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INTERNATIONAL BIOLOGICAL and CHEMICAL THREAT REDUCTION

SAND2016-5629PE

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

Study Process & Preliminary Findings

Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000. SAND XXXX-XXXX

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CDC Internal 90-day Review

Observation C:

Select agent laboratories do not currently implement a standardized risk assessment process to identify the highest risks.

- Recommendation 3:
- Review and implement options for standardized risk assessment.
    - *CDC, in collaboration, with APHIS, shall convene an independent scientific body to review the science and practice of risk assessment in the modern select agent laboratory and provide recommendations that improve the timeliness and effectiveness of the inspection process*

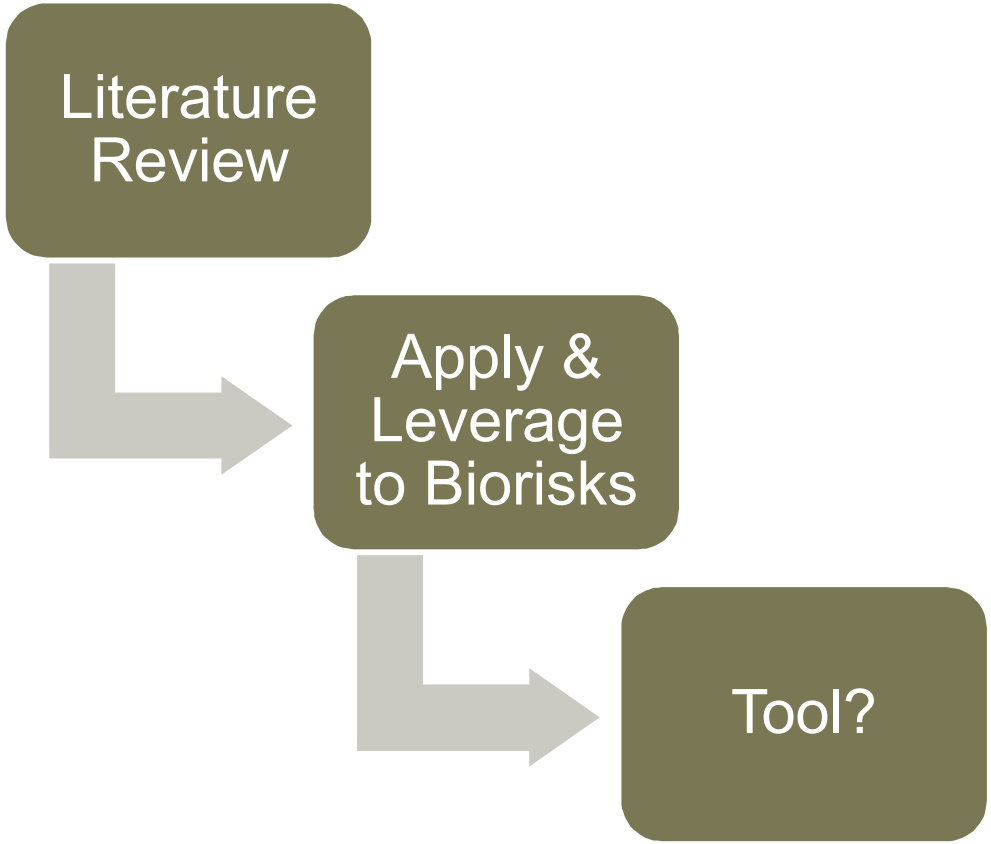
SNL/IBCTR Scope of Work

Support CDC in evaluating and strengthening the biorisk assessment process employed in regulated facilities in order to:

- Reduce biosafety and biosecurity risks associated with biological select agents and toxins within regulated facilities,
- Enhance effectiveness of inspection processes to identify safety and security vulnerabilities
- Enable FSAP to identify common vulnerabilities across multiple regulated entities that warrant prioritization for broad improvement.

