WHO GUIDANCE on implementing regulatory requirements for biosafety and biosecurity in biomedical laboratories – a stepwise approach

WORLD HEALTH ORGANIZATION
GENEVA, 2020

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FOREWORD

This document is the result of a scientific project initiated jointly by the World Health Organization (WHO) and the University of Applied Sciences Lübeck, Germany, and is a direct response to an expressed need for practical information and guidelines designed to support policy-makers and national regulatory bodies develop and strengthen national biosafety and biosecurity regulatory frameworks.

The first draft of this document was based on a detailed analysis of current practice, drawing on a comprehensive review of published documents detailing existing regulatory policies and structures and frameworks in a diverse set of countries. This review examined both primary and secondary legislation, as well as non-legally-binding instruments (standards, guidelines and recommendations) from multiple sectors. The review was conducted by staff at WHO and the University of Applied Sciences Lübeck, Germany.

As part of a pilot exercise, and in order to support the development of biosafety and biosecurity regulations in a country with limited capacity in this area, a first draft of this document was circulated, reviewed and discussed with stakeholders from the Democratic Republic of Ethiopia during July 2018. The valuable feedback received from those involved in the pilot exercise was used to further develop and refine the guidance.

Shortly afterwards, a meeting was held at WHO headquarters in Geneva to review the revised version of the guidance document. The three-day meeting (26–28 September 2018) involved the participation of representatives from WHO Member States, WHO Regional Offices and several international organizations. The views and comments expressed by participants during the in-depth interactive discussions were taken into consideration during the preparation of this final version of the guidance document.