Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

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REPORT OF THE MEETING OF THE OIE STANDARDS COMMISSION

Paris, 2–4 February 2000

The OIE Standards Commission met at the OIE Headquarters from 2 to 4 February 2000.

Dr J. Blancou, Director General, welcomed the participants, thanking them for all the work over the past three years. The importance of the work of the Commission is widely recognised and is reflected in the progressive diversification of the working agenda. He specifically focused on the value of the Commission's activities related to harmonisation of the standards and on quality systems for veterinary laboratories. He felt that the demands on the Commission would increase further in the future and he offered every possible assistance from the OIE Central Bureau. He also introduced Dr F. Crespo León from Spain, currently working as an attaché at the OIE.

Prof. M. Truszczynski, President of the Commission, thanked Dr Blancou for his support throughout his term as Director General, and in particular his positive attitude to the role of laboratories in helping to achieve the overall aims of the OIE. He also welcomed Dr A. Colling representing the OIE Collaborating Centre for ELISA[1] and Molecular Techniques in Animal Disease Diagnosis, at the FAO/IAEA[2], Vienna (Austria).

The Agenda and List of Participants are given in Appendices I and II, respectively.

1. OIE Reference Laboratories

1.1. New applications for OIE Reference Laboratory status

No new applications had been received. The Commission confirmed the recommendation (see Standards Commission Report for September 1999) of the Department of Veterinary Services, Nicosia, Cyprus as an OIE Reference Laboratory for Echinococcosis/Hydatidosis with Dr P. Economides as the designated expert.

1 Enzyme-linked immunosorbent assay
2 Food and Agriculture Organization of the United Nations/International Atomic Energy Agency

1.2. Reference Laboratory for tularemia

The Standards Commission had a request to establish a Reference Laboratory for tularemia. The request was referred to the OIE Working Group on Wildlife Diseases, which supported the request (see Standards Commission Report for September 1998). As this is primarily a disease of wildlife, the Standards Commission will ask the Working Group on Wildlife Diseases to indicate which laboratories are working in this area. The response will be discussed at the September meeting.

1.3. Updating the list of Reference Laboratories and Collaborating Centres

The following changes to named experts at OIE Reference Laboratories have been notified to the OIE. The Commission recommends their acceptance:

Leptospirosis

Dr R.A. Hartskeerl to replace Dr W.J. Terpstra at the Royal Tropical Institute, Amsterdam, The Netherlands.

Bovine spongiform encephalopathy and Scrapie

Dr M. Jeffrey to replace Dr G.A.H. Wells at the Veterinary Laboratories Agency, Weybridge, United Kingdom (UK).

Brucellosis

Dr K. Noeckler to replace Dr C. Staak at the Federal Institute of Consumers Health Protection and Veterinary Medicine, Berlin, Germany. The Commission would seek to clarify the position regarding Dr Staak's designation as expert for dourine.

Following discussion of the technical requirements of the OIE Reference Laboratories for brucellosis, the Commission agreed that it is inappropriate to differentiate between those specialising in bovine, small ruminant or porcine infections, although it is recognised that each laboratory will have its own particular strengths.

Maedi visna/caprine arthritis encephalitis

The Delegate of the UK has advised the OIE that the Veterinary Laboratories Agency, Weybridge, UK, is no longer in a position to sustain the responsibilities of OIE Reference Laboratory for maedi visna/caprine arthritis encephalomyelitis. The Standards Commission took note of this withdrawal.

Paratuberculosis and bovine tuberculosis

The Commission decided that in the interests of clarity, the Reference Laboratories for these two diseases would in future be listed separately.

1.4. Annual reports of Reference Laboratories and Collaborating Centres

Reports had been received from 101/119 Reference Laboratories and 6/8 Collaborating Centres. The Commission commented once again on the impressive range of activities by the Reference Laboratories and Collaborating Centres towards the objectives of the OIE, and the continuing support provided by individual experts to the work of the Standards Commission. Where provided, individual laboratory Web sites will be included in the published list of Reference Laboratories, and hypertext links provided from the OIE Web site. A small number of annual reports for 1999 have not been received so far and a reminder letter will be sent to those concerned. Laboratories that sent no report for both 1998 and 1999 will be advised that in the absence of further communication they will be removed from the list of OIE Reference Laboratories.

