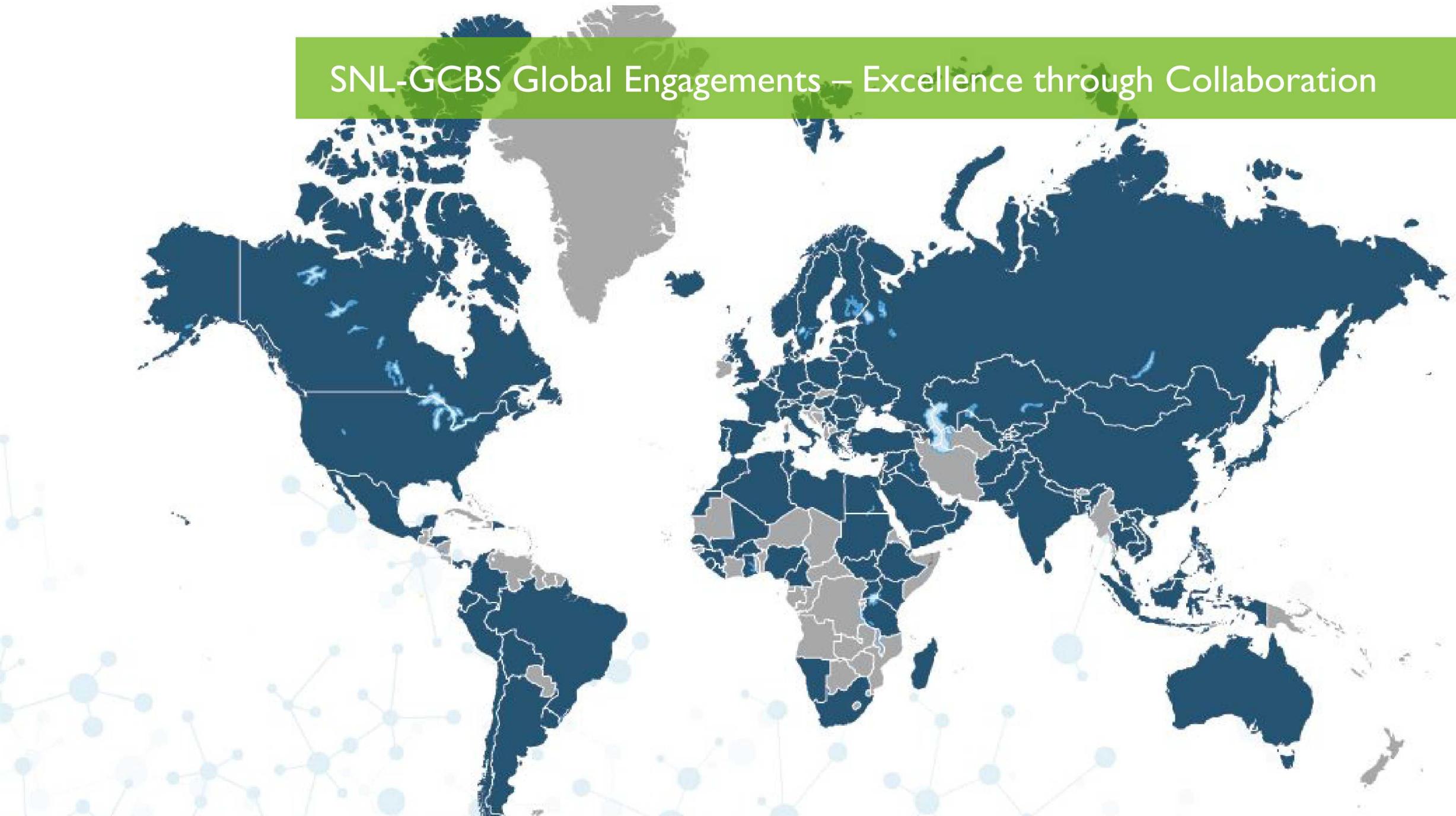
## Health Security



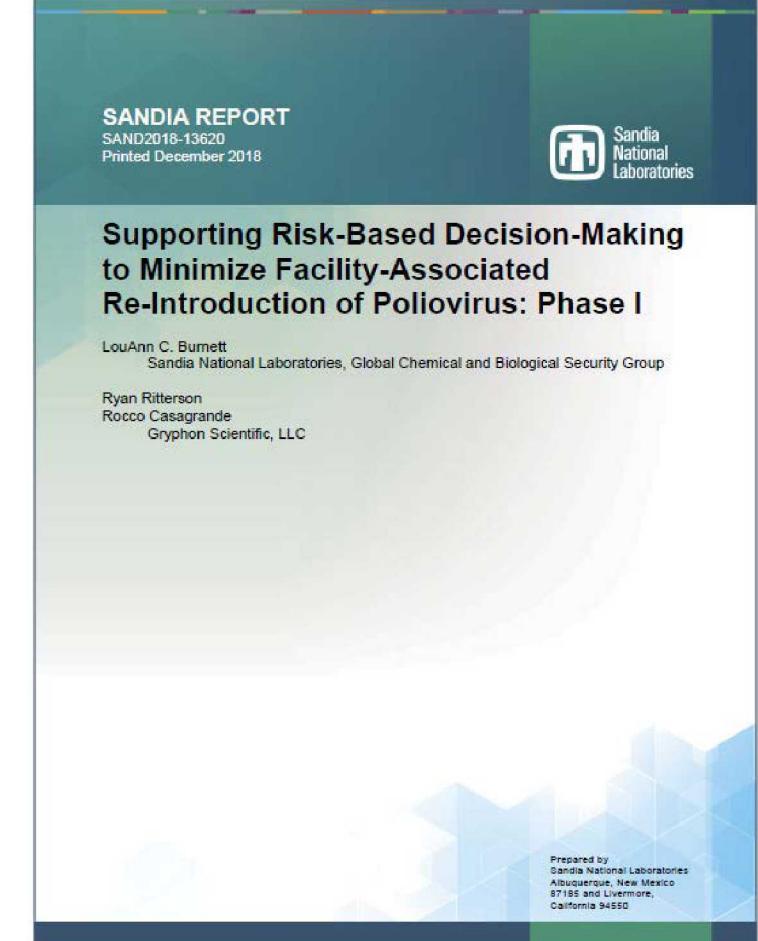
