Performance and Program Management

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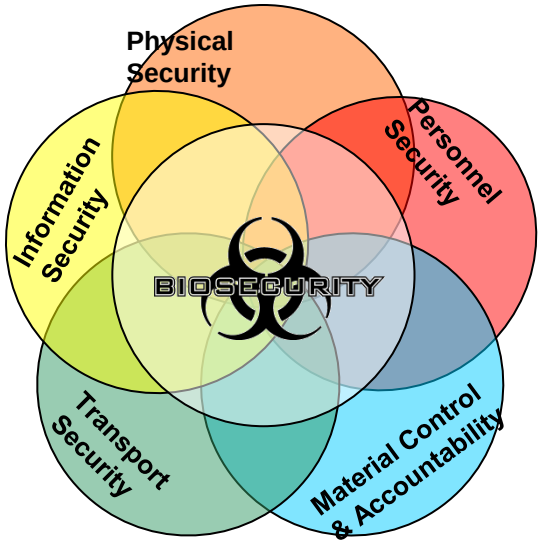

Controlling Laboratory Biorisks Training Course 2012

International Biological Threat Reduction Program

Global Security Programs

Sandia National Laboratories

Albuquerque, NM USA

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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.

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Access Control Performance Video

- **Secure research facility**
- **Risk assessment determined high likelihood for outside intruder**
- **As you watch, write down all the risk mitigation steps that you see**

Biorisk Performance

Biorisk Management =
Assessment, Mitigation, **Performance**

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Choose one of the following questions and discuss with your group:

What is performance?

In what way does performance improve biorisk management?

Or…what specific steps are still missing from the system after assessment and mitigation?

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Performance

Performance is the way in which someone or something functions

Performance is the result of all the efforts of a company or organization

Performance improves biorisk management: you know that your system works and is sustainable, and that the risk is acceptable

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Group Exercise

Split into groups

Review the performance scenario

- Identify the performance issues/problems in the scenario
- Write each issue on a separate *post-it* using a felt-tip marker

Place *post-its* on your flip chart

Present to the class

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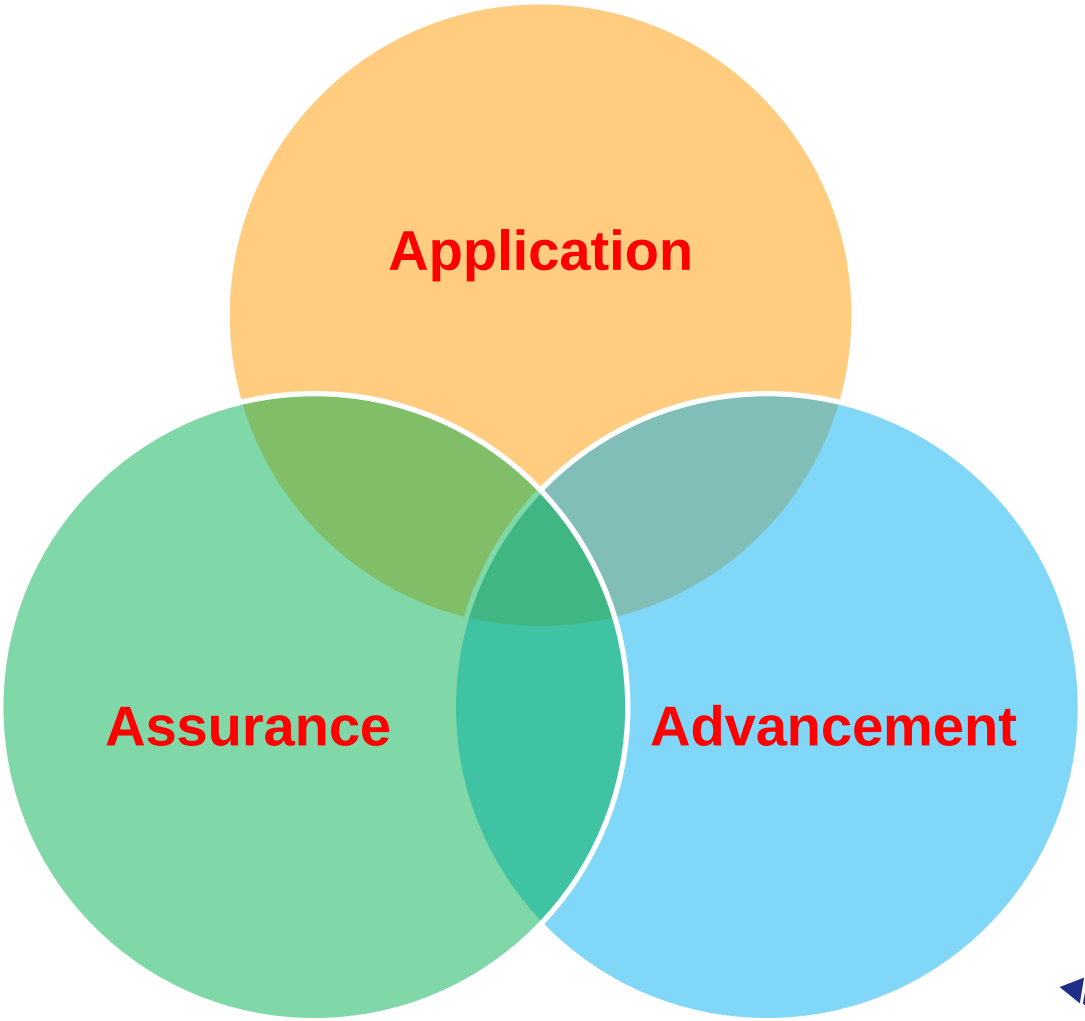
Performance



