



OPPORTUNITIES FOR RISK COMMUNICATION USING BIORAM

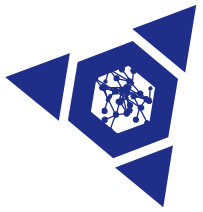


**"how to get people to understand
the risks you are talking about"**

SAND No. 2011-0083C

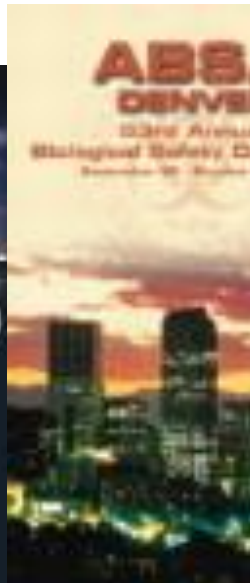
Sandia is a multiprogram laboratory operated by Sandia Corporation,
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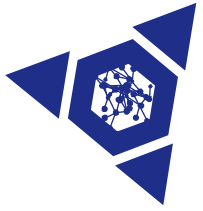




Once a year at ABSA – Why?

- To meet the friends
- Create network
- Find new tools and products

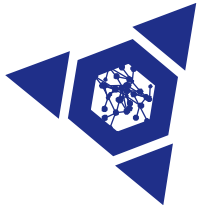




What do we have in common?

- Communicate with the staff
- Dialogue with PI's
- Enlighten the IBC's
- Struggle with management





How do we...

- Motivate ...
 - Convince ...
 - Inspire ...
 - Get money ...
 - Get support ...
-
- When all we can say is that ... we *think* we did make a difference in last fiscal year

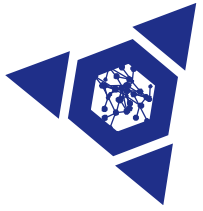




What is the value of ...

- An incident ...
- A LAI
- A parent





These are the questions...





Where do we want to be?

- **We want to live an easy life**



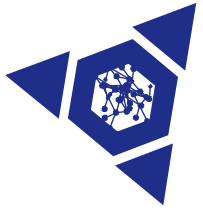
- **Everybody *immediately* will do what we ask them!**
 - Bosses
 - PI's
 - IBC's
 - Employees



What is the likelihood...

- ...that we will get that message conveyed smoothly, easily and without resistance?





What is the consequence...

- ...if we do not succeed as good Biosafety Communicators?





How do we get there?

- ... Use the BioRAM tool as a mean to make it obvious to the rest of the world, that there is ***NO BETTER WAY*** than do *exactly* as we say!



Biosafety risk assessment methodology
Biosecurity risk assessment methodology
Both have relied extensively on external
experts from the international community
BioRAM Lite is the version that was
created for this WHO training course
The full BioRAM models are still under
development, and we hope to release
them publicly in the next year

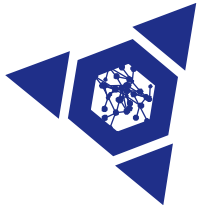


➤ Vision

- A standardized approach to risk assessment
- Create understanding
 - A tool for prioritization
 - A tool for communication

➤ Mission

- Get consensus
 - **What risks do we see in bio-labs**
 - Get stakeholders from all over the world to help
- Create tool
 - **Make it available**



Strategy

- **Brainstorming**
- **Workshops**
- **Software design**
- **Workshops**
- **Software modification**
- **Workshops**
- **Software adjustment**
- **α , β testing**
- **Software finalizing**
- **Workshops – report templates**





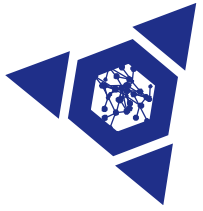
It takes more than just a strategy ...

➤ **A project lead ...**



➤ **Willingness ...**





BioRAM

Idea to Product: 3 years





Risk Questions: Humans and Animals

➤ **Transmissibility**

- Inhalation
- Percutaneous
- Contact
- Ingestion

➤ **Agent characteristics**

- Morbidity
- Mortality
- Stability
- Mitigation methods

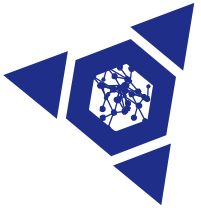
➤ **Likelihood of exposure**

- Laboratory process
- Animals

➤ **Biosafety mitigation measures**

- Containment
- Procedures
- Management
- PPE

➤ **Secondary transmission**



Biosafety RAM



Risks based on routes of exposure

Inhalation
Ingestion
Contact
Percutaneous

Agents

MSDS

Procedures

Safe

Unsafe

Risk Assessment Model Beta

File Preliminary Info Assessment

Likelihood of Infection

Transmissibility

Humans

Inhalation

Is this agent known to cause infection via inhalation in humans (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in a laboratory setting?

2

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

3

4 = Yes
2 = No
0 = If this is not an infectious route

Percutaneous

Is this agent known to cause infection via percutaneous exposure in humans (to cause infection through compromised skin or direct injection into the blood stream) in a laboratory setting?

1

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

2

4 = Yes
2 = No
0 = If this is not an infectious route

Direct Contact

Is this agent known to cause infection via direct contact in humans (to cause infection through the mucosal membranes) in a laboratory setting?

3

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

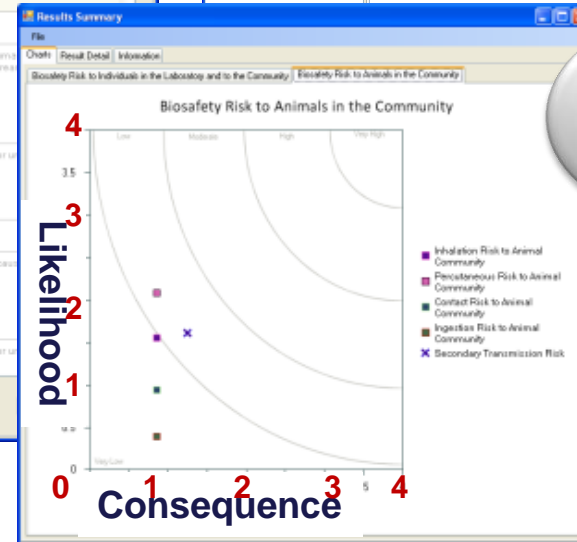
Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown in humans?

