GF-TADs
GLOBAL FRAMEWORK FOR THE PROGRESSIVE CONTROL OF TRANSBOUNDARY ANIMAL DISEASES

Food and Agriculture Organization of the United Nations

World Organisation for Animal Health
Founded as OIE

Standing Group of Experts on ASF in Europe

under the GF-TADs umbrella

24th meeting (SGE ASF-24)

3-4 April 2025

Laboratory biosecurity: GLP in IZS Umbria e Marche

[ITALY]

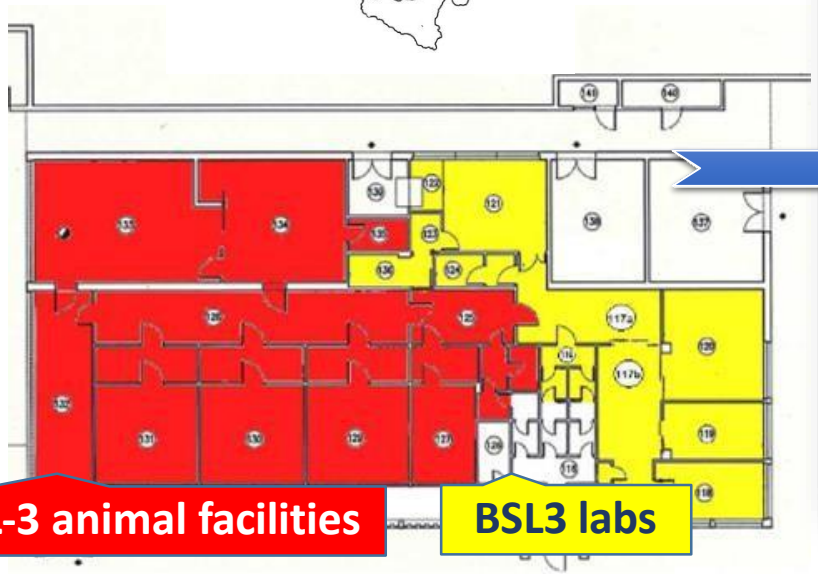
Evolutionary Approach to Biosafety and Biosecurity at the Italian NRL

Biosafety: containment principles/practices to prevent unintentional exposure to biological agents and toxins or their accidental release.

Biosecurity: measures to reduce the risk of loss, thievery, misuse, or intentional unauthorized release of biological materials.

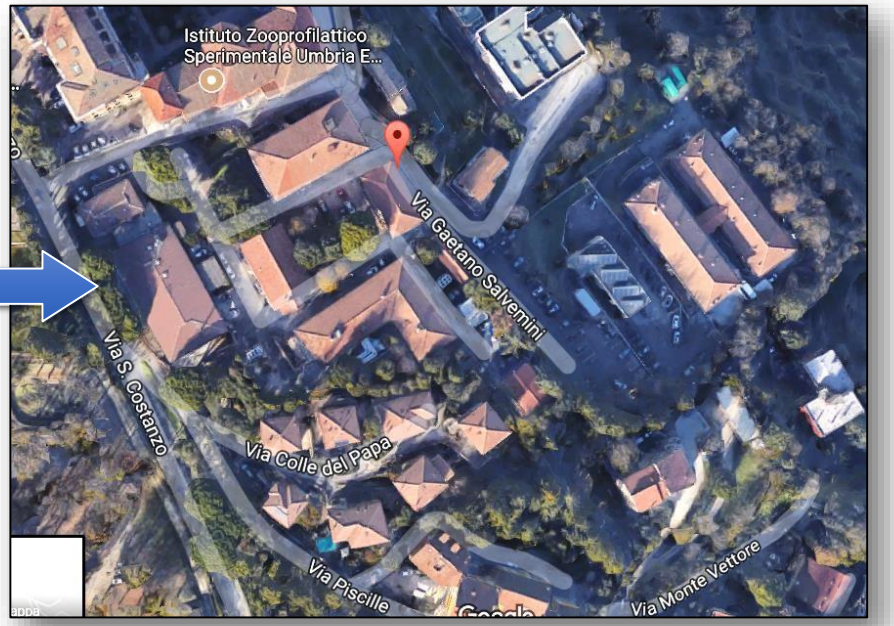
1971

Date of construction
Italian National Reference Lab for Swine Fevers



BSL-3 animal facilities

BSL3 labs



1995

Legal recognition of NRL (D.M. 12 agosto 1995)