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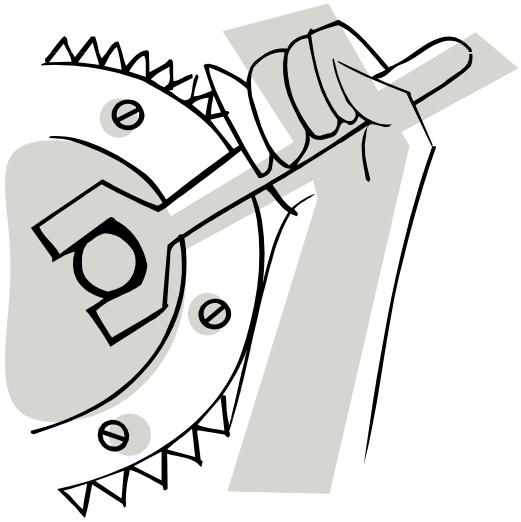
Performance

Application:

Processes, procedures, structures, and responsibilities to manage biorisk. Applying, working, doing the mitigation



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Performance

Assurance:

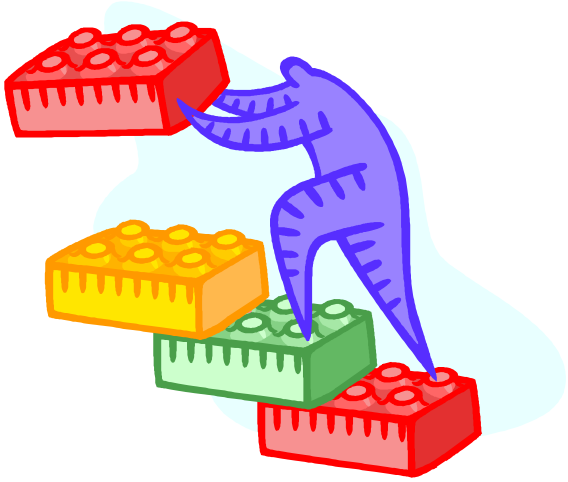
Systematic process of checking the system through audits and inspections

.

