

Policy on the laboratory testing for Group 3 organisms

PS3

1) Purpose

- 1.1) This statement sets out the **Irish National Accreditation Board** policy on the requirements for the laboratory testing for Group 3 organisms.
- 1.2) The granting of accreditation for the examination of samples or specimens for Group 3 organisms will be offered only to laboratories that comply with the INAB accreditation requirements. INAB has the right to withdraw accreditation for this testing from a laboratory that fails to comply with the INAB requirements at any time.

2) Statement

- 2.1) It is the policy of the Irish National Accreditation Board (INAB) that all laboratories holding INAB accreditation for the detection of *Group 3 organisms* adhere to the following requirements in regard to *containment, culture and identification technique(s)* and *staff qualifications*.
- 2.2) INAB's policy in relation to the accreditation of a laboratory for the detection of Group 3 organisms complies with the legal requirements of S.I. No. 146 of 1994 and S.I. No. 248 of 1998.
- 2.3) INAB will review this document after 12 months from the date of issue.

3) Definitions

Group 3 Biological agent

A biological agent that can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available. These organisms are a demonstrated hazard to laboratory personnel.

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.

Culture and Identification Techniques

The procedures employed to cultivate, concentrate, and identify a biological agent in the laboratory environment.

Staff Qualifications

The professional qualifications and relevant experience required by staff employed to work in the accredited laboratory.

4) Containment

- 4.1) The containment level required for Group 3 organisms is based on the activities associated with the growth and manipulation of the quantities and concentrations of the agents required to accomplish isolation, identification and typing.
- 4.2) In accordance with Regulation 12 (c) of S.I. No. 146 of 1994, where an uncertainty exists as to the presence of Group 3 organisms in a particular sample or specimen, and where the procedures being carried out do not involve cultivating or concentrating the agent, *Containment Level 2 measures* as specified in the Seventh Schedule of S.I. No. 146 of 1994 can be applied.
- 4.3) Such procedures include the preparation of the sample or specimen and the *inoculation of the enrichment broth*.
- 4.4) In the case of a suspect/outbreak involving a Group 3 organism these procedures shall be carried out in a *Containment Level 3 facility*.
- 4.5) All other procedures involved in the cultivation, concentration, identification and typing of *Group 3 organisms* shall be carried out in a *Containment Level 3 facility*.
- 4.6) The containment measures required for *Containment Level 3* as specified in the Seventh Schedule of S.I. No. 146 of 1994 shall be applied (see attached appendix 1). In the Seventh Schedule the word "Recommended" will be interpreted as "Yes" unless there is an acceptable justification as to another interpretation.
- 4.7) It is the responsibility of the laboratory to ensure that it complies with the best current international practice required for containment level 3 facilities, e.g. in relation to airflow, laboratory space, etc.

5) Identification Techniques

Suitable methods which are based on approved reference methods are eligible for accreditation.

6) Staff Qualifications

- 6.1) Staff in charge of the laboratory shall have appropriate professional qualifications and a minimum of two years relevant experience in an established laboratory.
- 6.2) The laboratory shall have at least one member of staff trained to work in a Containment Level 3 facility. Where such a facility already exists within the laboratory this training can be undertaken on site; however where a new facility is established a suitably qualified and experienced member of staff should attend a course in a laboratory approved for Containment Level 3 training.

Note:

This Policy Statement does not diminish the laboratory's responsibility to assess the probability of *Group 3 organisms* being transmitted within the work environment and implement procedures aimed at reducing workers' risk of exposure to these agents to a minimum and to comply with all relevant legislation.

APPENDIX 1

TABLE 1: SEVENTH SCHEDULE: INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS*

Regulations 11 (e) and 12 (1)

The measures contained in this Schedule shall be applied according to the nature of the activities, the assessment of risk to employees, and the nature of the biological agent concerned.

Containment Measures	Containment Levels	
	2	3
1. The workplace is to be separated from any other activities in the same building.	No	Recommended
2. Input air and extract air to the workplace are to be filtered using (HEPA) or likewise	No	Yes, on extract air
3. Access is to be restricted to nominated workers only.	Recommended	Yes
4. The workplace is to be sealable to permit disinfection.	No	Recommended
5. Specified disinfection procedures.	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere.	No	Recommended
7. Efficient vector control e.g. rodents and insects.	Recommended	Yes
8. Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor
9. Surfaces resistant to acids, alkalis, solvents, disinfectants.	Recommended	Yes
10. Safe storage of a biological agent.	Yes	Yes
11. An observation window, or, alternative, is to be present, so that occupants can be seen.	Recommended	Recommended
12. A laboratory is to contain own equipment.	No	Recommended
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment.	Where appropriate	Yes, where infection is by airborne route
14. Incinerator for disposal of animal carcasses.	Recommended	Yes (available)

*Council Directive of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (90/679/EEC).

7) Contact

For further information about this statement please contact an INAB officer at **The Irish National Accreditation Board**.

Phone: +353 1 6073003

Fax: +353 1 6073109

E-mail: inab@inab.ie

Website: www.inab.ie