

Biorisk Management, Vaccine Production, and Eradicated Pathogens

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SUMMARY



- » Polio eradication is within sight
- » Containment of polio within approved facilities essential element of post-eradication strategy
- » Biorisk management will be integral to achieving global containment of polio

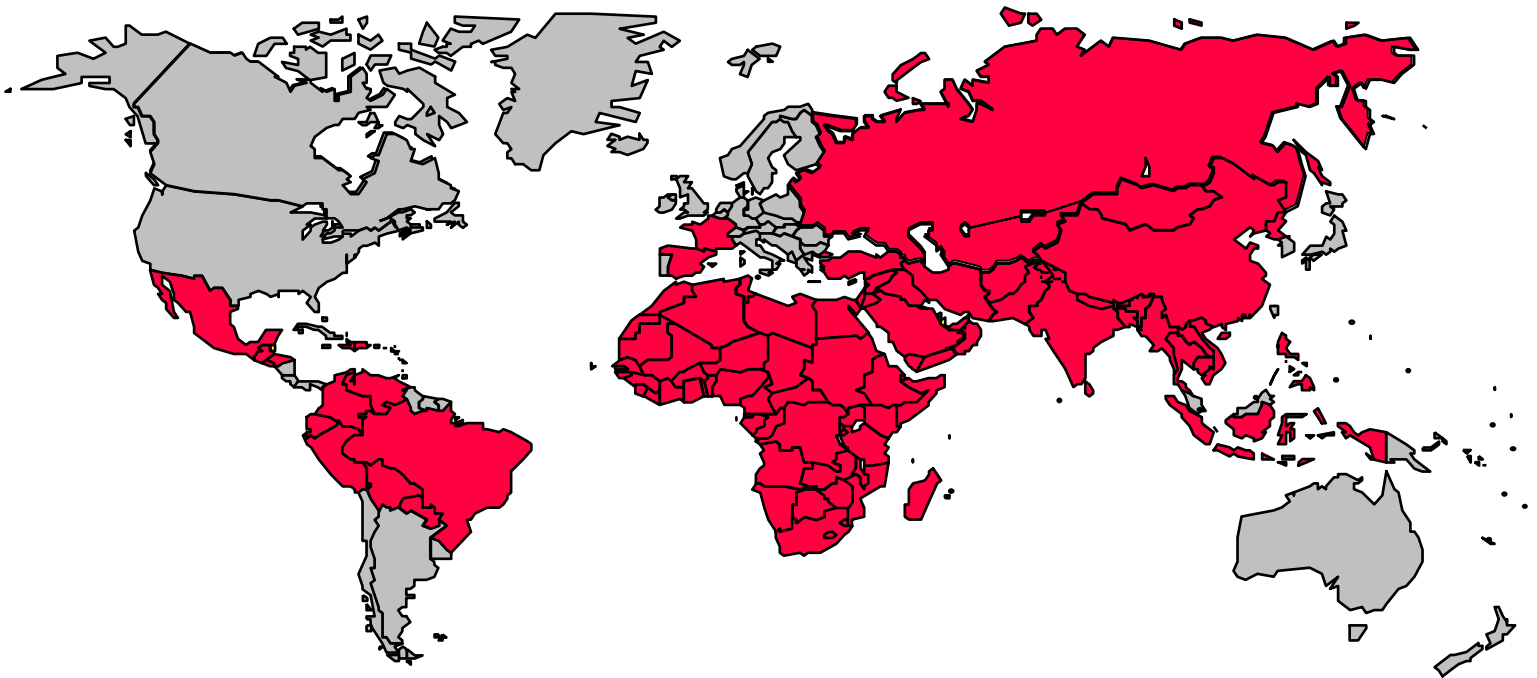
POLIO IS A TERRIFYING DISEASE



Nurses Tending Young Patients with Poliomyelitis in an Iron Lung, 1938.
Photograph by Hansel Mieth, Time Life Pictures, Getty Images.

