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Fundamentals of Laboratory Biosecurity and Biosafety Risk Assessments

Conceptual Considerations

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Dr. Morten Bremer Mærli,
Ronald Barø, Alexander Flesjø Christiansen, Dr. Stephen McAdam

Intentional – Unintentional Biorisk

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Biosecurity

Biosafety

Biosecurity is different

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- Dealing with actors that will

  - Explore and exploit opportunities to reach their goals

  - Potentially try to circumvent risk mitigating measures

➔ Proactive risk *mitigation* (“us”)

➔ Proactive risk *generation* (“them”)

Core Questions

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- What are the Implications of this New Paradigm?
- Does it affect me and my organization?
- If so, how and why ?

Outline

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- Biosecurity and Biosafety compared, standard risk assessment
- Conclusions

Risk Assessment

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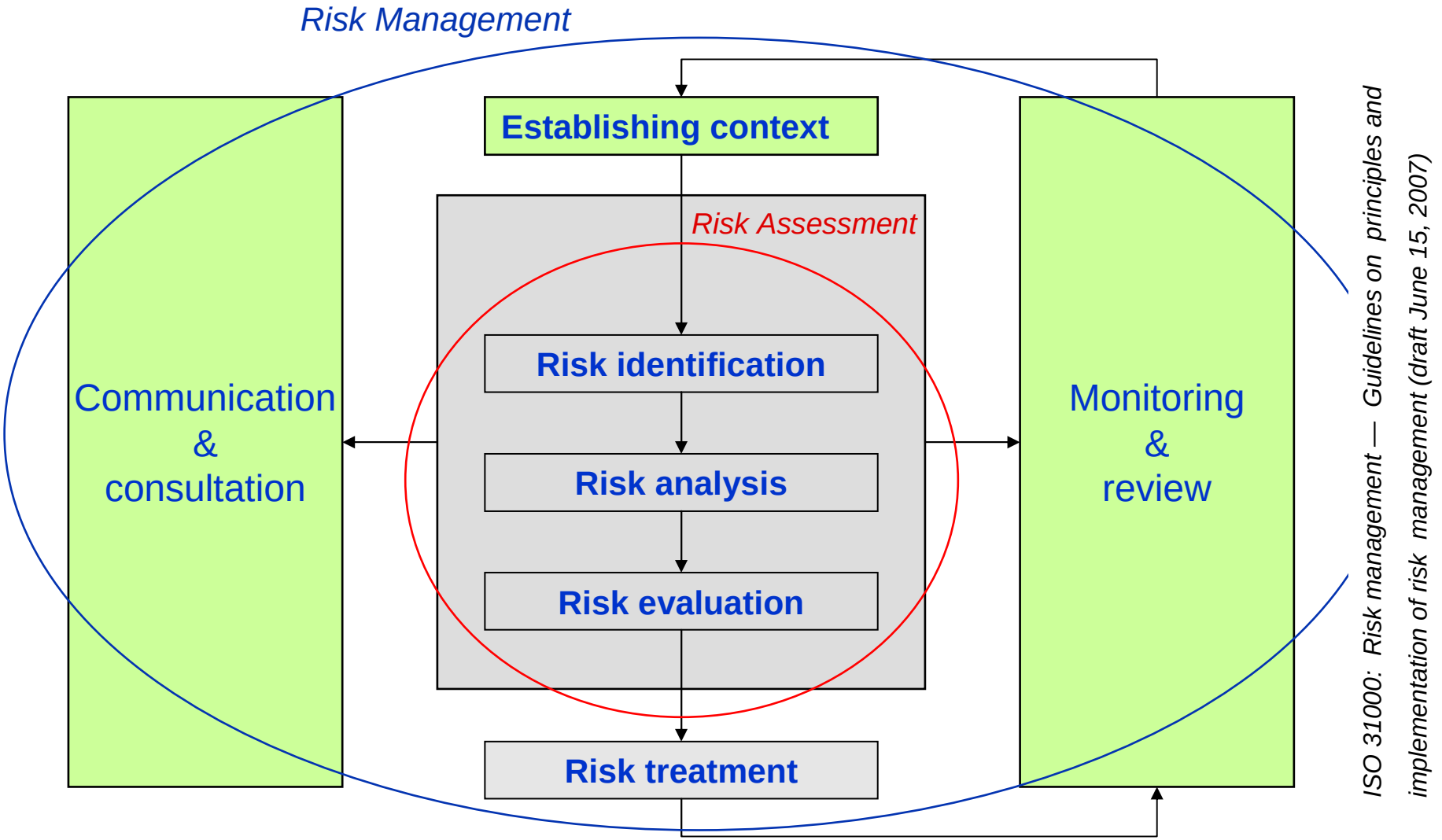
- Risk assessment is the overall process of
  - risk identification,
  - risk analysis, and
  - risk evaluation