Lack of a harmonious, consolidated, updatable BSL approach

BTWC Member States: Biological Weapons Convention (1972)

2003- 2015

Biosafety and biosecurity become concrete topics

COMMISSION DECISION 422 of 26 May 2003 approving an African swine fever diagnostic manual

WHO: International Health Regulations (2005)

ISO 31000:2009 about Risk Management

WOAH: Chapter 1.1.4. Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (version adopted in May 2015)

2016

Harmonized Containment System:

- ✓Dedicated Manual
- ✓SOPs
- ✓Internal Audit System
- ✓Internal Training System

- + POB.001 - REV.002 - MODALITA' DI STESURA, AGGIORNAMENTO E GESTIONE DELLA DOCUMENTAZIONE DEL SISTEMA BIOSICUREZZA PER L'AREA DI CONTENIMENTO BSL3
- + POB.002 - REV.007- VALUTAZIONE DEL RISCHIO DI RILASCIO ACCIDENTALE DI MATERIALE INFETTO DA VIRUS DELLA PSA O DA VIRUS DELLA PSC AL DI FUORI DELL'ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE
- + POB.003 - REV.003 - MODALITA' DI ACCESSO ALL'AREA DI CONTENIMENTO BSL3
- + POB.004 - REV.001 - NORME GENERALI DI COMPORTAMENTO NELL'AREA
- + POB.005 - REV.001 - GESTIONE DEI CAMPIONI AFFERENTI ALL'ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE E DI COMPETENZA DEL CEREP
- + POB.006 - REV.004 - DECONTAMINAZIONE DI SUPERFICI, STRUMENTI, AMBIENTI
- + POB.007 - REV.003 - STOCCAGGIO DI MATERIALE BIOLOGICO NELL'AREA DI CONTENIMENTO BSL3
- + POB.008 - REV.000 - GESTIONE TRATTAMENTO DELL'ARIA E MANTENIMENTO DELLA PRESSIONE NEGATIVA NELL'AREA DI CONTENIMENTO BSL 3
- + POB.009 - REV.001 - GESTIONE AUTOCLAVE NELL'AREA DI CONTENIMENTO BSL 3
- + POB.010 - REV.003 - GESTIONE DELLE EMERGENZE NON EPIDEMICHE NELL'AREA DI CONTENIMENTO BSL3
- + POB.011 - REV.000 - GESTIONE DELLE EMERGENZE SANITARIE NELL'AREA DI CONTENIMENTO BSL3
- + POB.012 - REV.001 - GESTIONE E SMALTIMENTO DEI RIFIUTI NELL'AREA DI CONTENIMENTO BSL3
- + POB.013 - REV.000 - GESTIONE DELLE VERIFICHE ISPETTIVE INTERNE PER LA BIOSICUREZZA

- + MOD.B.001 - REV.000
- + MOD.B.002 - REV.000
- + MOD.B.003 - REV.001
- + MOD.B.004 - REV.001
- + MOD.B.005 - REV.000
- + MOD.B.06A - REV.000
- + MOD.B.06B - REV.000
- + MOD.B.06C - REV.000
- + MOD.B.007 - REV.001
- + MOD.B.008 - REV.000
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- + MOD.B.010 - REV.000
- + MOD.B.011 - REV.000
- + MOD.B.012 - REV.000
- + MOD.B.013 - REV.000
- + MOD.B.014 - REV.000
- + MOD.B.015 REV.000


MOD.B.001 Rev.000

ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE	MANUALE DELLA BIOSICUREZZA	MdB Pag. 1 di 33
MANUALE BIOSICUREZZA		

MANUALE DELLA BIOSICUREZZA
DELL'ISTITUTO ZOOPROFILATTICO SPERIMENTALE
DELL'UMBRIA E DELLE MARCHE

QUESTO DOCUMENTO E' DI PROPRIETA' DELL'ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE E NE E' VIETATA OGNI RIPRODUZIONE ANCHE PARZIALE.
IL POSSESSORE E' RESPONSABILE DEL SUO IMPIEGO, DELLA RISERVATEZZA E DELLA CONSERVAZIONE.