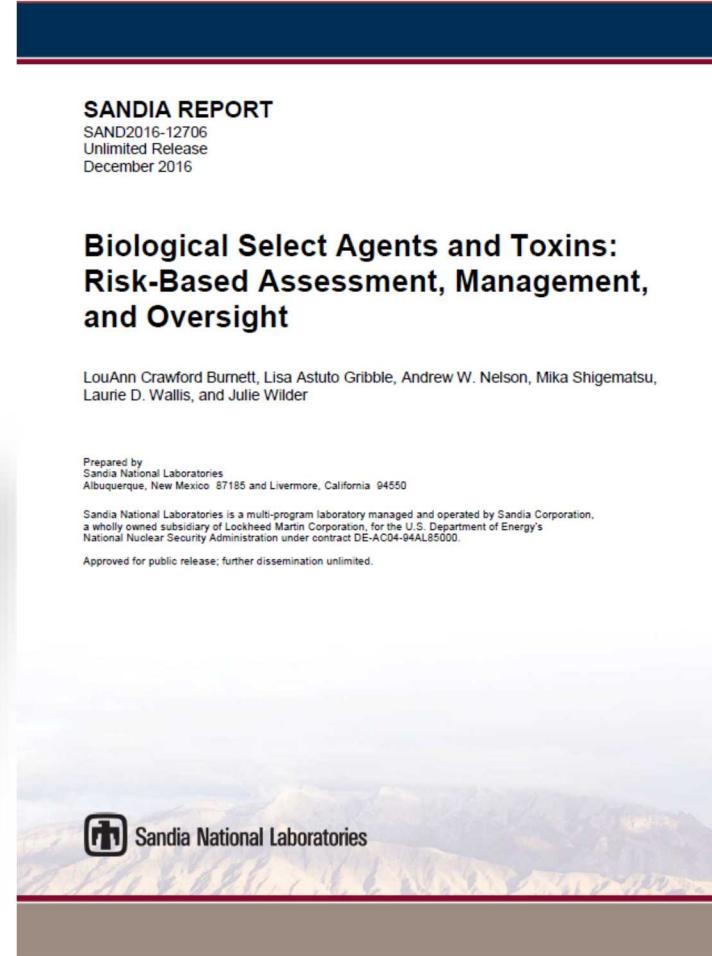
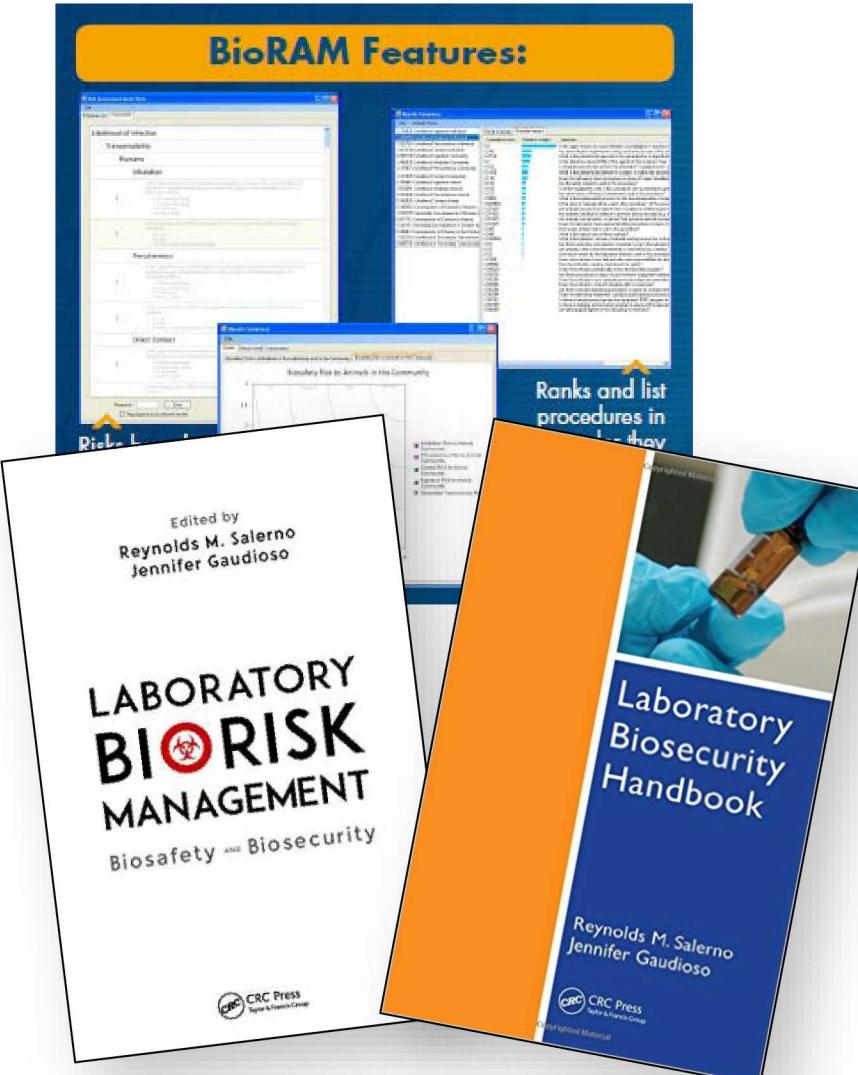
Laboratory and Diagnostic Efforts