The full set of reports will be supplied to Member Countries and to all the Reference Laboratories and Collaborating Centres. The international activities relevant to the work of the OIE are summarised below[3]:

	International activities	Percentage of Laboratories/Collaborating Centres carrying out these activities	
		Reference Laboratories	Collaborating Centres
(a)	Diagnostic testing	100%	67%
(b)	Production/testing/distribution of diagnostic reagents	92%	50%
(c)	Research	85%	33%
(d)	International harmonisation/standardisation of methods	39%	83%
(e)	Preparation and supply of international reference standards	33%	0%
(f)	Collection, analysis and dissemination of epizootiological data	29%	33%
(g)	Provision of consultant expertise	52%	50%
(h)	Provision of scientific and technical training	56%	67%
(i)	Organisation of international scientific meetings	12%	83%
(j)	Participation in international collaborative studies	60%	67%
(k)	Publications	73%	67%

1.5. Information on laboratory activities at regional level

Prof. E.J. Gimeno, Co-ordinator of the OIE Regional Representation for the Americas had confirmed that the coverage of the network for inter-laboratory quality control would extend to all countries in the Americas, with a special focus on the designated OIE Reference Laboratories in the Region (see Standards Commission report for September 1999). The Commission suggested that a linkage would be worthwhile to the network of laboratories supported in the Region by the OIE Collaborating Centre for ELISA and Molecular Techniques in Animal Disease Diagnosis, at the FAO/IAEA, Vienna (Austria) and the OIE Collaborating Centre for Diagnosis of Animal Diseases and Vaccine Evaluation, Ames (Iowa, USA).

2. International standardisation of diagnostic tests and vaccines

2.1. Stocks and supplies of current OIE International Standard Sera

Reference Laboratories had been asked to supply information of current stocks of OIE International Standard Sera and amounts of material supplied to Member Countries. This had produced a mixed and rather confusing response; accordingly laboratories will be asked to complete a simple table to try to clarify this information.

2.2. OIE standardisation programmes for diagnostic tests

LIST A DISEASES

Peste des petits ruminants – Co-ordinator Dr A. Diallo

Dr A. Diallo reported that results are still awaited from other Reference Laboratories confirming the validity of the candidate reference sera.

3 Reports from aquatic animal diseases laboratories are not included in this analysis

Rabies – Co-ordinator Mr M.F.A. Aubert

The OIE Reference Laboratory in Malzéville (France) had been very active in recent months in assisting diagnostic laboratories within Europe to establish harmonised methodology for rabies serology, and in advising the veterinary authorities in Norway, Sweden and the UK on a consistent approach to testing under new movement regulations for pet animals. In consequence, progress with additional reference materials (negative and weak positive sera) had been deferred.

Enzootic bovine leukosis – Co-ordinator Dr L. Renström

No additional validation data has yet been produced to confirm the performance characteristics of the PCR[4] assay.

Dourine – Co-ordinator Dr V.T. Zablotskij

The OIE Reference Laboratory in Moscow, Russia, has contacted laboratories in other Member Countries with a view to comparative testing of different sources of antigens.

2.3. OIE standardisation programmes for vaccines

Equine influenza – Co-ordinator Dr J. Mumford

Dr J. Mumford joined the Commission to report on this programme. Reference preparations of antigens and antisera for influenza/A/equine/1 and several strains of influenza/A/equine/2 have been prepared, freeze dried and are stored at NIBSC[5], UK. The Commission reviewed the data on these materials and decided to recommend that they be designated as OIE International Reference Standards for the *in vitro* standardisation of equine influenza vaccines.

In addition, equine antisera to strains influenza/A/equine/1/Newmarket/77, influenza/A/equine/2/Newmarket 1/93 and influenza/A/equine/2/Newmarket 2/93 have been prepared. These were freeze dried on behalf of the OIE Reference Laboratory by the European Pharmacopoeia, from where they are available for distribution. Discussion will be held with the European Pharmacopoeia with the view to granting permission for the OIE to designate them as OIE International Reference Standards for single radial haemolysis tests used to measure immunogenicity of equine influenza vaccines in horses or guinea-pigs.

