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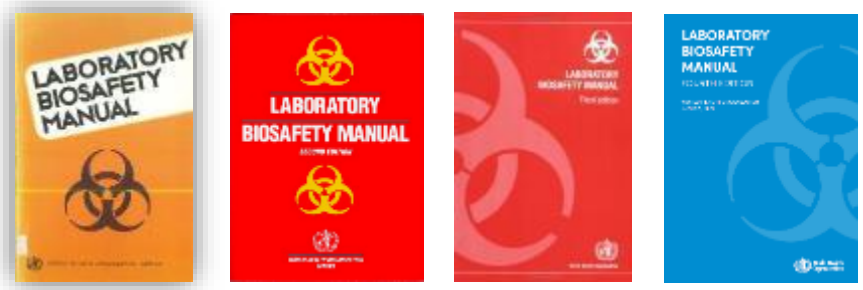
Biological Risk Assessment: How safe are we in our labs if we apply the risk based approach according to the new WHO Biosafety Manual?

Kathrin Summermatter



Who I am

Kathrin Summermatter
Head of the Biosafety Center ifik,
University of Berne, Switzerland

Scientific contributor to:
LBM, 4th edition
Monograph risk assessment
Monograph decontamination
Monograph PPE

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Where I work

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Institute for Infectious Diseases of the University of Berne

- Clinical microbiology (bacteriology, virology, parasitology, mycology) 24/7/365
- Research and development
- Teaching

- Staff: appr. 180
- BSL1,2 and 3; ABSL1 and 2
- Biosafety Center

Overview - structure

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Introduction

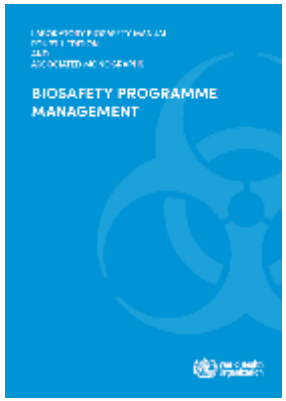
The WHO risk based approach

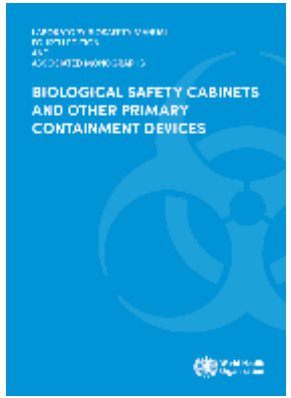
The new laboratory biosafety manual and monographs

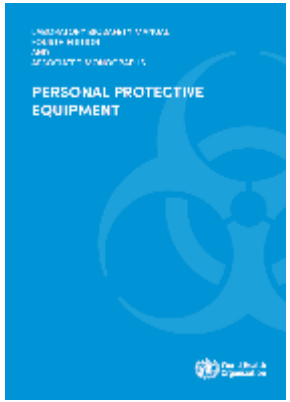
The risk based approach for SARS-CoV-2 diagnostic: an example

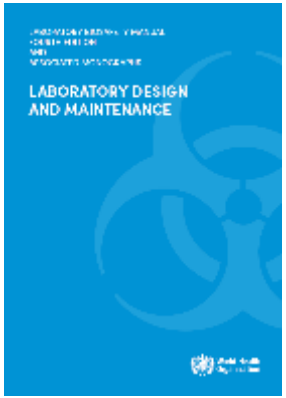
Conclusions

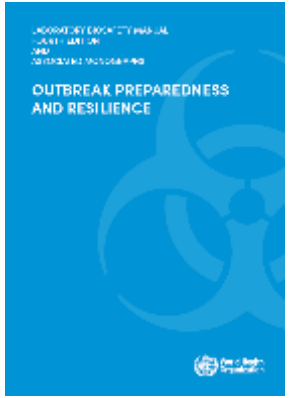
Introduction











https://www.who.int/publications/i/item/9789240011311

What is your opinion?

Will we be less safe if we apply the risk based approach?

☐ YES

☐ NO

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Laboratory associated infections

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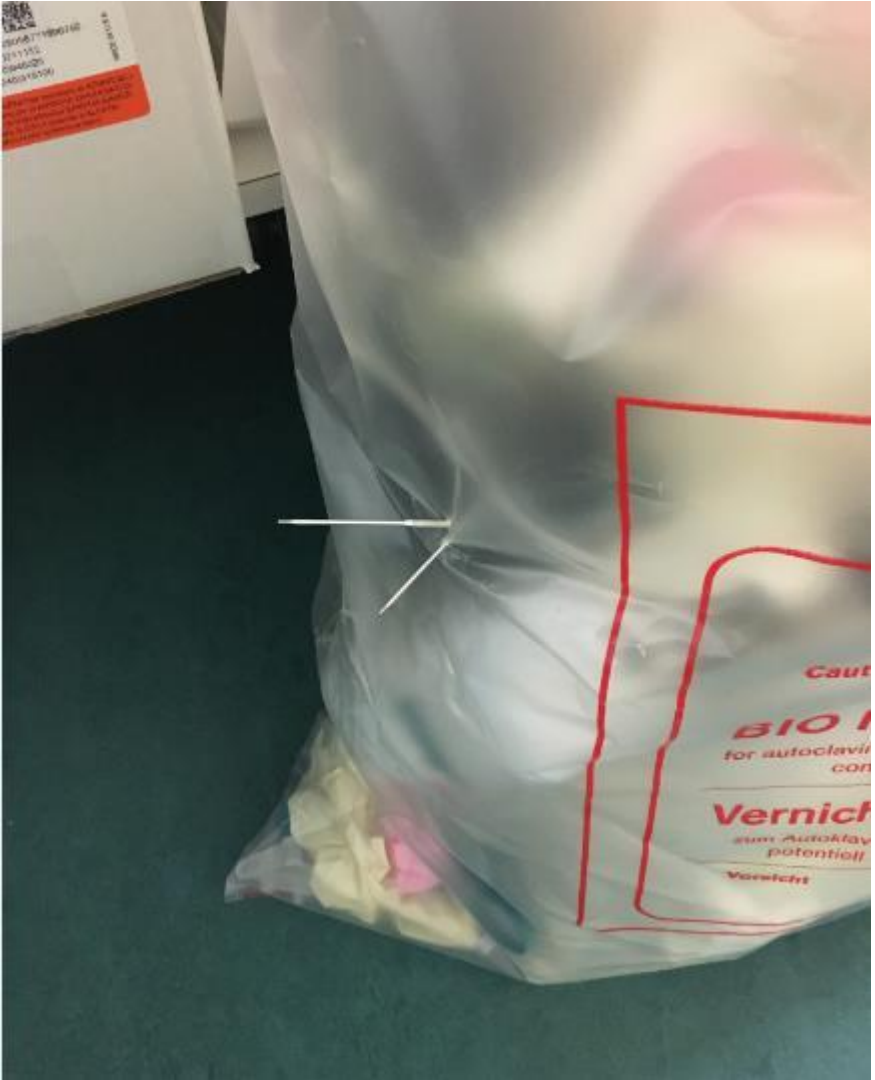
ClinMicroNet online survey of 2002-2004 (ASM):

