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HAZARDOUS BIOLOGICAL AGENTS REGULATIONS 2022

Reg 12: MAINTENANCE AND VERIFICATION

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VERIFICATION AND MAINTENANCE THROUGH *DOCUMENTED* RISK-BASED PROTOCOLS:

1. For all control measures (including PPE, plant, machinery, and facilities) risk-based maintenance and verification protocols must be:
   - developed,
   - maintained,
   - documented,
   - and made available
   - by a COMPETENT PERSON
2. All control measures must be maintained and verified in accordance with these protocols and,
3. Results documented and available

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RISK MANAGEMENT LIFE-CYCLE

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RISK MONITORING: Continuous Improvement

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DOCUMENTED RISK-BASED PROTOCOLS INCLUDE:

- performance parameters and minimum acceptance criteria;
- performance monitoring methodology and intervals;
- routine maintenance requirements, specifications and intervals;
- compliance with relevant standards, regulations and manufacturer's requirements;
- minimum competency and training required to perform monitoring and maintenance activities.

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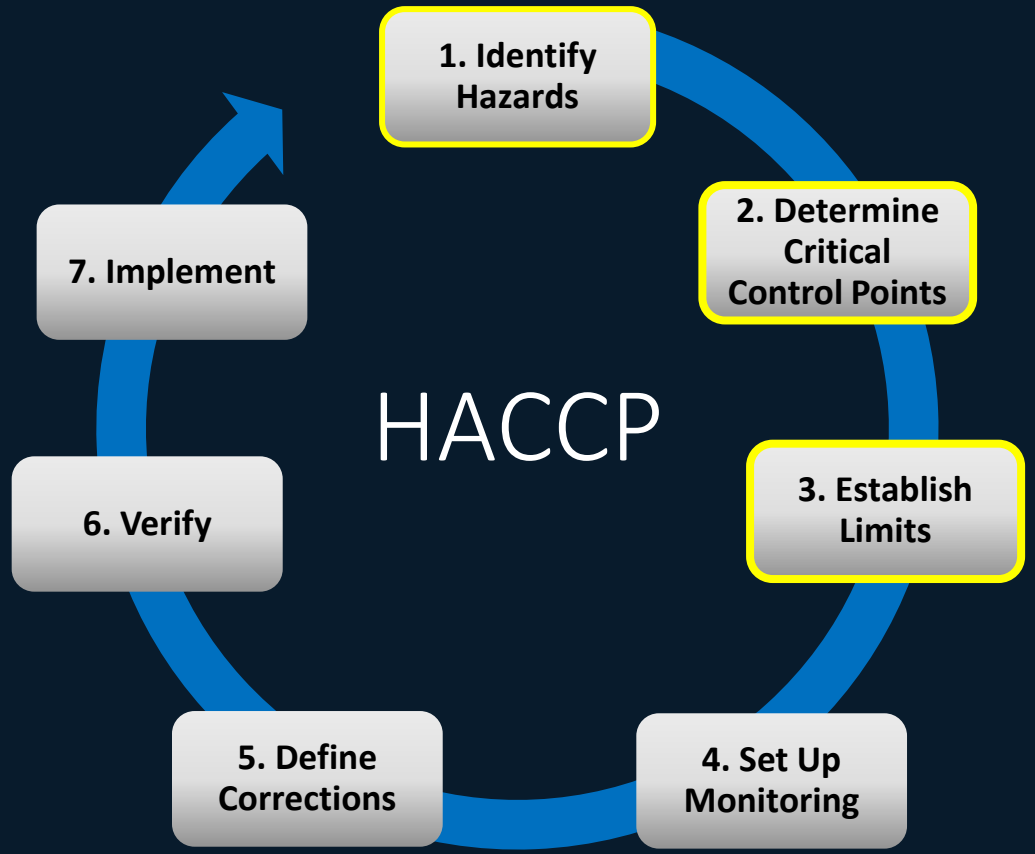
- performance parameters and minimum acceptance criteria;

DETERMINE PERFORMANCE PARAMETERS:



