AIM, SCOPE AND FIELD OF APPLICATION

The aim of this guide is to inform the users inclusively, to ensure its acknowledgement by the signatories of international mutual recognition agreements by assuring medical examination reports of New Business Education Foundation (NBE), accredited medical laboratories to be prepared in compliance with ISO 15189 Standard and particular requirements.

This guide comprises general and particular requirements concerning examination reports which will be prepared by medical laboratories, accredited by NBE, about their accredited scopes. The guide does not include any requirements for the analyses reports that has no accredited analyze results. Laboratories shall not use the name of NBE for the reports that has no accredited analyze results. If the laboratory have both accredited and not accredited analyses in the same analyze report, they have to define their differentiation clearly. (By putting a tick etc.)

ABBREVIATIONS

In this guide, following abbreviations
states;
NBE: New Business Education Foundation,
IEC: International Electrotechnical Commission,
ISO: International Organization for Standardization,
EA: European co-operation for Accreditation,
ILAC: International Laboratory Accreditation Cooperation.

RELATED DOCUMENTS

Requirements mentioned in this guide are available in following documents and standards:

- ISO 15189: Medical Laboratories- Requirements for Quality and Competence
- PR-7-01 Procedure for the Accreditation of Conformity Assessment Bodies
- NBE- Requirements Regarding the Use of NBE Accreditation Symbol by the Organizations Accredited by NBE (G-1-06)
- NBE- Guideline on Traceability of Measurements (G-1-12)
- EA-4/17 EA Position Paper on the Description of Scopes of Accreditation of Medical Laboratories
- ILAC P10 Policy on the Traceability of Measurement Results
- ILAC P8 Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies

GENERAL REQUIREMENTS

1- Examination reports prepared by accredited medical laboratories in their accredited scopes shall include, but not be limited to the following information:

a) Title (Medical Examination Report),
b) Name of the laboratory and its address (as mentioned in the accreditation application form),
c) Number of the medical examination report (on all pages),
d) Total page number and each page number of the medical examination report (eg. page 1/5, page 2/5, etc.),
e) A clear, unambiguous identification of the examination including, where appropriate, the examination procedure,
f) The identification of the laboratory that issued the report,
g) If accredited analyses are performed by a referral laboratory, it has to be mentioned in the report. (If the name of the laboratory is not mentioned, its records should be accessible in need)
h) Patient identification and location on each page,
i) Name or other unique identifier of the requester and the requester's contact details,
j) Date of primary sample collection (and time, when available and relevant to patient care),
k) Type of primary sample,
l) Measurement procedure, where appropriate,
m) Examination results reported in SI units, units traceable to SI units, or other applicable units,
n) Biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable,
o) Interpretation of results, where appropriate,
p) Other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure),
q) Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available,
r) Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed),
s) Date of the report, and time of release (if not contained in the report, readily available when needed),
t) If necessary, original and revised results,
u) A statement highlighting "The results are only related with the examined sample", where appropriate,
v) Critical results, where applicable,
w) A statement highlighting the situation when the quality of the primary sample do not properly fit the analysis or when the sample may have dangerous effect to the results.
z) All medical laboratories shall be compatible with the legal terms

2- Automated selection and reporting of results

In case the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that,

a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff,
b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning,
c) there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination,
d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate,
e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection,
f) there is a process for rapid suspension of automated selection and reporting.

3- The example for the first page of examination reports is given in Appendix 1, the example for the other pages is given in Appendix 2. The examples given in the Appendix are not obligatory. A laboratory may form their own report format as long as they include the information given in the general statement part of this guide.

The examination reports shall be prepared to meet the requirements of ISO 15189, and it shall be submitted for NBE's approval before use.

Laboratory shall follow "Requirements for Using NBE Accreditation Symbol by the Accredited Bodies" (G-1-06), while using NBE mark.

Appendix 1: First Page of NBE Marked Medical Examination Report (Example)

laboratory shall not be smaller than NBE logo (see G-1-06)

Accredited by
NBE

The name and address of accredited laboratory

NBE New Business Education
ACCREDITED BODY
NBE-ML-000

MEDICAL EXAMINATION REPORT

NBE-ML-000
000
00-00

Customer name/Location :

Request No. :

Date of primary sample collection :

Name or other unique identifier of the requester and the requester's contact details :

Type and identity of primary sample :

Date of the sample receipt :

Measurement procedure (Examination method):

Examination result unit : Remarks

(if any) :

Date of the report, and time of release :

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which arepart of this report.

Seal ***Date*** ***Person in charge of test*** ***Head of Medical Laboratory***

Appendix 2: Second and other Pages of NBE Marked Medical Examination Report (Example)

(The name of accredited laboratory)

The logo of the laboratory shall not be smaller than NBE logo (see G-1-06)

NBE New Business Education
ACCREDITED BODY
NBE-ML-000

This report shall not be reproduced other than in full except with the permission of the laboratory.
Examination reports without signature are not valid. Page 2 of Total
Accredited examinations marked with *.