MOTIVO DELLA REVISIONE
Aggiornamento dei capitoli relativi a: "Organigramma", "Termini e definizioni", "Normativa di riferimento", "Requisiti strutturali e gestionali"

REDATTO RB	AUTORIZZATO DG	DATA	REVISIONE
		10/11/2022	005

2020
2024

COMMISSION DECISION 422/2003 approving an ASF diagnostic manual
REPEALED by Reg UE 2020/689
WHO: 'Strengthening Laboratory Biological Risk Management', January 2024

LOOKING TO THE FUTURE…

NRL system is based on

1. Identify hazards
   - What may happen?
   - How may it happen?
2. Evaluate risks
   - How likely, how severe?
3. Determine controls to mitigate risk
   - To reduce risk if it is not acceptable
4. Implement controls
5. Review effectiveness of controls and adjust

Open Access Article

Animals **2024**, *14*(3), 454; https://doi.org/10.3390/ani14030454

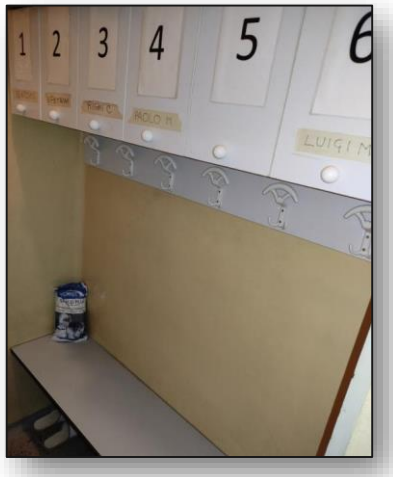
Biological Containment for African Swine Fever (ASF) Laboratories and Animal Facilities: The Italian Challenge in Bridging the Present Regulatory Gap and Enhancing Biosafety and Biosecurity Measures

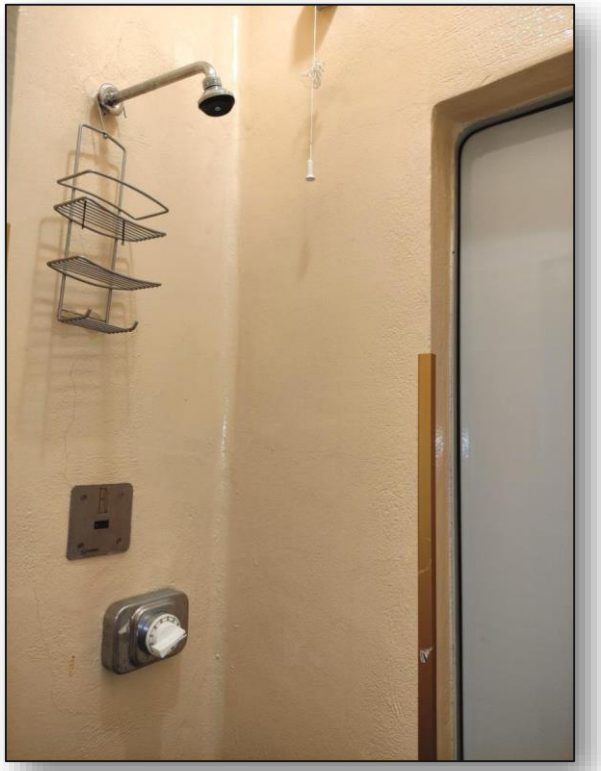
by Silvia Pavone [1,*], Carmen Iscaro [1], Monica Giammarioli [1], Maria Serena Beato [1], Cecilia Righi [1], Stefano Petrini [1], Silva Costarelli [2,†] and Francesco Feliziani [1,†]