Equine rhinopneumonitis

Dr Mumford suggested there is a need to develop international standards for vaccines against equine herpesvirus 1. The Commission suggested that she work with the other OIE Reference Laboratories to develop suitable proposals.

2.4. Development of diagnostic reference materials other than antisera

The Commission noted comments from a Member Country that international reference materials are needed for a variety of assays, and should include not only defined antisera, as at present, but also other biological materials, such as monoclonal antibodies, antigens, and nucleic acid standards. Given the difficulties encountered progressing the current range of OIE Standard sera, the Commission is reluctant to overextend itself. Nevertheless the importance of this subject was acknowledged and it will be taken forward as opportunities arise. In addition, individual Reference Laboratories are encouraged to make locally developed reference materials available to other Member Countries whenever possible.

Specifically the Commission wishes to promulgate the development of standard reference materials for diagnostic tests reliant on gene amplification systems. This will require close collaboration with the OIE Working Group on Biotechnology. It should also be considered as a possible theme for the next OIE Biotechnology Symposium, which may be held in conjunction with the WAVLD[6] meeting in Italy in June 2001. (See also Section 11 below.)

4 Polymerase chain reaction
5 National Institute for Biological Standards and Control
6 World Association of Veterinary Laboratory Diagnosticians

3. List of prescribed and alternative tests

3.1. Heartwater

As discussed earlier (Standards Commission report September 1999) expert opinion had confirmed that IFA[7] tests for heartwater are low in specificity. ELISA methods are available that have much higher specificity, however it appears that all available serological methods are low in sensitivity, particularly in cattle, which can become seronegative despite remaining carriers. The Commission therefore identified a need for further research on methods that would be applicable to testing of individual animals for trade purposes. Genome amplification systems, such as PCR, have potential for the identification of carriers, but will need considerable validation and standardisation before they can be recommended for trade purposes. Meanwhile the Commission will advise the International Animal Health Code Commission that the available tests are only meaningful as herd tests, and the *International Animal Health Code* (the *Code*) chapter may therefore need to be reviewed. It is recommended that the IFA be redesignated as an 'Alternative' test, and that ELISA also be added as an 'Alternative' test for heartwater (see Appendix III).

3.2. Enzootic bovine leukosis

A Member Country had commented that the AGID[8] test was lower in sensitivity than ELISA and should therefore no longer be listed as a prescribed test for enzootic bovine leukosis. The Commission had sought views from OIE experts, and whilst the lower sensitivity of AGID was acknowledged, it was also noted that this test continues to be of value to many Member Countries. Taking into account that the *Code* requires testing at herd, rather than individual animal level, the Commission decided that both AGID and ELISA are satisfactory for this purpose, and both should remain as 'Prescribed' tests. Where bulk testing of pooled serum or milk is practised, only ELISA would be suitable.

3.3. General review of the list

Following comments from a Member Country, the Commission undertook a review of the whole list of 'Prescribed' and 'Alternative' tests. The purpose of the list was re-emphasised, which is to define tests that are suitable for use in international trade, in support of the standards defined in the *Code.* It is important to understand that many excellent and validated tests that are applicable to disease diagnosis or surveillance are included in the *Manual* but are not listed as 'Prescribed' or 'Alternative' because they are not applicable to trade. There are a number of candidate tests that might be added to the lists once sufficient validation data had been submitted to, and endorsed by, the Standards Commission.

The Commission made the following recommendations, taking into account the above criteria. All proposed changes in the list of 'Prescribed' and 'Alternative' tests since May 1999 are shown in Appendix III.

3.2.9. Cysticercosis: add Agent identification as an alternative test.

3.3.3. Contagious agalactia: remove all tests pending review of the disease definition (see 4.2. below).

3.3.6. Contagious caprine pleuropneumonia: delete Agent identification from the list of alternative tests.

3.6.1. Infectious bursal disease: Add ELISA as an alternative test. The Code Commission should be advised to change the wording of their chapter to require 'serological tests' rather than AGID specifically.

3.6.4. Avian chlamydiosis: Remove CF[9] (inappropriate for trade).

X.2. Malignant catarrhal fever: Add PCR as an alternative test.