ERADICATION STATUS

IN 1988 > 350,000 POLIO CASES/YEAR, IN > 125 COUNTRIES







THUS FAR
POLIO
ERADICATION
HAS COST
> 6 BILLION US\$



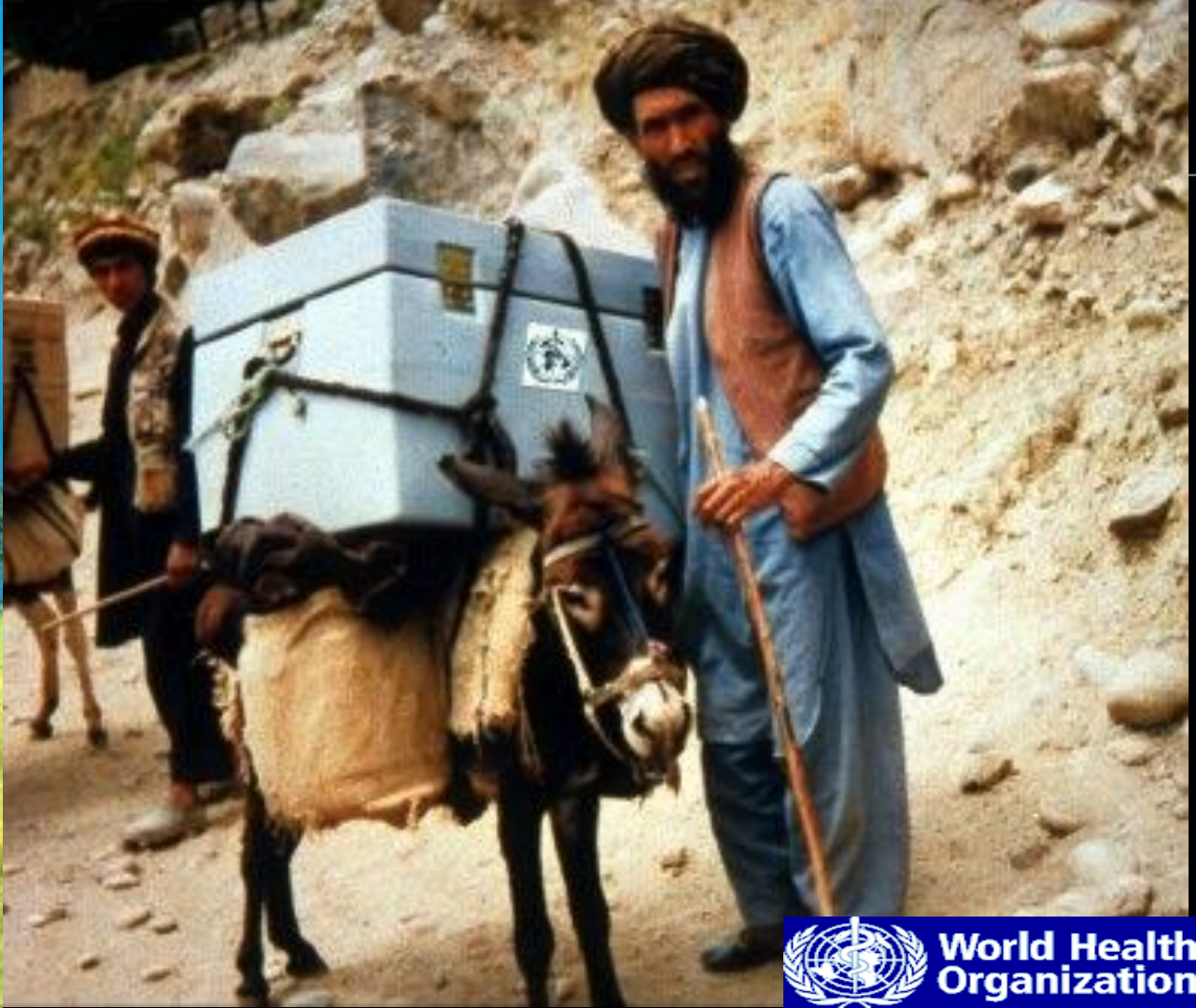