Performance

Advancement:

Setting and achieving biorisk management goals; improving existing mitigation or adding new mitigation based on internal and external feedback.



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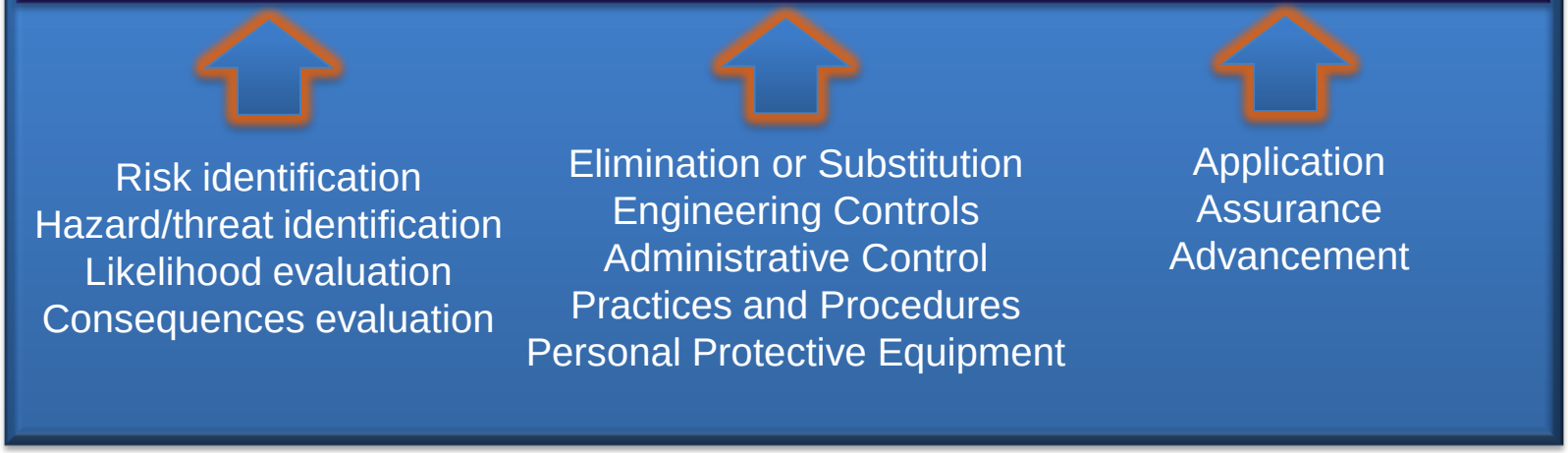
Biorisk Management = Assessment, Mitigation, Performance



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Summary Group Exercise – Step 1

Individually, carefully read the *Cataract University* exercise

Split into groups

- Identify ***problems*** in Assessment, Mitigation, and Peformance
- Use post-it notes, one for each problem
- Place post-it notes on “university board” in appropriate section

How have these problems affected the university?

Report out results to full group

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Awareness and Implementation of CWA 15793:2008

www.biosecurity.sandia.gov

Special thanks to Stefan Wagener

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for the United States Department of Energy's National Nuclear Security Administration
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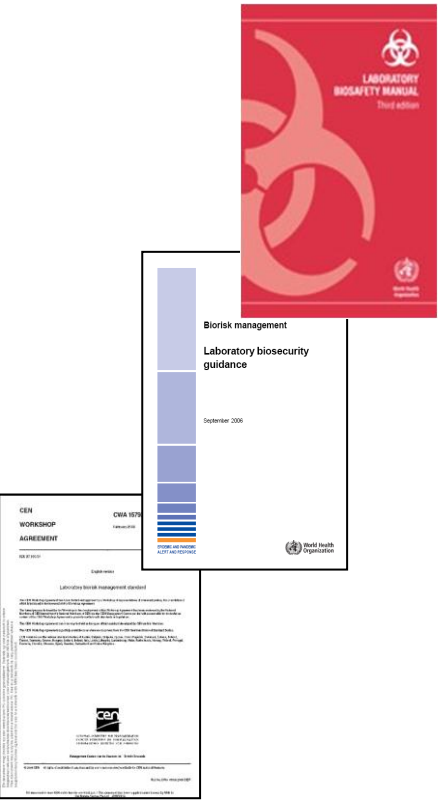
International Laboratory Biorisk Management Documents