Response:

Flag response as an unknown answer

Results Summary

File	Default Chart	Results Summary	Question Impact	
1.259205	Likelihood Ingestion Individual	Cumulative Weig	Relative Weight	Question
1.264723	Likelihood Inhalation Individual	0.0		Is this agent known to cause infection via inhalation in humans (to
1.020762	Likelihood Percutaneous Individual	0.246		Are aerosolization experiments being conducted as part of this pr
0.461329	Likelihood Contact Individual	0.2214		What is the potential for aerosols to be generated as a byproduct
0.800189	Likelihood Ingestion Community	0.162		Is the infectious dose (ID50) of this agent for this route less than
2.456538	Likelihood Inhalation Community	0.2		Is respiratory protection used in the procedure? (logical result a
1.275876	Likelihood Percutaneous Community	0.1476		What is the potential and extent of a splash or spill in the procedu
1.410125	Likelihood Contact Community	0.135		Does the laboratory have procedures in place for agent handling
0.938443	Likelihood Ingestion Animal	0.102		Are Biosafety cabinets used in this procedure?
1.553851	Likelihood Inhalation Animal	0.102		Is all the equipment used in this procedure with a potential to gen
2.003436	Likelihood Percutaneous Animal	0.102		Are other forms of Primary Containment used in this procedure?
0.938620	Likelihood Contact Animal	0.07425		What is the containment process for the decontamination of equi
0.348362	Consequence of Disease to Humans	0.063804		What type of material will be used in this procedure? (if the proc
1.263778	Secondary Consequence of Disease to Animals	0.07425		Are animals housed in a manner that isolates or sealed to prese
0.68176	Consequence of Disease to Animals	0.07425		Are animals handled in isolation to prevent aerosol escape (e.g. i
1.24215	Consequence of Disease to the Community	0.07425		Does this laboratory have animal handling procedures in place to
0.36883	Consequence of Disease to the Community	0.045		Are there any animals are in use in this procedure?
1.762752	Likelihood of Secondary Transmission	0.03		What is the local size of these animals?
1.638731	Likelihood of Secondary Transmission	0.038996		Will the greatest volume of material existing at one time in the
		0.03		Are there more than one species of animal in use in the laborato
		0.03		Are there any animals which have the potential to shed infectious particles
		0.03		How often do the laboratory animals used in this procedure
		0.02		Does the laboratory have defined roles and responsibilities for bio
		0.00594		Has the laboratory made a commitment to safety?
		0.00594		Does the laboratory periodically review the laboratory program?
		0.00336		Are there procedures in place for preventative equipment mainte
		0.00336		Does the laboratory have comprehensive biosafety documentation
		0.00336		Does the laboratory have biosafety skills or exercises?
		0.00336		Are there standard operating procedures in place for unexpected
		0.00336		Does the laboratory have standard good laboratory practices
		0.00152		Is there a formal training program in place for unexpected
		0.00152		Is there a formal training program in place for unexpected
		0.00096		Are all biological laboratory inventories?