# SNL-GCBS Global Engagements – Excellence through Collaboration



# SNL-GCBS Biorisk Assessment and Risk Management



# U.S. Federal Select Agents Program (2016)

**SANDIA REPORT**  
SAND2016-12706  
Unlimited Release  
December 2016

## Biological Select Agents and Toxins: Risk-Based Assessment, Management, and Oversight

LouAnn Crawford Burnett, Lisa Astuto Gribble, Andrew W. Nelson, Mika Shigematsu,  
Laurie D. Wallis, and Julie Wilder

Prepared by  
Sandia National Laboratories  
Albuquerque, New Mexico 87185 and Livermore, California 94550

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National Nuclear Security Administration under contract DE-AC04-94AL85000.

Approved for public release; further dissemination unlimited.

 Sandia National Laboratories

**CDC Internal Finding:**  
Select agent laboratories do not currently implement a standardized  
risk assessment process to identify the highest risks.

### §73.11 Security.

- (a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.
- (b) The security plan must be designed according to a site-specific **risk assessment** and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

### §73.12 Biosafety.

- (a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is **commensurate with the risk of the select agent or toxin, given its intended use**. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.



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# What comprises risk assessment? What are relevant examples/models of risk assessment?

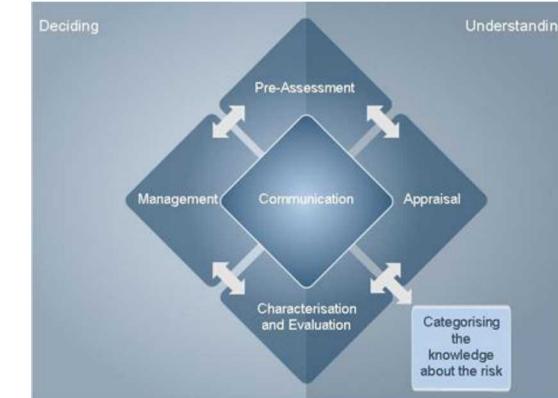
## Literature Review

Considerable variation in terminology and meanings assigned; even among respected frameworks

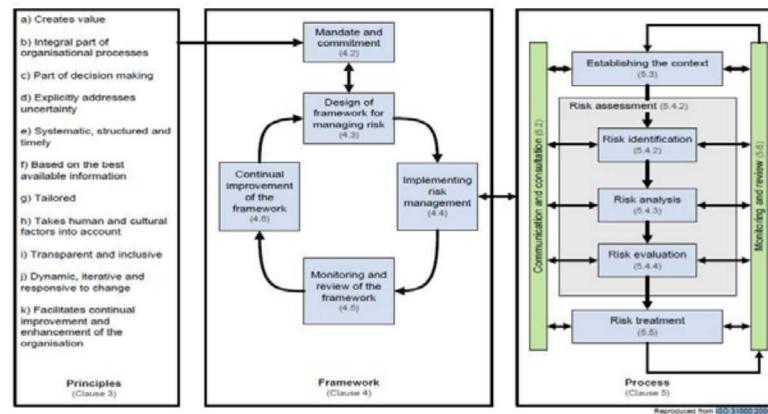
Diversity of opinion on what comprises and informs risk assessment