World Health
Organization



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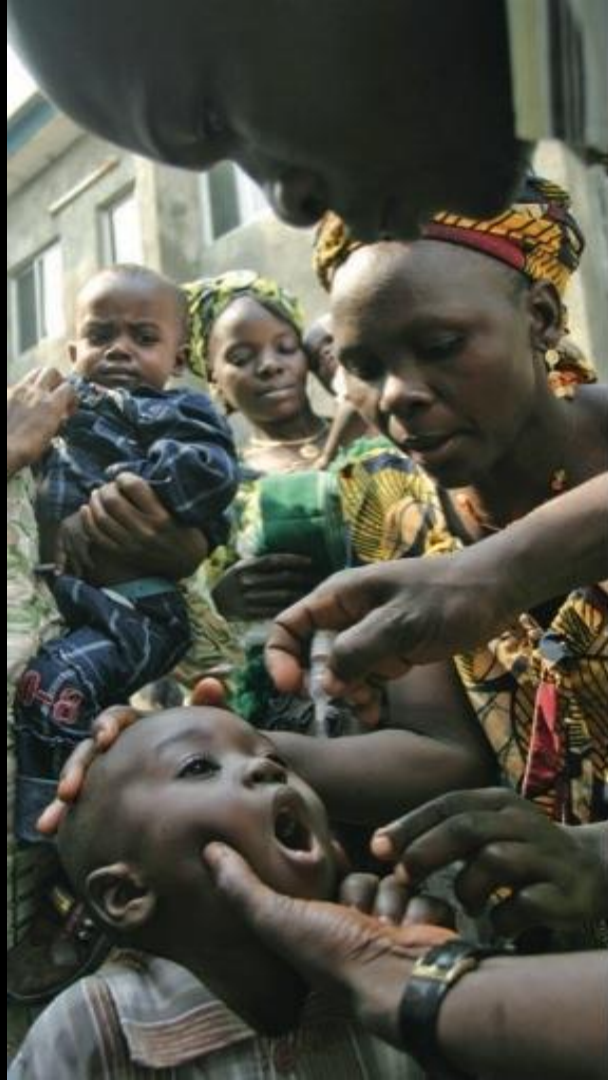
Afghanistan