Risk drivers

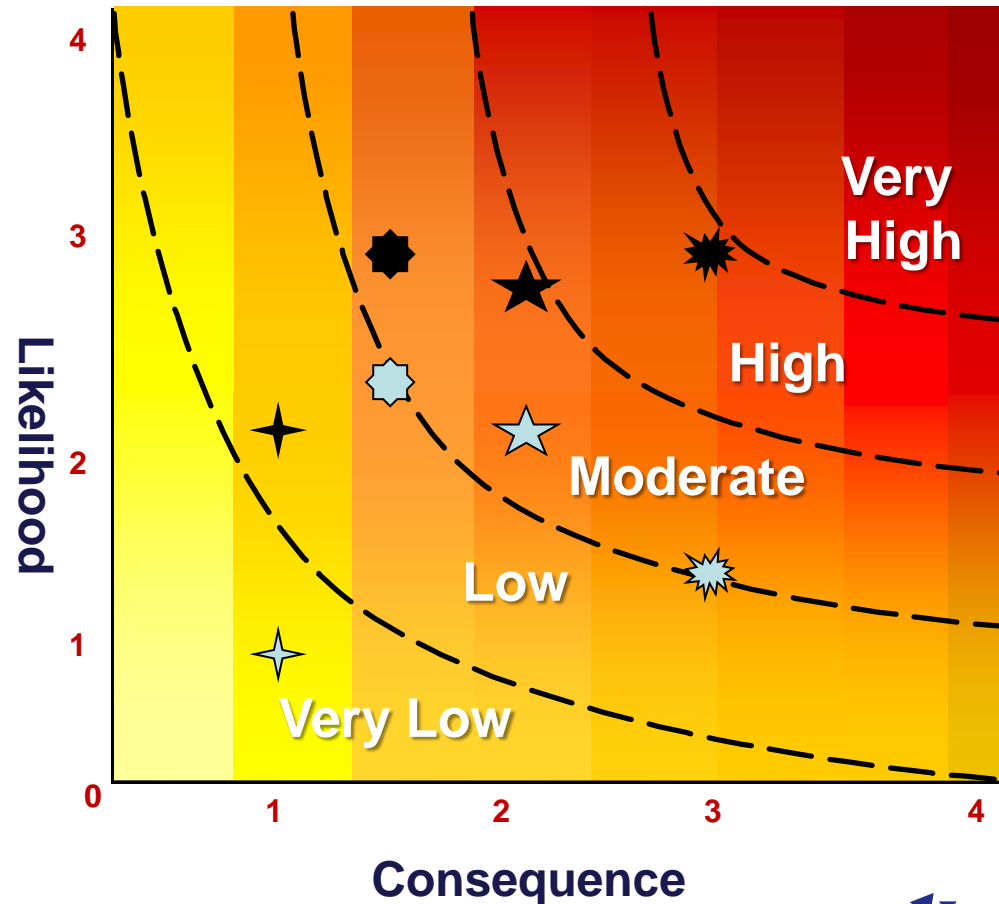


Likelihood – Consequence

Biosafety

Biosecurity

Both need to be addressed





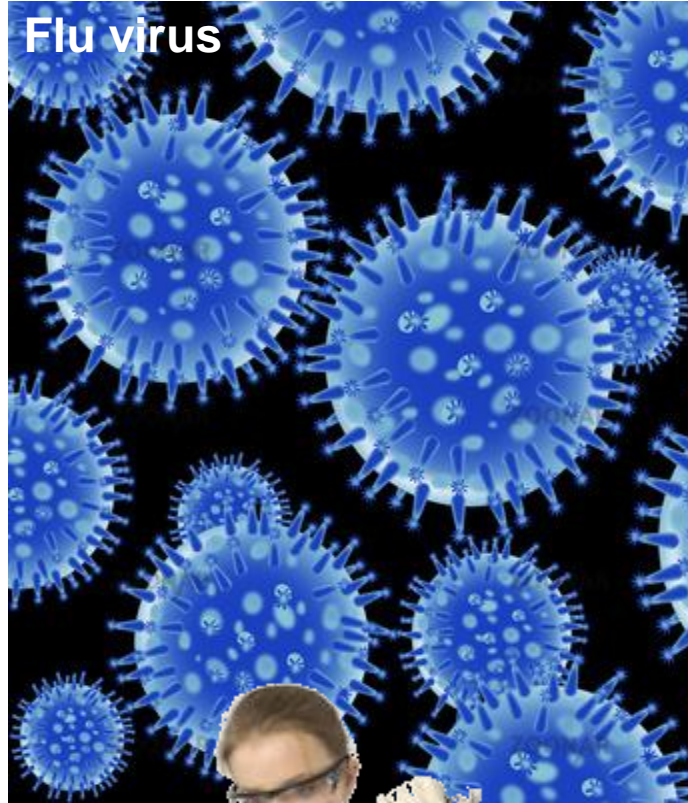
Biosafety RAM



Agents

Procedures

Flu virus





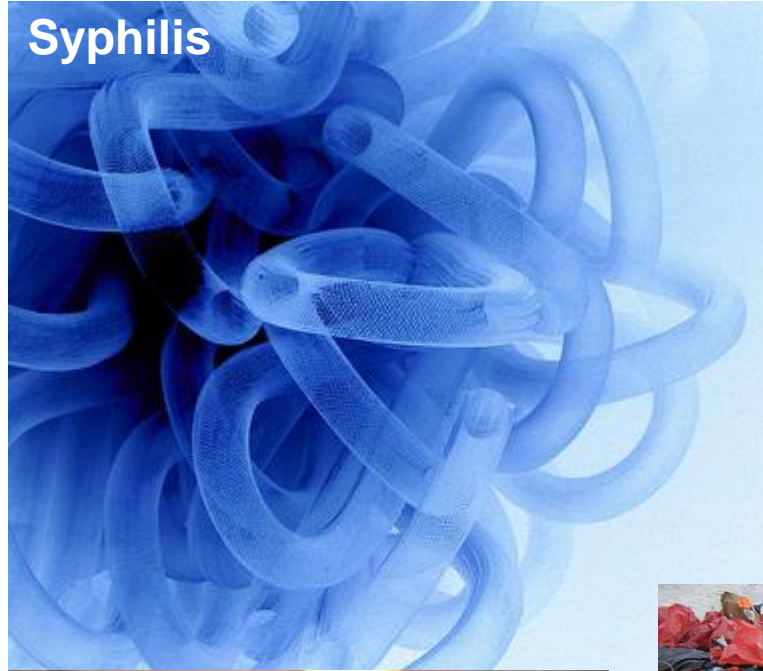
Biosafety RAM

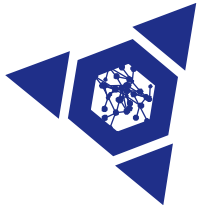


Agents

Procedures

Syphilis





BioRAM visual impact

Example

Spietz
Laboratory

Switzerland

Nipah Virus

Data from Spiez Laboratory Review of Biosafety RAM model (Daniel Kumin)

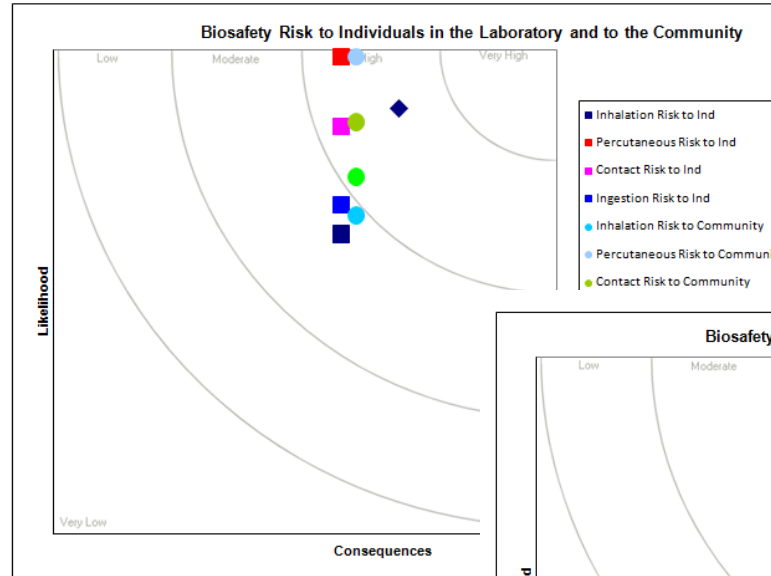


Figure 1: Risks posed by Nipah Virus prior to any implementation of Mitigation

After
mitigation

Before
mitigation

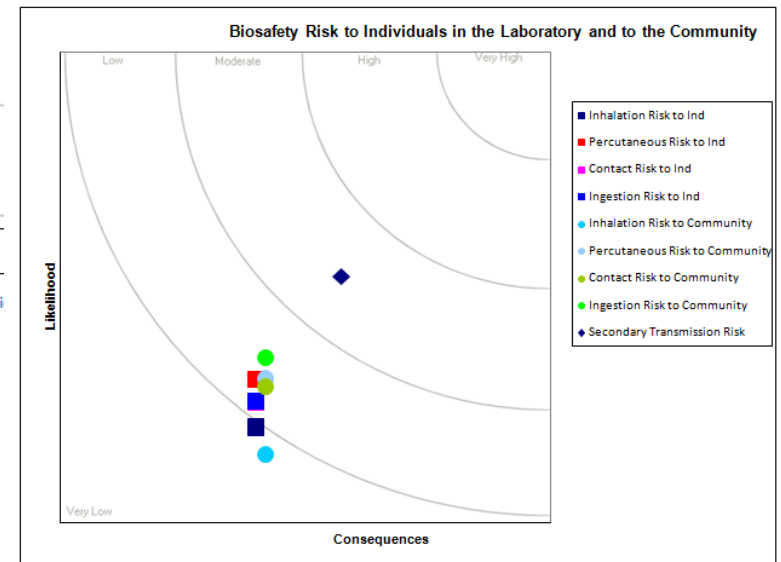
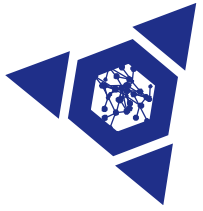


