Risk Based Facility Design

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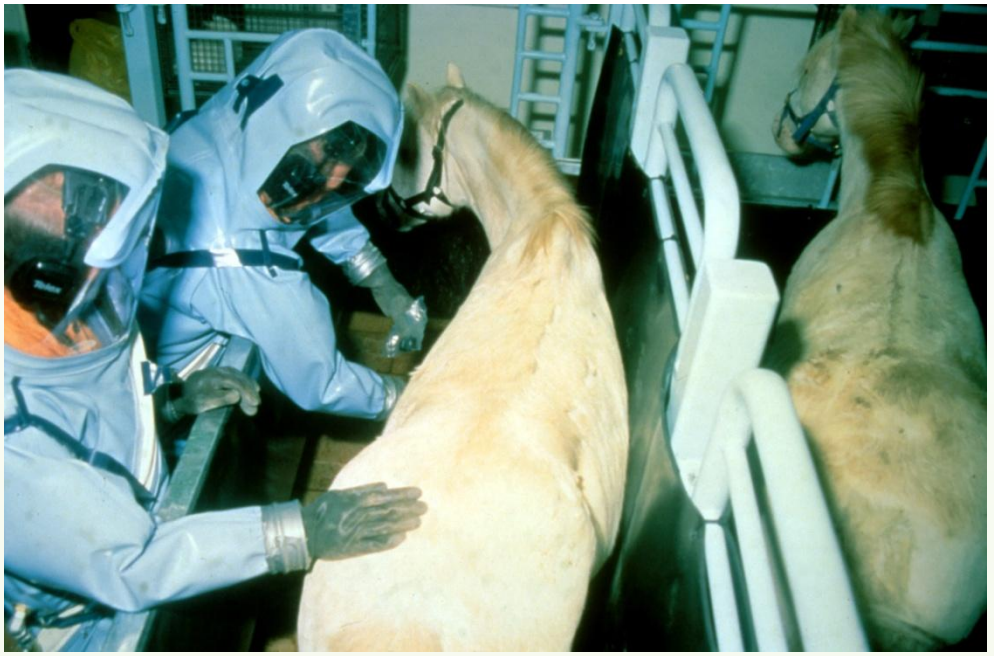
Piper Alpha and FMDV

- 6 July 1988
- 167 deaths in 22 minutes
- >3.4 billion GBP
- Safety Case regime in 1993
- IEC61508 philosophy

- 2007 outbreak – 200 m GBP
- 2001 outbreak – 8 billion GBP
- No proven transmission chain
- HSE: FMDV facilities –high hazard industries
- Single Regulatory Framework
- IEC61508 philosophy

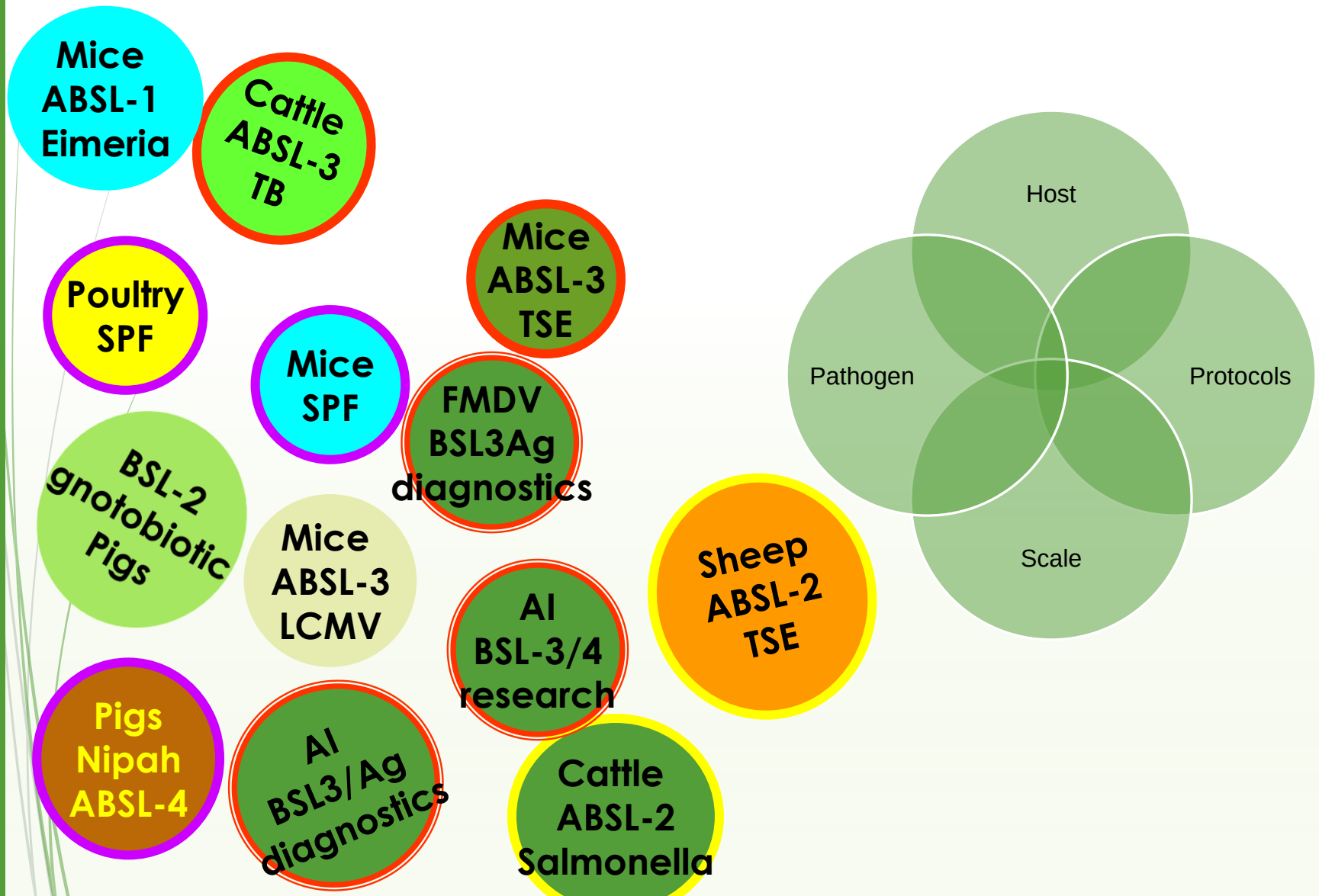
Full Suit Facilities

Suit in secondary containment (Delta)



Suit in primary containment (Dover)

What has to be contained?



Biohazard Definition

Viruses
Foot and Mouth Disease
Avian Influenza
Blue Tongue Disease
Rinderpest
Hog Cholera
African Horse Sickness
African Swine Fever
Rift Valley Fever

Bacteria
Salmonella
Bacillus anthracis
Coxiella burnetti

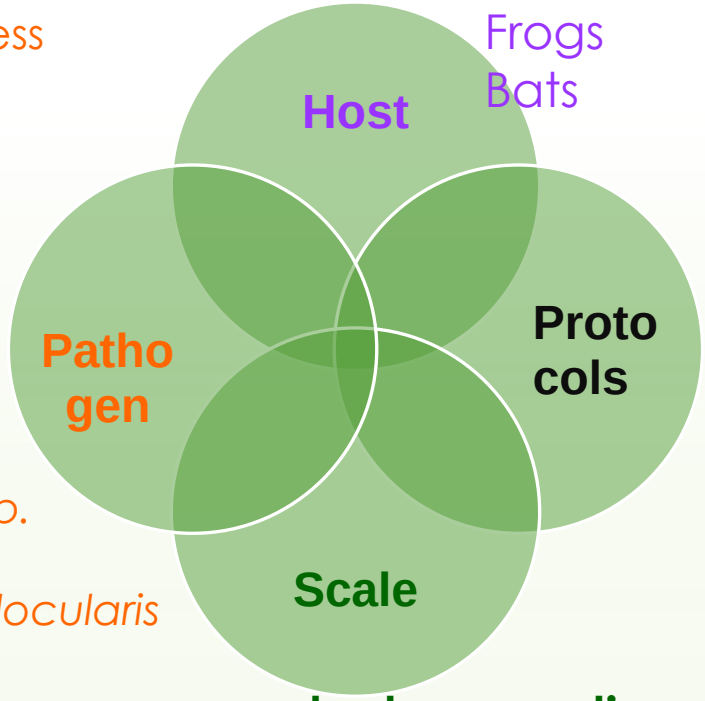
Parasites
Theileria parva
Cryptosporidium spp.
Eimeria spp.
Echinococcus multilocularis

Fungi
Dermatophilus congolensis
Encephalitozoon.