Identify potential additional enforcement and compliance options (including incentives) that could lead to more effective biorisk management without excessive burden on regulated entities, using lessons drawn from other established industries subject to regulation in order to reduce safety and security risks.

SNL/IBCTR Scope of Work



Statement of Purpose

Desired End State

- Regulators and regulated community will utilize risk assessment in a consistent way to:
  - Improve (targeting of) safety and security at the individual entity level,
  - Contribute to lessons-learned for the FSAP community, and
  - Support options for oversight and enforcement that enhance safety and security without excessively burdening the regulated community.
- Regulatory oversight and enforcement will be informed by models used in other industries to successfully mitigate risk.

Study Outcome

Gain an understanding of current status of program relative to desired end state. Make informed recommendations to move the program from current state to the above desired end state

Research Methods

Literature Review

Interviews

Expert Panel Discussions

Interviews

14-15 May – Visit to DSAT offices

- Acting Director, Deputy Director, Program Operations Team (inspectors), Program Services Lead, Science Lead, Policy Lead

8, 9, 10, 13 June – Regulated Entity Forum (webinar)

- Summary (pending completion of webinars)

Panel Discussions

- Summarize available knowledge about the risks of concern for BSAT and risk-based strategies that may be utilized for management and oversight of BSAT, particularly approaches that have not received detailed attention
- Summarize knowledge about the actions of the FSAP community (regulation, regulators, regulated entities) to govern the risks of concern for BSAT
- Test the usefulness of risk-based decision making concepts from several disciplines against the challenges of BSAT
- Contribute to scientific understanding of the challenges of governing newly emerging biorisks and minimizing as-yet undefined hazards
- Inform draft recommendations for utilizing “risk assessment” more effectively in the management and oversight of BSAT.