- Essential part of any risk management processes

The Platform: ISO 31000 - *Risk Management*



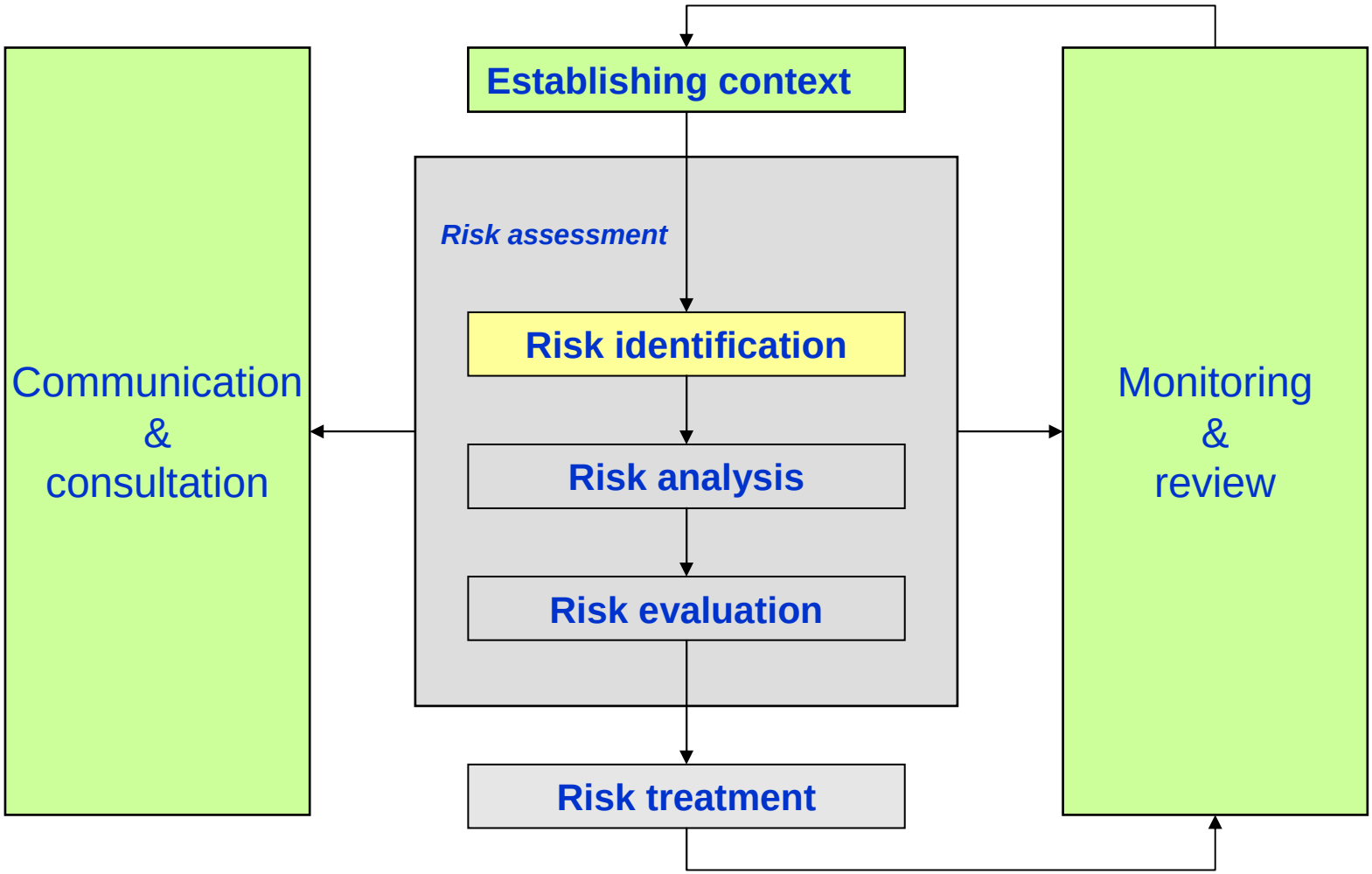
- Risk assessment is always done towards one or more objectives