“Scientific” risk assessment may not fully address all factors necessary to apply appropriate risk mitigation measures

## International Risk Governance Council



## ISO XXX



## SNL/IFBA (based on CWA 15793)

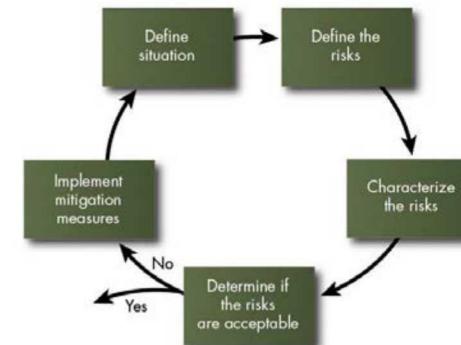
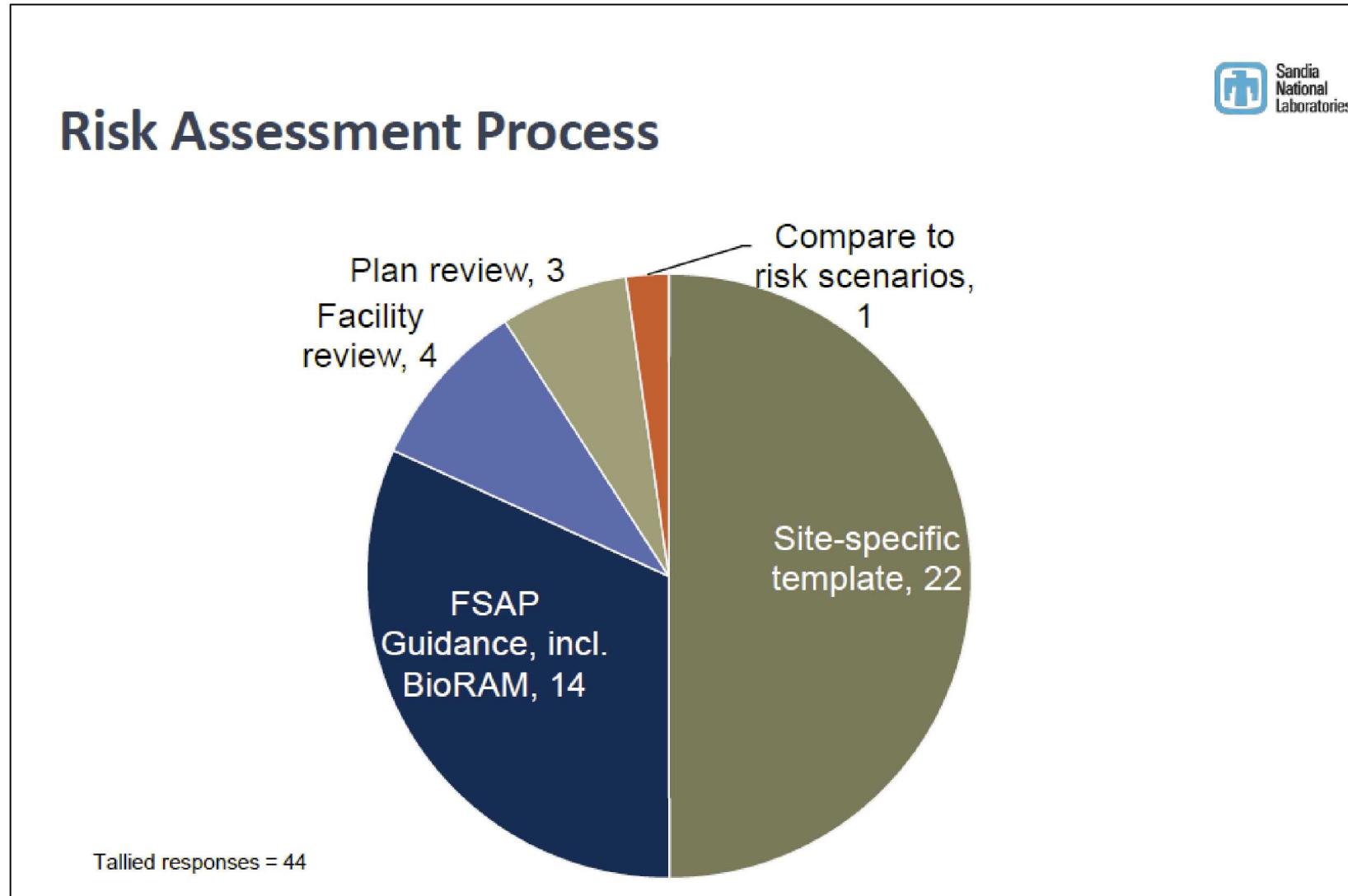


Figure 5. Common Risk Assessment Process



# What comprises risk assessment at facilities housing Select Agents?



“Regulated entities, for the most part, do not feel that they need to make changes to their risk assessment procedures.”