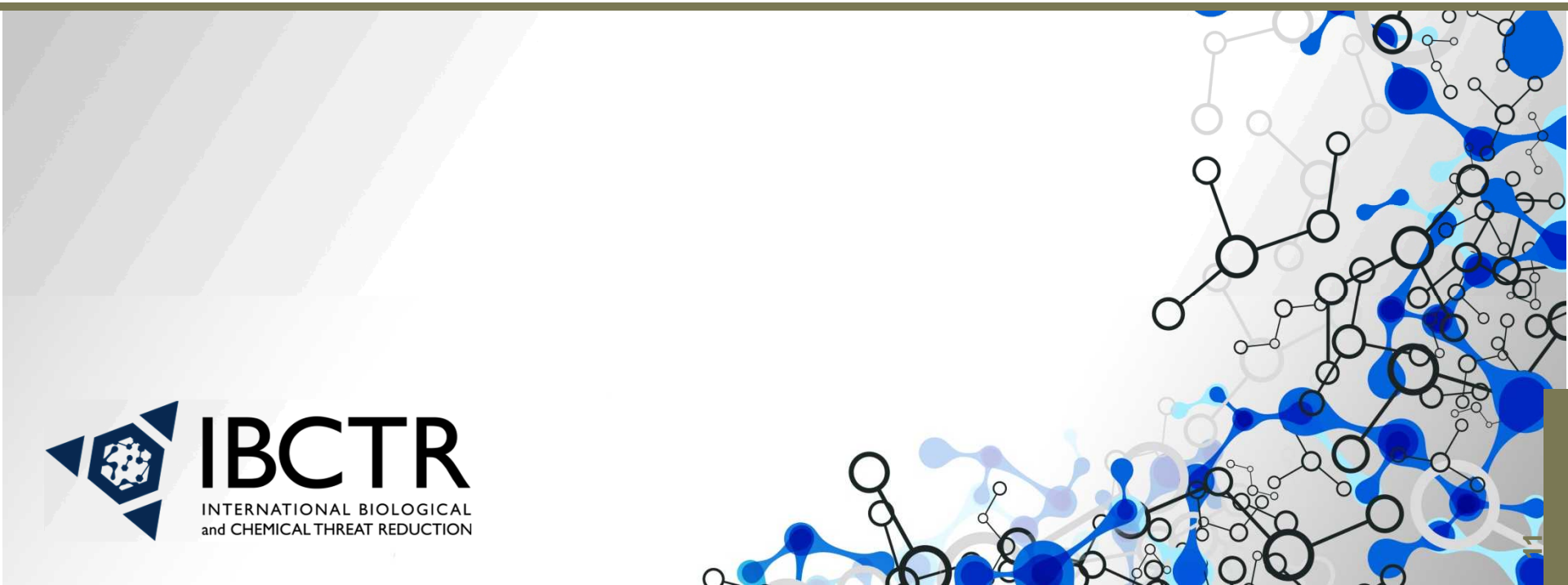
Research Questions, 1

- What risks are targeted by the FSAP program?
- Who are the current regulators and how do they do their work? How is risk assessment currently used?
- Who comprises the current regulated community and how do they do their work? How is risk assessment currently used?
- What would desired utilization of risk assessment look like for regulators?
- What would desired utilization of risk assessment look like for regulated community?
- Where has the current program been successful? Are these successes translatable to other areas?
- Where has the current program been less-than-successful? What is the perception of the reason for the lack of success?

Research Questions, 2

- What comprises risk assessment? What are relevant examples/models of risk assessment?
- How has consistent, standardized risk assessment been used elsewhere to reduce risks, particularly within a regulatory framework?
- What are examples of mechanisms to support and encourage use of risk assessment by 1) regulators and 2) regulated community, especially within a regulatory framework?
- What are examples of mechanisms to support and encourage timely and effective corrective and preventive action by regulated community?
- What are examples of regulatory models and methods from other industries used to reduce safety and security risks?
- What are examples of regulatory frameworks and oversight mechanisms to address unknown and emerging risks?

Preliminary Research Report



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Research Questions, 1

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What risks are targeted by the FSAP program?

Methods Used:

- Review of regulations
- Review of materials on www.selectagent.gov
- Interviews with DSAT staff
- Review of materials provided by DSAT
- Interviews with regulated entities

Summary:

- Regulators: theft, loss, release, public health
- Regulated entities: pending webinar data
- Annual Report –
  - ***Listed BSAT*** *have potential to pose severe threat to:*
    - HHS BSAT: public health & safety
    - USDA BSAT: animal health or animal products
    - USDA Plant Protection & Quarantine BSAT: plant health or plant products
  - ***Tier 1 BSAT*** *pose risk of deliberate misuse with most significant potential for mass casualties or devastating effects on the economy, critical infrastructure, or public confidence*

Who are the current regulators and how do they do their work? How is risk assessment currently used?

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Methods Used:

- Review of materials on www.selectagent.gov
- Interviews with DSAT staff
- Review of materials provided by DSAT
- *Interviews with regulated entities*

Summary:

- Science Office via Intergovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) – list, delist, exclusions, etc.
- Program Operations – refer to regulated entity risk assessment only when compliance is "grey"; internal effort to weight citations according to risk; identify "riskiest" activities
- Program Services – import permits applications (no detail on work) used to determine whether on-site visit is needed to assure facility suitability,

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Who comprises the current regulated community and how do they do their work? How is risk assessment currently used?