- In our setting:

  - Biosecurity

  - Biosafety

Risk Identification



Risk Identification

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- *A process to find, list and characterize elements of risks* (ISO 73)
- Include risks whether or not they are under the control of the organization

Risk Identification: *Conceptual* Risk Traits and Triggers

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	Biosecurity Risk	Biosafety Risk
Trigger	Gain, or desire to harm or threaten	Breakages, errors in operation, or system failures
Trait	Purposeful	Accidental
Initiator	Man	Man or nature
Origin	External, possibly with insider(s)	Internal, possibly external

Risk Identification: *Conceptual* Risk Characteristics

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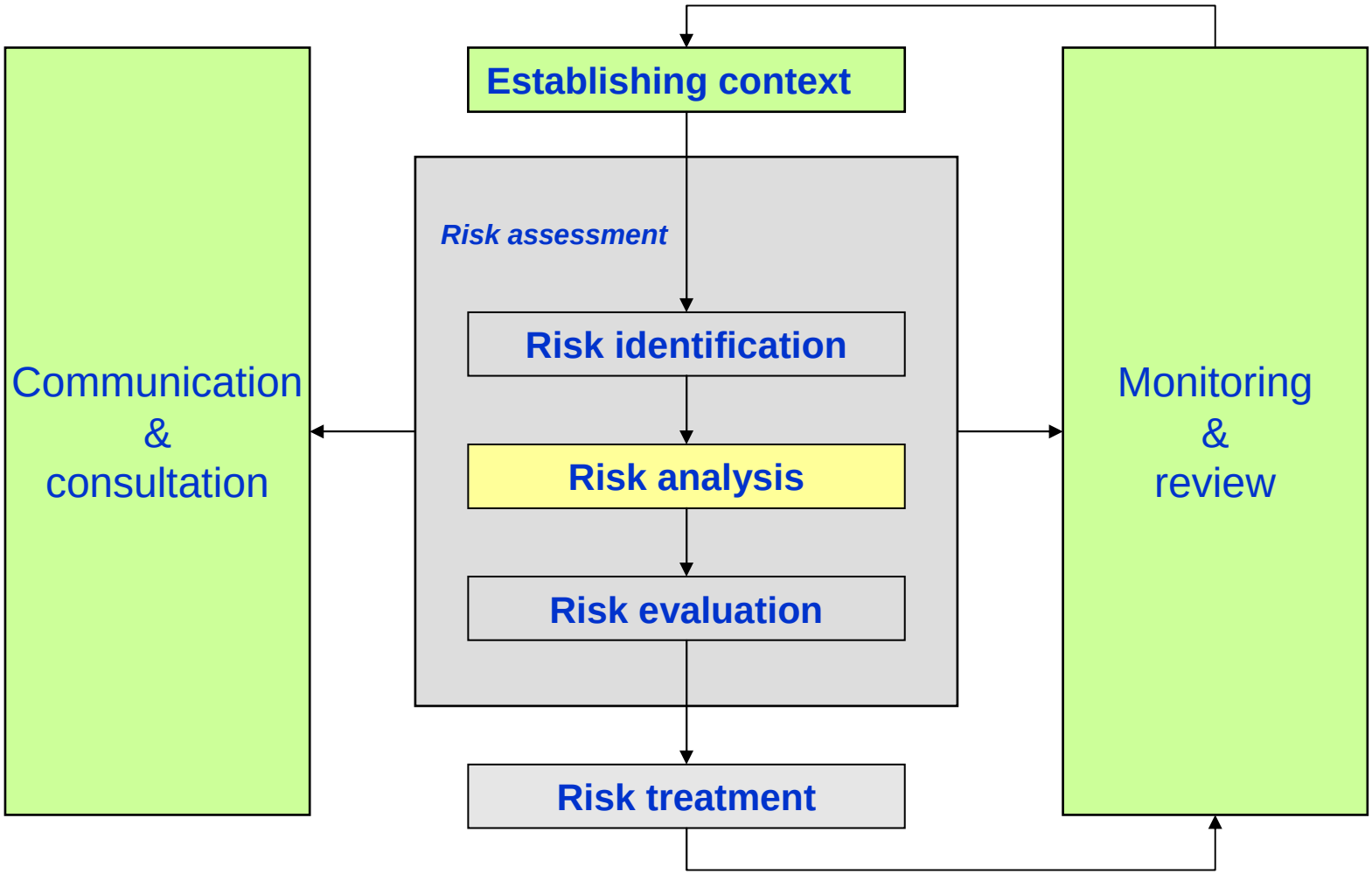
	Biosecurity Risk	Biosafety Risk
Targeted (time, scope, location)	Yes	No
Tailored	Yes	No
Damage-maximizing	Possibly	No
Discriminatory	Possibly	No
Opportunistic	Often	Never

