



MS ISO GUIDE 33:2008

MALAYSIAN STANDARD

USES OF CERTIFIED REFERENCE MATERIALS (ISO GUIDE 33:2000, IDT)

ISO GUIDE 33:2000 is endorsed as Malaysian Standard with the reference number MS ISO GUIDE 33:2008.

ICS: 71.040.30

Descriptors: certified reference materials, uses, definitions, statistical considerations, assessment

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DEPARTMENT OF STANDARDS MALAYSIA

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Committee representation

The Industry Standards Committee on Medical Devices and Facilities for Healthcare (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysian Medical Industries
Association of Private Hospitals of Malaysia
Atomic Energy Licensing Board
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Nuclear Agency
Malaysian Organization of Pharmaceutical Industry
Malaysian Rubber Board
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Ministry of Health Malaysia
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Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
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Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems which recommended the adoption of the ISO Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia (The College of Pathologists)
Association of Private Hospitals of Malaysia
Institute for Medical Research
Institute of Quality Malaysia
Malaysia Institute of Medical Laboratory Sciences
Malaysian Association of Clinical Biochemists
Malaysian Association of Private Medical Laboratories
Malaysian Medical Devices Association
Malaysian Society of Infectious Diseases and Chemotherapy
SIRIM Berhad (Secretariat)
Universiti Kebangsaan Malaysia (Biomedical Science Department)
Universiti Sains Malaysia (School of Health Sciences)

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NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Clinical Laboratory Testing and In Vitro Diagnostic Test Systems under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with ISO GUIDE 33:2000, *Uses of certified reference materials*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, “this International Standard” should read “this Malaysian Standard”;
and
- b) the comma which is used as a decimal sign (if any), to read as a point.

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.