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The African Swine Fever Virus (ASFV) is a highly contagious and lethal virus that affects swine populations, causing significant economic losses worldwide. In the current epidemiological context, with ongoing ASF outbreaks in several countries, including Italy, it is imperative to promote research. However, to mitigate the risk of virus spread, handling ASFV in laboratory and animal facility settings requires stringent, applicable, and cost-effective biosafety and biosecurity measures recognized by the scientific community. These measures are crucial to prevent accidental release and environmental contamination.

Evolutionary Approach to Biosafety and Biosecurity at the Italian National Reference Laboratory (NRL) for *Pestivirus* and *Asfivirus* (CEREP)

1971



Construction of the BSL-3 Biocontainment Area

1995



Italian NRL for the study and diagnosis of swine fevers (African Swine Fever, Classical Swine Fever) was officially established with the Ministerial Decree of August 12, 1995. Research and diagnostic activities started and biosafety measures were observed by researchers voluntarily.

2003

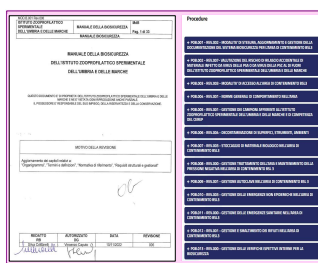


Commission Decision 2003/422/EC approved an African Swine Fever diagnostic manual with minimum and additional requirements for ASF laboratories and animal facilities. Legislative Decree n. 81/2008 on Occupational Health and Safety was issued. Biosafety measures in accordance with legislation were observed.

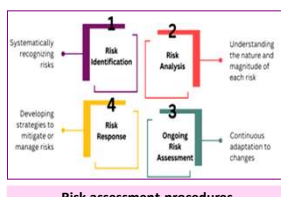
2016



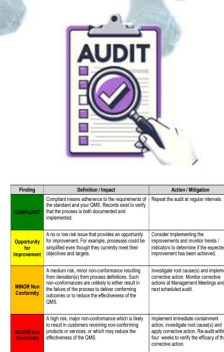
A harmonized and proceduralized biosafety system was established. Biosafety Manual based on risk analysis assessment and 13 operational and management procedures (POBs) were created. An audit system was developed to verifying of the management system.



Biosafety Manual and Biosafety Standard Procedures (POBs)



Risk assessment procedures



ELenco delle Revisioni Precedenti	
MOTIVI DELLA REVISIONE	DATA
NA	20.02.2019
Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza, Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza, Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza.	20.02.2019
Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza, Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza.	20.02.2019
Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza, Aggiornamento della versione del manuale BSL, Aggiunta dei controlli interni alla Direzione di Ricerca e Sviluppo e alla Direzione di Gestione della Sicurezza.	20.02.2019

Updates to the Biosafety Manual based on audit system recommendations and ongoing risk assessment results

2020



2024

Commission Delegated Regulation (EU) 2020/689 repealed Commission Decision 2003/422/EC, which had provided minimum and supplementary requirements for ASF laboratories. This regulatory change created a gap that has yet to be fully addressed. In response, and following the suggestions of WHO in the document 'Strengthening Laboratory Biological Risk Management' (January 2024), the Italian NRL has reviewed and further improved its biological containment tools for ASF laboratories and animal facilities. A Biosafety Committee was established, Biosafety Manual was changed accordingly and the adaptation of the POBs is ongoing. The new biological containment framework for ASF laboratories and animal facilities of Italian NRL was published.

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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
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