Unconventional Agents
CJD, TSE

Large Animals
Horses, Cattle
Pigs, Sheep
Camels
Wild ungulates
Ostriches

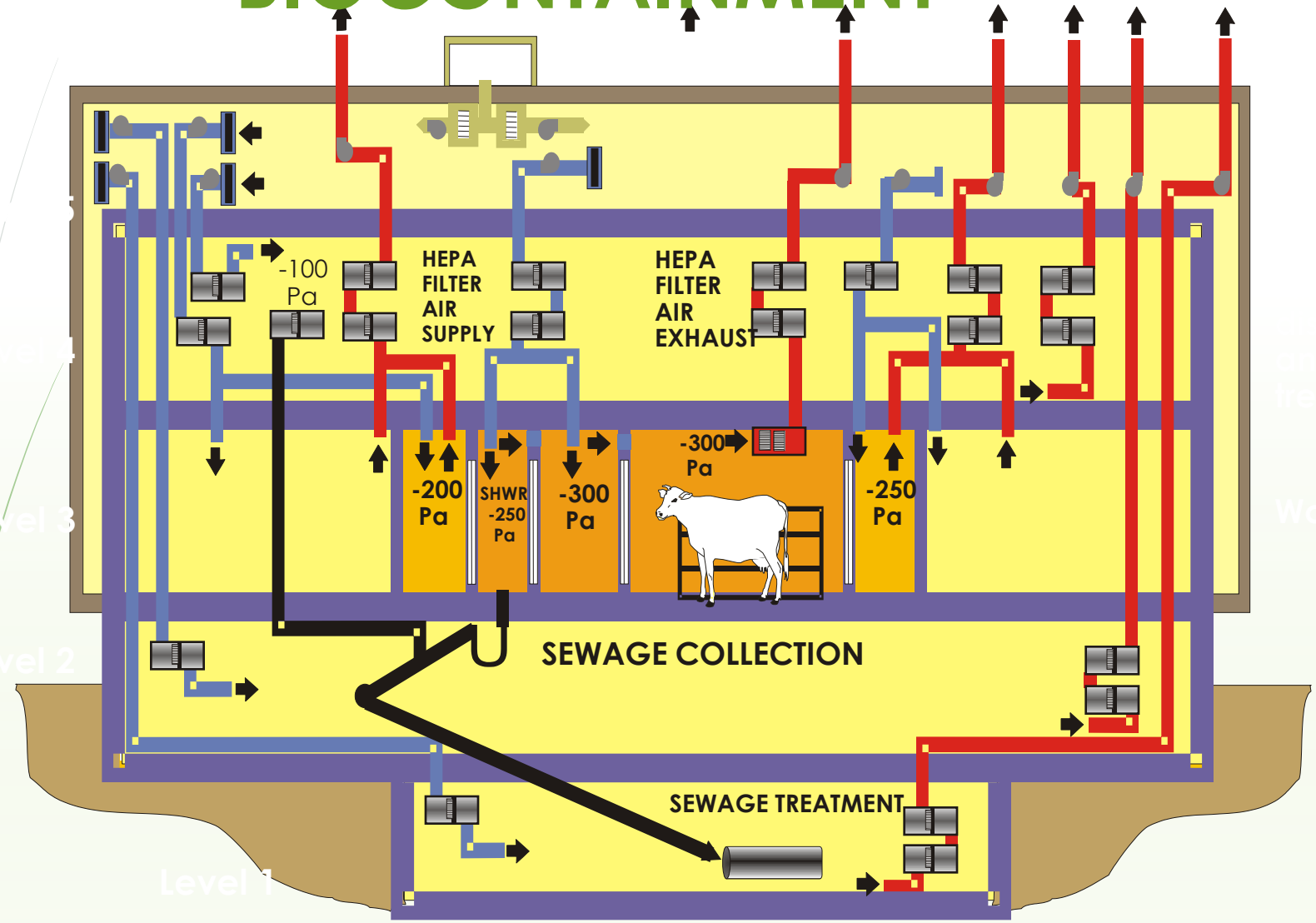
Small Animals
Rabbits
Poultry
Rodents
Ticks
Mosquitoes
Frogs
Bats



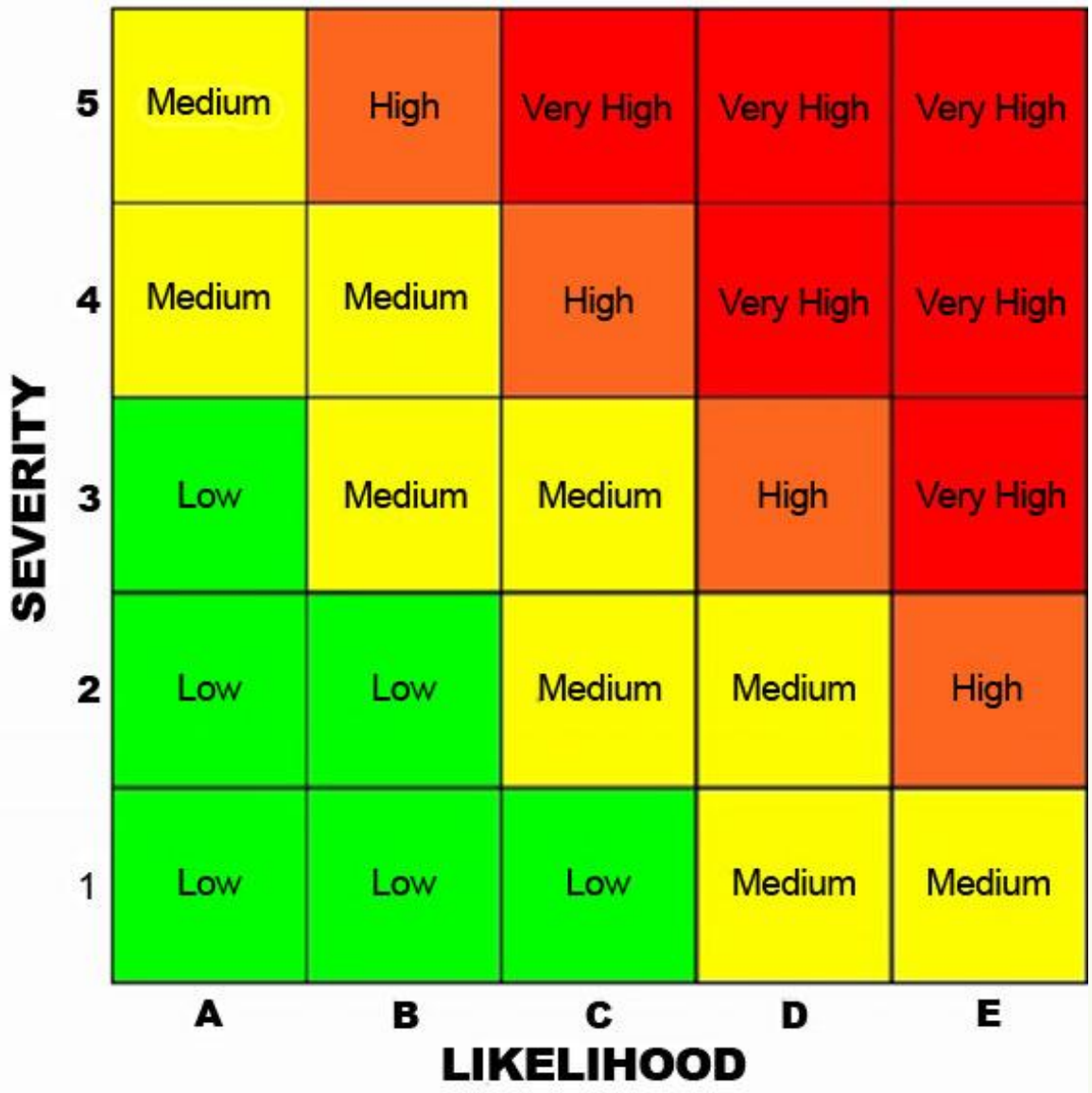
constant - sporadic
small vs large
short term vs long term

In vitro - *In vivo*
Diagnostics – Research
Molecular
Cellular
Analytical - preparative
Immunology
Pathogenesis
Epidemiology
Vaccine/drug testing
GLP/GMP compliance

BIOCONTAINMENT



courtesy AAHL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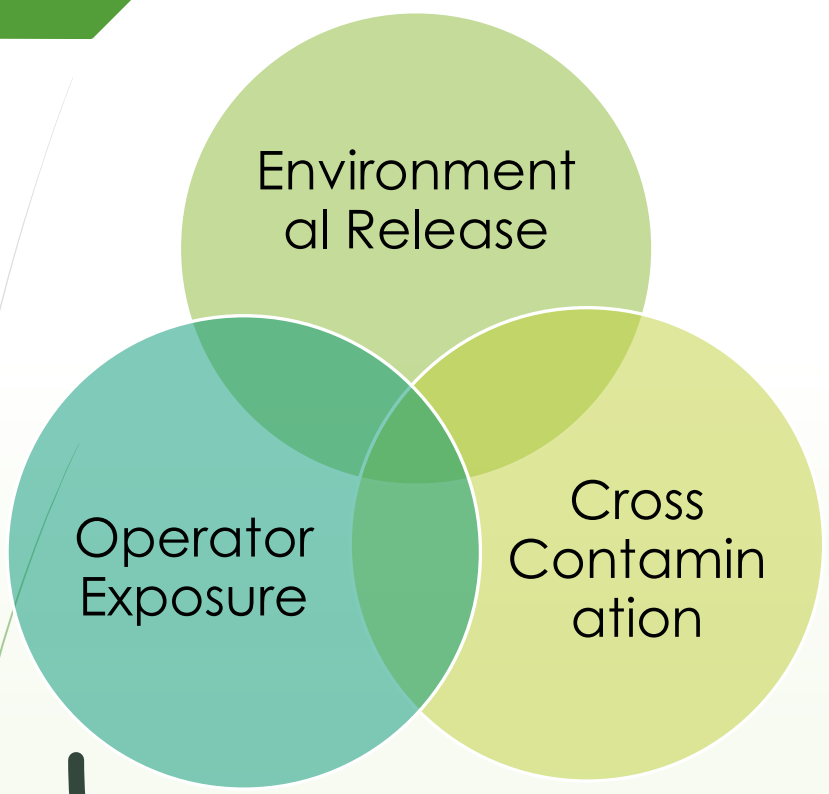
LIKELIHOOD

Risk Assessment Determinants



- Likelihood
- Severity
- Detectability

Acceptability of the Residual Risk

How to Assess Risk?