Technical: World Health Organization

- Laboratory Biosafety Manual (2004)
- Biorisk Management: Laboratory Biosecurity Guidance (2006)

Management: CEN Workshop Agreements

- CWA 15793 Laboratory Biorisk Management Standard
- CEN WS 55 – CWA 15793 Guidance Document (under development)
- CEN WS 53 – Biosafety Professional Competence

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What is CEN?

- **CEN = Comité Européen de Normalisation**
- **CEN has 30 national members**
- **Produces technical specifications, technical reports, and European Standards (EN)**

- **CEN Workshop Agreements (CWA) produced by**
  - Any interested parties
  - Consensus documents

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CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards such as**
  - ISO 9001 / 14001 and OSHAS18001
- **The Standard is performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization
- **Does not replace national regulations**
  - Compliance with regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs

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Purpose of the CWA 15793:2008

The Standard is used for:

- Improving overall laboratory biorisk performance
- Increasing awareness and the adoption of performance approaches for biosafety and biosecurity
- Improving international laboratory collaboration and safety harmonization
- Support laboratory certification/accreditation, audits/inspections

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CWA 15793:2008

International Approach

- Extensive definition section
- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

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Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- **The standard is not a technical document**
- **Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives**
- **Provides Biorisk management framework for the day-to-day functions of the institute / organization**
  - **During normal operations and times of emergency**

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Reasons for Implementing CWA 15793

Enables organizations to:

- Establish and maintain a biorisk management system to control or minimize risk to acceptable levels to employees, the community and others
- Provide assurance that the requirements are in place and implemented effectively
- Provide a framework that can be used as basis for training and awareness raising
- Seek and achieve certification or verification by an independent third party

- **Document available on CEN website**

  ftp://ftp.cenorm.be/PUBLIC/CWAs/workshop31/CWA15793.pdf

- **Electronic copy provided in your supplementary materials**

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CWA 15793:2011

Examples of topics covered:

- Biorisk Management Policy
- Hazard identification, risk assessment and risk control
- Roles, responsibilities and authorities
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review


CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2008

Laboratory biorisk management standard

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Group Exercise, Step 2

Use the table of contents of the CWA15793 to develop recommendations for change at Cataract University

- Identify ***solutions*** for Assessment, Mitigation, and Performance
- Identify the specific paragraphs in CWA 15793 that apply to your selected solutions

Record your conclusions on a flip chart

Report the results to class

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Individual Reflection

How does AMP apply to your own lab?

How could you improve biorisk management at your own lab, short-term and long-term?

What would be the challenges of implementing AMP?

What would be the benefits of implementing AMP?

Write your answers on a piece of paper; you only have to share your answers if you wish

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Summary

How does performance improve biorisk management?

- You know that your system works and is sustainable, and that the risk is acceptable

Three components of performance

- Apply, assure, and advance

CWA 15793:2008: Laboratory Biorisk Management standard

- Plan, do, check, act

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Biorisk Management = Assessment, Mitigation, Performance

Risk identification
Hazard/threat identification
Likelihood evaluation
Consequences evaluation

Elimination or Substitution
Engineering Controls
Administrative Control
Practices and Procedures
Personal Protective Equipment