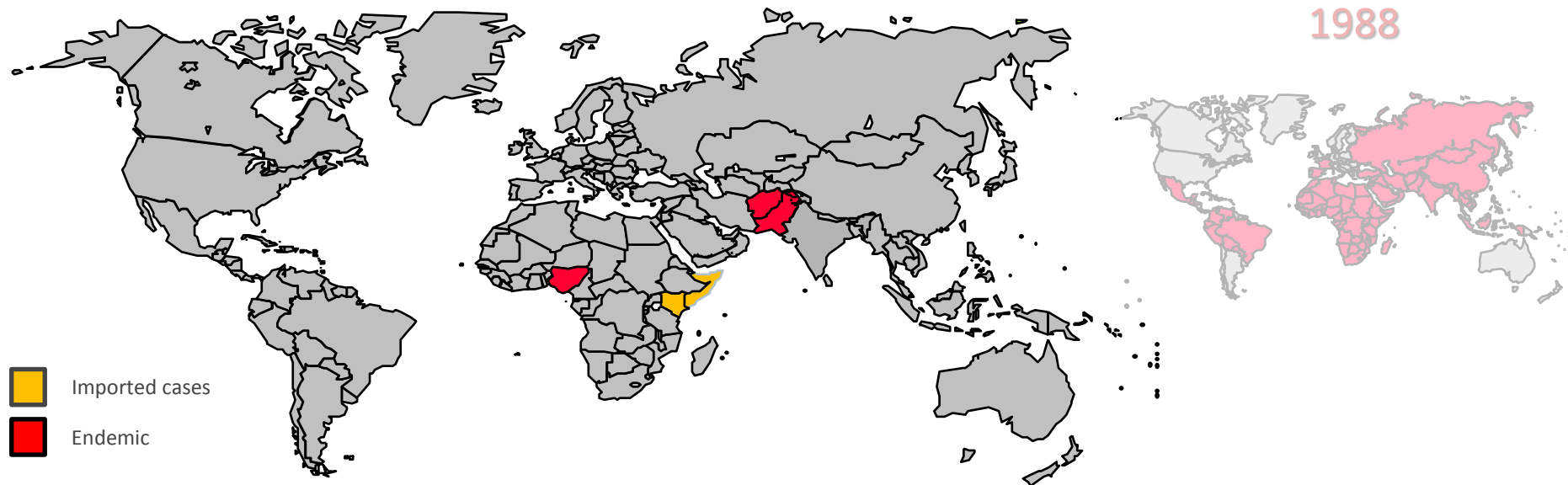






From *Science*,
6 Feb 2009

IN 2013: 199 CASES IN 5 COUNTRIES, A REDUCTION OF > 99.94%



WPV Type 1: 193

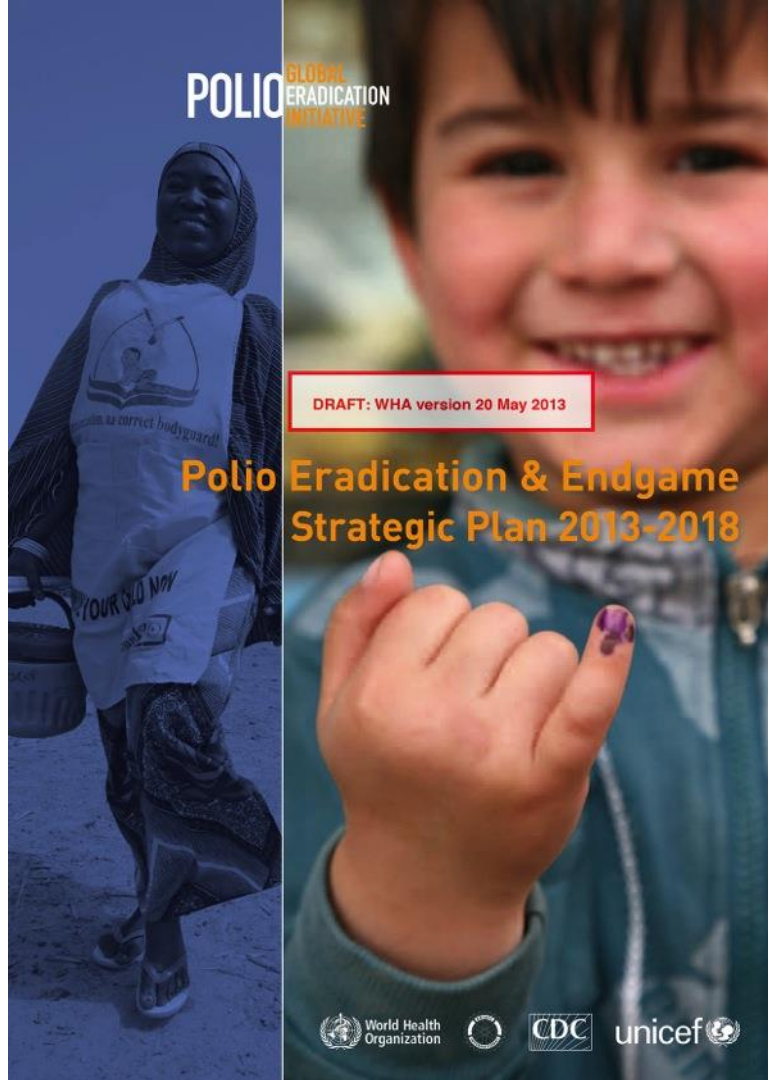
WPV Type 3: 6

Data in WHO HQ as of June 25.

Excludes vaccine derived poliovirus and virus detected from environmental surveillance.

ERADICATION AND ENDGAME

» World Health Assembly draft
May 2013



World Health
Organization



unicef





WHAT IF ...