- Qualitative
- Semiquantitative
- Quantitative

- Sensitivity
- Specificity
- Reproducibility

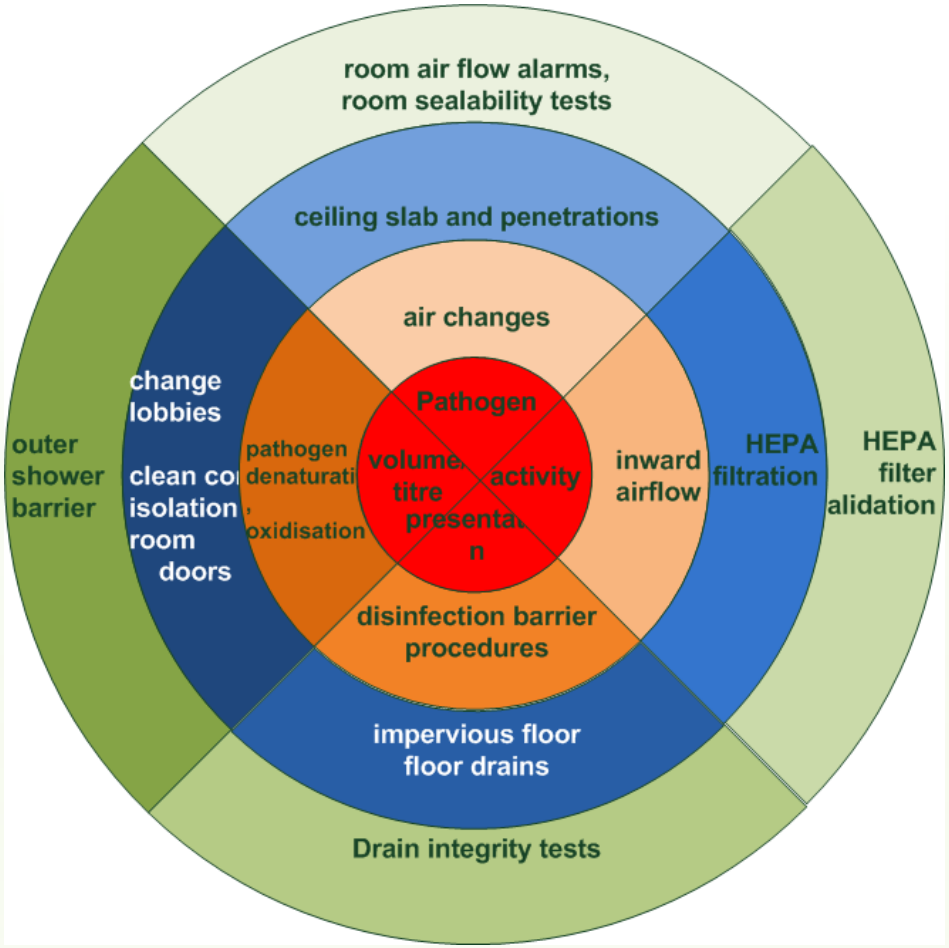
- Prompt Lists
- Fault Tree
- Event Tree
- LOPA
- HAZOP
- SWIFT
- HACCP
- Bowtie

Integrated Protection Layers

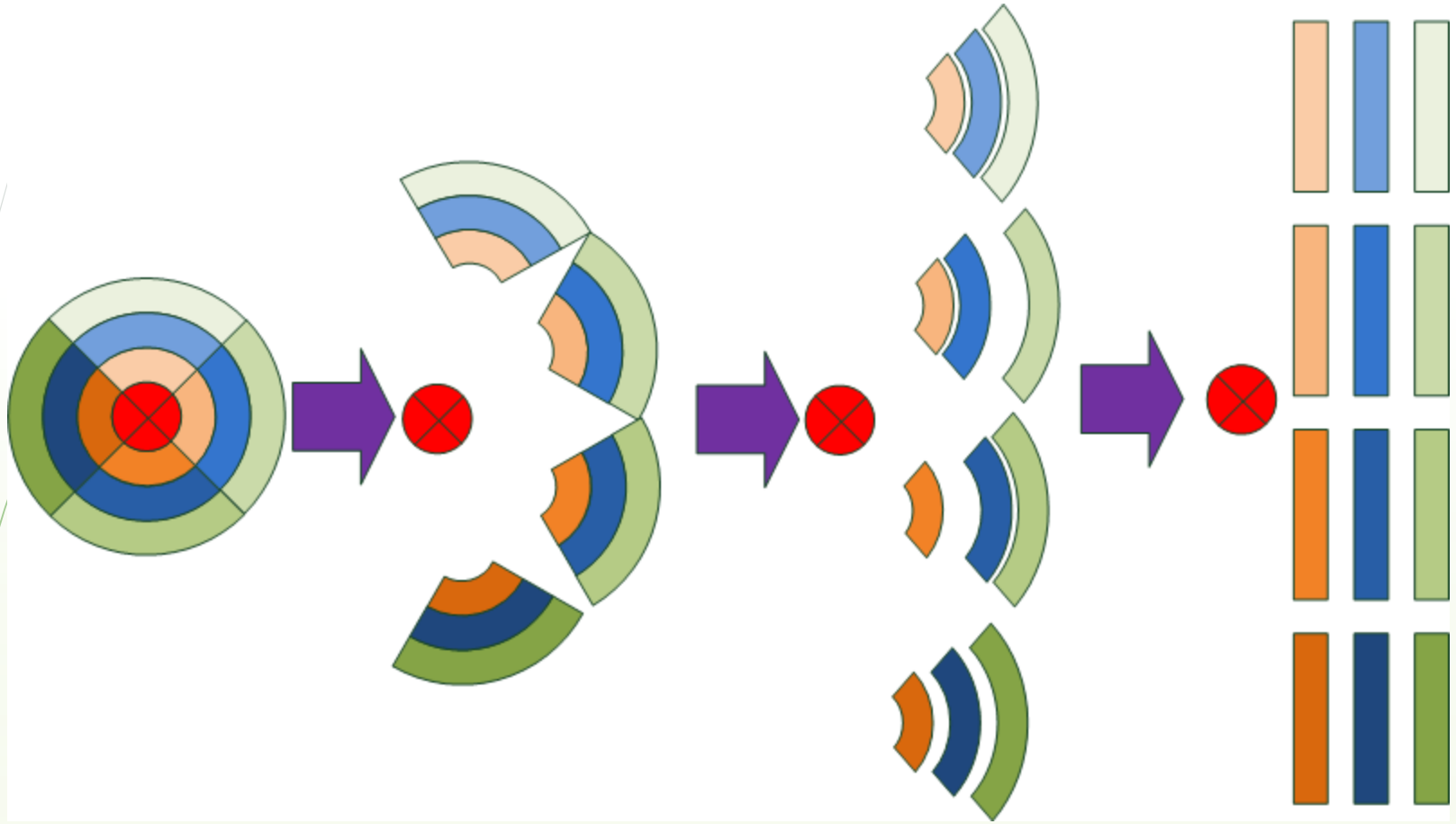
The acceptability of any single protection layer will depend on the

- likelihood of failure
- consequence of failure
- detectability of failure

For CL-4 multiple layers will be required in most cases to achieve the acceptable residual risk.