Figure 2 Risks posed by Nipah virus post implementation of procedural, engineering, and ppe control measures



A TOOL FOR COMMUNICATION



Strengths

Weaknesses

Opportunitites

Threats

**MANY STRENGTHS
FEW WEAKNESSESS**



BioRAM - SwOT

Combines
expertise from
many sources



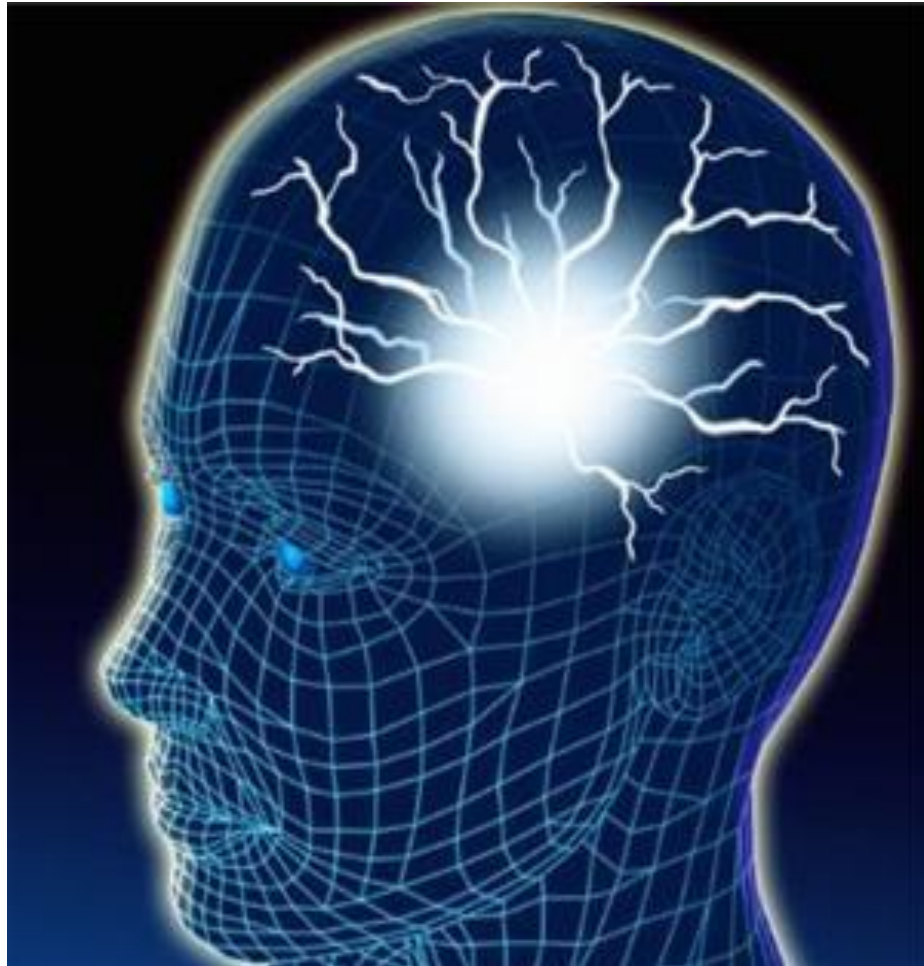


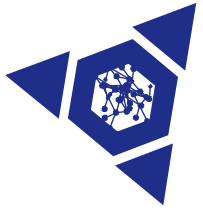
BioRAM - SwOT

Intuitive
Straight forward

Short training

Visual





BioRAM - Swot

Time saving

Same agent -
different
procedures

Same
procedure -
different agent

Repeated
analysis

Comparison of
results





BioRAM - SwOT

Fast

Takes out
years of trial
and error for
making a good
risk
assessment

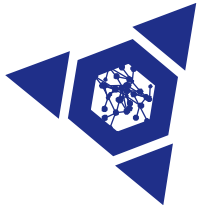




BioRAM - SwOT

Precise





BioRAM - SwOT

Standardized

**Encompasses
what many
have found
relevant**

Structured

Systematic

Prioritizes





BioRAM - SwOT

Flexible

Allow for interpretation

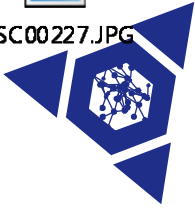
Allow for own decision of :

- what to mitigate
- when
- how to shape your strategy





DSC00227.JPG



BioRAM - SwOT

Cheap!!

➤ **Actually – it is free !!!**

➤ <http://www.biosecurity.sandia.gov/BioRAM/BiosafetyRAMSoftware.zip>

➤ <http://www.biosecurity.sandia.gov/BioRAM/BiosecurityRAM.zip>



BioRAM - sW_{OT}

Clinical labs

“Unknowns”





BioRAM - sW_{OT}

Training
needed for full
success?

Probably yes

... When is
training not
needed for
mastering a
new skill?

GARBAGE IN,
GARBAGE OUT.