ACCIDENTAL INFECTION



ENVIRONMENTAL CONTAMINATION





EXTREMISTS

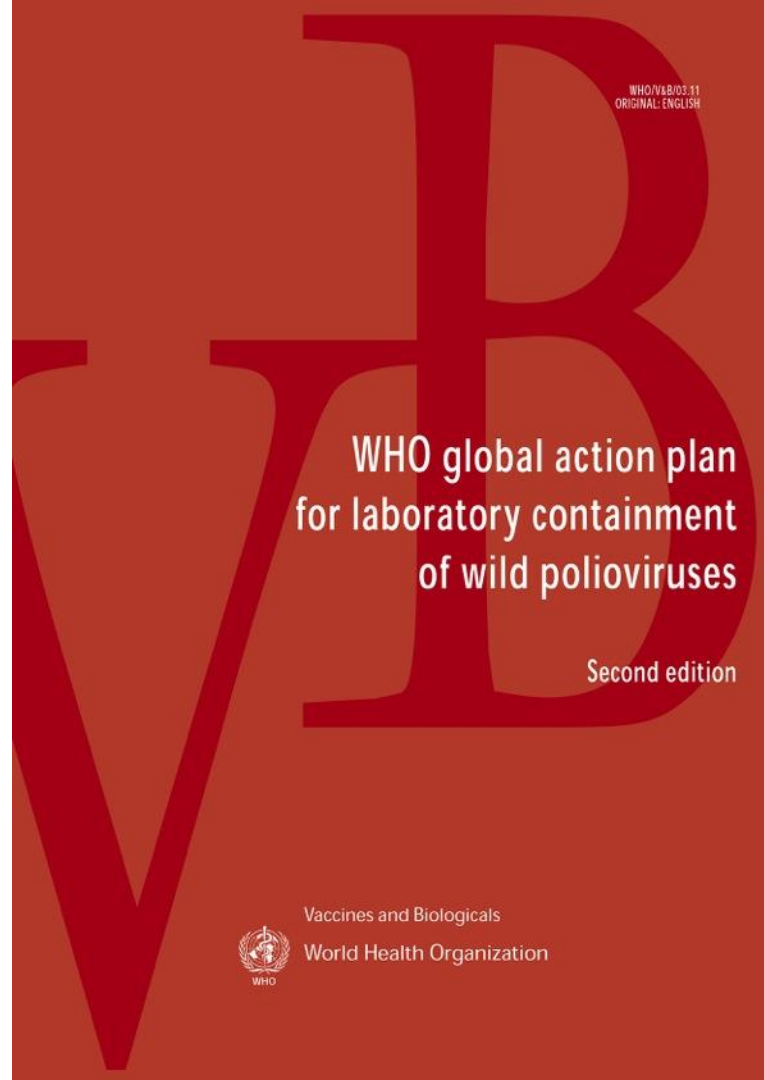


BIOTERRORIST S



WHO GLOBAL ACTION PLAN

- » Phase I: Lab surveys and inventories
 - » BSL2 enhanced
- » Phase II: Global certification
 - » BSL2 enhanced for work with potential WPV infectious materials
 - » BSL3 enhanced for all activities with WPV and poliovirus-permissive cells or animals
- » Phase III: Post global certification
 - » If OPV immunization is stopped, biosafety requirements “will become more stringent”



What containment concerns do vaccine manufacturers have today?