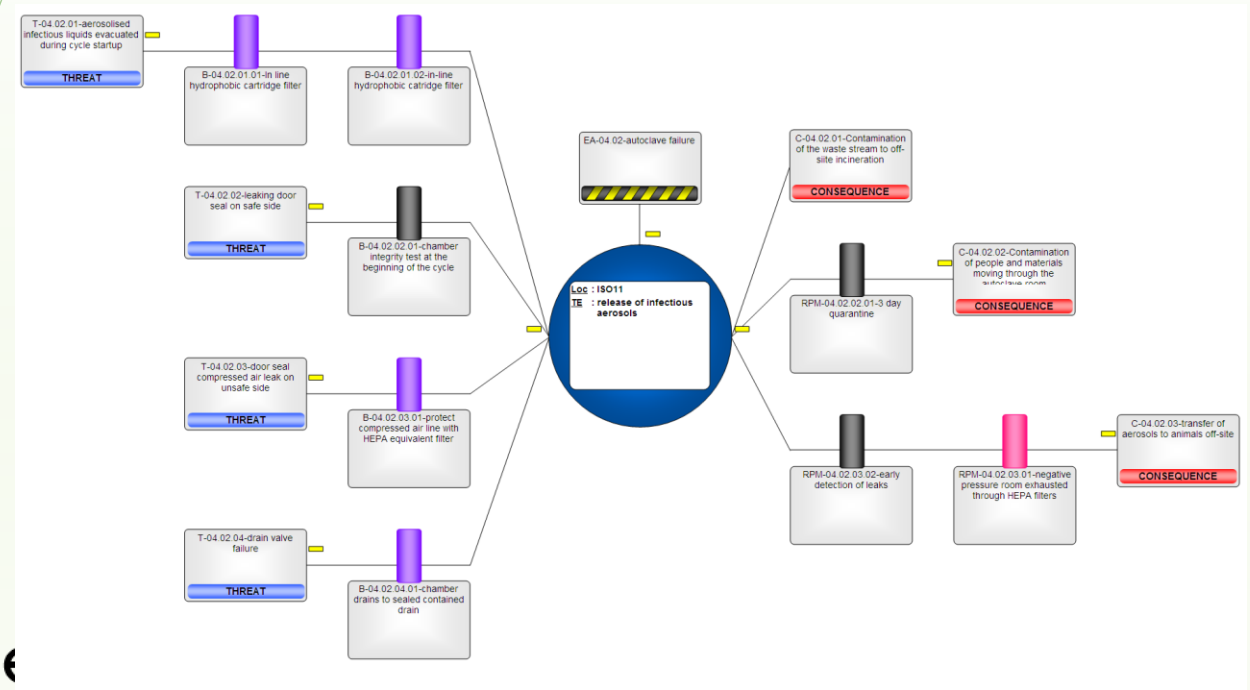


Layer of Protection Analysis



Bowtie Risk Assessment Methodology

Source……critical event……receiver



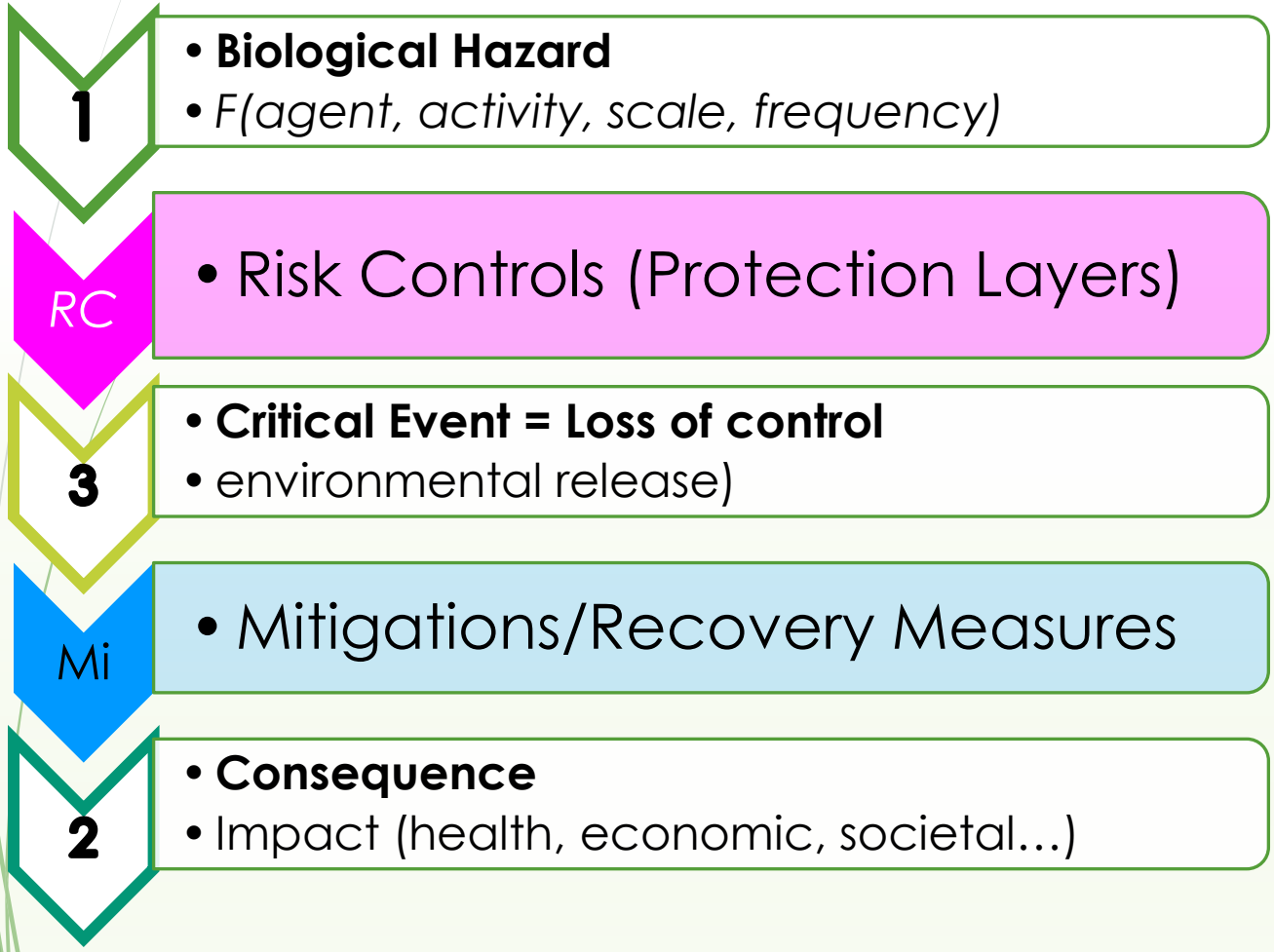
Risk Assessment Process

1
- **Biological Hazard**
- *F(agent, activity, scale, frequency)*

2
- **Consequence**
- Impact (health, economic, societal…)

3
- **Critical Event = Loss of control**
- environmental release)

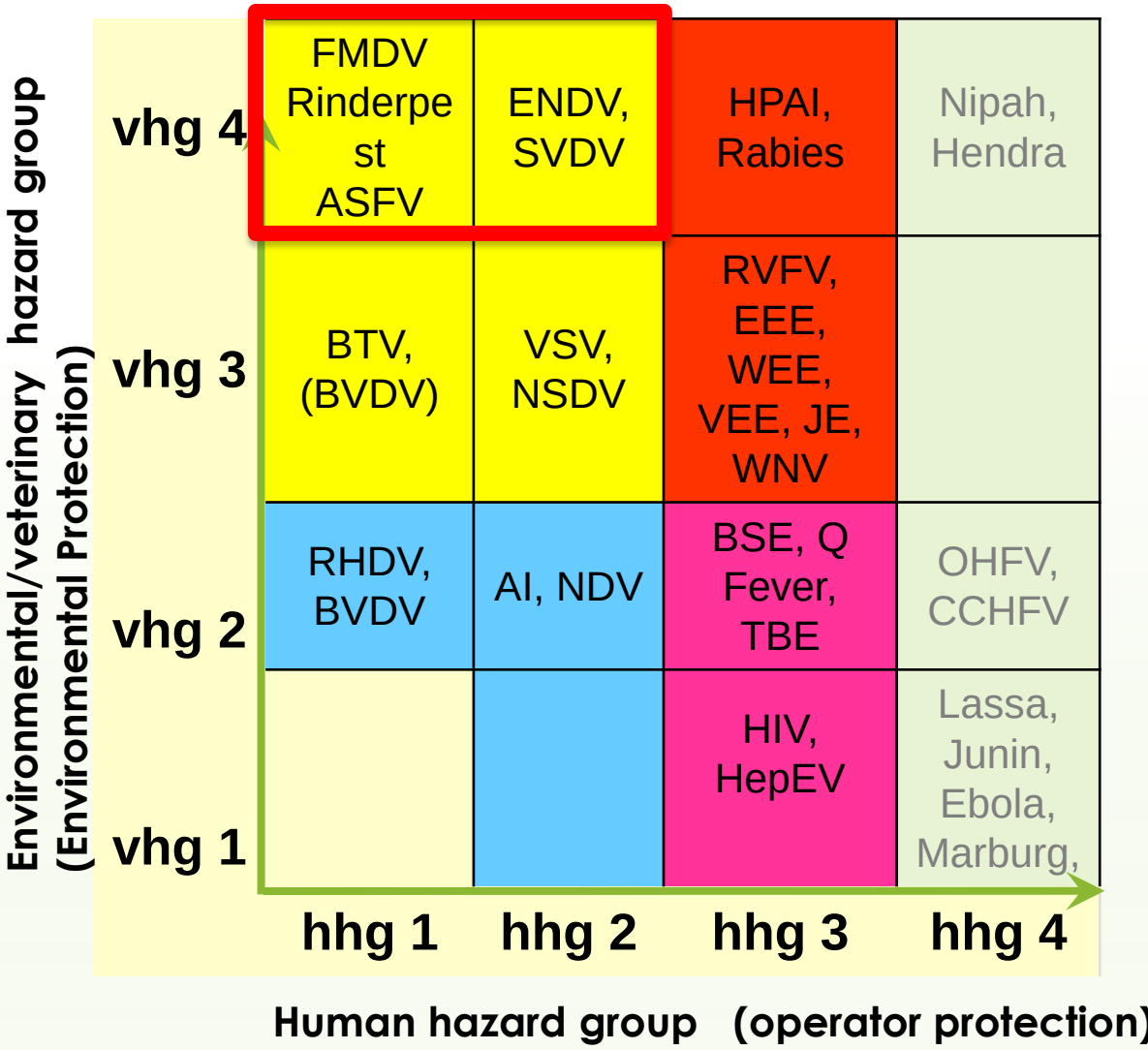
Risk Assessment Process



Hazard and Threat Characterisation

- The principle hazard managed in the institute are viral biological agents, namely Foot and Mouth Disease Virus (FMDV)as the most significant hazard due to its economic impact. There is limited but increasing work on human hazard group 3 viruses, but the systems for these are still evolving.

- The principles threats are activities that have the potential to result in a release of the virus unless stringent controls to prevent this are in place. The actual risk (capacity and likelihood to cause harm) will depend on the agent, quantity, concentration, matrix and activity.

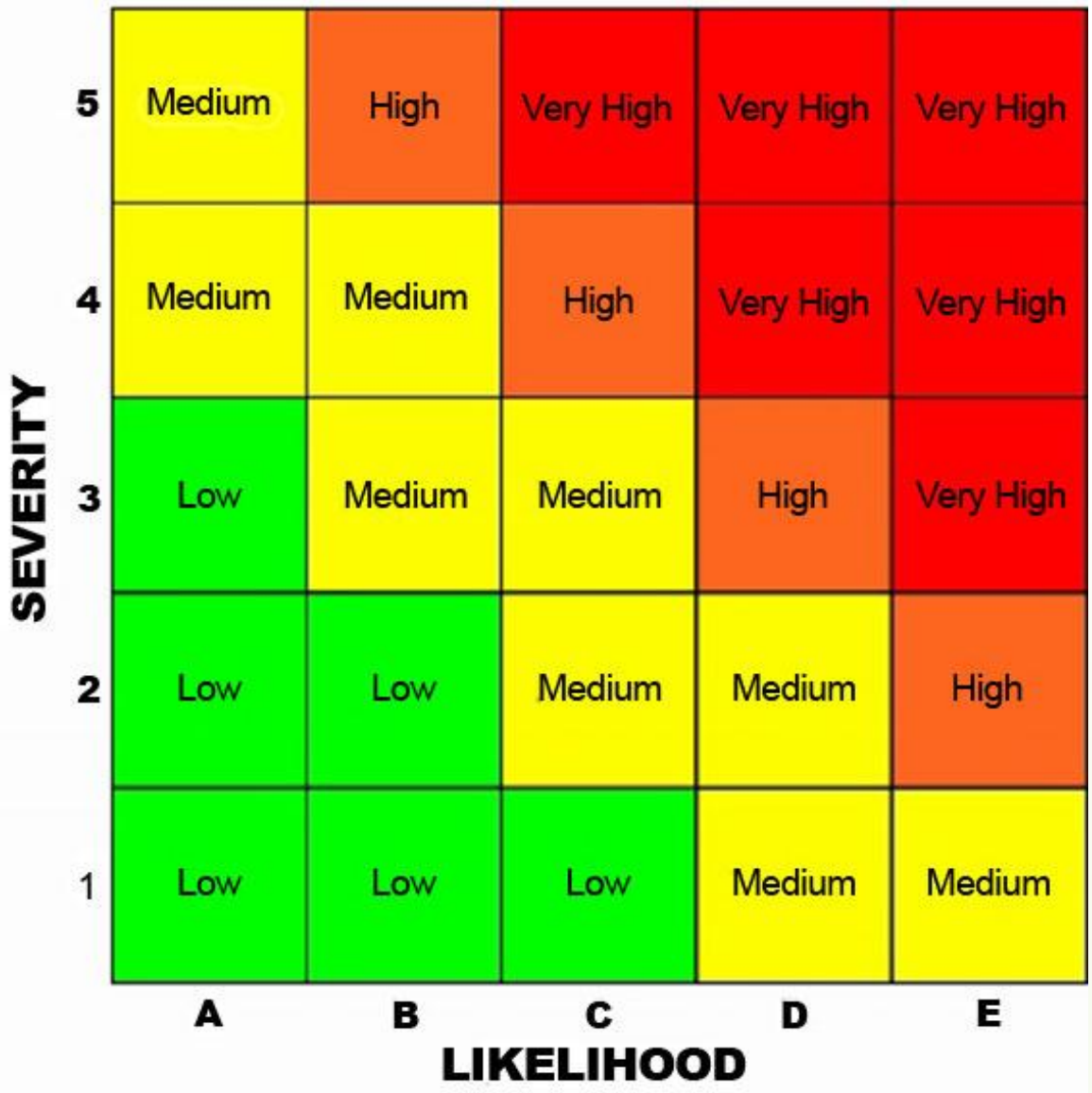


How to Assess Risk?