BioRAM - swO_T

2011

Chinese,
Indonesian,
Japanese,
Spanish

2012

Arabic, Urdu,
French, Dari





BioRAM - swO_T

Have an
accepted
communication
tool

Up

Down

Across

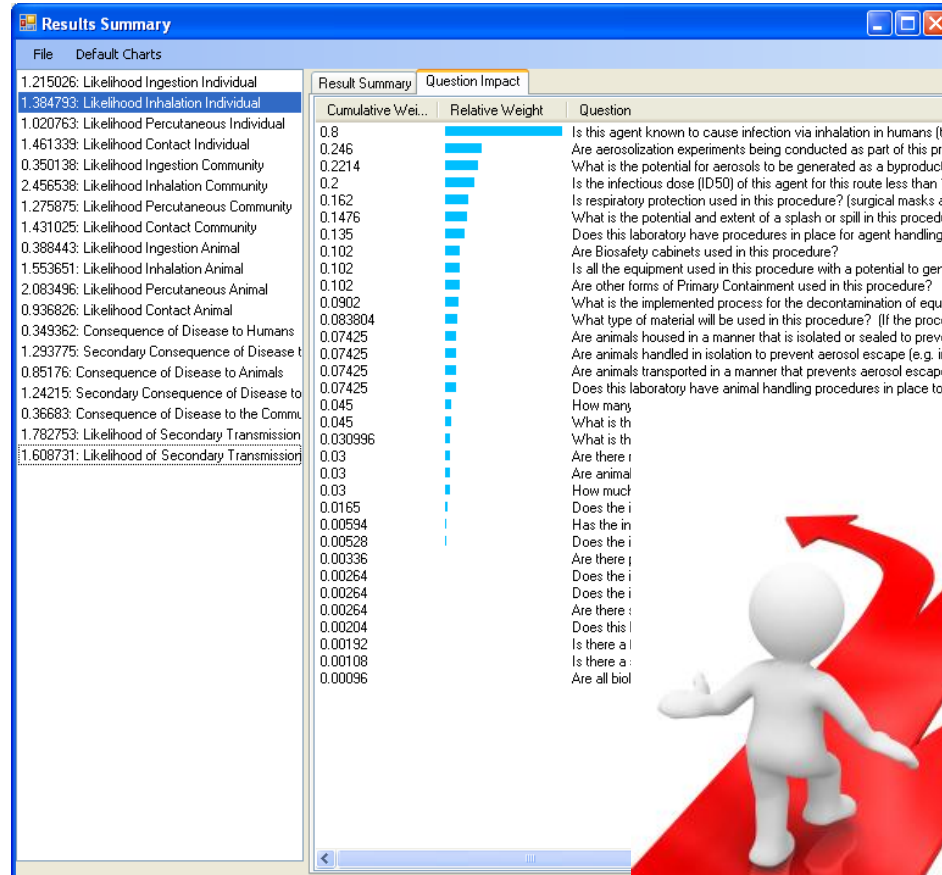


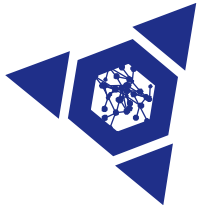


BioRAM - swOT

Prioritizes

Which risk drivers ramp the risk up





BioRAM - swoT

People
“forget” to use
their brains

Accepting at
“face value” the
results of the
BioRAM

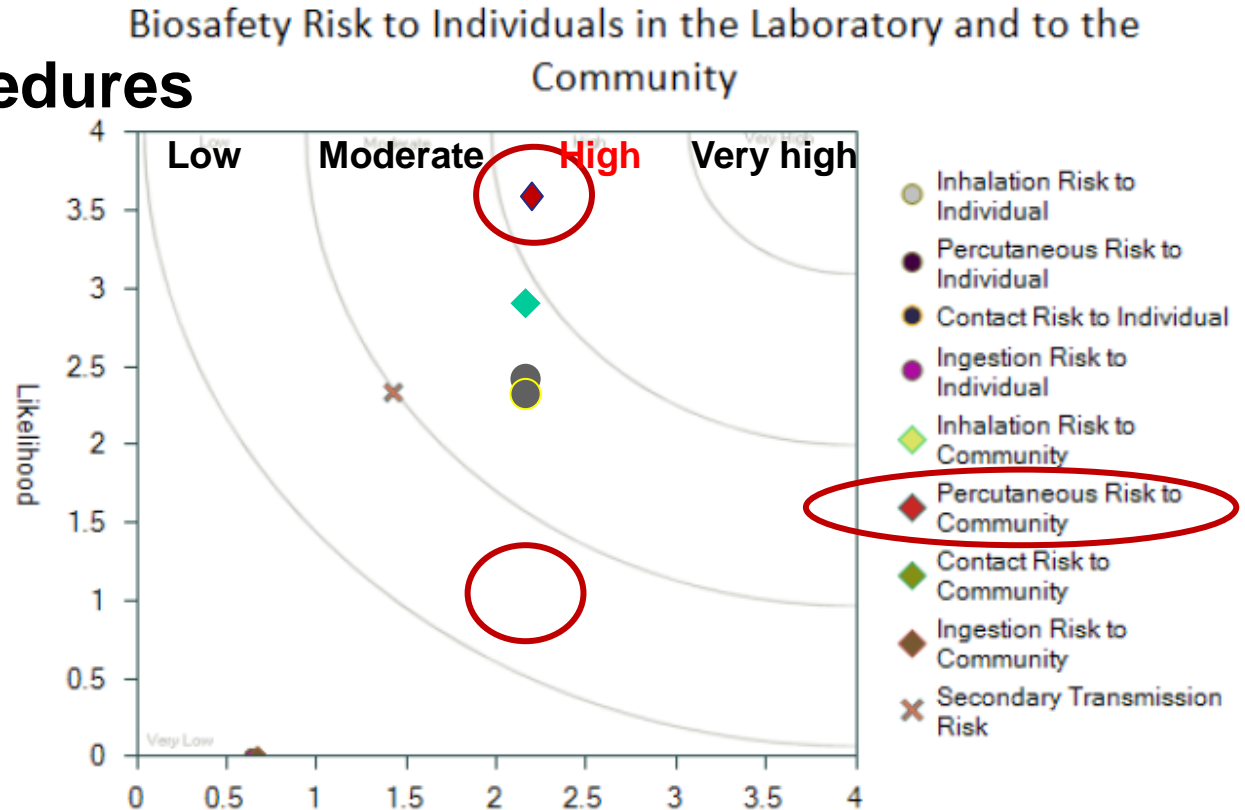




BioRAM – Waste Example

Waste procedures

- Before
- After



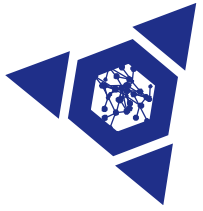
Is there a waste and decontamination program in place?