Application
Assurance
Advancement

CWA 15793:2008

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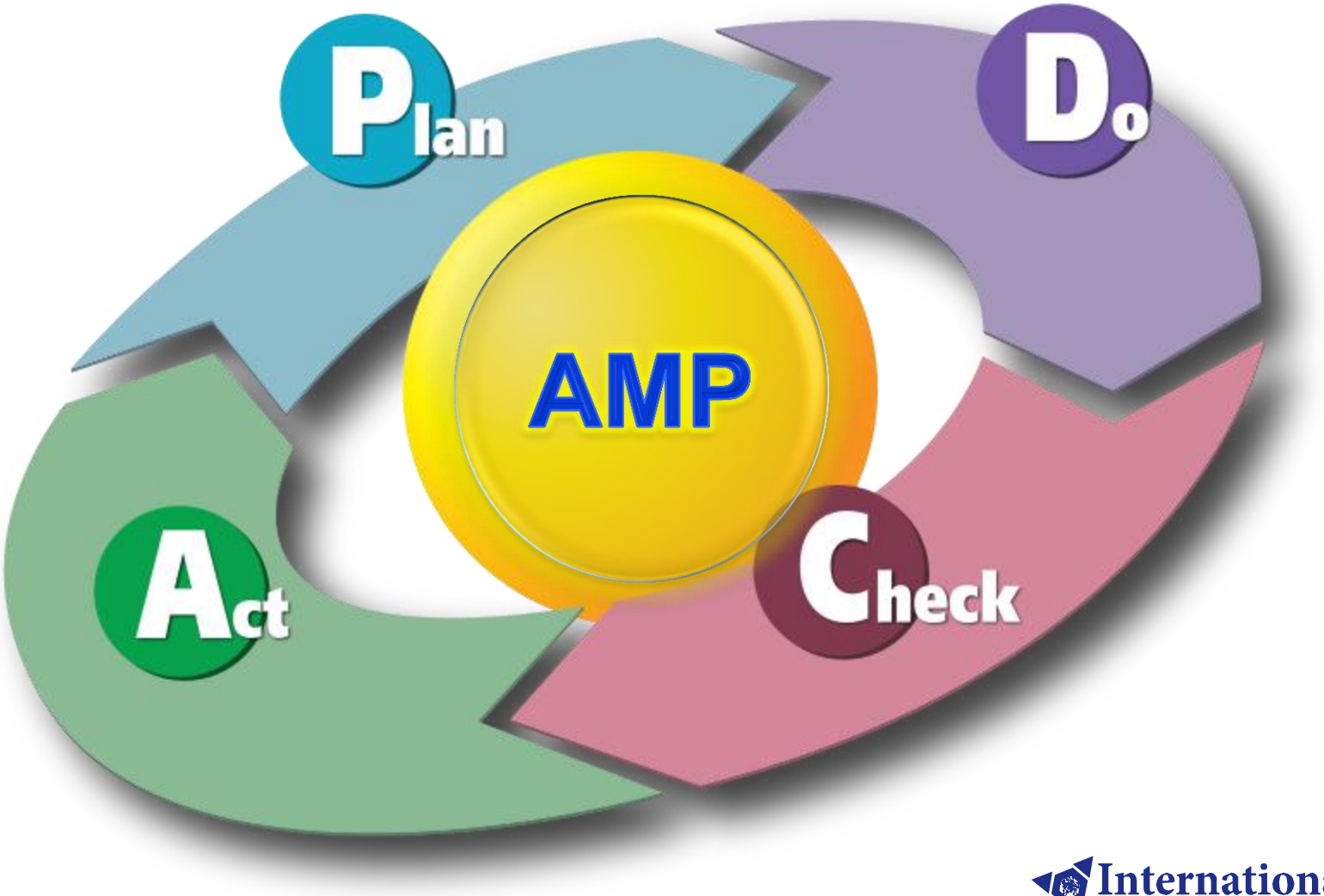

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OPTIONAL SLIDES
TIME AND INTEREST PERMITTING

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How does performance affect risk over time?