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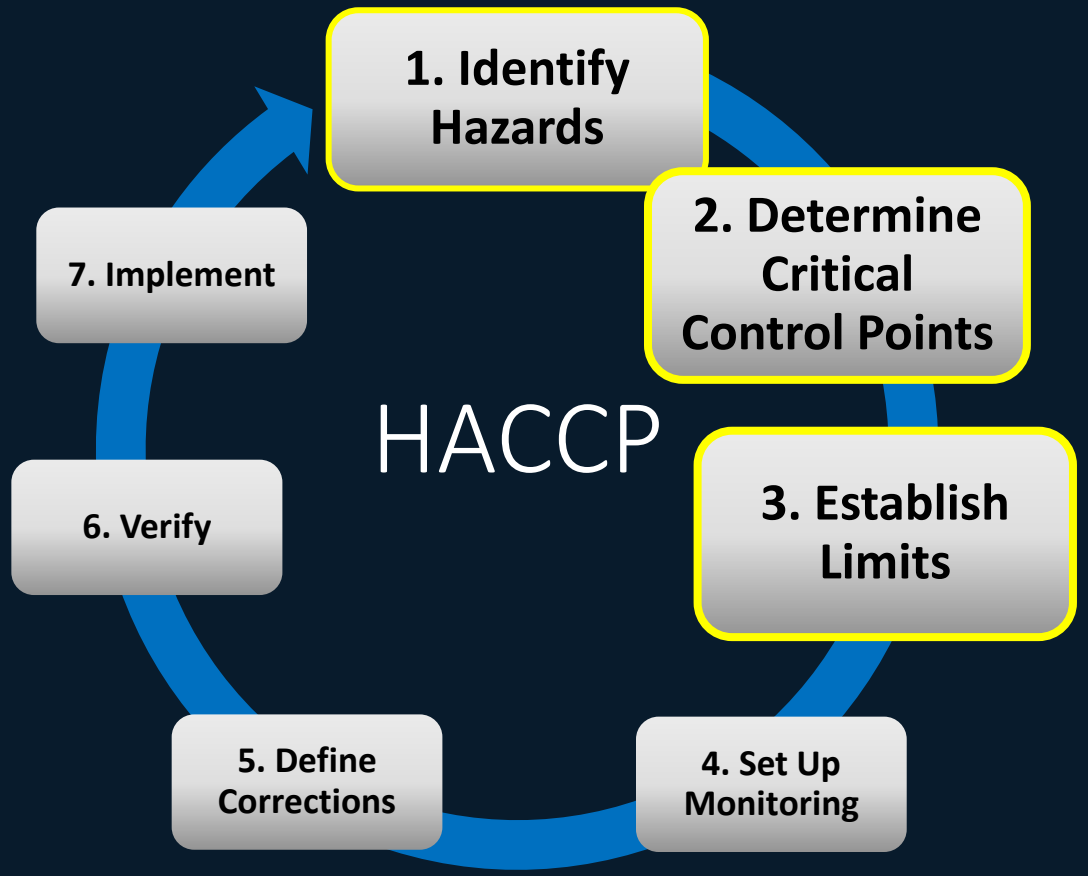

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performance parameters and minimum acceptance criteria;

RISK CONTROLS – (ENGINEERING)

Risk	Control	Performance limits (typical)
Agent Aerosolization & Transmission	Static Air Pressure difference	Negative from uncontaminated to contaminated zone (-15Pa)
	Local Exhaust Ventilation	Exhaust air volume rate (8 m/s , 0.6 m^3/s)
	Primary containment equipment (BSCs)	Downward and inward flow as per VC 8041: 2001, SANS 12469:2002
Exposure to contaminated exhaust air	Safe discharge or decontamination of exhaust air	8 m from inlets, 14m/s vertical discharge or HEPA (H13) final filter