0 = There is no waste management and decontamination program at this laboratory

1 = This laboratory has limited procedures in place for waste management and decontamination

2 = This laboratory has some procedures in place for waste management and decontamination, but lacks oversight in implementation

4 = This laboratory has a comprehensive waste management and decontamination program, and well-defined procedures in place



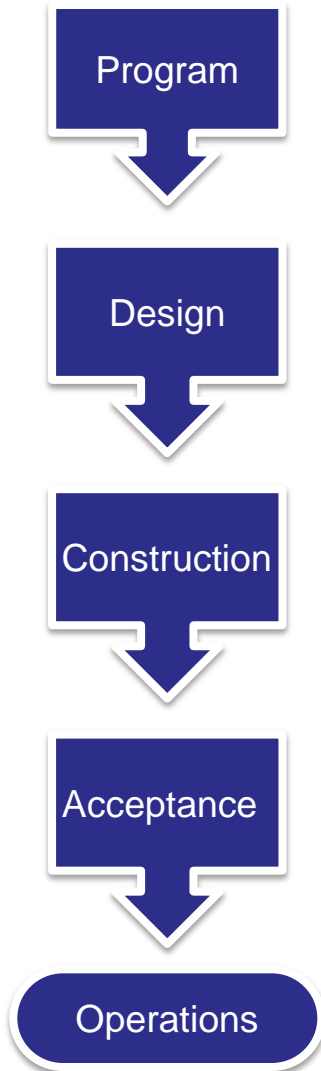
BioRAM during a building project

- To identify important key components in Impact Assessment during a building phase
- To counterbalance Value Engineering and stop contractors in time





BioRAM during a building project



➤ **Programming phase.**

- Compare agents, and make sure that mitigation measures makes sense and is tailor suited to the actual risk

➤ **Design Phase**

- Use as a tool to go for different mitigation measures if budget is narrow

➤ **Construction phase**

- SOP or engineered design?
- Use as an evaluation tool for deciding which engineering controls to take out