Risk Analysis



Risk Analysis

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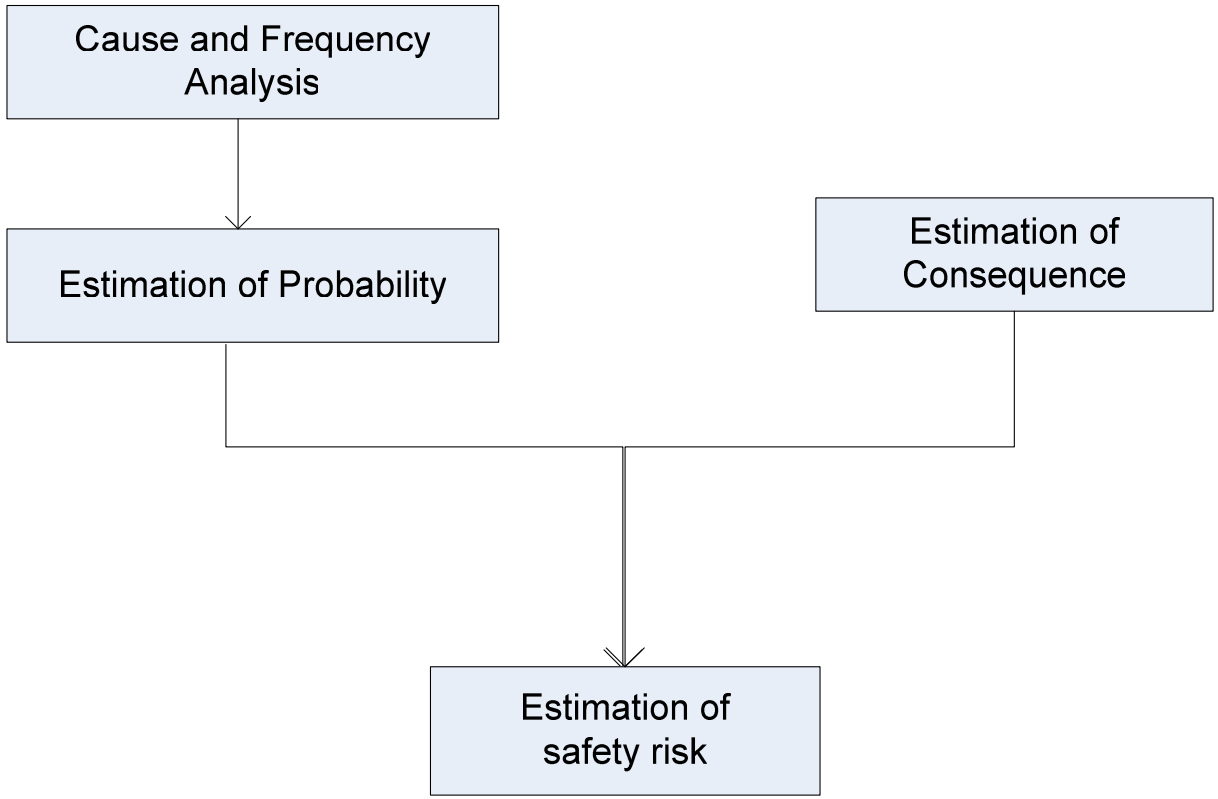
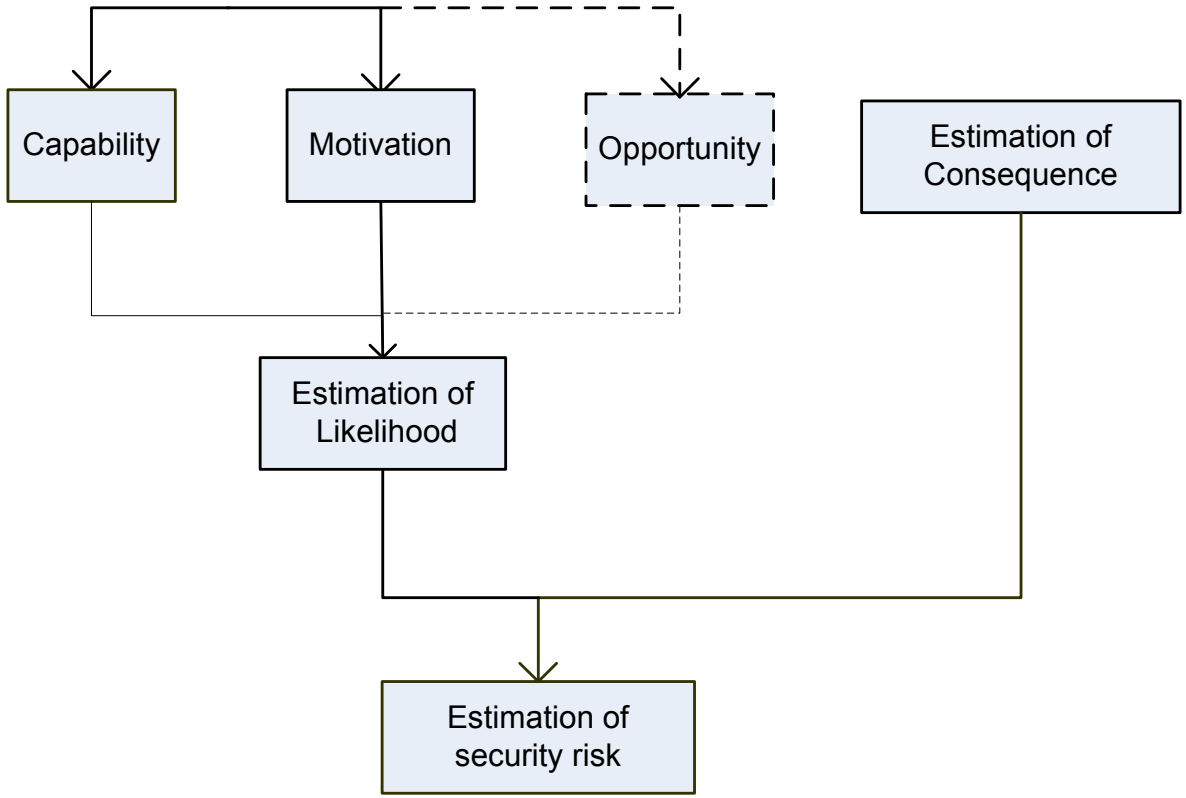
- *Systematic use of information to identify sources and to estimate the risk* (ISO 73)
- Information can include **historical data**, **theoretical analysis**, **informed opinions**, and the **concern of stakeholders** (ISO 73)
- Involves consideration of the **causes** and **sources** of risk, their **consequences**, and the **likelihood** that those consequences may occur.
- Risk analysis may be **qualitative**, **semi-quantitative** or **quantitative**, or a **combination** of these