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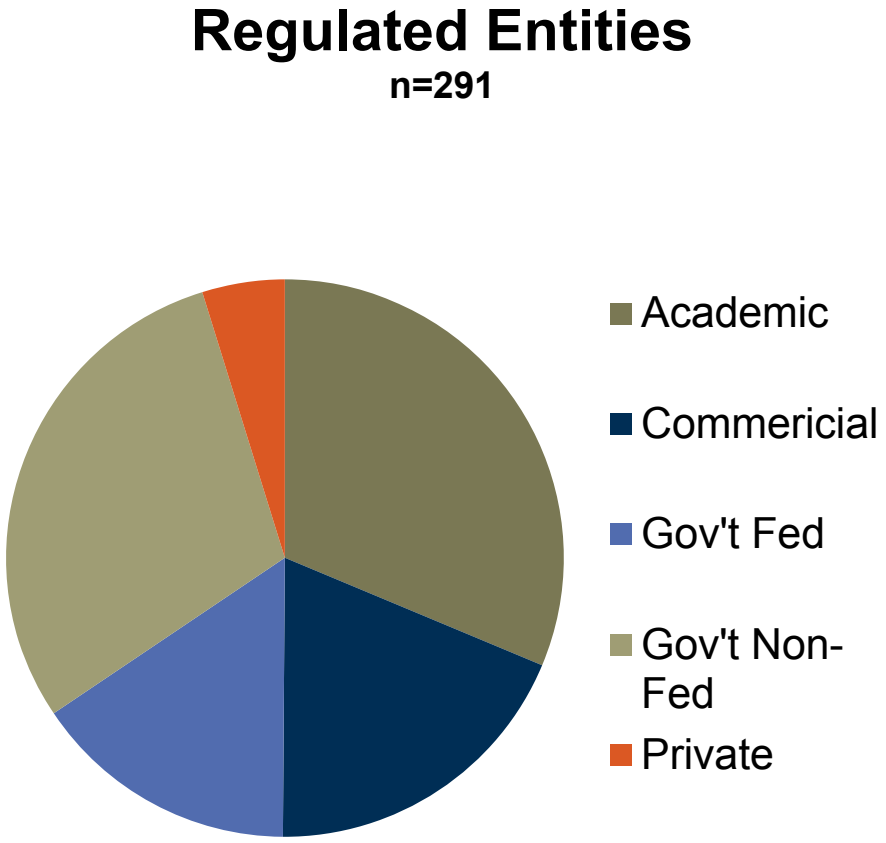
Methods Used:

- Draft Annual FSAP Report
- *Interviews with DSAT staff*
- Interviews with regulated entities

Summary:

- Academic vs. Non-fed gov't labs
- Striking diversity in mission, methods, and predictability
- Additional findings pending completion of webinars
- Entities are using BiosecurityRAM, among other methods



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Placeholder for webinar summary data, x

What would desired utilization of risk assessment look like for regulators?

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Methods Used:

- Interviews with DSAT staff
- *Interviews with regulated entities*

Summary:

- Tool that "throws everything in a pot" (agents, animals, existing mitigation, etc.) and calculates risk score. Tool would give more power at the front end of the inspection; more effectively anticipate where to focus attention
- Process that allows entities to score themselves, FSAP builds tailored inspections
- Differentiation between personnel risk and environmental risk
- Ongoing efforts: weighted citations; focus on riskiest areas; reduce variability in language between inspectors/inspection teams
- Better articulate meaning of "risk assessment" and core principles for risk assessment/management.
- *Pending webinar completion*

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What would desired utilization of risk assessment look like for regulated community

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Methods Used:

- *Interviews with DSAT staff*
- Interviews with regulated entities

Summary:

- Pending webinar summary
- Anecdotal data from first two webinars – regulated entities, for the most part, do not feel that they need to make changes to their risk assessment procedures

- *Entities need to actually implement the plans and procedures they have in place. Most workers don't know what plans says – "ask 3 people, get 3 answers"*
- *Riskiest activities: aerobiology, lyophilizer, non-human primates*
- *Inspectors don't accept training as mitigation*

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Where has the current program been successful? Are these successes translatable to other areas?

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Methods Used:

Interviews with DSAT staff

Interviews with regulated entities

Summary:

- DSAT: improved qualifications and experience of inspectors
- Regulated entities: program helps focus investigator attention on safety and security (pending webinar completion)

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Where has the current program been less-than-successful? What is the perception of the reason for the lack of success?