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SAND2016-12706  
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## Selected Findings

### ***Imprecise and inconsistent use of risk assessment and risk management terminology and processes.***

- Prevents constructive dialogue between regulators and regulated community.

### ***Intent of risk assessment is to inform decisions on control of identified risk.***

- Regulated community and inspectors tend to follow check lists to assure compliance, rather than using risk assessment to inform decisions.

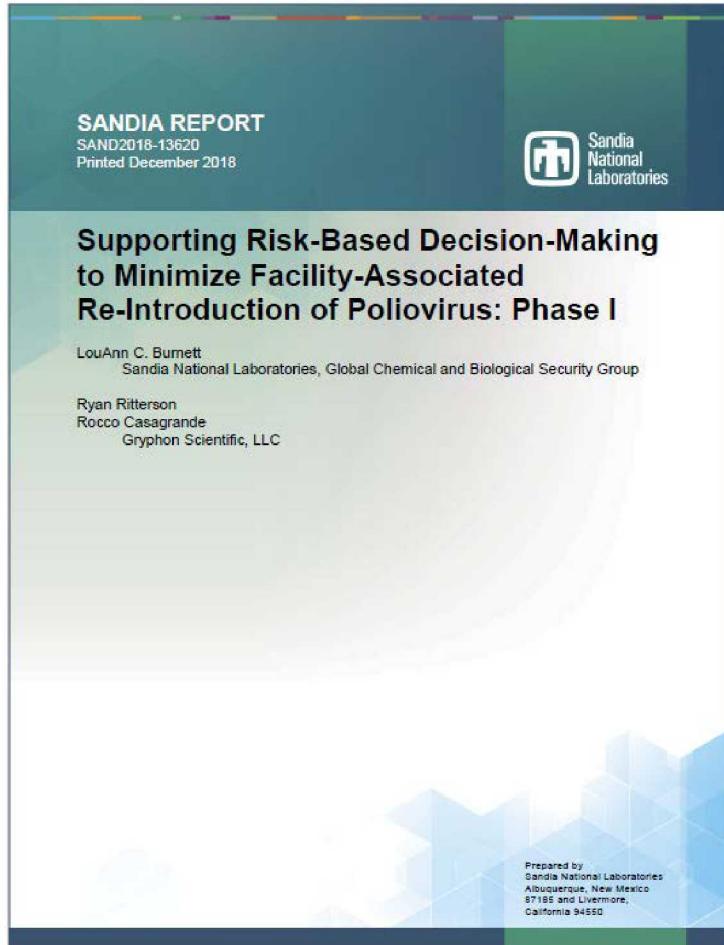
### ***Risk assessment is only as good as the input.***

- Very little consistent “front-loading” of data to inform risk assessments. Different persons may use different data and different assumptions to guide their choices on risk control.
- Risk assessments are often “back-filled” to justify risk control decisions.



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# Poliovirus Containment & the Global Poliovirus Eradication Initiative (2017-18)