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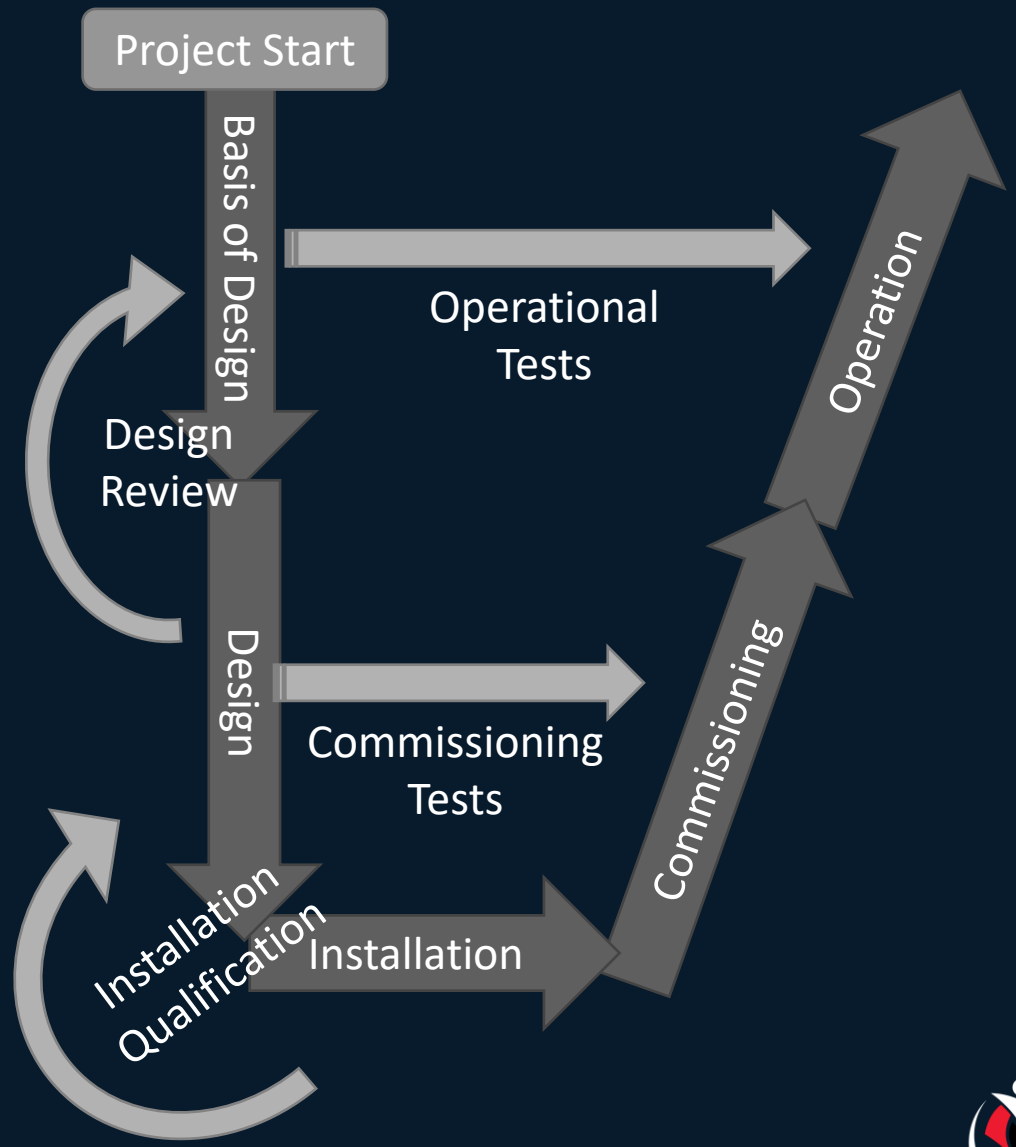
MONITORING AND TESTING LIFE-CYCLE



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PROBLEM SOLVING DISCIPLINES

- **D1** • Assign Team
- **D2** • Define Problem
- **D3** • Interim Solution
- **D4** • Root Cause Analysis
- **D5** • Identify Corrective Action
- **D6** • Implement Corrective Action
- **D7** • Implement *Preventative Controls*
- **D8** • Team Close-out