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Methods Used:

- Interviews with DSAT staff
- Interviews with regulated entities

Summary:

- Regulation is vague
- Too many issues to be tackled before dealing with issue of risk assessment
- Reliance on entity to provide solid risk assessment; no allowance for inspectors to offer guidance
- Pending webinar results

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Research Questions, 2

- What comprises risk assessment? What are relevant examples/models of risk assessment?
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- What are examples of regulatory frameworks and oversight mechanisms to address unknown and emerging risks?

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

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Methods Used:

- Literature Review

Summary:

- 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

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How has consistent, standardized risk assessment been used elsewhere to reduce risks, particularly within a regulatory framework?

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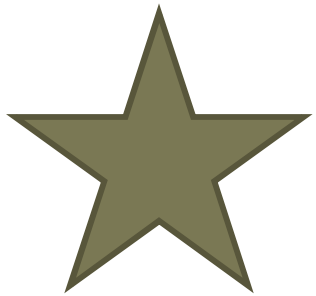
Methods Used:

- Literature Review

Summary:

- Questions about how to do risk assessment seem more frequent than solutions.
- When used in regulated industries, risk assessment (by regulated community) is more likely to be found as part of voluntary, above-and-beyond programs (accreditation, certification, etc.)
- Recent discussion on roles of “risk assessors” and “risk managers” – previous code of practice was to keep roles/actions separate; new thinking questions the benefit of separation; history of life sciences is reverse of this.



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What are examples of mechanisms to support and encourage use of risk assessment by 1) regulators and 2) regulated community, especially within a regulatory framework?

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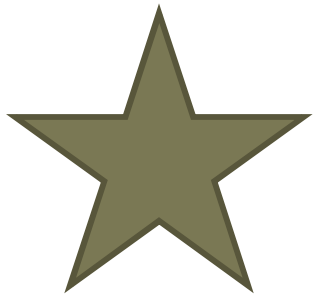
Methods Used:

- Literature Review

Summary:

- Not much data on this question



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What are examples of mechanisms to support and encourage timely and effective corrective and preventive action by regulated community?

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Methods Used:

- Literature Review

Summary:

- Recent discussions across a variety of industries highlighted a safety or security culture approach to improve regulated community response to unsafe or insecure conditions.

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What are examples of regulatory models and methods from other industries used to reduce safety and security risks?

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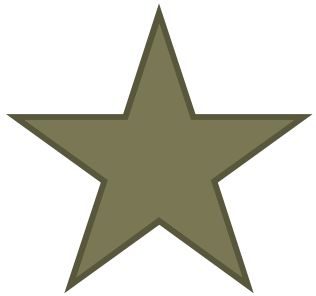
Methods Used:

Literature Review

Summary:

- Most current literature focuses on “culture”
- Evolution of incident prevention:
  - ***Technology*** *– the application of engineering or other technical measures to control hazards and prevent injuries; this approach presumes that a linear chain of events causes accidents*
  - ***Systems*** *– utilizing understanding of interactions between people, tasks, technology and the environment to pursue risk reduction goals; accidents result from complex interactions*
  - ***Culture*** *– targeting organizational shared values, assumptions, and beliefs towards and relative importance of workplace safety; highlighted by management commitment and involvement; this approach recognizes that it is rare that a single individual bears the entire responsibility for an undesirable outcome*



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What are examples of regulatory frameworks and oversight mechanisms to address unknown and emerging risks?

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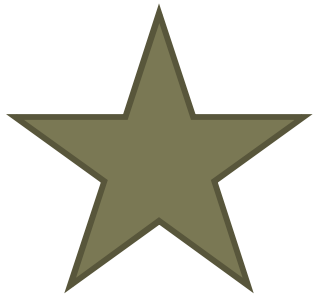
Methods Used:

Literature Review

Summary:

- Utilize same risk assessment framework focusing on what is known:
  - *What can go wrong?*
  - *How likely is the incident?*
  - *What are the consequences?*
- Advocate an integrated approach to risk assessment where personnel are competent and utilize critical thinking to address unexpected situations.



