World Health Organization

WHO BioHub System

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ISBN 978-92-4-004452-4 (electronic version)
ISBN 978-92-4-004453-1 (print version)

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Suggested citation. WHO BioHub system biosafety and biosecurity: criteria and operational modalities. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Introduction

The aim of the World Health Organization (WHO) BioHub System is to implement the timely sharing of biological materials between laboratories and partners globally. This international exchange system will enable rapid assessment of risk and subsequent mitigation measures for epidemic- and pandemic-prone diseases, and thus make global preparedness and response against these diseases more effective.

Laboratories wishing to receive biological materials as part of this international exchange system will need to be accepted by WHO as a Qualified Entity (QE). To acquire QE status, laboratories must meet pre-agreed conditions, including biosafety and biosecurity measures, and various regulations.

Laboratories applying for QE status sign the standard material transfer agreement (SMTA) 2 (non-commercial use) or 3 (all uses including commercial ones), which means that when receiving biological materials with epidemic or pandemic potential (BMEPP) they are deemed to have confirmed proper conformance to the biosafety and biosecurity criteria. This is, in addition to compliance with other relevant WHO guidance documents, and applicable national and international regulations. WHO reserves the right to ask QEs to provide more details for the purpose of application processing and review the QEs' biosafety and biosecurity conformance and performance.

A checklist for QEs is given below, for indication purposes; full details can be found in the document available from the WHO BioHub webpage *(1)*.

Criteria for Qualified Entities

This checklist of criteria can be used to ensure that biosafety and biosecurity measures are in place within your facility, to fulfil the assessment criteria for obtaining QE status:

1. Facility biosafety and biosecurity capacities, capabilities and risk assessments in place and documented.

2. Compliance with "core requirements" as defined in the *WHO Laboratory biosafety manual* 4th edition (LBM4), including observance of good microbiological practice and procedure (GMPP) and standard operating procedures (SOPs).

3. Compliance with "heightened control measures", as defined in the LBM4 and as determined by the risk assessment for the planned experiments.

4. Where applicable, compliance with "maximum containment measures", as defined in the LBM4 and as determined by the risk assessment for the planned experiments.

5. A complete biosafety manual in place, containing institutional policies, programmes and plans as well as responsibilities of biosafety personnel and other staff.

6. A biosecurity plan in place, outlining the security measures, including physical security of the facility, access restrictions, information control and personnel reliability.

7. Commitment and a transparent regime in place to address dual-use research of concern (DURC) and report such research to WHO.

8. Training programme, competency assessments and associated records in place.

9. Medical surveillance programme (occupational health) in place.

10. Emergency and incident response plan in place.

11. Incident reporting system and records in place.

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