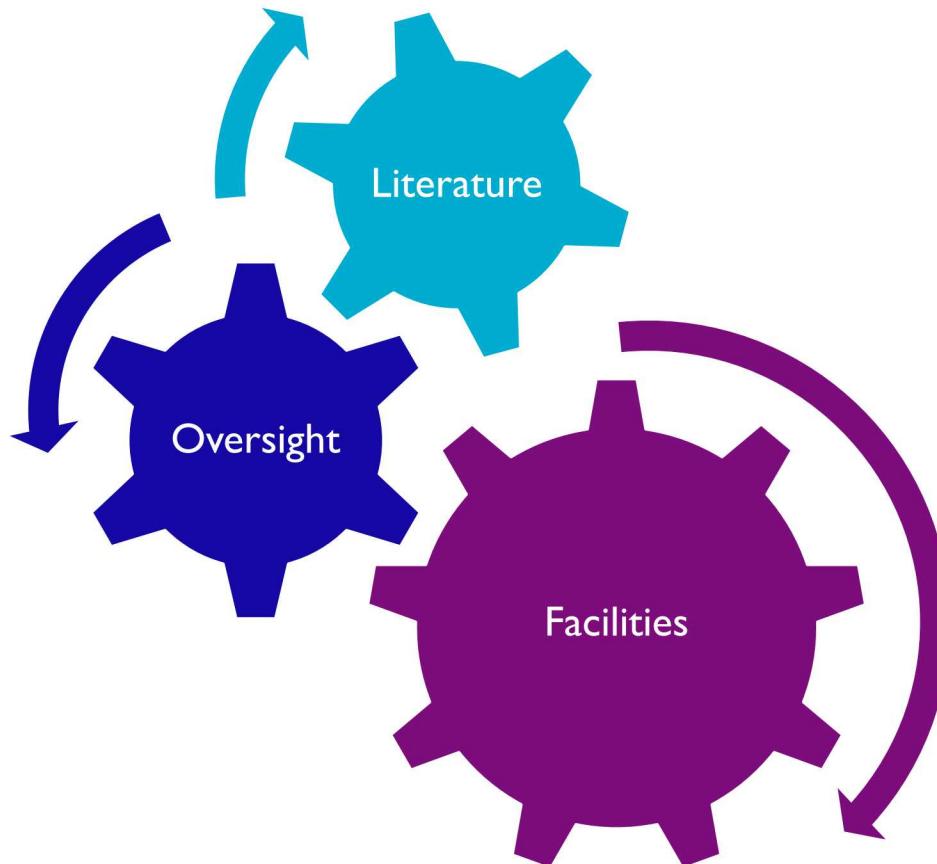


Study the process of assessing poliovirus risk and choosing risk-reducing measures in anticipation of developing a tool to support risk management for poliovirus containment activities to meet the requirements of the WHO Global Action Plan (GAPIII).

**“[T]he organization is best placed to understand the risks** associated with its work and can manage those risks in a number of ways acceptable to the national and international bodies responsible for facility oversight. This standard further assumes that poliovirus-essential facility personnel and management at all levels **fully appreciate the enormity of the consequences** of accidental or malicious poliovirus release in the post eradication/post-OPCV era and are prepared to demonstrate that the appropriate systems and controls are in place to manage those risks.” pg 29, GAPIII

**GAPIII contains more than 40 unique references to facility-specific risk assessment.**

# Data Sources and Methods



## Literature

- Reviewed >150 articles relevant to poliovirus public health, safety and risk, dating between 1940 and 2018

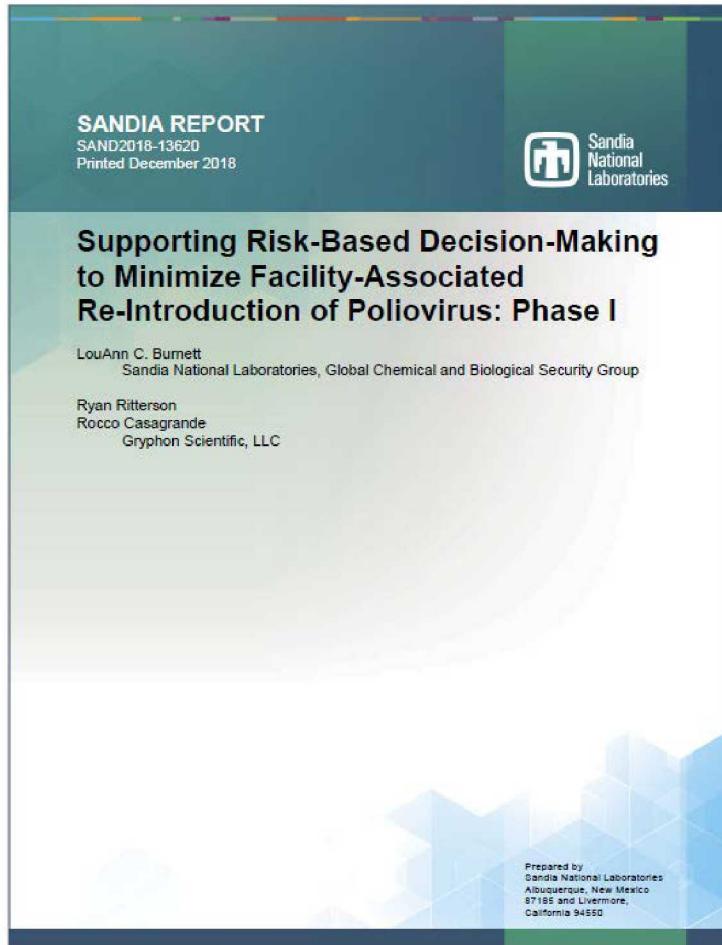
## Oversight

- Reviewed WHO GAPIII and GAPIII-derived guidance for references to and expectation for risk assessment and facility-based risk assessment

## Facilities

- Solicited input from all US laboratories that declared PV2 to the CDC
- Facilitated discussions with personnel from seven facilities

# Poliovirus Containment: Risk-Based Decision-Making



## Findings

Risk management of poliovirus will be aided by more **rigorous and consistent risk assessment and risk-based decision-making**.

- Experience-based risk assessment is, by itself, inadequate to understand risk in a post-eradication world.

GAPIII and GAPIII-derived guidance, by design, **rely heavily on facilities to make their own decisions** on risk and risk management.

