

Policy for Laboratories Performing Tests on Biological Agents

PS3

1) Purpose

- 1.1) This statement sets out the **Irish National Accreditation Board** policy on the requirements for the organisations handling Biological agents.

2) Definitions

Biological agent

“Biological Agent” means micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity, classified into 4 risk groups according to their level of risk of infection. These risk groups are further defined in the legislation as per section 3) below.

Containment

A term used to describe safe methods for handling known or potentially infectious materials in the laboratory environment. Four levels of containment are defined based on combinations of laboratory practices and techniques, safety equipment and laboratory facilities. These containment requirements are further defined in the legislation as per section 3) below.

CAB

Conformity assessment body – any applicant or accredited organisation.

3) References

- 3.1) ISO 17025:2017 ‘General requirements for the competence of testing and calibration laboratories’.
- 3.2) ISO 15189:2012 ‘General requirements for the competence of medical testing laboratories’.
- 3.3) SI No 539 of 2020 Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations 2020
- 3.4) Directive 2000/54/EC - biological agents at work.
- 3.5) PS 11 INAB policy on the accreditation of flexible scopes.

4) Policy

- 4.1) When a laboratory is involved in handling, testing of any biological agents, or any samples potentially containing biological agents, it must assess its compliance with the relevant legislation as per section 3 above. This review shall be documented.
- 4.2) If a laboratory wishes to become accredited for the testing of biological agents it shall apply to INAB for an extension to scope as per the normal extension to scope process.
- 4.3) The initial assessment for this activity shall be an on-site to allow the assessment team to assess the competence of staff to carry out such testing and to ensure the accommodation and environmental conditions used for the handling and testing of such samples is adequate.

- 4.4) It is the responsibility of the laboratory to ensure that it complies with the best current international practise required for containment facilities, as needed.
- 4.5) Containment measures as defined in the legislation shall be applied and the word 'recommended' will be interpreted as 'yes'.
- 4.6) Following a successful recommendation for extension to scope by the on site assessment team, this will be referred to the INAB manager for decision.

5) Contact

For further information about this statement, please contact your INAB assessment manager at **The Irish National Accreditation Board**.

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