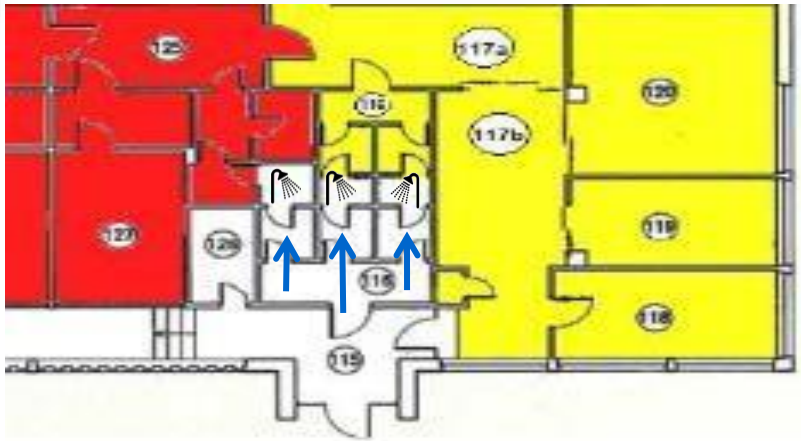
BSL-3: structural and equipment requirements

Entry (animals)

Entry (facilities/labs)







Facilities Labs

Audible and visual alarm system

Recommended: working area to be maintained at negative pressure (> in the facilities)

Recommended: working area to be sealed to allow disinfection

Biosafety compartment (Class II) for all handling of live virus.
The compartment must be equipped with dual HEPA air filtration.

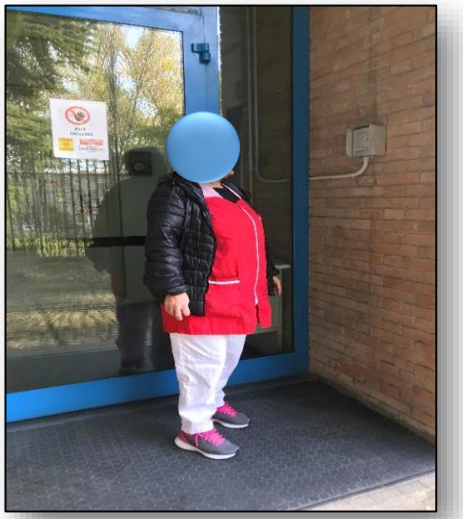
Treatment (chemical or thermal) of waste to inactivate ASFV

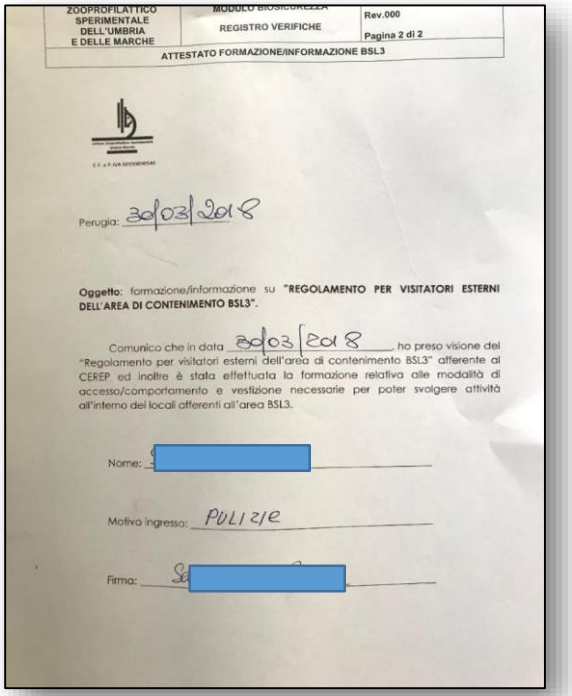
BSL-3: management requirements

Recommended: entry only authorized people

- ✓ Secret personal access code
- ✓ Team of persons authorized to enter BSL3 reported in official document
- ✓ Prohibition of keeping pigs, and contact with them in the 48 hours following the exit from BSL-3