X.12. Porcine reproductive and respiratory syndrome: add IPMA[10], IFA and ELISA as alternative tests.

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7 Indirect fluorescent antibody
8 Agar gel immunodiffusion
9 Complement fixation
10 Immunoperoxidase monolayer assay

4. OIE *Manual of Standards of Diagnostic Tests and Vaccines*

4.1. General progress

For this section of the Agenda, the Commission was joined by the consultant editor, Dr G.A. Cullen. Progress on the preparation of chapters for the next edition of the *Manual* was reviewed. Only seven chapters remain to be sent for Member Country comments. The Commission provided detailed advice to the editor on specific technical issues in individual chapters. The remaining chapters will be sent for comment shortly, and all Delegates will therefore have had opportunity to comment on the entire content of the new edition of the *Manual* by the 68th General Session in May 2000.

The report on the preparation of this fourth edition of the *Manual* will be presented to the International Committee in May 2000 by the President of the Standards Commission. He will also seek permission from the Committee for any remaining minor modifications to be dealt with by the Standards Commission at its meeting in September 2000. This will avoid the introduction of any delays into the very tight production schedule.

4.2. Contagious agalactia

Comments from a scientific reviewer had highlighted a lack of clarity in the OIE disease definition of contagious agalactia. As described in the chapter there is a variety of mycoplasma infections that may be associated with the clinical syndrome of 'contagious agalactia' in sheep and goats. More traditionally the disease was considered to be only that associated specifically with *Mycoplasma agalactiae* infections. The Commission felt that there was insufficient data one way or the other to alter the chapter in the *Manual* at this late stage. Nevertheless a dialogue should be opened with the Code Commission to decide how OIE wished to treat this disease in the future. From the point of view of disease control and regulation it may be better to consider the disease as only those cases caused by *M. agalactiae* infection. This would facilitate the development of specific diagnostic tests to assist in disease control and regulation of trade.

5. OIE disease cards

The draft cards on Aujeszky's disease and infectious bovine rhinotracheitis/infectious pustular vulvovaginitis have now been reviewed by OIE experts. They are included at Appendix IV to this report (at present these two sheets exist in English only, but French and Spanish translations will be available in the future). Having now completed cards for all the List A diseases together with nine of the List B diseases, the Commission decided that no additional cards will be issued unless there is a strong demand from Member Countries.

6. Liaison with other Commissions

6.1. Transmissible spongiform encephalopathies

The International Animal Health Code Commission had asked for additional information on the validation of immunodiagnostic methods for transmissible spongiform encephalopathies. The Commission is aware of ongoing developments in this field, whereby techniques such as immunoblotting and various forms of enzyme immunoassay for PrP protein in brain tissue are being validated progressively. In order to ensure that the most up-to-date advice is given, and to ensure that the *Manual* is as current as possible when published, the Commission will consult Reference Laboratory experts for the latest position on these techniques. It should be emphasised that so far all techniques have been validated for use on post-mortem examination of tissues only.

6.2. Surra

The Foot and Mouth Disease (FMD) and Other Epizootics Commission had referred a comment from a Member Country concerning the validity of diagnostic tests for Surra (*Trypanosoma evansi*) when applied to horses. The Commission would seek specialist advice from an expert in this area.

6.3. Contagious bovine pleuropneumonia

The FMD and Other Epizootics Commission had raised a question concerning the proposal from the September meeting of the Commission that the ELISA be made an alternative test. They did not believe that there was adequate validation data to support adding this test to the list. The Commission reviewed the data again and felt that the data was adequate and would not change their recommendation. The data will be forwarded to the FMD and Other Epizootics Commission.

6.4. Aujeszky's disease

The International Animal Health Code Commission asked if a country could be considered to be free from Aujeszky's disease if it was still vaccinating with a gene-deleted vaccine. The opinion of the Standards Commission is that the country could not be considered to be free as there could be infected herds that would not be identified.

7. International Cooperation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products

For this part of the Agenda, the Commission was joined by Dr C. Folkers, representing the Working Group of the VICH[11]. He presented a progress report, outlining the primary objectives of the Group, which are (a) to provide a forum for dialogue between regulatory authorities for veterinary medicinal products, particularly among the European Union, the United States of America and Japan; (b) to identify areas where modifications of technical procedures could reduce costs without compromising quality; (c) the harmonisation of technical requirements for product registration, including the elimination of unnecessary requirements and, wherever possible, a reduction in the amount of animal testing.