Biosafety Risk Estimation



Biosecurity Risk Estimation



Risk Analysis: Risk Probabilities and Consequences

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	Biosecurity Risk	Biosafety Risk
Probability	Likelihood	“Frequency”
Consequence	Optimized	Often predicable, yet arbitrary

Risk

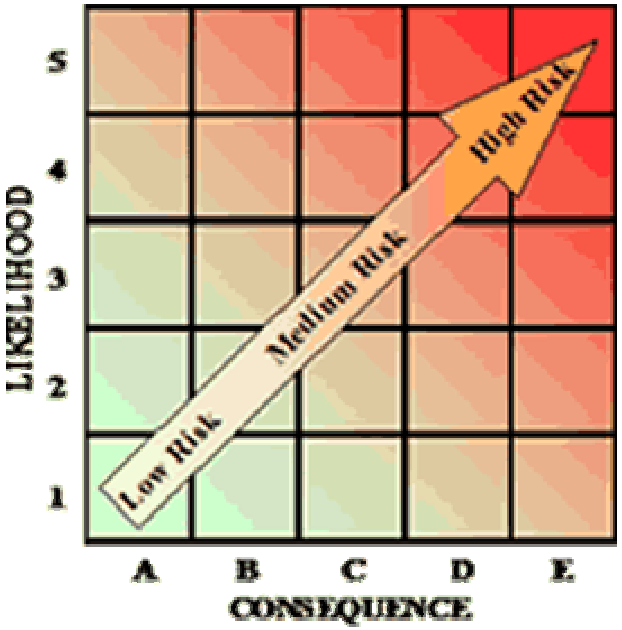
- *Combination of the probability of an event and its consequences* (ISO 73)