- 88 hospital microbio labs and 3 national ref. labs
- 33 % of laboratories reported at least 1 laboratory associated infection
- Most common : shigellosis, brucellosis, salmonellosis
- Highest incidence : Brucella and Neisseria meningitidis

Incidence of infection	General population	Laboratory worker
Brucella species	0.08/100.000	641/100.000
Neisseria meningitidis	0.62/100.000	25.3/100.000

https://academic.oup.com/cid/article/49/1/142/371797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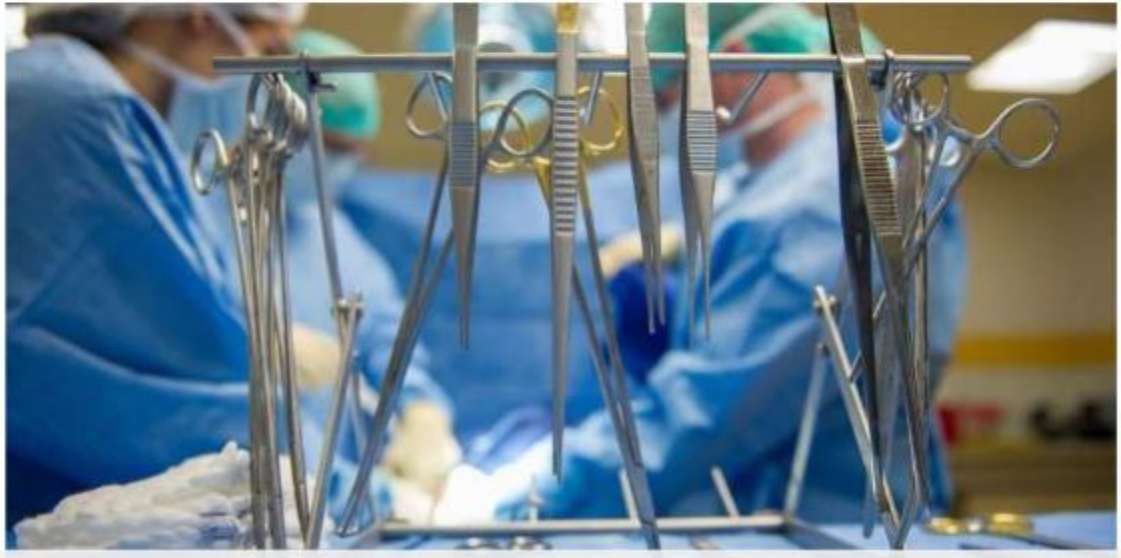
A Lab Accident Likely Led to a Woman's Death From Brain-Destroying Prions 9 Years Later

Ed Cara · 4 days ago

A lab accident in 2010 likely led to a woman's untimely death nearly a decade later, according to doctors in France. In a recent case study, they describe how a woman in her early 30s developed a universally fatal brain disorder years after she had pierced her skin with equipment used to handle infectious rogue proteins called prions.



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CORRESPONDENCE

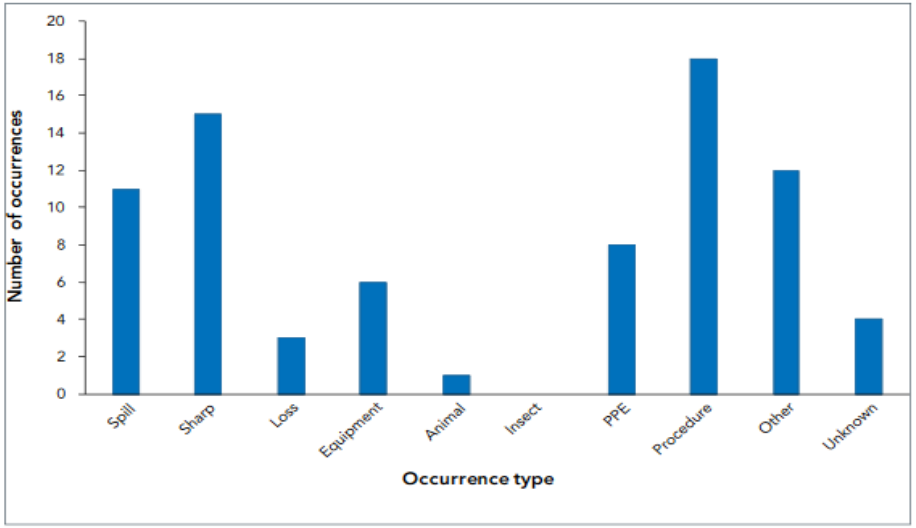
Variant Creutzfeldt–Jakob Disease Diagnosed 7.5 Years after Occupational Exposure