- Qualitative
- Semiquantitative
- Quantitative

- Sensitivity
- Specificity
- Reproducibility

- Prompt Lists
- Fault Tree
- Event Tree
- LOPA
- HAZOP
- SWIFT
- HACCP
- Bowtie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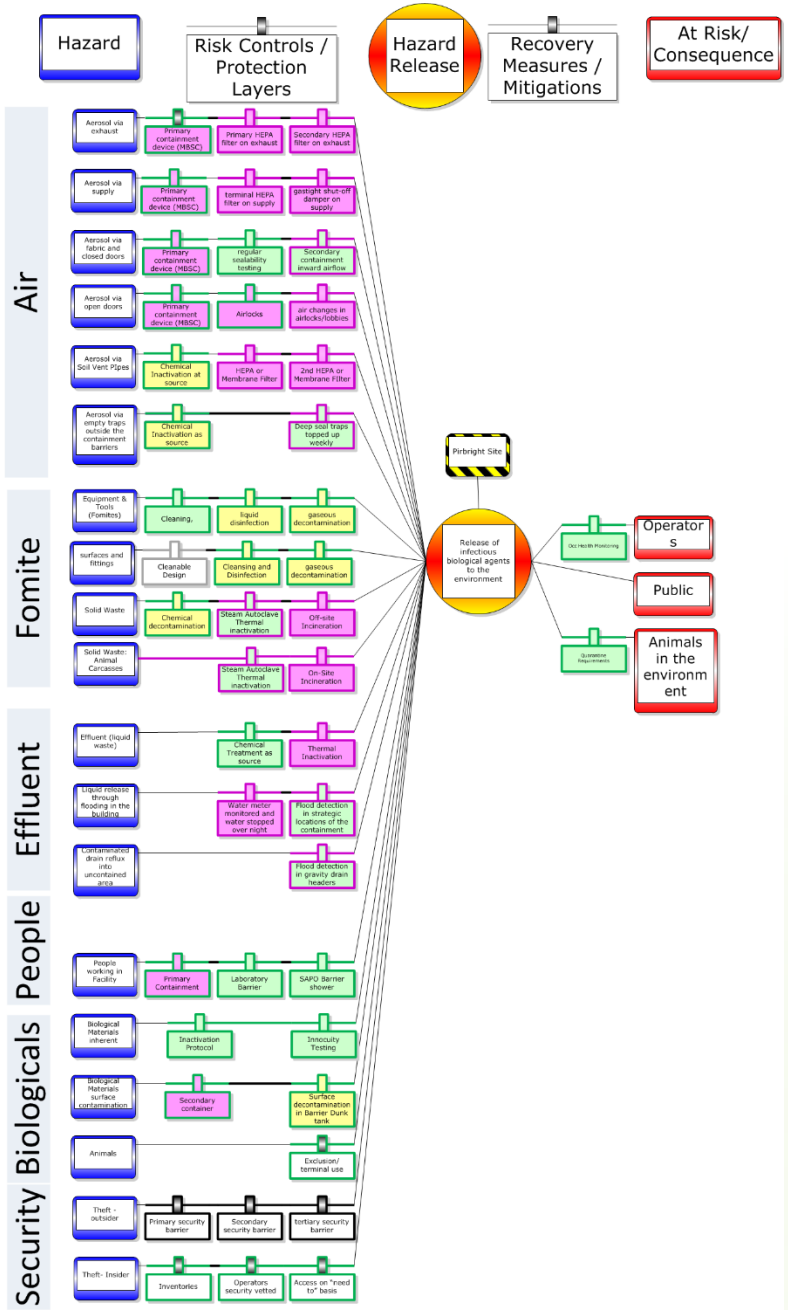
Environmental Risk Model

- Critical Event: Loss of environmental containment
- Risk Path Category
- Risk Path defined by biohazard, activity and escalation path
- Definition of



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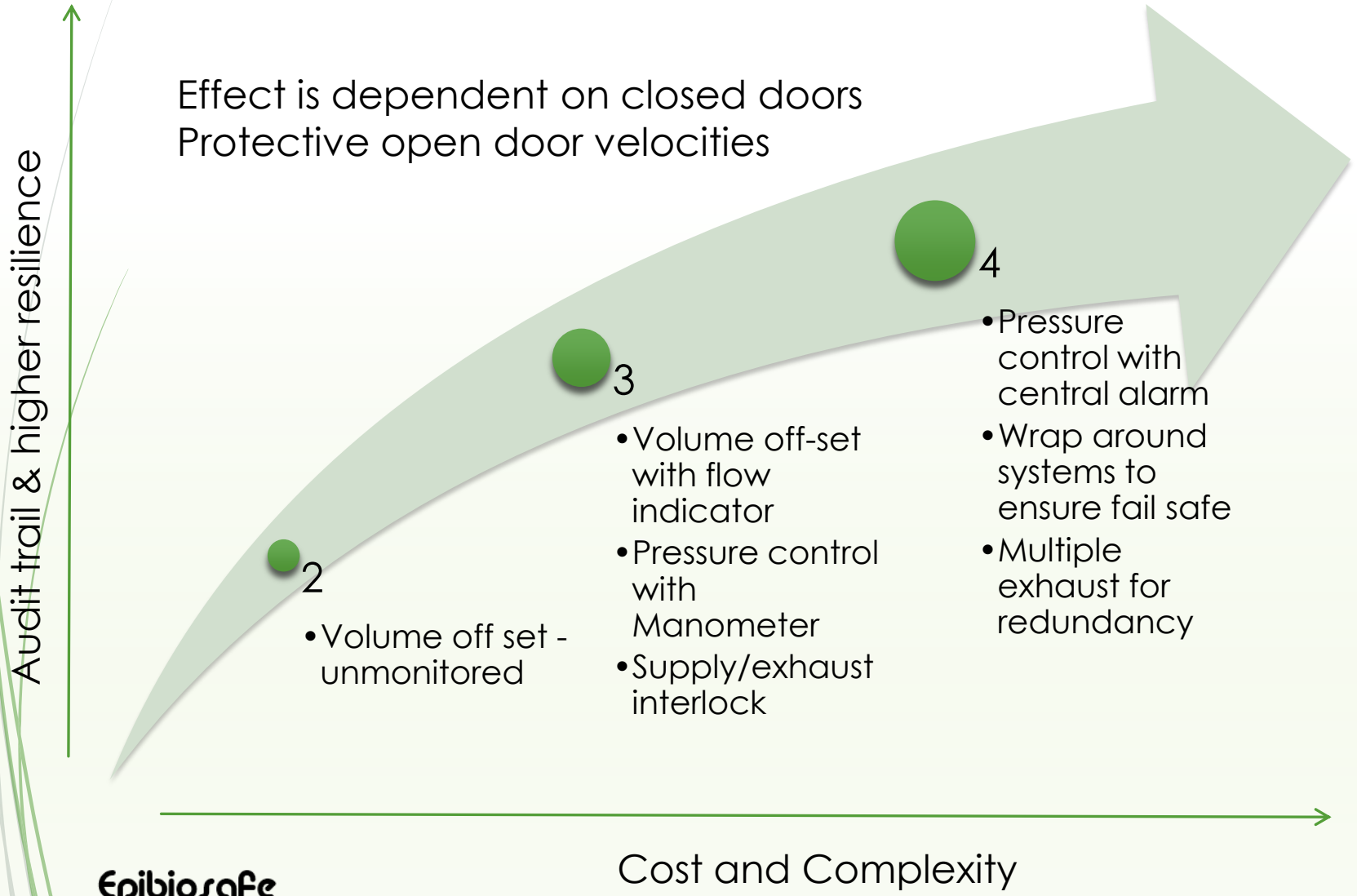
Directional Airflow



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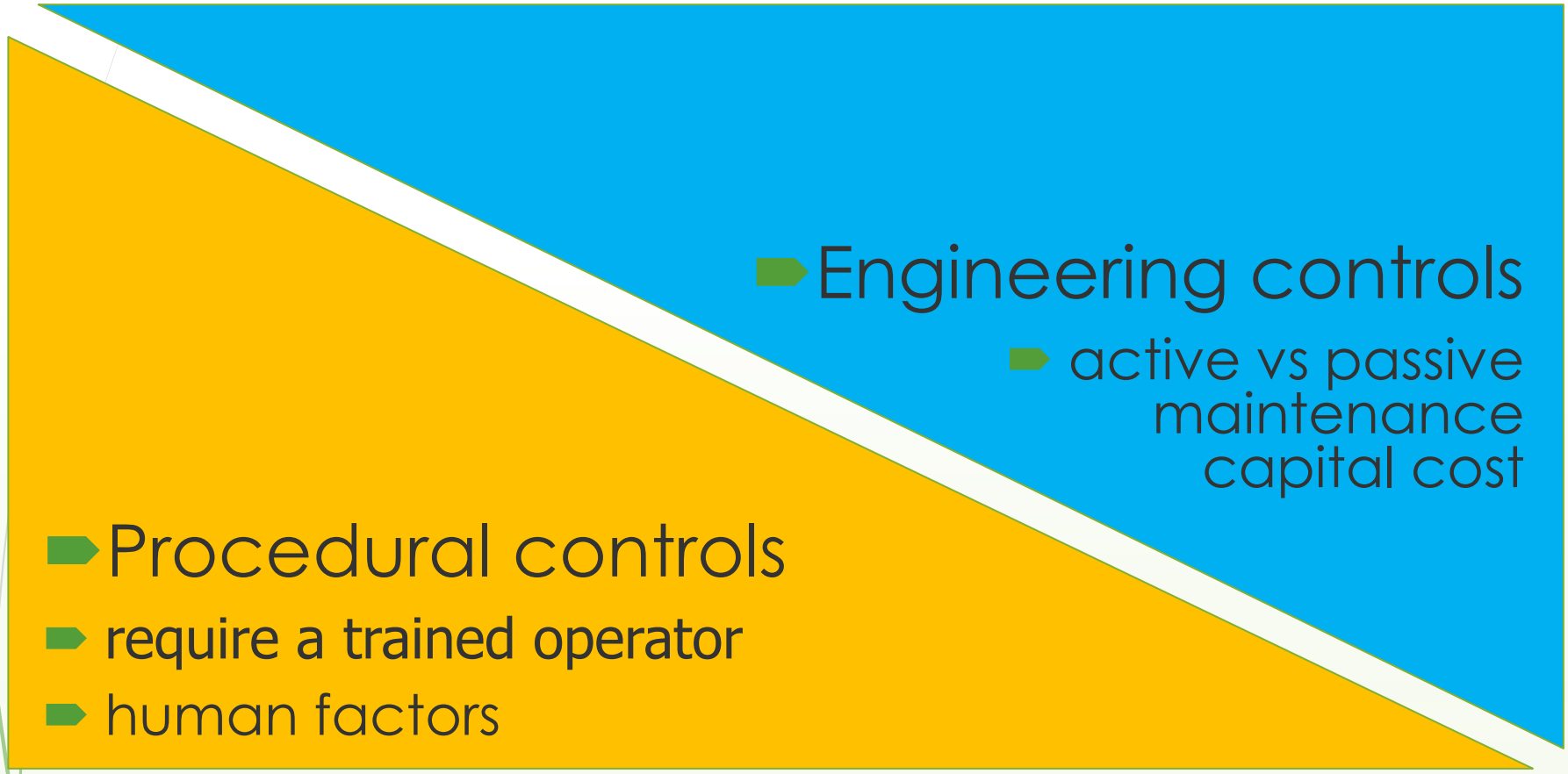
CONCEPTS… Control types