- Risk = Probability x Consequences

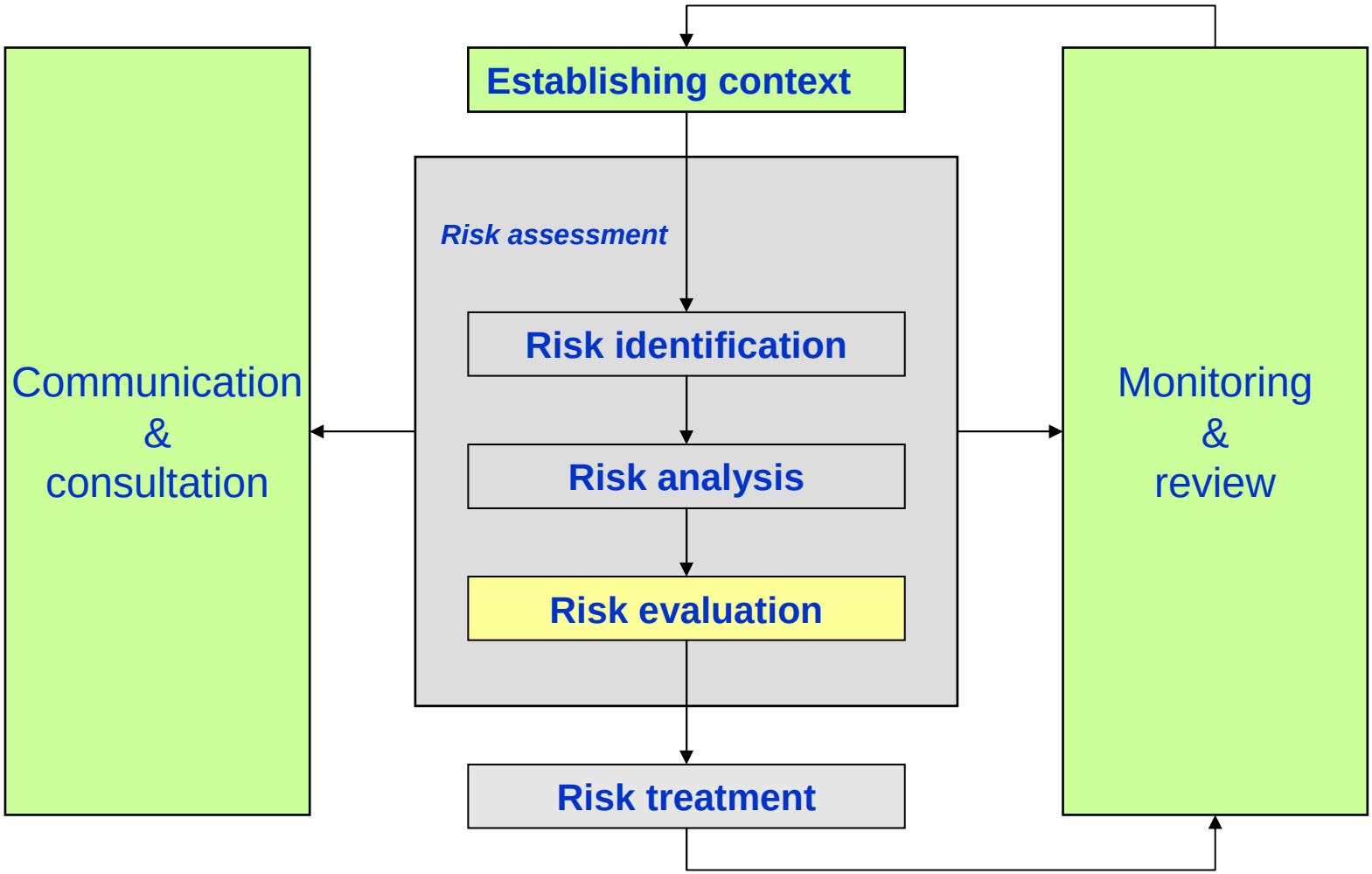
- Risk (safety) = P (“frequency”) x C (“arbitrary”)

- Risk (security) = P (Intentions, capabilities) x C (“optimized”)

“Optimized” does not necessary mean “maximized”



Risk Evaluation



Risk Evaluation

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- Determine the significance of the risk
- Assist in making decisions about treating or accepting risk