- While she was using forceps to handle the samples, she accidentally stabbed her thumb through a double pair of latex gloves, enough to break the skin and cause bleeding (2010).
- Conclusions: Percutaneous exposure to prion-contaminated material is **plausible in this patient, since the prion strain that she had handled was consistent with the development of variant CJD**. The 7.5-year delay between the laboratory accident and her clinical symptoms is congruent with the incubation period in the transfusion-transmitted form of the disease.

https://www.nejm.org/doi/full/10.1056/NEJMc2000687

Surveillance of laboratory exposures to human pathogens and toxins, Canada 2019

Figure 4: Reported occurrence types involved in reported exposure incidents, Canada 2019 (N=78)



Abbreviation: PPE, personal protective equipment

Table 3: Root causes reported in follow-up reports of exposure incidents, Canada 2019 (N=144) *(continued)*

Root cause	Examples of areas of concern	Citations	
		n	%
Human interaction	A violation (cutting a corner, not follow correct procedure, deviating from standard operating procedure)	35	24
	An error (a mistake, lapse of concentration, or slip of some sort)		
Management and oversight	Supervision needed improvement	20	14
	Lack of auditing of standards, policies, and procedures		
	Risk assessment needed improvement		
Training	Training not in place but should have been in place	17	12
	Training not correct for the task/activity		
	Staff were not qualified or proficient in performing the task		
Standard operating procedure	Documents were followed as written but not correct for activity/task	27	19
	Procedures not in place but should have been in place		
	Documents were not followed correctly		
Other	Not applicable	8	5

Note: Percentages rounded to the nearest whole number

https://www.canada.ca/content/dam/phac-aspc/documents/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2020-46/issue-9-sept-3-2020/ccdrv46i09a07-eng.pdf

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The WHO risk based approach

Are we less safe in the future?

- We still have laboratory acquired infections despite highly sophisticated BSLs
- Risk groups differ in description, name and expression between countries
- Different countries have differents cultures, climates, requirements and resources
- Funding to sustain the labs is not always guaranteed or underestimated

- The one fit all approach does not fit all

- WHO issues guidelines that should be applicable worldwide

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https://science.sciencemag.org/content/360/6386/260?rss=1/share

Facts

Most laboratories:

- BSL1 – BSL2
- Increasing number of BSL3
- Few BSL4

Despite existing regulations:

- Each BSL3 and BSL4 is unique
- Sophisticated enigeering controls
- Cost intensive

Question: What do we really need to perform our activities safely and secure?

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An example: Risk assessment according to Swiss containment ordinance

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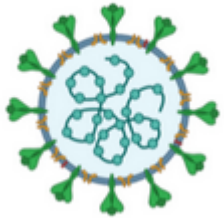
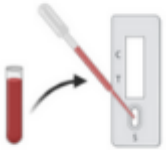
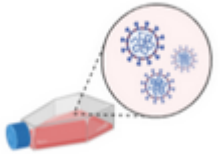
Risk group for organisms



Risk class for activities





Biosafety level for laboratories
Safety equipment
Practices and procedures

Pro’s and con’s for biosafety professionals

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So far:
Risk group -> biosafety level
National classification systems for organisms
Prescriptive measures not always based on risk
Checklist approach

WHO approach:
Risk assessment for activities (characteristics of agents, activity, facility, local / national circumstances)
Risk based mitigation measures based on available and sustainable resources

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The new laboratory biosafety manual and monographs

How to use the manual and the monographs

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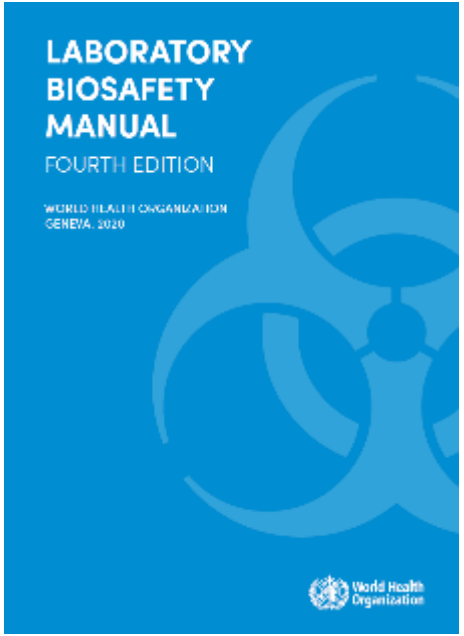
- Existing national regulations are still to be implemented at the national level and will not be undermined by the new WHO manual.
- The manual is intended to serve as a guideline and resource for biosafety professionals.
- It is open for state-level regulation that uses risk groups and biosafety levels, as well as activity-based, list-based, etc. regulation.
- Templates in the monographs
- Recommended reading to start: core document, biosafety programme management, risk assessment

4th Laboratory Biosafety Manual of WHO

Core document – nine section (appr. 90 pages):