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PERFORMANCE MONITORING AND INTERVALS:

Performance Standards & Monitoring Intervals can be derived from:

• Regulations (VC 8041) :	BSCs Compulsory spec
• SANS 12469 : 2002	BSCs Performance
• SANS 10226: 2015	BSc Maintenance
• SANS 15189:2014	Lab Quality & Competence
• SANS 15190: 2021	Lab Safety
• Regulation R178:	Registration of BSLs
• NBR A19, O:	Building Regulations
• SANS 1866-1 & 2 (2018):	FFRs & surgical masks
• OIE / WHO:	LBM4 & monographs
• Animal Diseases Act, Act 35:	Act and Ass. Checklists

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minimum competency and training required to perform monitoring and maintenance activities.

COMPETENCE - Responsibility and Accountability

- "competent person" means a person who has, *IN RESPECT OF THE WORK OR TASK TO BE PERFORMED*, the required knowledge, training, experience and, where applicable, qualifications specific to HBAs;

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COMPETENCE – Responsibility and Accountability

- Consider Developing a RACI Matrix

  -(**R**esponsible, **A**ccountable, **C**onsulted, **I**nformed)
- Define RACI by role not person/company

Maintenance / Verification Task	Engineering Maintenance	Quality Assurance	Lab Manager	Validation Contractor
Filter Testing	A	C	I	R
Airflow Testing	R	C, A	I	R
Cleanup Times	C	R	A	R
Cleaning Validation	I	R, A	R	--
Test Safety Showers	R	A, C	I	
BSC Testing	I	C	A	R

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COMPETENCE - Training Plan Skills Matrix

Name	Role	Activity 1 / Course 1	Activity 1 / Course 2	Activity 2 / Course 1	Activity 4	Activity 5
Peter, B	Operator	3/2	4/4	5/4	4/4	4/4
Thabo, P	Eng Man	4/3	5/2	3/4	4/4	3/4
Linda, M	Clean	2/4	4/4	5/4	4/4	3/4
Saresh, R	Sales	1/1	1/1	4/4	3/4	5/4
Juliet, T	QAM	5/5	5/5	4/4	3/4	4/4
Tshiamo, N	V Tech	4/3	5/2	3/4	4/4	3/4

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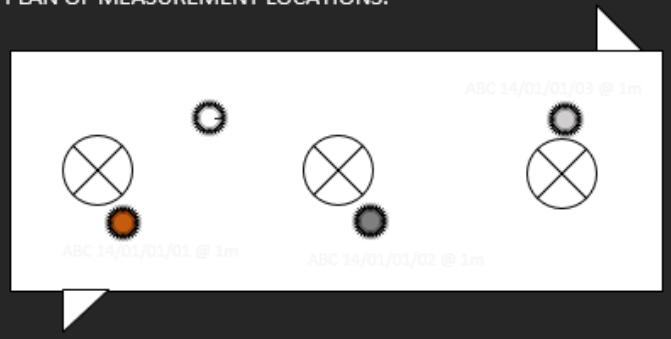
DOCUMENTATION: Should be simple and contain essential information

APPENDIX B MAINTENANCE RECORD TEMPLATE - EXAMPLE

Facility:		Room Name:				Year:
Sample rate (L/s)		Acceptance Criteria (μ CFM/cm² @ 1m)	Record Monthly Readings (Pre and Post Cleaning)			
			Quarter 1	Quarter 2	Quarter 3	Quarter 4
Device ID: ABC 14/01/01/01		≥ 230				
Device ID: ABC 14/01/01/02		≥ 230				
Device ID: ABC 14/01/01/03		≥ 220				
Lower room:		≤ 0.4				
Serial number of Sampler:						
Approved by:						
Date:						
Lamps replaced/Date:						
Comments:						

SKETCH-PLAN OF MEASUREMENT LOCATIONS:



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REMEMBER: USE RISK MANAGEMENT LIFE-CYCLE FOR MONITORING

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QUESTIONS

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