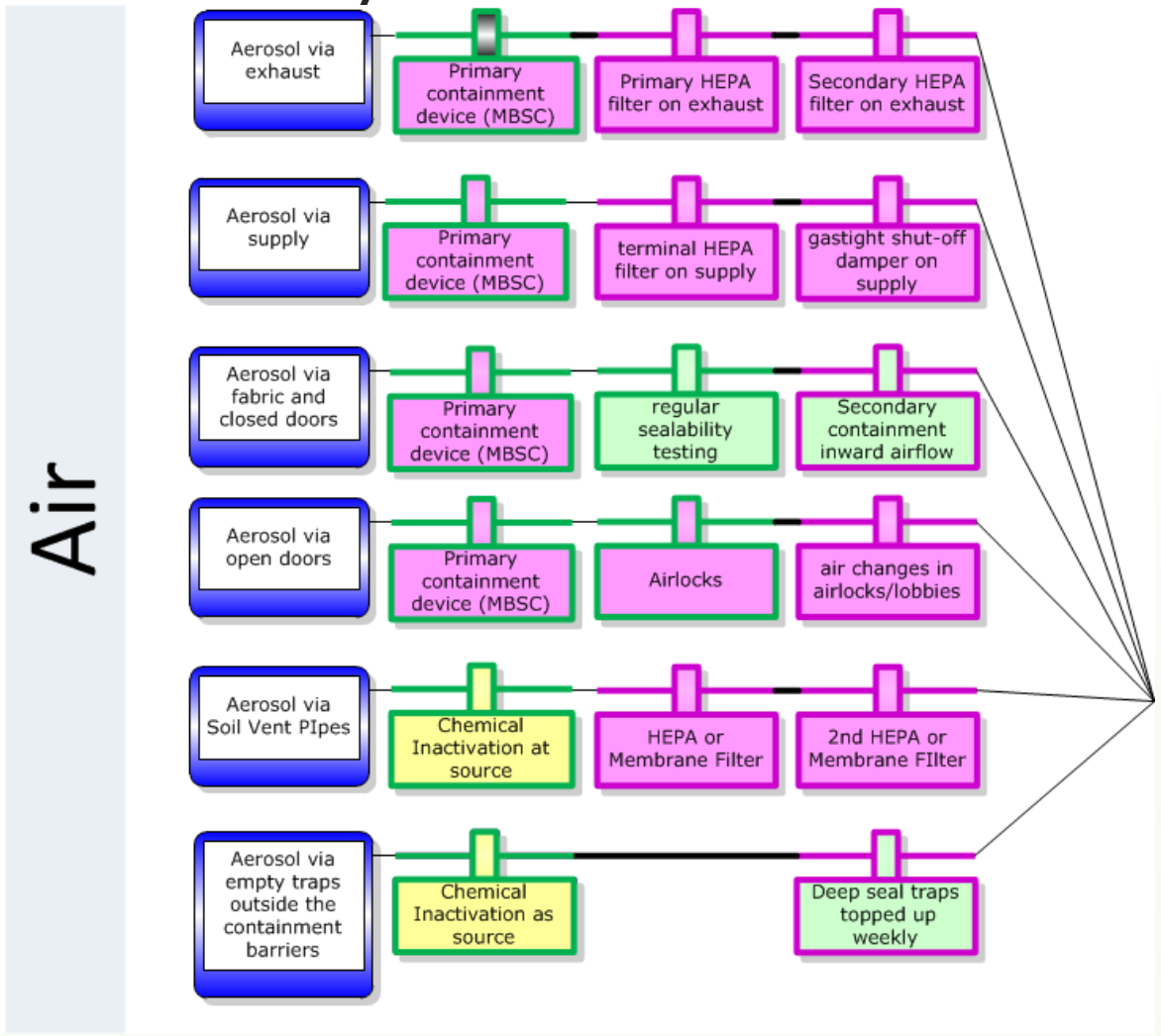
Controls – Protection Layers

Passive Controls	Dynamic Controls	Management Controls
air tight barrier construction	directional inward air flow	Alarm Response Protocol
Double Exhaust HEPA filtration, supply HEPA protection	Air changes Open door velocity air flow	HEPA filter validation
Compression seal door	Inflatable seal door	Protective Clothing
Multiple compartment access lobbies	Barrier shower & change protocols	Process validation
Box in a box principle	Fully encapsulated suits ?	Procedures

- risk path consequence
- risk path likelihood
- detectability of failure

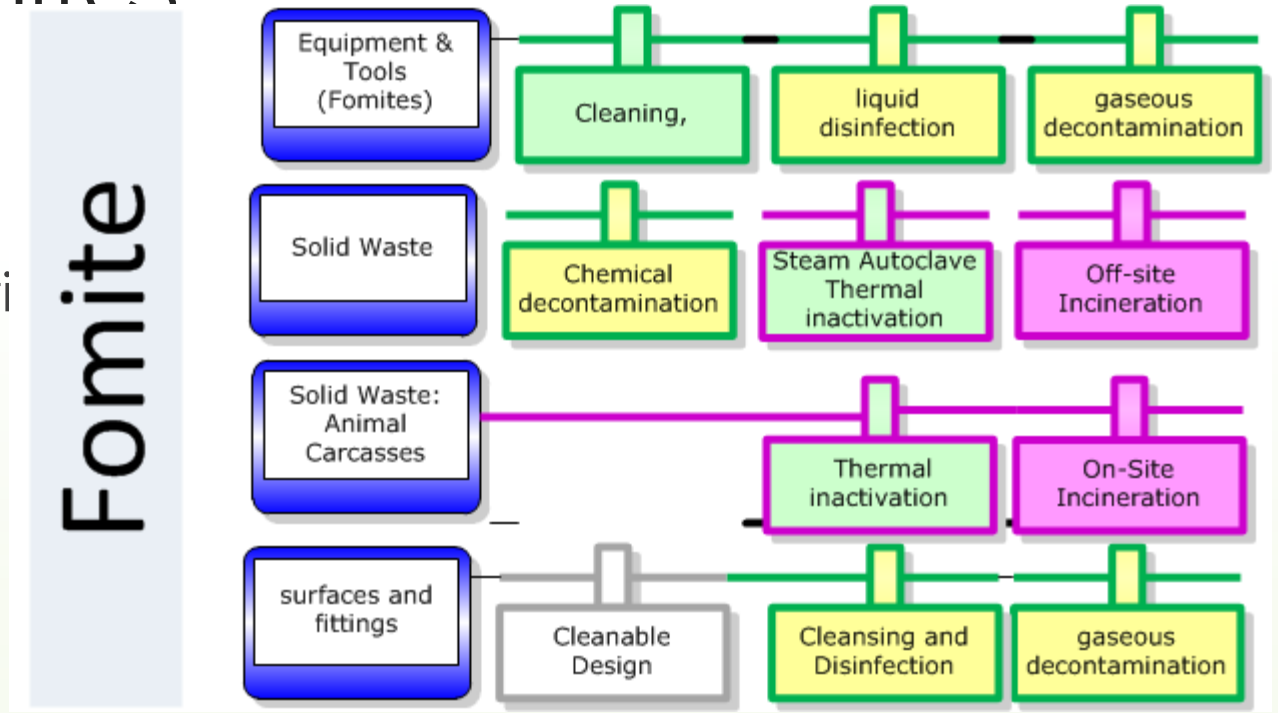
Risk Control Systems Air

1. Primary containment devices
2. HEPA filtration on extract
3. 2nd HEPA on extract and HEPA on supply
4. Deep seal traps
5. Soil vent filters
6. Airlocks
7. Inward directional airflow (pressure cascades)
8. Room Sealability for gaseous decontamination
9. Ability to isolate each space supply and exhaust
10. Air pre-filtration in primary containment spaces
11. Air changes in laboratories
12. Laminar airflow