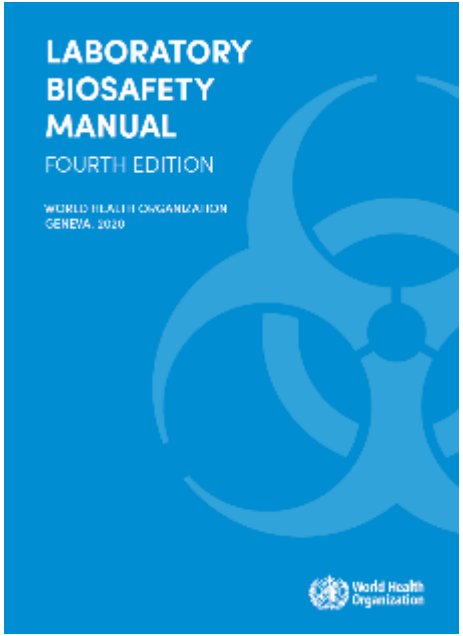
- Glossary
- Introduction
- Risk assessment
- Core requirements
- Heightened control measures
- Maximum containment measures
- Transfer and transportation
- Biosafety programme management
- Laboratory biosecurity
- National / international biosafety oversight



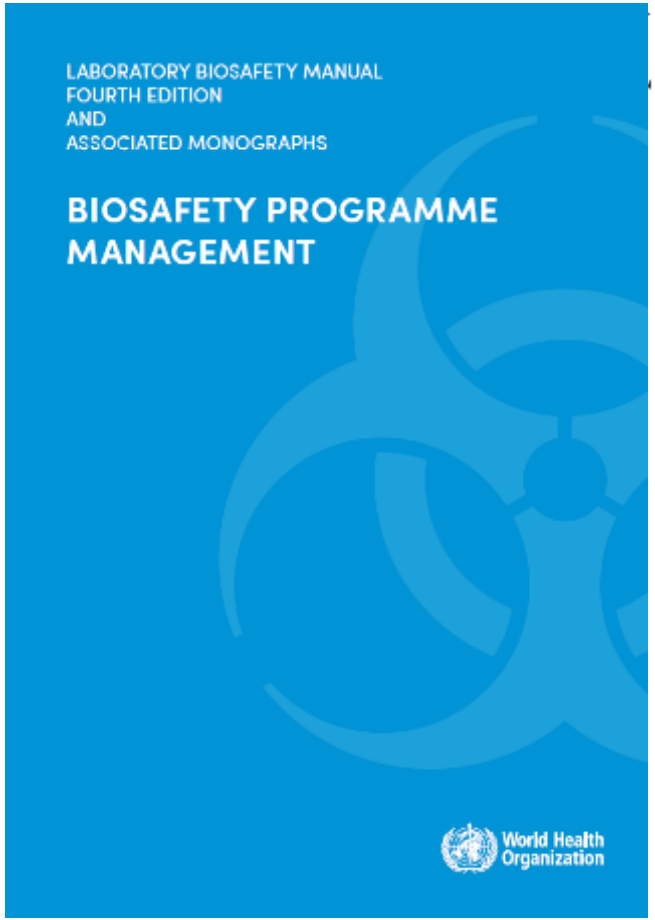
4th Laboratory Biosafety Manual of WHO

Monographs with more detailed information:

- Risk assessment
- Biosafety cabinets and other primary containment devices
- Personal protective equipment
- Decontamination and waste management
- Laboratory design and maintenance
- Biosafety programme management
- Outbreak preparedness and resilience



Biosafety programme management



Biosafety programme management cycle

- Facilities handling biological agents
  -> biosafety programme
- Roles and responsiblities (biosafety committee, BSO etc.)
- Facilities can be of various complexities
- Use of low to high consequence pathogens

Figure 2.1 Biosafety programme management cycle

Helpful templates

ANNEX 1. Pathogen safety data sheet template

ANNEX 2. Biosafety risk assessment template

ANNEX 3. Biosecurity risk assessment template

ANNEX 4. Biosafety manual template

ANNEX 5. Biosecurity plan template

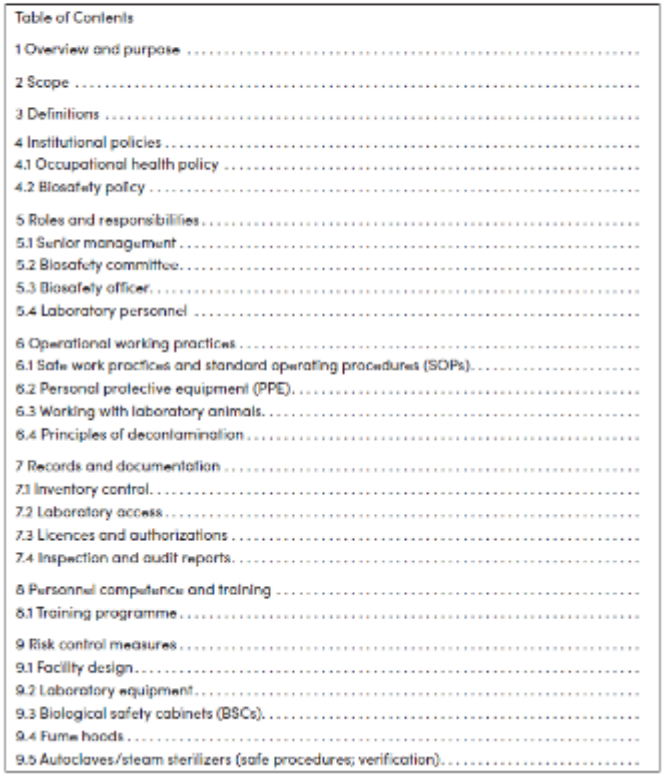
ANNEX 6. Occupational health and safety programme template

ANNEX 7. Emergency response template

ANNEX 8. Incident reporting form and investigation report

ANNEX 9. Inventory template

ANNEX 4. BIOSAFETY MANUAL TEMPLATE



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Pathogen safety data sheet template