WHAT'S IMPORTANT

➤ cGMP

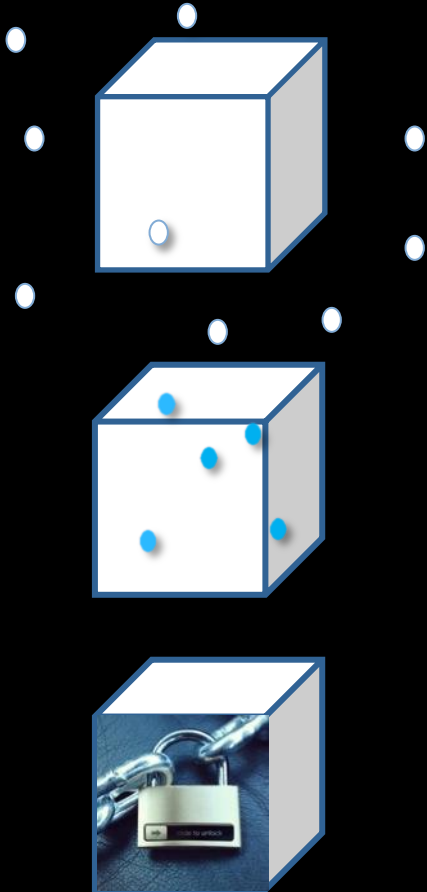
Protect end-user from an unsafe agent

➤ Biosafety

Protect humans and the environment
from the agent

➤ Biosecurity

Protect agent from those with evil intent





REGULATORY

- cGMP
- Biosafety Levels
- Biosecurity
 - "Select Agent" Inspection

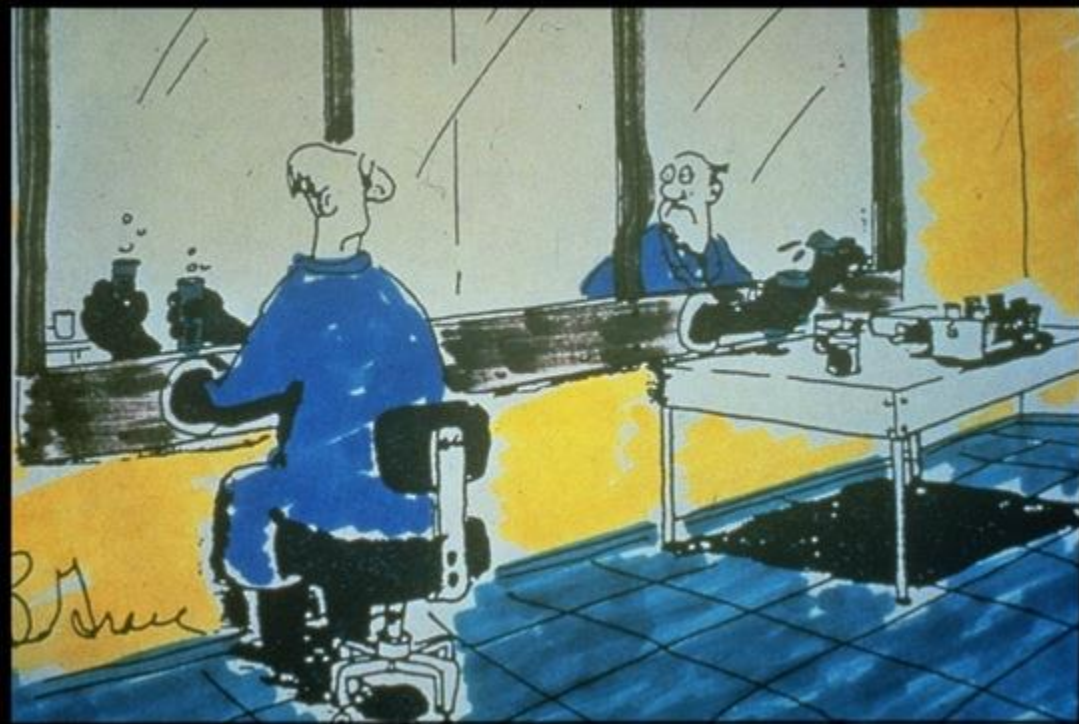


HOW TO RESOLVE CONFLICTING GUIDELINES



cGMP VERSUS CONTAINMENT

DESIGN





LARGE-SCALE PRODUCTION

➤ Vaccine production facilities

...handle large volumes

... and a lot of waste.

EFFLUENT TREATMENT



SPILLS



SPILL CONTROL AND CLEANUP



Picture courtesy:
NNE Pharmaplan



SECURITY



RISK MANAGEMENT



CEN

CWA 15793

WORKSHOP

September 2011

AGREEMENT

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

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Ref. No.: CWA 15793:2011 D/E/F

INTERNATIONAL BIORISK MANAGEMENT

- » CWA 15793:2011
- » Used by the WHO Smallpox Lab inspection program
- » Draft of WHO GAP III reflects the concepts in this document





World Health
Organization

**Report of the World Health Organization (WHO) Biosafety
Inspection Team of the Variola Virus Maximum
Containment Laboratories to the Centers for Disease
Control and Prevention (CDC)**

Atlanta, Georgia, USA, 2-6 March 2009

EXECUTIVE SUMMARY

The WHO Inspection Team visited CDC in order to conduct an inspection of one of the two authorized repositories of live variola virus with the aim of ensuring that the conditions of storage of the virus, and that the research done in the laboratories meet the highest requirements of biosafety and biosecurity, as mandated by the World Health Assembly in resolution WHA60.1. The team, in agreement with CDC, used a new Laboratory Biorisk Management standard for the assessment.