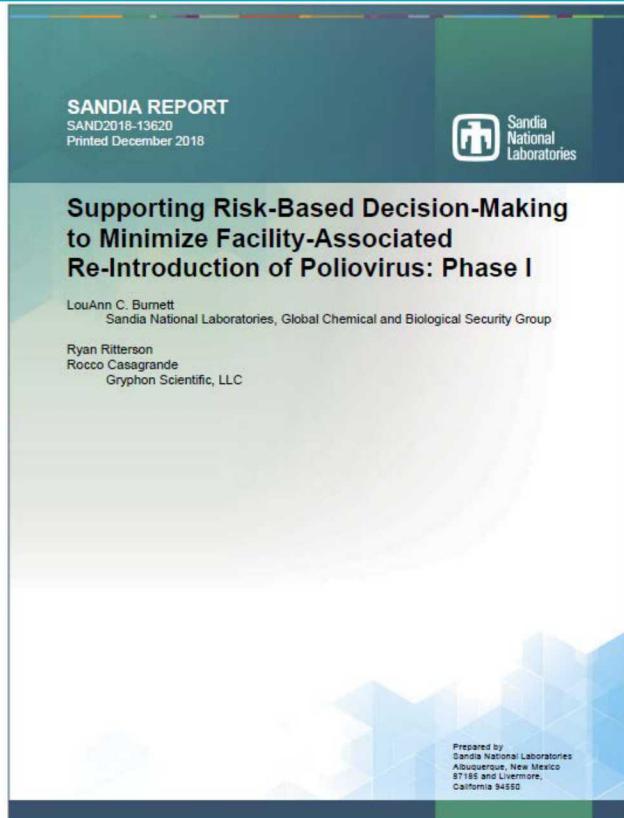
**Little poliovirus-specific information for choosing best practices is provided by GAPIII, GAPIII-derived guidance, or the literature.**

**Risk-based decision-making** at facilities **varies** in content, contributors, and rigor. All processes observed are experience-based.



# Poliovirus Containment: Risk-Based Decision-Making

## Recommendations



## Improve Quality of and Access to Data

**“Crowd-source” development of data sources** on poliovirus properties and poliovirus manipulations that influence risk to provide consistent data agreed upon by the community.

**Identification, consolidation and cataloging practices** according to their (experience-based) potential for risk reduction to aggregate the options available.

**Identification of gaps in guidance** available on risk-reducing practices and development of new guidance to fill those gaps.

## Develop Quantitative RA Tool

### Step I: Data collection

- Significant granular data is necessary to inform quantitative risk calculations

### Step II: Model & Interface Development

- A: Model development
- B: User Interface development

### Step III: Piloting

- Training for initial user groups
- Observation and/or user guides
- Feedback to and refinement by study team



A photograph of a woman with long brown hair, wearing a light blue jacket and jeans, bungee jumping from a bridge. She is suspended in mid-air by a long red bungee cord. Her arms are outstretched, and she is smiling. The background shows a dense green forest. A person's arm and hand are visible on the right side of the frame, holding a camera. The image is used to illustrate the concept of risk assessment.

So...what IS risk assessment?



The fastest way to move from a group hug...

A close-up photograph of two dogs, likely Golden Retrievers, playing tug-of-war with a blue and white braided rope toy. The dog on the left is on the left side of the frame, and the dog on the right is on the right side. They are both pulling on the toy, which is positioned horizontally between them. The background is a bright, green, grassy field.

... to a bar room brawl.



My observations and ruminations on risk assessment. . .