Risk Evaluation: Information and Competence

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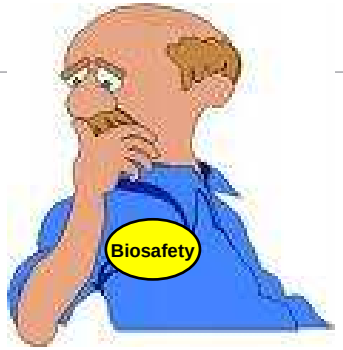
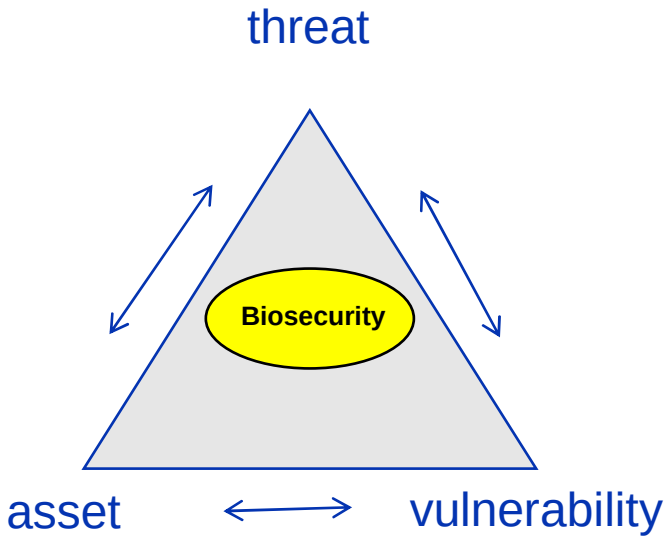
	Biosecurity Risk	Biosafety Risk
Facility information	Interest to suppress	Interest to share
Competence demands	Understanding of Assets, Threats, Asset-Threat relations	Understanding Assets

Concerns and Competence

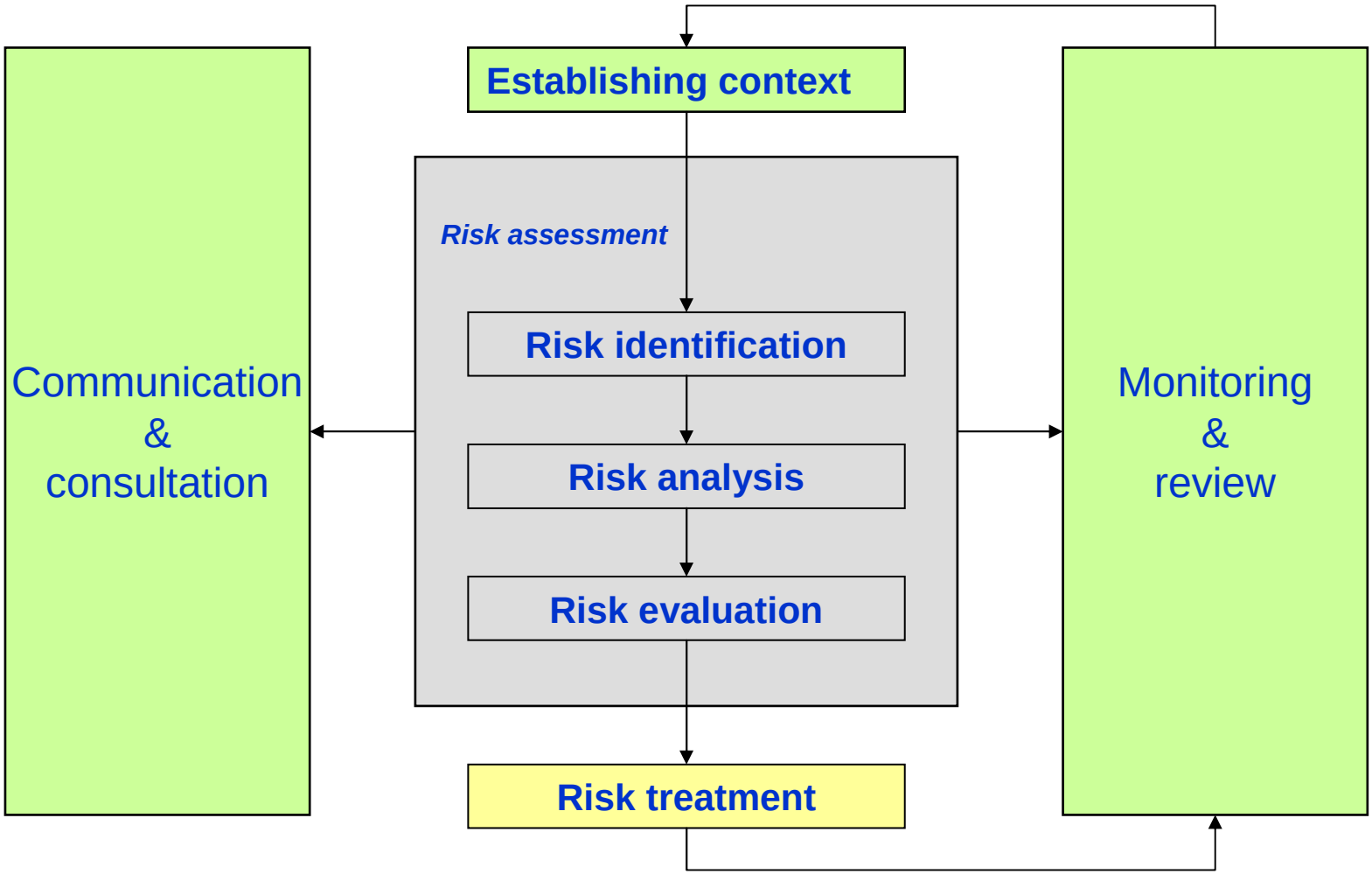
- Core Concern: Biosafety
- Core Competencies:
  - Pathogens and toxins
  - Work processes and procedures
  - Rules and regulations