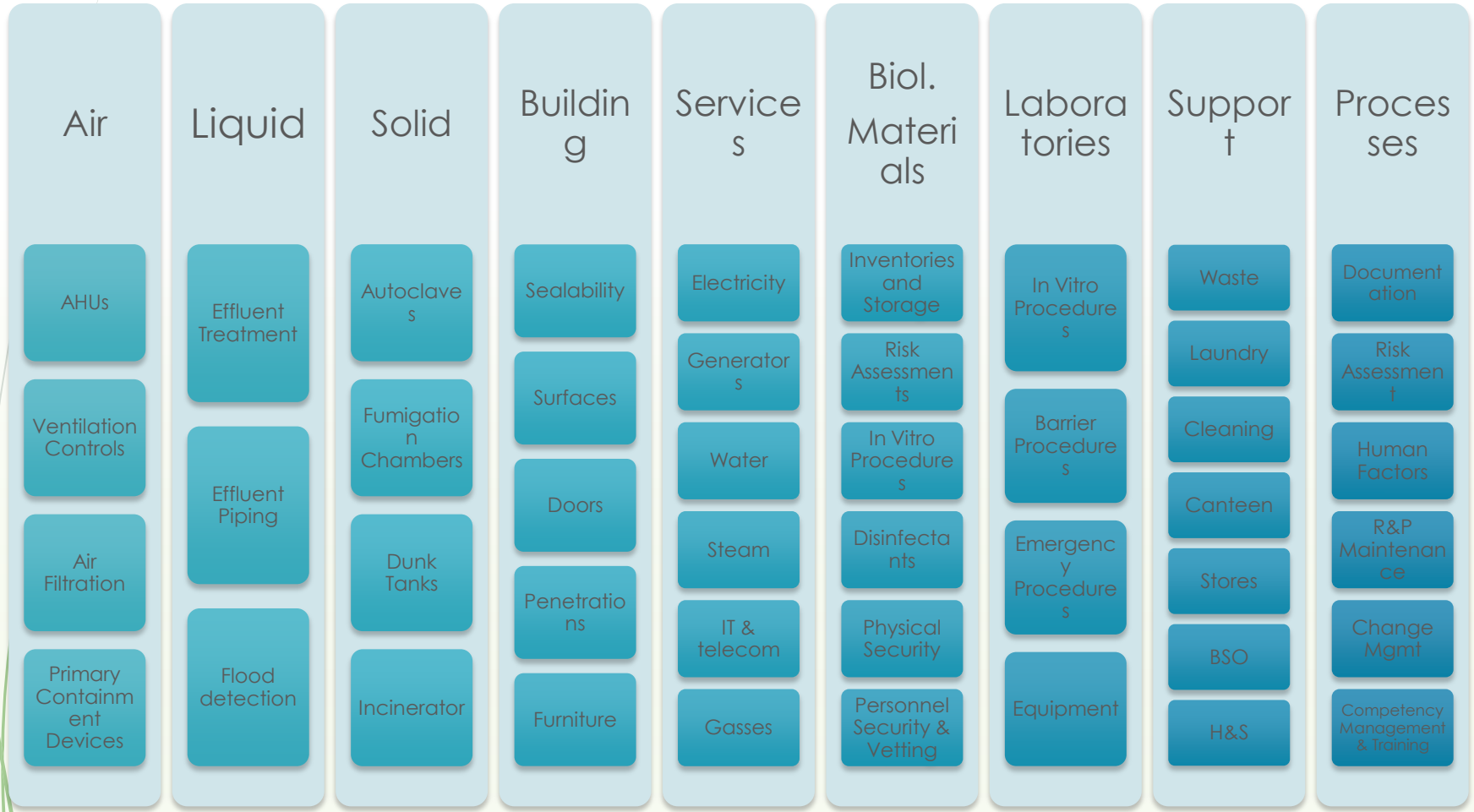
Risk Control Systems - Fomites

1. Cleaning
2. Disinfection
3. Gaseous decontaminati on
4. Steam Autoclave
5. Dunk Tank
6. On/off- site incineration
7. (natural inactivation)



During operation fomites can be any inanimate objects that are removed from the containment, including waste. During shut-down and with respect to operator exposure the ability to decontaminate fabric, fixtures and fittings

Main Risk Paths and Control Elements

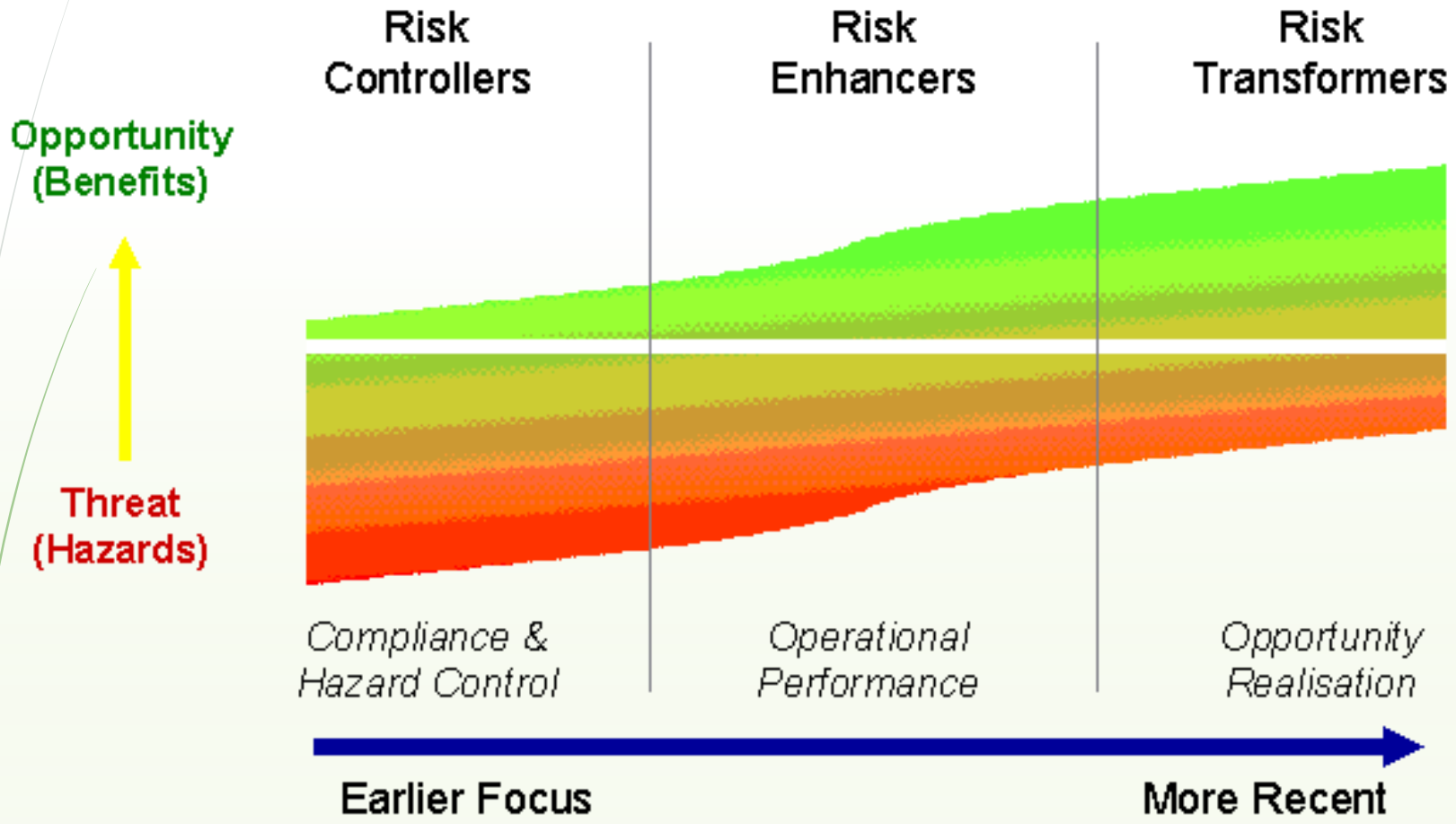


Process Based Biorisk Management Elements

Prioritise the user requirements

- Critical - mission is compromised without
- Essential – key benefits of the mission are compromised
- Nice to have – maximise the scientific benefits
- Today, tomorrow, in 10 years – Ensure short term needs to not compromise critical and essential long term needs. If the shut-down does not work the start-up will not happen