Observation #1 – we've been doing risk assessment for a very long time



Observation #2 – we aggregate risks unconsciously



Observation #3 – we rely on authority in unknown situations

## Observation #4 – same, same...but different

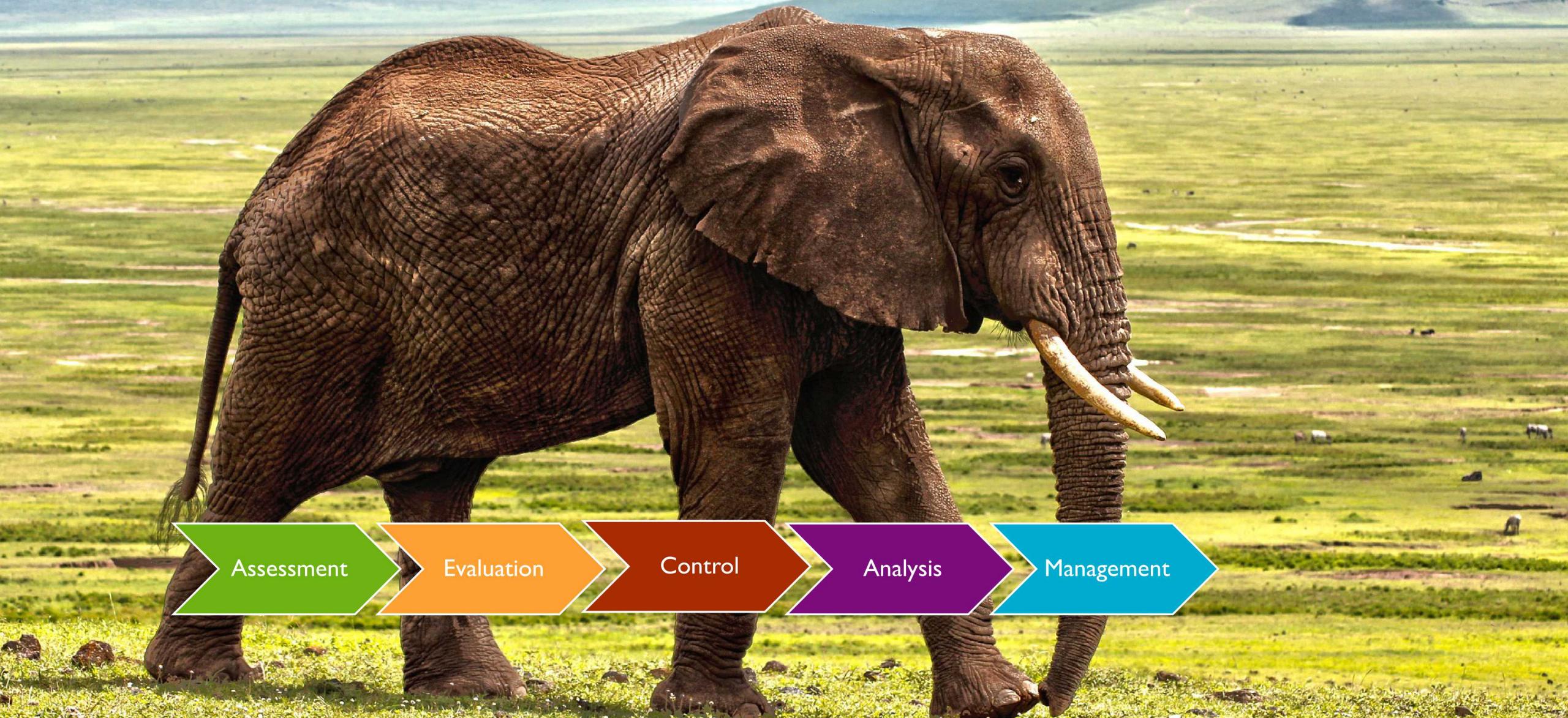


And so these men of Indostan  
Disputed loud and long,  
Each in his own opinion  
Exceeding stiff and strong,  
Though each was partly in the right  
And all were in the wrong!

"The Blind Men and the Elephant" by John Godfrey Saxe (1816–1887)

By Illustrator unknown - From Charles Maurice Stebbins & Mary H. Coolidge, Golden Treasury Readers: Primer, American Book Co. (New York), p. 89., Public Domain, <https://commons.wikimedia.org/w/index.php?curid=4581171>

Same process, different words





Same hazard, different risk

Natural Disease Outbreak

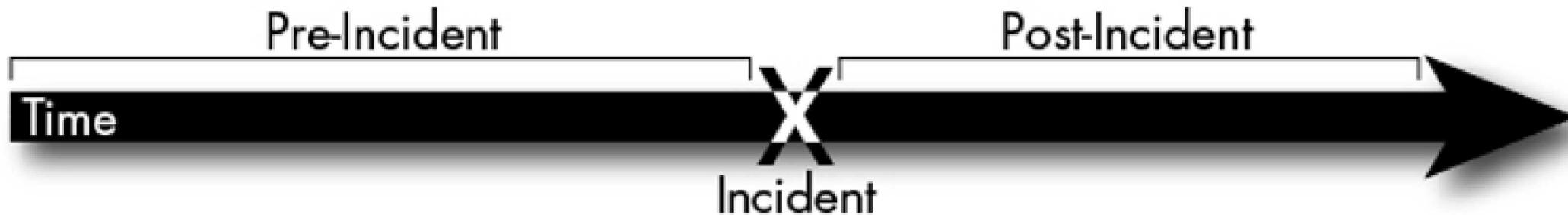
Pandemics

Accidents

Biocrime

Bioterrorism

# Risk



## Likelihood

Factors that affect whether or not the incident happens

## Consequences

Factors that affect the severity or the incident

## Observation #5: Risk must be defined precisely





Observation #6: Risk assessment is only as good as the data used

Same situation...different data, different decision



By Illustrator unknown - From Charles Maurice Stebbins & Mary H. Coolidge, Golden Treasury Readers: Primer, American Book Co. (New York), p. 89., Public Domain, <https://commons.wikimedia.org/w/index.php?curid=4581171>

A close-up photograph of a Canada goose and its gosling. The adult goose is in the background, its wings spread wide, showing a mix of brown, white, and black feathers. Its long, dark beak and legs are visible. In the foreground, a fluffy, yellowish-brown gosling stands on a patch of green grass and brown leaves, looking down at the ground. The background is a soft-focus view of a park-like setting with trees and more greenery.

Observation #7: Risks are best understood in relation to each other



Observation #8: Risk assessment is intended to inform risk control



## My suggestions for peace-keeping:



Precisely define the risk to be assessed.

Agree on the data to be used. Avoid assumptions. Document everything.

Assess one risk at a time. Be articulate and intentional when you aggregate risks.

Use the relationship between risks to help communicate priorities and risk-based decisions.

Be articulate about how the risk assessment informs risk control measures (and which specific risk is being controlled by which measure).



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# Thank you!

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