- Core Concern: Biosecurity
- Core Competencies:
  - Pathogens and toxins
  - Work processes and procedures
  - Rules and regulations
  - Potential perpetrators
  - Site Vulnerabilities
  - … **and** their **interplay**..



Risk Treatment



Risk Treatment

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- *Process of selection and measures to modify risks* (ISO 73)

- Measures may include avoiding, optimizing, transferring or retaining risks

Risk Treatment: Residual Risk

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	Biosecurity Risk	Biosafety Risk
Residual risk	"Dynamic"	"Static"

➔ "Proactive (and continued) risk *generation*"

Risk Treatment: Risk Perception

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We act on **perceived risk** rather than objective measures of risk

- Perceptions likely to grow particularly strong when
  - Risk assessments more dependent upon assumptions, than a strong experience- and knowledge-base
  - Strong (excessive) media attention
  - Several factors increasing personal concerned are fulfilled….:

Inclinations: Factors Increasing Concern

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Biosecurity more prone to personal “preferences” than biosafety…!?

	Biosecurity	Biosafety
Uncontrollable	++	+
Fatalities grouped in space and time	++	+
Effects dreaded	++	+
Unfamiliar	+++	+
Children at risk	++	+
Identifiable victims	++	++
Much media attention	+++	+
Involuntary	+++	+++
Caused by human actions or failures	+++	+++

Covello V.T., Sandman P.M. and Slovic P. (1988), Risk Communications, Risk Statistics and Risk Comparisons:A manual for plant managers. Washington DC: Chemical Manufactures Association.

Legend: more pluses, potentially higher perceptional impact (possible values)

Risk Treatment: Other Persistent Challenges…

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- Organizational factors
  - Risk management
- Resources, prioritizations
  - Limited funds highly likely
  - Low-probability/high consequences
- Synergies and conflicts
  - Signs, information,…,
  - Learning
- Updated competence
  - “moving target”

Conclusions

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- Biosecurity more than an extension of strong Biosafety
- Intentional acts add important dimensions to Biosecurity risks
- Biosecurity scenarios entail different actors, triggers and origins
- **Biosecurity risk assessments and responses differ accordingly,**
  - **Need for dedicated expertise, tools, and assessments**

Conclusions, resource-wise

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- **A definitive need to understand <u>implications</u> of biosecurity risk responses**
- New demands on the organization, the management, and personnel
  - Competence: biosecurity risk assessment and risk management
  - Acceptance: new SOPs and measures beyond personal protection
  - Awareness: e.g. new considerations on role of perception
  - Alertness: new set of persistent risk treatment challenges
- Tools and methodology development

Conclusions, finally

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- **Biosecurity and Biosafety assessments should be conducted separately,**

  BUT

- **Biosecurity and Biosafety governed under the same Biorisk Management System**

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