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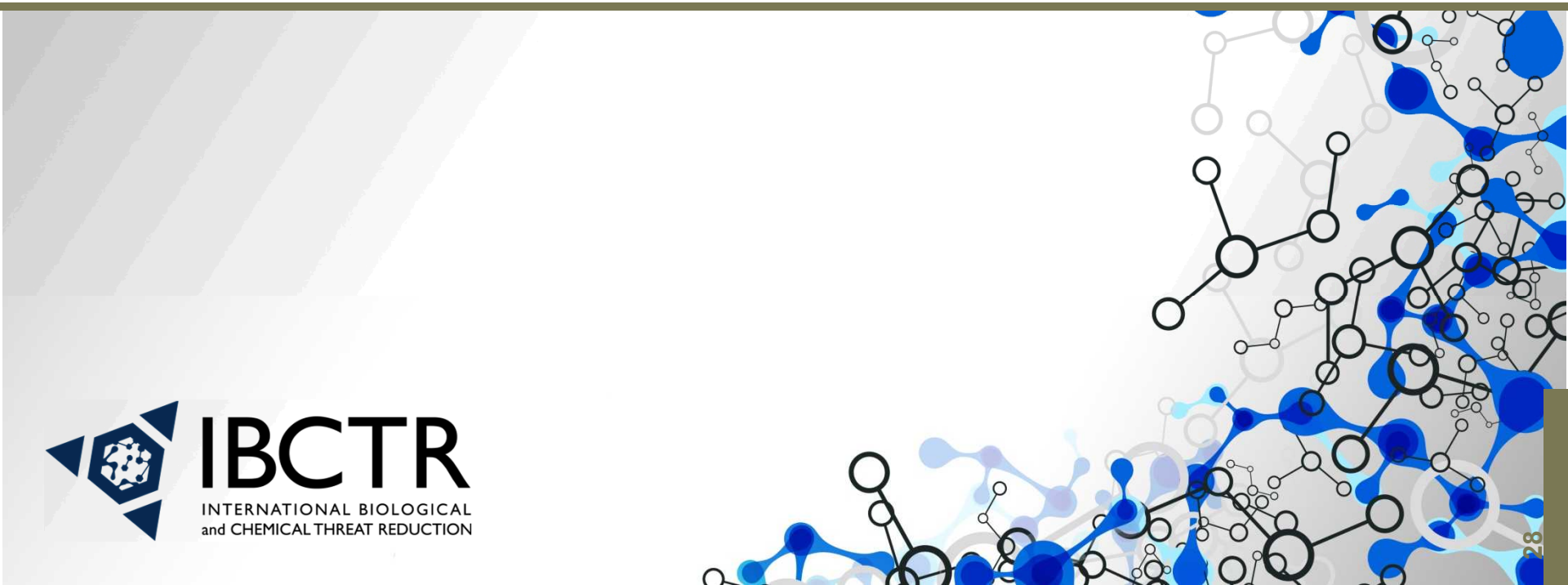
Preliminary Findings



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Terminology and Process for Risk Assessment

Common terminology around risk and risk assessment holds different means for different persons and organizations making meaningful dialogue difficult.

The specific definition of FSAP-targeted risk(s) is imprecise and, at times, unstated.

Risk assessment is utilized more as a working concept than as a documented, repeatable, or comprehensive, objective process.

Pre-Determined Risk Assessment/Assignment

FSAP (and other governing entities) assign a significant number of risk governance determinations (e.g., the BSAT list, the containment level assigned for each agent, the mitigation strategies comprising the containment level, etc.). It is unclear what benefit a risk assessment at the regulated entity level will have.

The listing of agents and the subsequently assigned containment levels and mitigation strategies appear to focus merely on consequence regardless of the likelihood of the risk occurring.