At the beginning of 2009, CDC operationalized a new maximum containment laboratory for work with live variola virus. Stocks have been transferred from the existing maximum containment BSL-4 laboratory building. The original laboratory is being maintained.

The WHO inspection team was satisfied with the security and safety arrangements for maintaining, and working with live variola viruses. The CDC Maximum Containment BSL-4 facility was assessed to have the capacity to conduct work safely with live variola virus as it stands. Although a number of recommendations have been made, no issues compromising safety or security were identified during the assessment.

A positive finding was the recognition of the need for a policy and process of constant improvement of biosafety and biosecurity standards.

The WHO Inspection Team found the new assessment protocol to be a useful methodological tool for standardizing the WHO biosafety inspections of the variola virus repositories. It contributes to better structuring of the process, making it more objective. It is proposed to use the protocol as a methodological framework for conducting such inspections in the future.

In summary, the WHO inspection team found the CDC maximum containment BSL-4 facility to be safe and secure for the work with live variola virus.



**Report of the World Health Organization (WHO) Biosafety Inspection
Team of the Variola Virus Maximum Containment Laboratories to the
State Research Centre of Virology and Biotechnology ("SRC VB
VECTOR"), Federal Service for Surveillance on Consumer Rights
Protection and Human Well-being, Novosibirsk**

Kol'tsovo, Novosibirsk Oblast', Russian Federation
30 November – 4 December 2009

EXECUTIVE SUMMARY

The WHO Inspection Team visited VECTOR in order to conduct an inspection of one of the two authorized repositories of live variola virus with the aim of ensuring that the conditions of storage of the virus, and that the research done in the laboratories meet the highest requirements of biosafety and biosecurity, as mandated by the World Health Assembly in resolution WHA60.1. That same resolution also strongly reaffirmed the decisions of previous World Health Assemblies that the remaining stocks of variola virus should be destroyed. The team, in agreement with VECTOR, used a new Laboratory Biorisk Management standard for the assessment. The protocol used was based on the CWA 15793 Biorisk Management Standard.

The WHO inspection team was satisfied with the security and safety arrangements for maintaining, and working with, live variola viruses within the Maximum Containment BSL-4 (Biosafety Level-4) Laboratory and its associated facilities. The VECTOR BSL-4 facility was assessed to have the capacity to conduct work safely with live variola virus as it stands.

Although a number of recommendations have been made, the WHO inspection team found that VECTOR implements appropriate levels of biosafety and biosecurity for its work with variola virus.

A positive finding was that VECTOR staff recognizes the need for a policy and process of constant improvement of biosafety and biosecurity systems at VECTOR.

The WHO inspection team recommended that VECTOR staff collaborate with CDC (Centers for Disease Control and Prevention) staff and WHO experts in order to establish a tool for future WHO biosafety inspections of the two repositories based on the CWA 15793 Biorisk Management Standard.

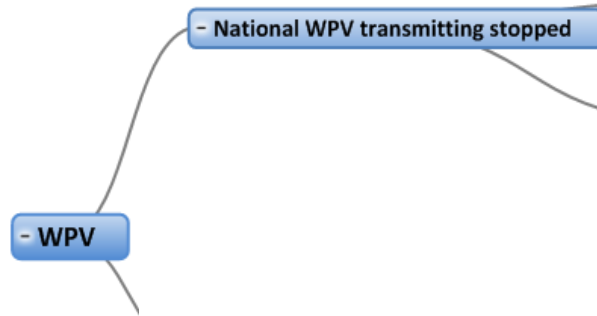
In summary, the WHO inspection team found the VECTOR Maximum Containment BSL-4 facility to be safe and secure for the work with live variola virus.



SMALLPOX VS. POLIO



THE WHO GLOBAL ACTION PLAN (3RD ED)



POST-ERADICATION CONTAINMENT



- » Large number of facilities that store and/or use wild polio virus will exist
- » Global community must formally embrace and implement a biorisk management system now



POLIO ERADICATION WILL NOT END WITH THE LAST NATURALLY OCCURRING CASE OF POLIO

International commitment and resources are required to manage the risk of polio retention



¡muchas gracias!
Thank you!