For external people…





ZOOPROFILATTICO SPERIMENTALE DELL'UMBRIA E DELLE MARCHE

MODULO BIOSICUREZZA

REGISTRO VERIFICHE

Rev.000

Pagina 2 di 2

ATTESTATO FORMAZIONE/INFORMAZIONE BSL3

Perugia: 30/03/2018

Oggetto: formazione/informazione su **"REGOLAMENTO PER VISITATORI ESTERNI DELL'AREA DI CONTENIMENTO BSL3".**

Comunico che in data 30/03/2018 ho preso visione del "Regolamento per visitatori esterni dell'area di contenimento BSL3" afferente al CEREP ed inoltre è stata effettuata la formazione relativa alle modalità di accesso/comportamento e vestizione necessarie per poter svolgere attività all'interno dei locali afferenti all'area BSL3.

Nome: [redacted]

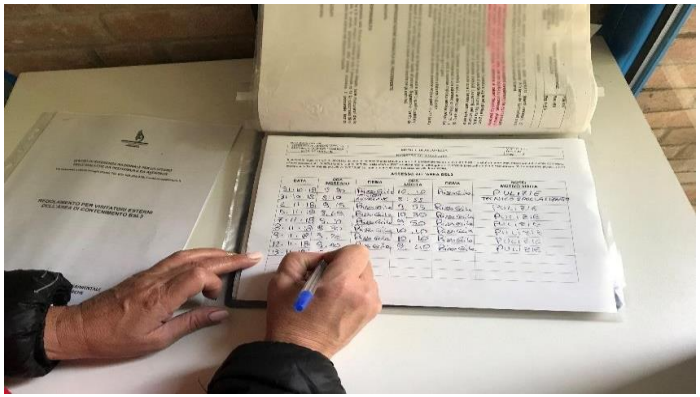
Motivo ingresso: PULIZIE

Firma: [redacted]

Pre-agreement with external cleaning service

Training of assigned personnel

Register for visitors



Personnel behavior in entry

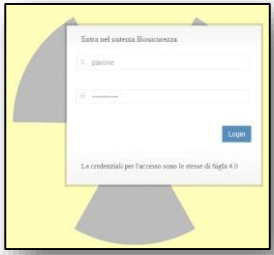
Specific disinfection procedures

For the BSL-3 environment

For material leaving BSL-3 environment

Storage of biological material in BSL-3 labs

- ✓*Controlled access*
- ✓*List of persons authorized*
- ✓*SOPs for material traceability*



NRL, IIZZSS Laboratories and Biosafety requirements for ASFV

2019: NRL distributed a survey on biosafety principles for IIZZSS labs, during the process of approval for ASF diagnosis

2022: NRL launched a path in order to assess, improve and harmonize the management of the biosafety system adopted by IIZZSS labs

1. Check list
2. Gap analysis
3. Analysis and report

GAP ANALYSIS

- ❑ Lab rooms
- ❑ Lab personnel
- ❑ Lab equipment
- ❑ Training procedures
- ❑ Biosafety documents






- ✓ identify the gaps between the actual condition and the required one;
- ✓ define activities and tools to be implemented for the compliance with the reference standard.

Results: main strenghts

Full awareness of including ASF diagnostic activities into an adequate biosafety management system.

Use of risk analysis as the most appropriate tool to address the critical issues.

Preparedness to lab ASF emergency (labs immediately activated following ASF confirmation in their territories).

Results: main critical points

Space/rooms/equipment: not totally assigned for ASF samples;

Staff: not enough for number of qualified people;
emergency team not always available;

Training courses/events: not enough, regarding biosafety/risk analysis;

Waste disposal: to be improved in control (traceability and destination).

Conclusions

It is necessary working with a view to a constant and continuous improvement process, so that the biosecurity and biosafety management system can be applied in an effective form.

Thank you for your attention