Biorisk Management Maturity



Thank You

EUFMD Biorisk Committee

International Veterinary Biosafety Workgroup
www.ivbw.camp9.org

OIE ad hoc group for biosafety

European Biosafety Association
www.ebsaweb.eu

Uwe Mueller-Doblies
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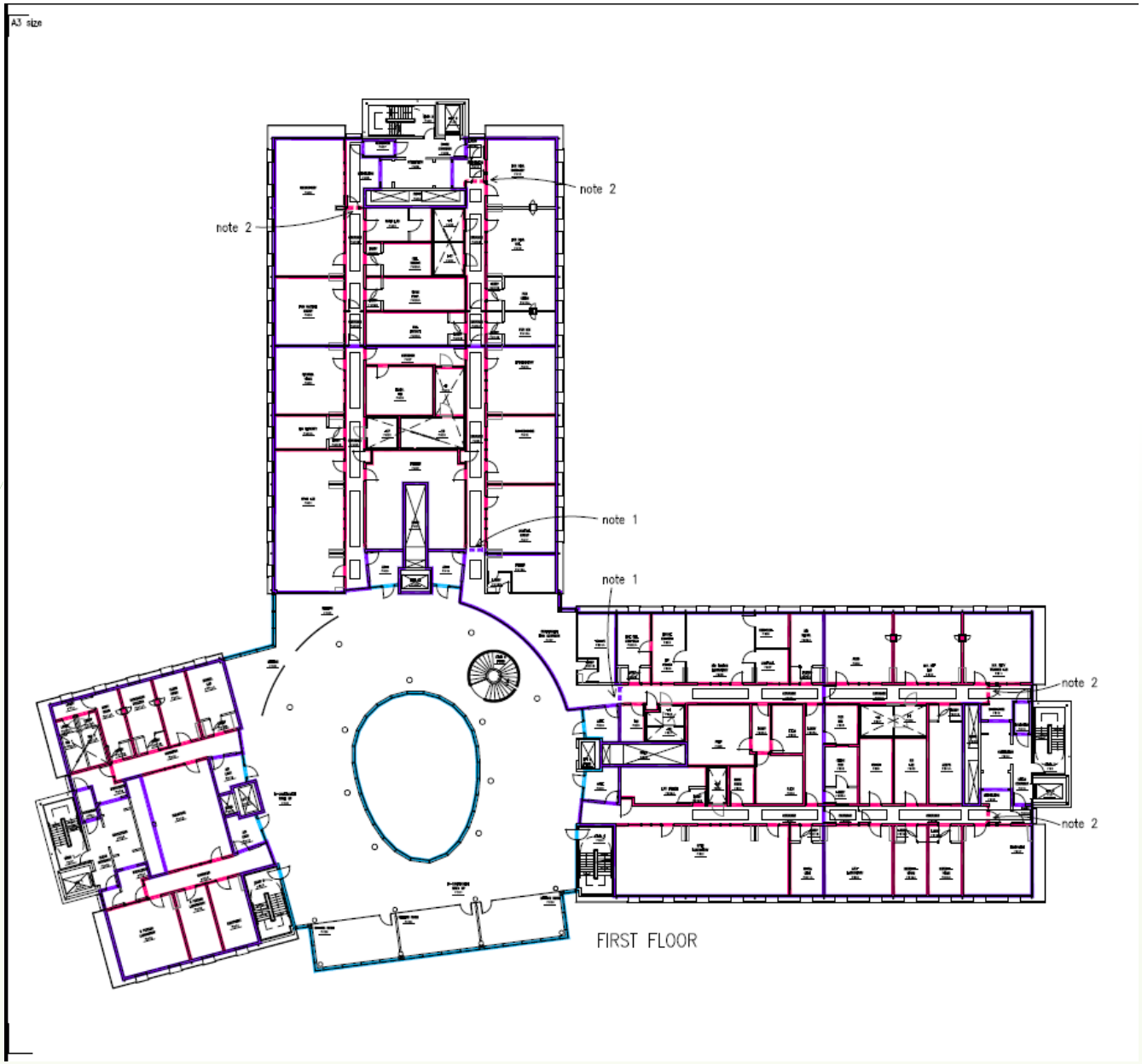
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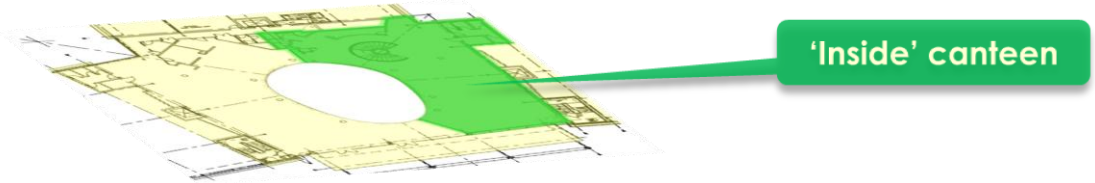
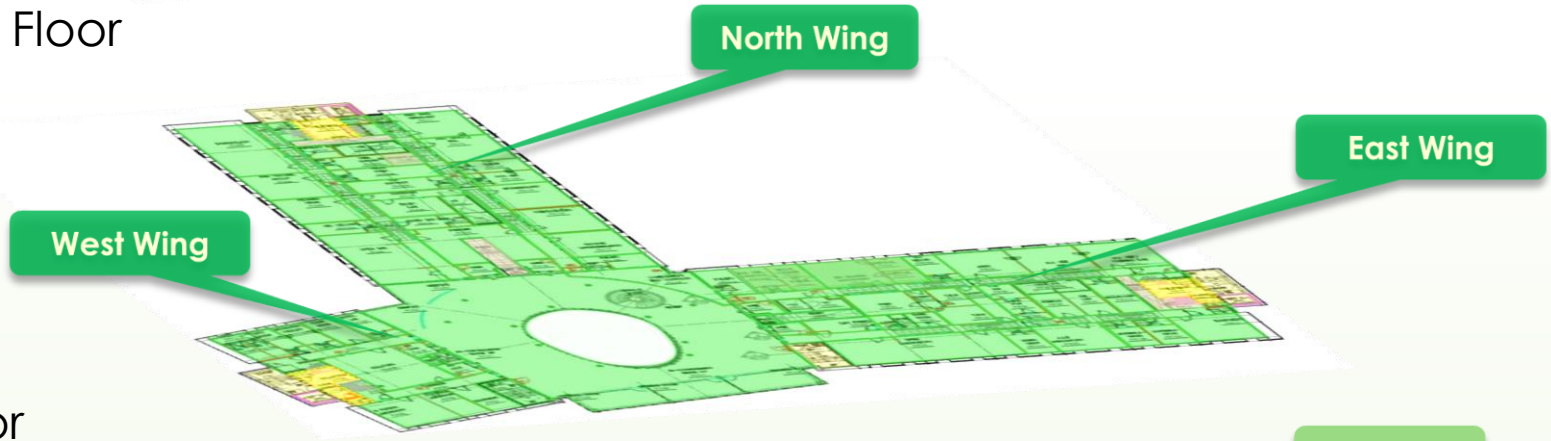
note 2
FIRST FLOOR

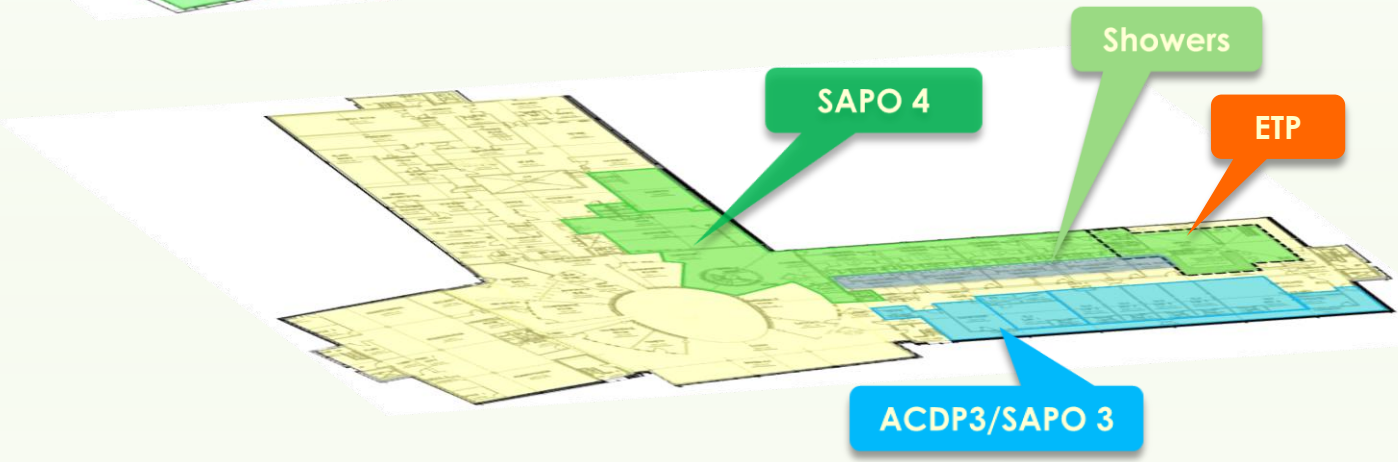
DP1 all floors



Second Floor



First Floor



Ground Floor

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Functional Space Coordination

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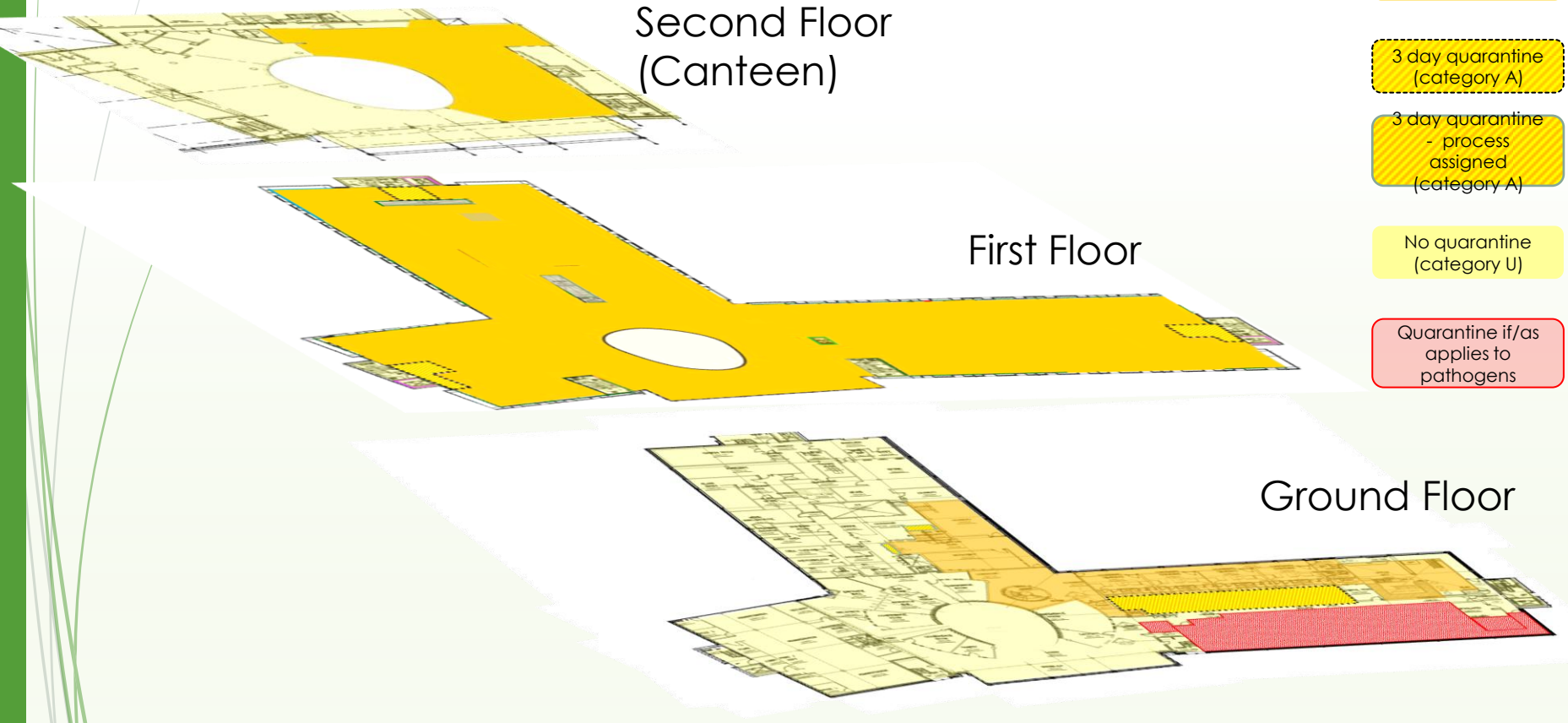
Quarantine areas – all floors



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Ground floor plan: RS spaces

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