Risk Assessment or Risk Mitigation?

- The regulation requires the entities to prepare a risk assessment in order to develop their biosafety, security, and incident response plans; however, it is unclear what specifically the application of the risk assessment is to be. Is this the point where the entities evaluate how they are using the organism and the likelihood of the specific risk occurring and then develop plans to address that? If so, what is evaluated during an inspection? It appears that the "space" allowed the entity for risk assessment would be for the entity to choose, using risk-based decision making, between various mitigation options – each of which must meet the approval of the inspection team.
- In order to effectively align risk mitigation strategies with the risks defined and characterized in the risk assessment, the regulated entity must be privy to the information utilized to characterize the risk.
- While containment levels and the comprising mitigation strategies are pre-assigned, there is limited information and evaluation on the actual alignment of the identified risks with the assigned mitigation strategies.

Communication

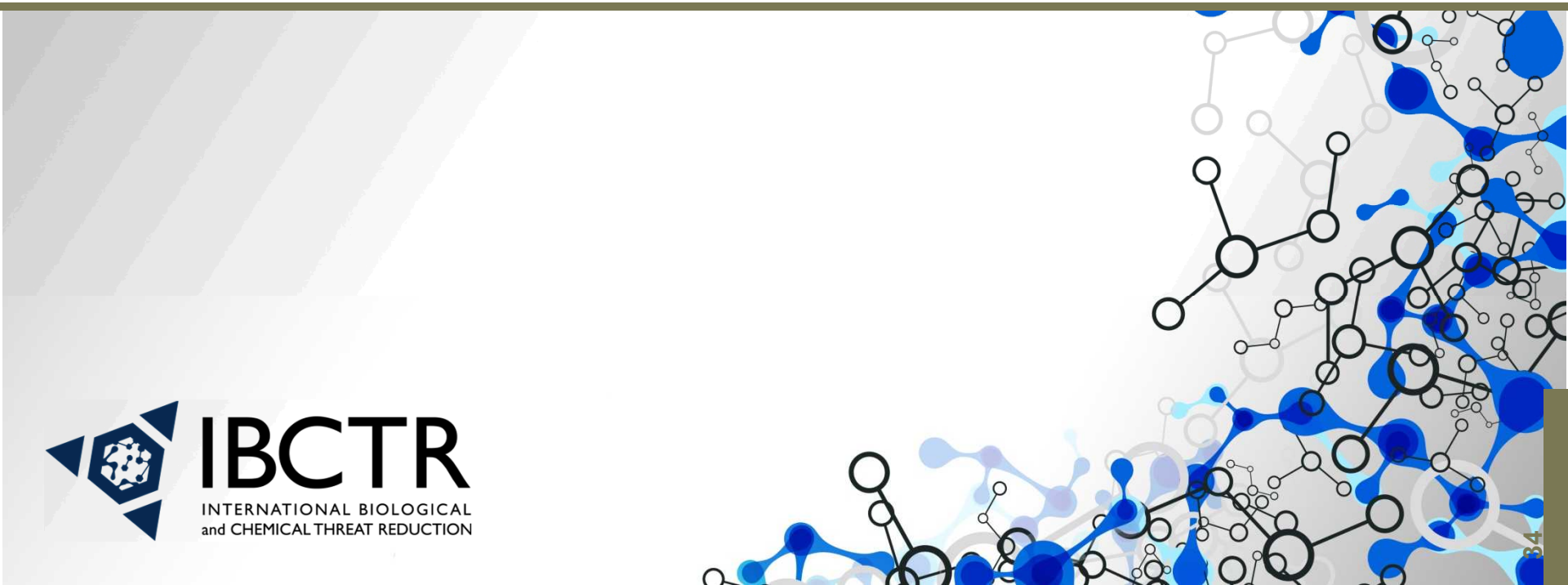
Regulators indicate that entity risk assessments “support what the entity wants to do.” In the best case, this is exactly what should happen. A risk assessment is performed and the entity determines if it can or cannot go forward with the work. However, a “self-fulfilling” risk assessment might also be presumed to be back-filled merely to support desired work without regard to actual risks or effective risk controls. Entities must be able to articulate and justify their risk assessment and the alignment of the risk assessment with the risk mitigation strategies chosen

FSAP inspectors have accumulated a wealth of knowledge on best practices of biorisk management (and not-so-best practices) of BSAT that could be of benefit to risk reduction. These are not being shared with the community.