Pathogen safety data sheet template

SECTION 1 Biological agent

Pathogen		
Pathogen *(Official taxonomic naming convention)*		
Other names *(for example, former taxonomic name, common name)*		
Agent type	☐ Bacterium ☐ Fungus ☐ Parasite	☐ Virus ☐ Prion ☐ Other (describe)
Taxonomy	Family	
	Genus	
	Species	
	Subspecies/strain/clonal strain	
Characteristics	Appearance	
	Size	
	Shape	
	Genome structure *(for example, RNA/DNA virus, sense/antisense)*	
	Other (describe)	
Properties contributing to risk	Modifications from parental strain	
	Sporulation	
	Toxin production	
	Oxygen requirements	
	Enzymatic activity	
	Life cycle	
	Reproduction	

Laboratory-associated infections		
Are there known exposure incidents within the organization?	☐ No ☐ Unknown	☐ Yes (describe incidents and circumstances)
Are there known exposures external to the organization? *(Evidence from the literature [research, diagnostic, health care] of laboratory-associated infections with the biological agent, including the circumstances)*	☐ No ☐ Unknown	☐ Yes (describe)
Sources/specimens		
List primary biological specimens likely to contain the biological agent *(for example, blood, urine, semen, mucous, faeces, necropsy tissues)*		
Primary hazards		
Indicate primary hazards	☐ Ingestion ☐ Exposure ☐ Auto-inoculation ☐ Inhalation ☐ Fomites	☐ Bites/scratches (from infected animal) ☐ Exposure to animal waste or carcasses ☐ Other (describe)
Special hazards		
Indicate special hazards *(for example, in diagnostic laboratories that receive potentially contaminated testing request forms shipped in the same box as the specimens)*		

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Risk assessment

How to use the monograph

- Monograph is designed to accompany and support the core document as well as other monographs
- Other monographs provide details for systems and strategies to mitigate risks
- Monograph describes the risk assessment process including the selection of the team
- Questions to be addressed
- Ranking of risks
- Risk control strategies
- Lessons learnt
- Two templates for risk assessments
- Examples or key steps in the risk assessment
- Examples of completed risk assessments

Core element: Risk Assessment

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ADORA - principle:

All **D**epend **O**n **R**isk **A**ssessment

Risk

Risk = likelihood x consequence

Likelihood: probability of an incident (exposure / release) occurring in the course of laboratory work

Consequence: Outcome of an incident (exposure / release) of varying severity of harm, occurring in the course of laboratory operations (laboratory associated infections, illness, physical injury, environment contamination, asymptomatic carriage of a biological agent)

The risk assessment framework

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Standardized and structured way:

- Gather information
- Evaluation of risk
- Development of risk control strategy
- Selection and implementation of controls
- Review

We have to know what we are doing!

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- Biological Material
- Type of laboratory work / procedures
- Type of equipment
- Laboratory facility
- Human factors (e.g. competency)
- Other factors (legal, political, cultural, public perception etc.)

Likelihood of an exposure or release occuring during the laboratory work

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- *Rare*: almost impossible to occur
- *Unlikely*: not very possible to occur
- *Possible*: might occur
- *Likely*: very possible to occur
- *Almost certain*: highly probable to occur

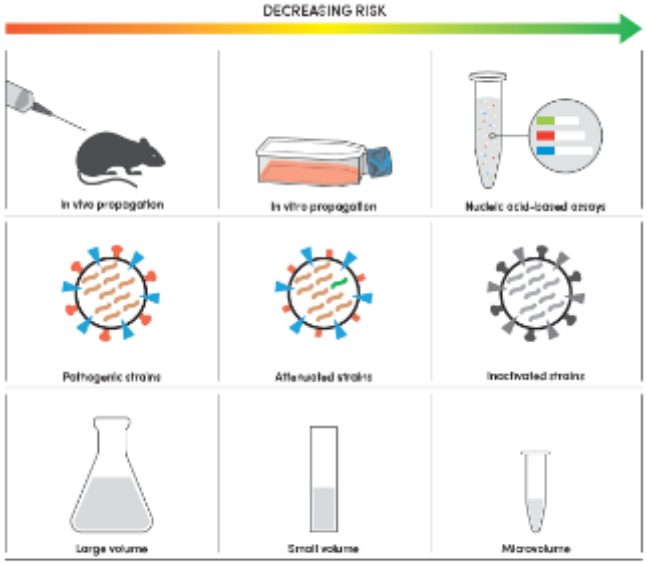

Figure 3.2 Examples of techniques to reduce or eliminate the risks of infection associated with manipulating biological agents. The lower risks reduce the need for risk control measures that would otherwise be required.

Severity of consequences

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- *Negligible*: Trivial incident or near miss requiring reporting and follow up
- *Minor*: Incident with self-limiting consequences
- *Moderate*: Incident that requires medical treatment and/or has insignificant environmental consequences
- *Major*: Incident with potential lost time due to infection but non-permanent consequence and/or limited environmental impact
- *Severe*: Potential fatality or serious illness with permanent disability and/or serious environmental impact

Qualitative vs. quantitative approach

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Although a qualitative approach to combining likelihood and severity parameters in a risk matrix is provided as a risk evaluation method here, it is important to note that quantitative (for example, simple numerical scoring schemes to complex mathematical models) and hybrid (semi-quantitative) methods can also be used for risk evaluation. Laboratories should use a risk evaluation/ assessment method that best meets their unique needs, without excluding the possibility of developing customized evaluation approaches, scoring methods and definitions of the parameters.