The Working Group has made significant progress in four specific areas of testing: for residual moisture, for formaldehyde, for mycoplasmas and for extraneous viruses. The Commission agreed to ensure that the forthcoming edition of the *Manual* was in accordance with the developing harmonised VICH guidelines, particularly in these four areas and in the relevant terminology as defined in the glossary. Dr Volkers agreed to make a final check of the texts of the introductory chapters dealing with vaccines.

8. Quality systems for veterinary laboratories

Further Member Country comments had been received on the revised draft text on the 'Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases'. There was a general consensus of support for the Standard, although it was recognised there is some confusion over its relationship to the draft ISO 17025 Standard. This will be clarified in a modified introduction to the OIE Standard, which is effectively an interpretation of ISO 17025 for veterinary laboratories, but which may be used as a standard in its own right for those laboratories who so wish. Taking into account the comments received, the Commission finalised the text of this standard and will propose its adoption by the International Committee in May 2000 (see Appendix V).

9. Antimicrobial resistance in bacteria

The Commission noted that an Ad hoc Group on antimicrobial resistance in bacteria will meet at the OIE headquarters in March 2000, and will report to the International Committee. They have a seven-point agenda:

- To develop technical guidelines on prudent use of antimicrobial substances and on quality control of the antibiotics used in livestock;
- To harmonise, after gathering the necessary information, the national antibioresistance surveillance programmes in animals and in foodstuffs of animal origin;
- To develop an appropriate methodology for ascertaining risk concerning the impact on public health of bacterial resistance to antibiotics used in animal husbandry;

11 International Cooperation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products

- To gather information on the procedures used in veterinary laboratories and clinical biology laboratories in different countries for quantitative and qualitative analysis of bacterial resistance to antibiotics;
- To present proposed standardised protocols for analysing the antibiotic resistance of bacteria isolated from animals or products of animal origin, and notably specific procedures for different bacterial groups;
- To present proposals on harmonisation of assays on antibiotics in the veterinary laboratories of OIE Member Countries;
- To formulate recommendations on the preparation and distribution of resistant bacterial strains taking account of international reference strains and the requirement for biosecurity.

The Standards Commission will have a specific interest in the harmonisation of laboratory methods for determination of antimicrobial resistance, and will develop appropriate recommendations for veterinary laboratories in Member Countries based on the conclusions of the Ad hoc Group.

10. Collaboration with the World Health Organization's International Laboratory for Biological Standards

For this session, the Commission was joined by Dr G.C. Schild, Director of the National Institute for Biological Standards and Control (NIBSC), UK, which also houses the WHO[12] International Laboratory for Biological Standards. Dr Schild outlined the history and operational remit of NIBSC. It is funded principally by the UK Department of Health to provide standardisation and control of biological substances used in human medicine. It has an ancillary remit for some substances used in veterinary medicine, particularly where they have public health implications. Since 1948 the institute has also been recognised by WHO as an International Laboratory for Biological Standards, and more recently has taken over the maintenance and distribution of WHO International Reference Materials previously held by the Veterinary Laboratories Agency, Weybridge, UK, and by the Staten Serum Institute, Copenhagen, Denmark.

NIBSC has an active and growing programme of activities covering areas such as virology, bacteriology, cell biology, immunobiology, haematology, and endocrinology. As well as the development of new reference materials, considerable effort is devoted to the storage and maintenance of existing materials in stable conditions.

Prof. Truszczynski outlined the work of the Standards Commission and how this relates to the OIE Mission and Aims. Specifically he referred to the work over recent years on the programmes of international standardisation of diagnostic laboratory tests, and the ongoing development of OIE Standard Sera for various key diseases. Following extensive discussion about areas of possible mutual collaboration, it was noted that NIBSC would be willing to assist OIE Reference Laboratories with the filling of ampoules, freeze drying, and distribution of designated Standard Sera. Other areas of potential future collaboration might include antimicrobial resistance, xenotransplantation, transmissible spongiform encephalopathies, and the production of Reference Materials for gene amplification systems. The Standards Commission would be invited to send an observer to an international working group looking at standardisation of gene amplification systems in the medical field.