Compliance versus culture

Risk assessment and management described in the regulations and in guidance documents is strictly technical and laboratory-based. Little to no acknowledgement of the role that a management system or institutional structure plays in risk management is present. Incidents from other industries consistently point to the lack of a “culture of safety (or security)” as key to the failure.

Questions for Panel Consideration



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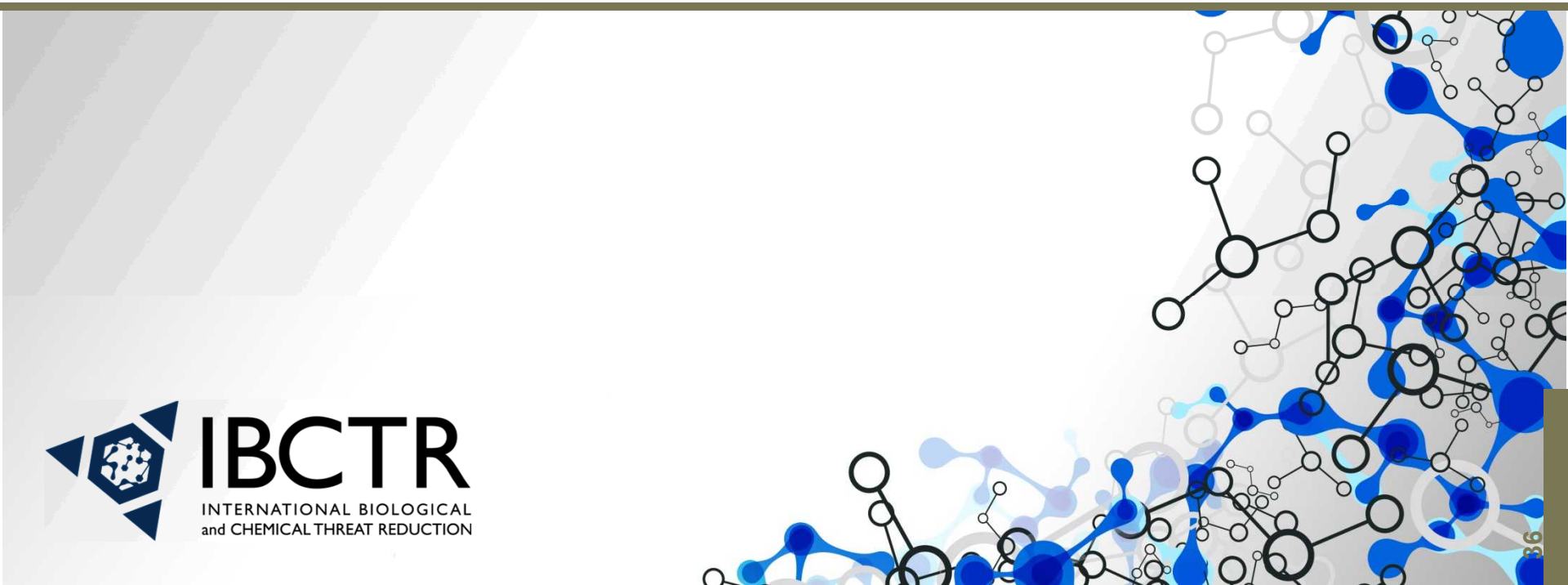
Comments? Questions?



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