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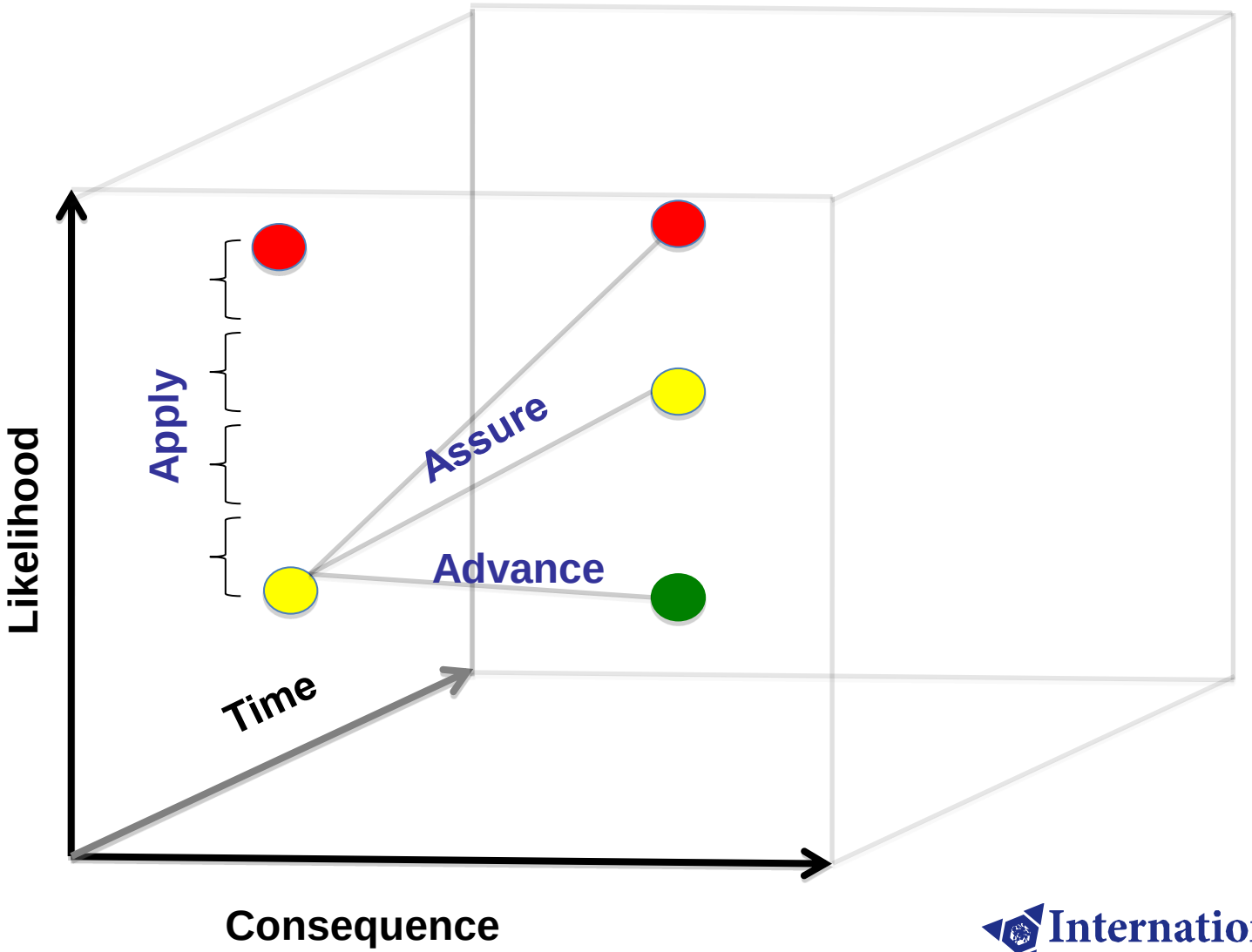

Group Exercise

Organize the performance issues that you identified into either

- Application
- Assurance
- Advancement

Present your results to the class

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