

CCS A 00

RB

**CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

RB/T 040-2020

**Guidelines for Biosafety Risk Management of Pathogenic
Microorganism Laboratories
(English Translation)**

Issued on: August 26, 2020

Implemented on: December 1, 2020

Issued by: National Certification and Accreditation Administration

Table of Contents

Preface
1 Scope
2 Normative references
3 Terms and definitions
4 Principle
5 Implementation process
5.1 Overview
5.2 Task Source
5.3 Preparation for implementation
5.4 Risk management implementation
5.5 Reassessment
Appendix A (informative appendix) Common methods of laboratory biosafety risk assessment
Appendix B (informative appendix) Laboratory Biosafety Risk Assessment Matrix
Appendix C (informative appendix) Reference example for the implementation of risk assessment of pathogenic microorganism experimental activities
References

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009:

This standard was proposed and managed by the National Certification and Accreditation Administration Committee:

Drafting organizations of this standard: China National Accreditation Center for Conformity Assessment, China Animal Health and Epidemiology Center, China Construction Science Research Institute Co., Ltd., Academy of Military Medicine, Chinese Center for Disease Control and Prevention, Wuhan Institute of Virology, Chinese Academy of Sciences, China Agricultural Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences, Lanzhou Veterinary Research Institute, Chinese Academy of Agricultural Sciences, China Customs Science and Technology Research Center, China Certification Recognized associations:

1 Scope

This standard provides guidelines for the principles and implementation process of biosafety risk management carried out by pathogenic microorganism laboratories (hereinafter referred to as "laboratory"):

Use guide:

This standard applies to pathogenic microorganism laboratories carrying out risk management work, and can also be used to supervise and manage the risk of laboratory biosafety:

Evaluation and assessment of risk management:

2 Normative references

The following documents are indispensable for the application of this document: For dated reference documents, only the dated version applies to this article. For undated references, the latest version (including all amendments) applies to this document:

GB 19489-2008 General requirements for laboratory biosafety GB/T 23694-2013 Risk Management Terminology WS233-2017 General Guidelines for Biosafety of Pathogenic Microorganism Laboratories

3 Terms and definitions

The following terms and definitions defined in GB/T 23694-2013 apply to this document: For ease of use, the following is repeated. Certain terms and definitions in GB/T 23694-2013:

Biological agents

Microorganisms and biologically active substances:

[GB 19489-2008, definition 2:4] 3.2 Risk the impact of uncertainty on goals:

Note 1: Risk is usually expressed by a combination of the consequences of an event (including changes in circumstances) and the possibility of an event:

Note 2: Rewrite GB/T 23694-2013, definition 2:1:

Biorisk

The impact of uncertainty associated with biological factors on the target:

Riskmanagement

In terms of risk, direct and control the coordination activities of the organization:

[GB/T 23694-2013, definition 3:1] 3.5 Risksource Internal elements that may individually or jointly cause risks:

Note: The source of risk can be tangible or intangible:

[GB/T 23694-2013, definition 4:5:1:2]