11. Any other business

- It was agreed that it would be worthwhile developing a Standards Commission home page within the OIE Web site. This could contain a number of documents related to the work of the Commission, as well as information about the Members of the Commission. It will be taken forward at a future meeting.
- The OIE Working Group on Wildlife Diseases had informed the Standards Commission that the European Association of Zoo and Wildlife Veterinarians would be invited to discuss aspects of the validity of diagnostic tests for wildlife diseases.
- A Member Country had suggested that OIE might develop a database of veterinary vaccines available in each Member Country. The Commission felt that this would be too complicated both to set up and to maintain, given the limited resources of the OIE.

12 World Health Organization

- The Commission proposed various ideas on themes for future editions of the OIE *Scientific and Technical Review*.
- The Commission discussed possible themes for the OIE World Association of Veterinary Laboratory Diagnosticians (WAVLD) Biotechnology Seminar which will be held in Italy in the summer of 2001. The recommendation of the Commission was that the seminar address the subject 'Standardisation of diagnostic tests that rely on gene amplification systems'. The Commission will develop a list of proposed speakers at the September meeting. The Commission also requested that the Working Group on Biotechnology advise the organising committee of the WAVLD that the OIE would only support this seminar if it was fully integrated into the programme of the Seminar so that a large attendance can be expected.

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.../Appendices

Appendix I

MEETING OF THE OIE STANDARDS COMMISSION

Paris, 2–4 February 2000

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Agenda

1. OIE Reference Laboratories
2. International standardisation of diagnostic tests and vaccines
3. List of prescribed and alternative tests
4. OIE Manual of Standards for Diagnostic Tests and Vaccines
5. OIE diseases cards
6. Liaison with other Commissions
7. International Cooperation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products
8. Quality systems for veterinary laboratories
9. Antimicrobial resistance in bacteria
10. Collaboration with the World Health Organization's International Laboratory for Biological Standards
11. Any other business

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MEETING OF THE OIE STANDARDS COMMISSION

Paris, 2–4 February 2000

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Appendix III

OIE *MANUAL OF STANDARDS FOR DIAGNOSTIC TESTS AND VACCINES*

Proposed changes to the List of prescribed and alternative tests

Ref. No.	Disease	Prescribed tests	Alternative tests
A060	Contagious bovine pleuropneumonia	CF	ELISA
B055	Heartwater	[IFA]	ELISA, IFA
B058	Rabies	VN	[Agent id., FAVN]
B106	Cysticercosis	–	Agent id.
B114	Malignant catarrhal fever	–	IFA, PCR, VN
B154	Contagious agalactia	–	[Growth inhibition]
B155	Contagious caprine pleuropneumonia	CF	[Agent Id]
B253	Porcine brucellosis	BBAT	ELISA, FPA
B257	Porcine reproductive and respiratory syndrome	–	ELISA, IFA, IPMA
B309	Infectious bursal disease	–	AGID, ELISA
B312	Avian chlamydiosis	–	[CF]

Agent id. = Agent identification
AGID = Agar gel immunodiffusion
BBAT = Buffered *Brucella* antigen test
CF = Complement fixation
ELISA = Enzyme-linked immunosorbent assay
FAVN = Fluorescent antibody virus neutralisation
FPA = Fluorescence polarisation assay
IFA = Indirect fluorescent antibody
IPMA = Immunoperoxidase monolayer assay
PCR = Polymerase chain reaction
VN = Virus neutralisation

Double underlined text = new proposal.
Reduced-size text between square brackets = proposed deletion.

Appendix V

DRAFT OIE STANDARD FOR MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES CONDUCTING TESTS FOR INFECTIOUS ANIMAL DISEASES

STANDARDS COMMISSION OF THE OFFICE INTERNATIONAL DES EPIZOOTIES

Contents

Introduction

This document describes the OIE Standard for management and technical competence that serves as the basis for accreditation of laboratories that conduct tests for infectious animal diseases, especially those laboratories involved in testing for international trade. It contains the specific requirements unique to laboratories conducting tests for infectious animal diseases. These specific requirements represent an interpretation of the generally stated requirements of ISO/IEC[13] 17025:1999, *General requirements for the competence of testing and calibration laboratories* (as outlined in Annex B of ISO/IEC 17025).