Determination of initial risk

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- How could an exposure / release occur?
- How likely is an exposure or release?
- What are the consequences of an exposure or rerlease?
- What can influence the likelihood or consequences?
- What measures are already in place?
- What is the overall risk of the activities?
- What are the advantages and disadvantages of different types of controls?
- Is the risk acceptable? If no, can the risk be controlled?

Factors associated with high likelihood of incidents occuring

- Aerosol formation
- Sharps
- Low competency of lab personnel
- High environmental stability
- Malfunctioning equipment, poor availability of electricity, poorly maintained facility, access of insects and rodents

Factors associated with greater consequences if an incident were to occur

- Low infectious dose
- High communicability
- High severity and mortality
- Limited availability of prophylaxis or treatment
- Large susceptible population
- Lack of endemicity (e.g. exotic disease)

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Factors associated with high likelihood and greater consequences if an incident were to occur

- High concentration or volume or numbers of samples
- Airborne route of transmission

Templates for the risk assessment

Institution/Facility name	
Laboratory name	
Laboratory manager/Supervisor	
Project titles/Relevant standard operating procedures (SOPs)	
Date	

If using this template, complete all sections following the instructions in the grey boxes. The instructions and bullet points in the grey boxes can be copied into the text boxes beneath the instructions and used as prompts to gather and record the necessary site-specific information. The grey instruction boxes can then be deleted, and the text remaining will form a risk assessment draft. This draft must be carefully reviewed, edited as necessary and approved by the risk assessment team members.

STEP 1. Gather information (hazard identification)

Instructions: Provide a brief overview of the laboratory work and summarize the laboratory activities to be conducted that are included in the scope of this risk assessment.	
Describe the biological agents and other potential hazards (for example, transmission, infectious dose, treatment/preventive measures, pathogenicity).	
Describe the laboratory procedures to be used (for example, culturing, centrifugation, work with sharps, waste handling, frequency of performing the laboratory activity).	
Describe the types of equipment to be used (personal protective equipment (PPE), centrifuges, autoclaves, biological safety cabinets (BSCs)).	
Describe the type and condition of the facility where work is conducted.	
Describe relevant human factors (for example, competency, training, experience and attitude of personnel).	
Describe any other factors that may affect laboratory operations (for example, legal, cultural, socioeconomic).	

STEP 2. Evaluate the risks

Instructions: Describe how exposure and/or release could occur.	
What potential situations are there in which exposure or release could occur?	
What is the likelihood of an exposure/release occurring (unlikely, possible, likely)?	
What is the severity of the consequences of an exposure/release (negligible, moderate, severe)?	

Instructions: Evaluate the risk and prioritize the implementation of risk control measures. Circle the initial risk of the laboratory activities including risk control measures described in STEP 1 but before any additional risk control measures have been put in place.

Note:

- **When assigning priority, other factors may need to be considered, for example, urgency, feasibility/sustainability of risk control measures, delivery and installation time and training availability.**
- **To estimate the overall risk, take into consideration the risk ratings for the individual laboratory activities/procedures, separately or collectively as appropriate for the laboratory.**

		Likelihood of exposure/release		
		Unlikely	Possible	Likely
Consequences of exposure/release	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium

Laboratory activity/procedure	**Initial risk (very low, low, medium, high, very high)**	**Is the initial risk acceptable? (yes/no)**	**Priority (high/medium/low)**

Select the overall **initial** risk.	☐ Very low	☐ Low	☐ Medium	☐ High	☐ Very high
Should work proceed without additional risk control measures?	Yes ☐ No ☐				

Templates for the risk assessment for more complex activities

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2.4 Describe the initial risk of the laboratory activities before additional risk control measures have been put in place

Instructions: Circle the initial risk of the laboratory activities before additional risk control measures have been put in place. Based upon your evaluation of the likelihood and consequences of an exposure/release as listed above, assess the initial, or currently existing, risk of the laboratory activity using the table below. Find the likelihood of exposure (top row of the chart) and the consequences (left column of the chart).

		Likelihood of exposure/release				
		Rare	Unlikely	Possible	Likely	Almost certain
Consequences of exposure/ release	Severe	Medium	Medium	High	Very high	Very high
	Major	Medium	Medium	High	High	Very high
	Moderate	Low	Low	Medium	High	High
	Minor	Very low	Low	Low	Medium	Medium
	Negligible	Very low	Very low	Low	Medium	Medium

Instructions: Check the initial risk to determine the appropriate risk control measures required.

Templates for the risk assessment for more complex activities

Assessed initial risk		Potential consequences	Actions
☐	Very low	If an incident occurred, harm would be very unlikely.	Undertake the laboratory activity with the existing risk control measures in place.
☐	Low	If an incident occurred, there would be a small likelihood of harm.	Use risk control measures if needed.
☐	Medium	If an incident occurred, harm would result that would require basic medical treatment and/or simple environmental measures.	Additional risk control measures are advisable.
☐	High	If an incident occurred, harm would result that would require medical treatment and/or substantial environmental measures.	Additional risk control measures need to be implemented before the laboratory activity is undertaken.
☐	Very high	If an incident occurred, a permanent, impairing harm or death and/or extensive environmental effects would be likely.	Consider alternatives to doing the laboratory activity. Comprehensive risk measures will need to be implemented to ensure safety.

