INTERNATIONAL STANDARD

ISO 15190

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Medical laboratories — Requirements for safety

Laboratoires de médecine — Exigences pour la sécurité

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15190 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

Introduction

This International Standard specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, there are requirements to ensure that there is a named person ultimately responsible and that all employees take personal responsibility for

— their own safety at work and,

— the safety of others who may be affected by it.

Every task requires risk assessment, with the aim that hazards be eliminated wherever possible. Where this cannot be done, the risk from each hazard is reduced to as low a level as practicable, using the following order of priority:

a) by substitution;

b) by containment; or

c) by the use of personal protective measures and equipment.

Safety is the primary consideration; cost is of secondary importance.

While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, other services and disciplines may find it useful and appropriate. However, medical laboratories handling human pathogens requiring containment levels 3 and 4 will need to meet additional requirements to ensure safety.

While this International Standard is not intended to provide guidance on accreditation, it may be used for such purposes by a government, professional, or other authoritative body.

International, national or regional regulations or guidelines may apply to specific topics covered in this International Standard.

Medical laboratories — Requirements for safety

1 Scope

This International Standard specifies requirements for safe practices in the medical laboratory.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 and the following apply.

3.1
aerosols
system of particles dispersed in a gas, smoke, or fog

3.2
antisepsis
method for avoiding infection in a wound or during a clinical procedure by the use of a chemical agent such as an antiseptic

[BS 6324-1]

3.3
antiseptic
chemical germicide formulated to be used on skin or tissue

3.4
biological agent
any microorganism, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity

NOTE For classification of biological agents into risk groups, see Clause 4.

3.5
cleaning
process to remove any type of contamination, visible or not

3.6
control of infection plan
set of procedures to be used to limit spread of infection in either a hospital or a laboratory