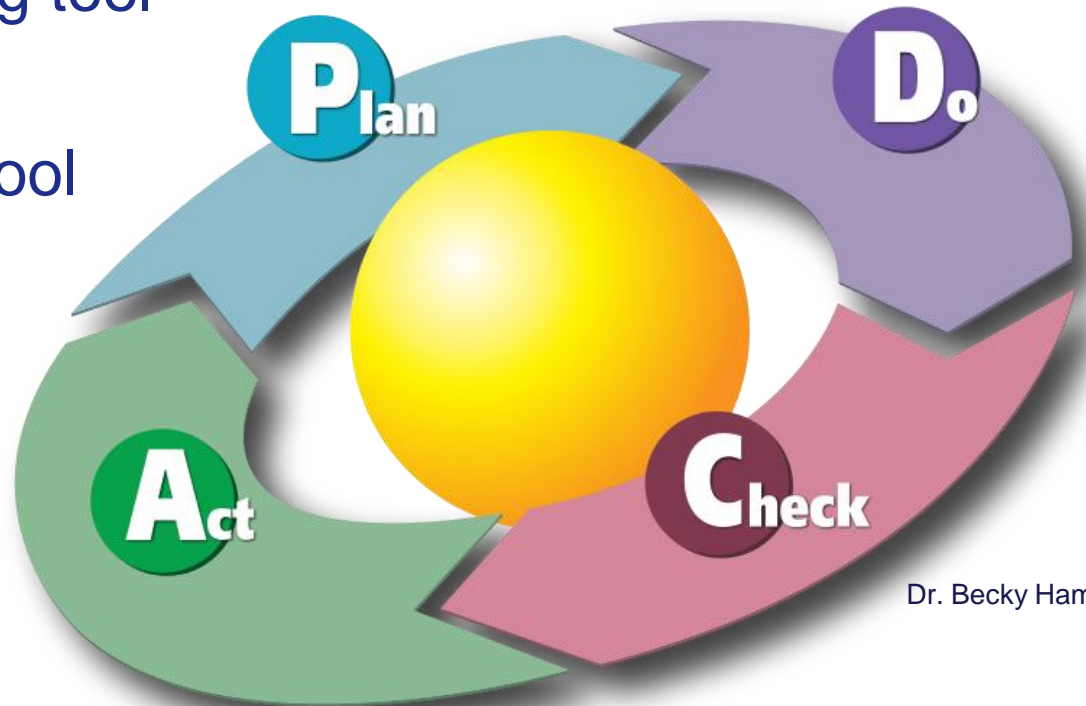


BioRAM

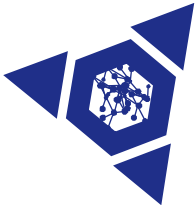
CWA 15793:2008

➤ PDCA cycle

- As a planning tool
- As a check tool
- Reporting



Dr. Becky Hammonds



CWA 15793:2008

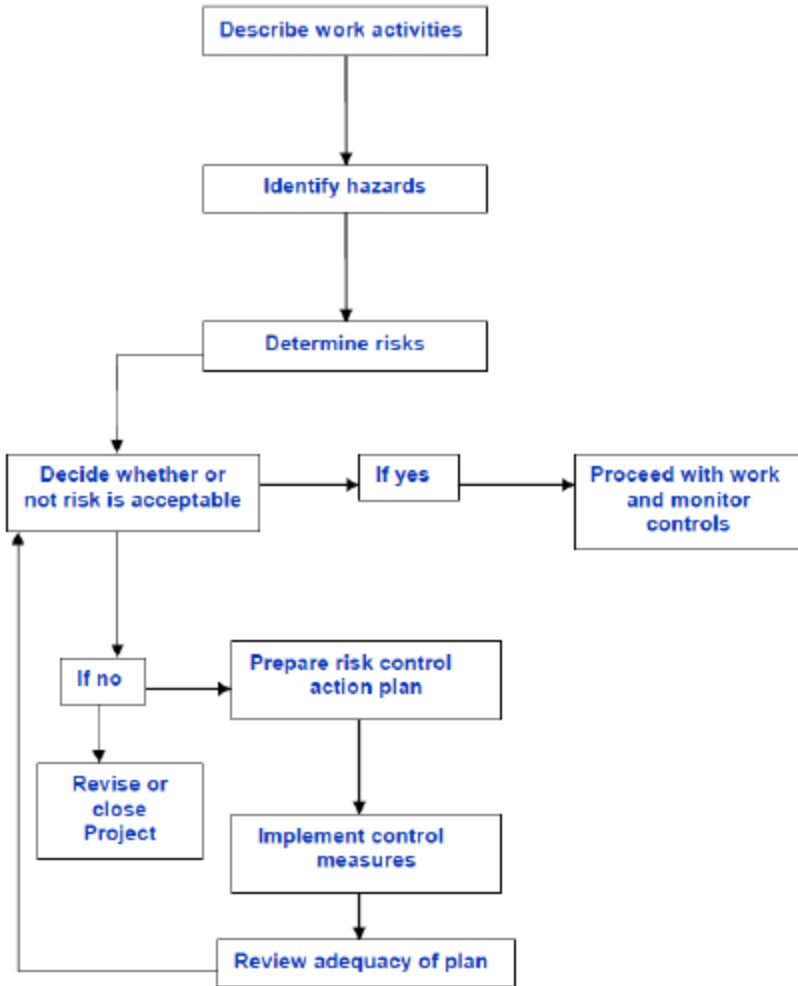
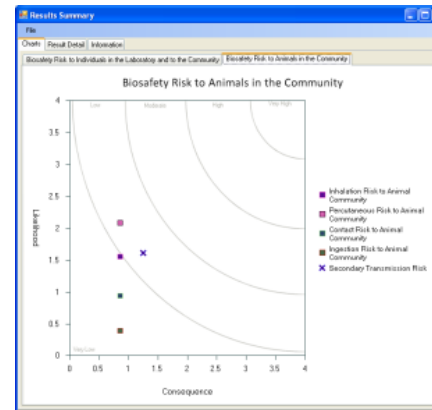


Figure 1 — Risk assessment strategy

Risk Assessment

- Physical Description of Laboratory Environment:
- Describe Procedure:
- Identify Biological Hazards:
- BioRAM results:

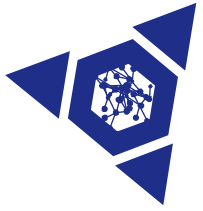


Question ID	Relative Weight	Question
1.215026	0.8	Is the agent known to cause infection via inhalation in humans?
1.020763	0.245	Are aerosolization experiments being conducted as part of this project?
1.401333	0.2214	What is the potential for aerosols to be generated as a byproduct of the infectious dose (IC50) of the agent for this route less than 100 µg?
1.239076	0.1762	Is respiratory protection used in the procedure? Typical masks or respirators?
1.410025	0.1476	What is the potential and extent of a splash or spill in this procedure? Does the laboratory have procedures in place for agent handling?
1.391443	0.1192	Are biohazard cabinets used in this procedure?
1.253651	0.1102	Is all the equipment used in the procedure with a potential to generate aerosols?
2.003496	0.102	Are other forms of Primary Containment used in this procedure?
1.933025	0.09504	What type of materials will be used in this procedure? If the procedure involves the use of animal tissues, are they decontaminated or autoclaved prior to use?
0.345362	0.07405	Are animals housed in a manner that prevents aerosol escape?
1.231775	0.07405	Are animals handled in isolation to prevent aerosol escape (e.g. in a biosafety cabinet or a manner that prevents aerosol escape)?
0.30503	0.07405	Does the laboratory have animal handling procedures in place to minimize aerosol escape?
1.34215	0.045	What is the typical size of these animals?
1.609721	0.03266	What is the greatest volume of material being at one time in the laboratory?
1.231775	0.03	Are there more than one species of animal in use in the laboratory?
1.609721	0.03	Are animals which have the potential to shed infectious particles housed in a manner that prevents aerosol escape?
1.231775	0.03	How much waste do the laboratory animals used in the procedure generate?
1.609721	0.0119	Does the institution have defined roles and responsibilities for biohazard waste management?
1.609721	0.0094	Has the institution made a commitment to safety?
1.609721	0.0052	Does the institution periodically review the biosafety program?
1.609721	0.0033	Are there procedures in place for preventative equipment maintenance?
1.609721	0.0024	Does the institution have comprehensive biosafety documentation?
1.609721	0.0024	Does the institution conduct biosafety drills or exercises?
1.609721	0.0024	Are there standard operating procedures in place for unexpected events?
1.609721	0.0024	Does the laboratory implement standard good laboratory practice (GLP) procedures?
1.609721	0.00132	Is there a formal personal protective equipment (PPE) program in place?
1.609721	0.00108	Is there a shipping and receiving program in place at the laboratory?
1.609721	0.00066	Are all biological agents in the laboratory inventory?

- Discuss the results
- Determine Acceptability of Risks:
- Action control plan (mitigation measures):
- Plans for review and validation:



**DOES IT MATTER IF IT IS NOT
110% CORRECT?**



110%?



➤ **It depends!**

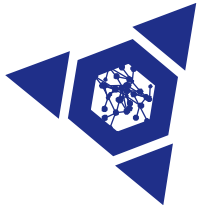
➤ How is it used?

- If used as a relative tool, before and after ... it takes out the bias

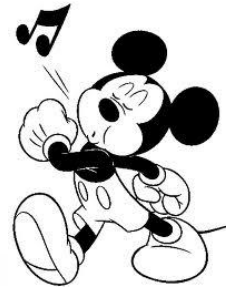
➤ Use the brain!

- **GI GO**

GARBAGE IN,
GARBAGE OUT.



110%?



- **The context is important**
 - Comparing
 - Not in absolute numbers

- **We are already used to putting arbitrary numbers on biorisk**

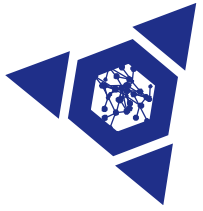
- **And we can only count to 4 !**





The new unskilled PI

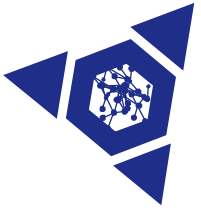




A PI stuck in his old ways

- **Might be so happy with his own knowledge that he will "forget" to call in the other stakeholders**
 - Does he know all there is to ask?
 - Has he gotten lazy and skips some of the questions?