Risk tolerance

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*It is important to note that risk can **never be completely eliminated unless the work is not performed** at all.*

X

✓

Select and implement risk control measures

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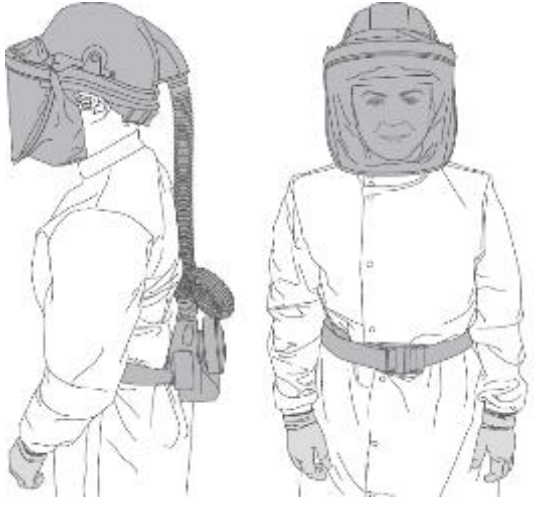
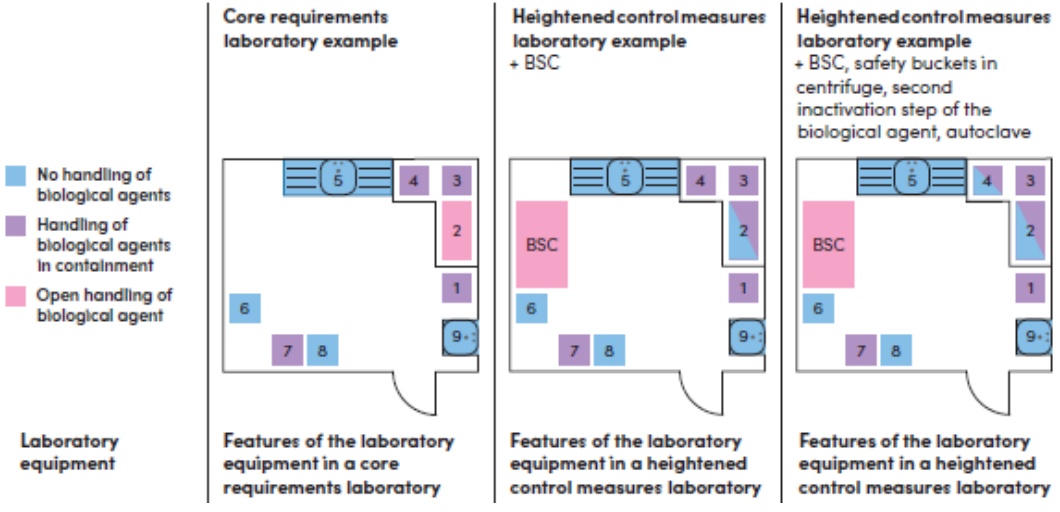
- National / international regulation -> measures need to comply / permits
- What risk control measures are locally available and sustainable?
- Are these efficient or are additional control measures needed to enhance efficacy?
- What is the residual risk, is it tolerable?
- Enough resources (operation, maintenance) ?
- Are additional resources needed?
- Have personnel been trained?

Risk mitigation measures

- Core requirements (e.g. GMPP)
- Heightened control measures (e.g. BSC)
- Maximum containment measures: highest protection of worker, community and population





Good microbiological practices and procedures

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GMPP are the most essential risk control measures because human error, suboptimal laboratory techniques and improper use of equipment have been found to cause the most laboratory injuries and laboratory-associated infections.

Source:
Monograph: Laboratory design and maintenance

Break – 15 minutes

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Please submit questions and comments by using the chat function!

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The risk based approach for SARS-CoV-2 diagnostic: an example

Activities in a diagnostic setting

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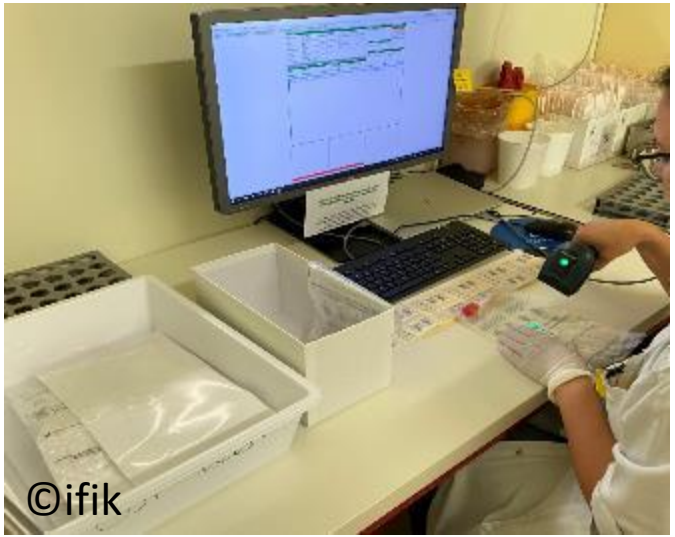
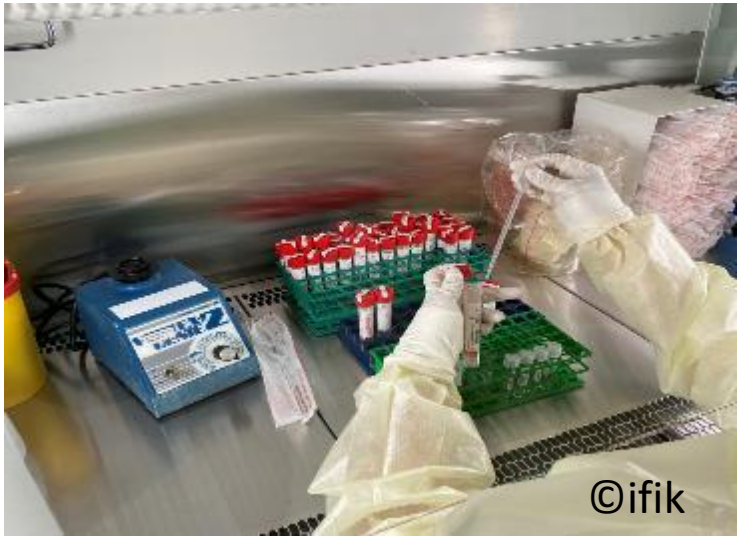
Unpacking, sample splitting, inactivation of samples
PCR of inactivated samples
PCR of non inactivated samples





Activities involving SARS-CoV-2: the traditional approach

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The traditional approach:

- SARS-CoV-2: *Risk group 3*
- Diagnostic of SARS-CoV-2: *biosafety level 2 laboratory* -> need to be notified to the authorities
- Research or activities involving cultivation: *biosafety level 3 laboratory* -> needs a permit

-> Which safety measures for which step?
-> Biosafety level 2, but is this enough?
- > What about the procedures?

Risk assessment of the different activity steps

Procedures	Hazards	How likely is this ?**	Consequence	Inherent Risk
A) Sample check, registration	• Container leaks, spill inside plastic bag • Container breakage (sharps)	**Possible**	**Negligible**	**Low**
B) Unpacking samples – vortexing samples	• Aerosol exposure during sample processing • Eye splash during sample processing • Infectious material spill	**Possible to likely**	**Moderate**	**Medium to High**
C) Pipetting samples		**Possible to likely**	**Moderate**	**Medium to High**
D) Centrifugation	• Aerosol formation • Breakage of a tube	**Possible**	**Moderate**	**Medium**
E) Decapping and loading of the automate – removal and recapping of samples	• Spill of tubes • Dropping of tubes	**Possible**	**Moderate**	**Medium**

**The likelihood will depend on control measures that are already in place

Initial risk categorisation

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Consequences of exposure/ release	Severe	Medium	High	Very high
	Moderate	Low	D/E	B/C High
	Negligible	Very low	A Low	Medium
		Unlikely	Possible	Likely
		Likelihood of exposure/release		

Which of the following would you select?

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- ☐ FFP3 respirator for pipetting samples
- ☐ HEPA-filter exhaust air
- ☐ Safety bucket for centrifuge
- ☐ Biosafety cabinet
- ☐ Spill kit

Procedures	Hazards	How likely is an exposure or release?**	Consequence	Inherent Risk
Sample check, registration	• Container leaks, spill inside packaging system • Container breakage (sharps)	**Possible**	**Negligible**	**Low**
Unpacking samples – vortexing samples **-> Biosafety cabinet**	• Aerosol exposure during sample processing • Eye splash during sample processing • Infectious material spill	**Unlikely**	**Moderate**	**Low**
Pipetting samples: **-> Biosafety cabinet**		**Unlikely**	**Moderate**	**Low**
Centrifugation **-> safety buckets**	• Aerosol formation • Breakage of a tube	**Unlikely**	**Moderate**	**Low**
Decapping of tubes and loading of the automate – removal and recapping of samples **-> respiratory protection**	• Aerosols due to dropping tubes	**Unlikely - Possible**	**Moderate**	**Low - Medium**

**The likelihood will depend on control measures that are already in place

Overall risk

Overall risk with additional measures: low – medium

Consequences of exposure/ release				
	Severe	Medium	High	Very high
	Moderate	Low	Medium	High
	Negligible	Very low	Low	Medium
		Unlikely	Possible	Likely
		Likelihood of exposure/release		

Some challenges triggering risk assessments

- Personnel (risk awareness, training, stress, fatigue, rules for social distancing)
- Space (testing equipment, BSC, storage …..)
- Reagents and material inlcuding PPE
- Waste management (solid – liquid)
- How to react to constant changes and to keep the risk assessment up-dated?

Conclusions

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- Intended to prevent **exposure** and **release**
- Risk based approach to be used in a more structed way
- It is more flexible and globally applicable
- Applicable to outbreak situations

Challenges:

- Awareness raising to promote the risk based approach
- Need to share information about biosafety solutions and biosafety best practices
- Need to share lessons learnt

“The overall effect of such developments may **increase global risk of accidental or intentional deliberate release**.”

https://science.sciencemag.org/content/360/6386/260/tab-e-letters

☐ YES

☐ NO

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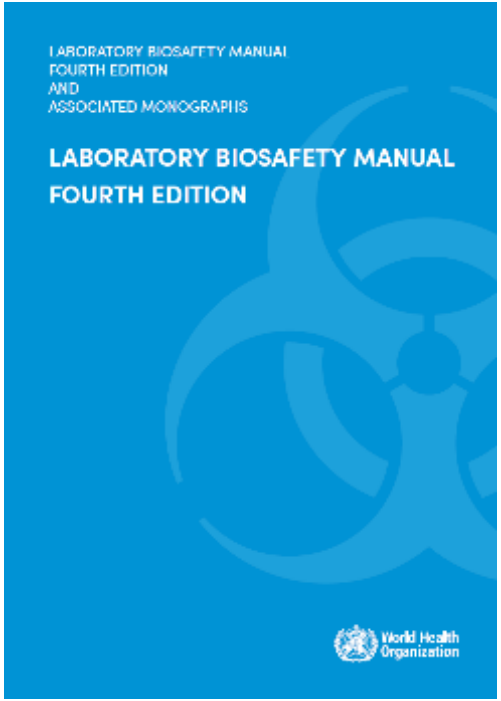
The manual should **complement** any national regulation and oversight mechanisms that may be in place!

It may help countries establishing their own regulations.



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Thank you for your attention!

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Link to WHO website:
Safeguarding biosafety and biosecurity in laboratories

https://www.who.int/activities/safeguarding-biosafety-and-biosecurity-in-laboratories

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