The BSO's



- **WHO?**
 - New BSO

 - New tasks for the old BSO
 - **New expertise areas**

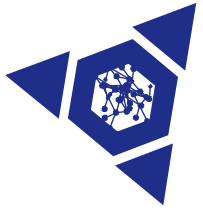
- **A tool for communication with the PI's**



Communication with PI's

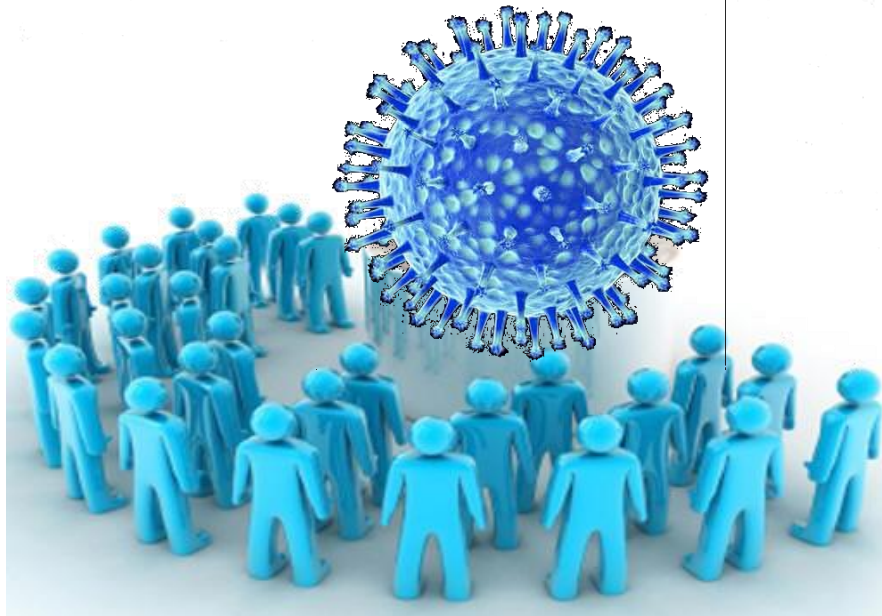
- ...”It is not me chasing you ...
 - ... it is the tool that tells us that this can be done safer!”
- **Outcome:**
 - Closes the discussion about “who is the expert here in my lab – Huh?”





More than the BSO and the PI

- Too often universities are happy to outsource risk assessment to a single person
- The BioRAM process forces people to work together and **get better buy in**

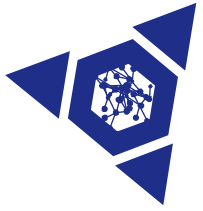




Communication with Management

- Show “the bang you get for your buck”
- Communicating several levels up the chain
 - Give them a message they can use without diluting the message
 - “We are *here* this year compared to *there* last year”
 - Easy way to quantify and communicate an average risk across an institution





Communication tool to IBC's

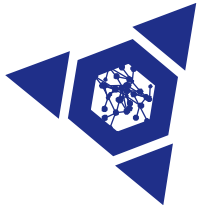


- **Make a complex topic understandable for non-experts in less than 5 minutes for approval or rejection**



- **If IBC feels timid and unsure, they want more information and postpones decisions**

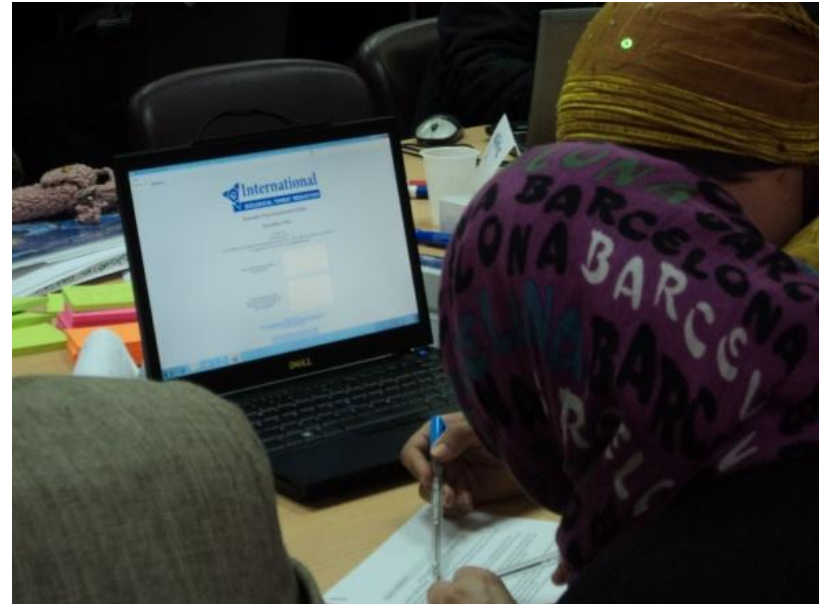
- **Graphics is understood in a split second**



Biosafety RAM

Biosecurity RAM

2 TOOLS





Laboratory Bio*safety* Risk Assessment Project (Biosafety RAM)

$$\text{Risk} = f(\text{Likelihood, Consequence})$$

Likelihood

- The likelihood of **infection by the agent** and the likelihood of **exposure** through an infectious route based on the **procedures and work practices**

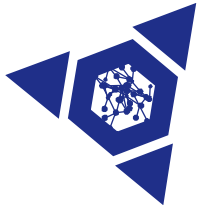
Consequences

- Of disease from **accidental exposure**

Risks

- To laboratory workers
- Risk of accidental exposure to human and animal community
- Risks of secondary infection





Laboratory Bio*security* Risk Assessment Project (BioRAM)

$$\text{Risk} = f(\text{Likelihood, Consequence})$$

Likelihood

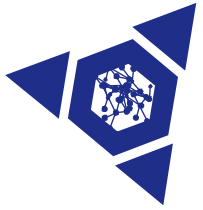
- The likelihood of **targeting a laboratory** based upon the agent's **potential for malicious use** and the likelihood of **successful acquisition** of the agent from the laboratory

Consequences

- Of disease from **malicious release**

Risks

- Risks to human and animal community



It is free
We want your input
We need to improve
We can only do this, if even more stakeholders take part in the last tuning of the tool



THIS WAS MADE WITH PUBLIC MONEY
IT WAS DEVELOPED FOR PUBLIC USE
IT NEEDS PUBLIC INPUT TO SUCCEED

Go to: <http://www.biosecurity.sandia.gov>.. and follow the links





Discussion and Questions

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