Accreditation bodies that recognise the competence of such testing laboratories may use this Standard as the basis for their accreditation. Laboratories that comply with the OIE Standard also operate in accordance with ISO/IEC 17025 with respect to testing for infectious animal diseases. Clause 4 specifies the requirements that a laboratory shall meet in order to demonstrate sound management. Clause 5 specifies the requirements needed to demonstrate technical competence and validity of results for the testing activities it undertakes.

The OIE Standard will also serve as a foundation document from which further interpretations and/or guides will be developed as required.

The need to control or eradicate the major animal epizootics and eliminate technical barriers to trade of farm animals and related commodities has led to a need to ensure that national veterinary laboratories or their delegates, that conduct testing for infectious animal diseases, can operate a quality system that is compliant with the ISO 9000 series as well as with this Standard. Therefore, as with ISO/IEC 17025, care has been taken to incorporate the requirements of the ISO 9000 series that are relevant to the scope of testing services that are covered by the laboratory's quality system.

The acceptance between countries of test results and diagnostic interpretations will be facilitated if laboratories comply with this Standard and obtain accreditation from bodies who have entered into mutual recognition agreements with equivalent bodies in other countries using this Standard.

1. Scope

1.1. This Standard specifies the general requirements a laboratory shall meet if it is to be recognised as competent to perform tests for infectious animal diseases. It is intended for use by OIE Member Countries for the assessment of laboratories that are performing tests to qualify animals and animal products for international movement. It covers the use of internationally recognised, standard methods and methods not covered by international standards, including in-house developed methods.

1.2. This Standard is applicable to all laboratories conducting tests for infectious animal diseases. This includes national veterinary laboratories and those public or private laboratories contracted to a national veterinary authority to provide such services

1.3. This Standard is applicable regardless of the number of personnel or the extent of the scope of testing for infectious animal diseases. When a laboratory does not undertake one or more of the activities covered by this Standard, the requirements of those clauses do not apply.

1.4. The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this Standard.

1.5. This Standard is for use by laboratories in developing the management and technical systems that govern their operations. It can also be used by laboratory clients, regulatory authorities and accreditation bodies involved in confirming or recognising the competence of laboratories.

13 International Organization for Standardization/International Electrotechnical Commission

2. Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this Standard. Parties to agreements based on this Standard are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.

ISO/IEC Guide 2: 1996. *General terms and their definitions concerning standardization and related activities.*

ISO 8402: 1994. *Quality management and quality assurance – Vocabulary*

ISO 9001: 1994, *Quality systems – Model for quality assurance in design, development, production, installation and servicing*.

OIE *Manual of Standards for Diagnostic Tests and Vaccines*, 1996.

NOTE: Further related standards, guides, etc., on subjects included in this Standard are given in the bibliography.

3. Terms and definitions

For the purposes of this Standard, the relevant definitions given in ISO/IEC Guide 2, ISO 8402, the OIE *Manual of Standards*, and the following terms and definitions apply

3.1. Sample:

the material that is derived from a specimen and is used for testing purposes.

3.2. Specimen:

the material, exclusively of animal origin, submitted for testing.

3.3. Validation:

the process through which a test method is confirmed to be fit for the intended purpose.

4. Management requirements

4.1. Organisation and management

4.1.1. The laboratory or the organisation of which it is part shall be an entity that can be held legally responsible.

4.1.2. The laboratory shall be organised and shall operate in such a way that it meets the requirements of this Standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.3. The laboratory shall have a clearly defined organisational system and structure. This shall be supported with organisational charts and job descriptions. Organisational charts shall indicate key personnel and the laboratory's place within the larger organisation. Relationships between management, technical operations, support services, and quality activities shall be specified.

4.1.4. The laboratory shall

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or the procedures for performing tests, and to initiate actions to prevent or minimise such departures;

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define the organisation and management structure of the laboratory, its place in the parent organisation, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and inter-relationships of all personnel who manage, perform or verify work affecting the quality of the tests and diagnostic interpretations;

g) provide adequate supervision of staff, including trainees, by persons familiar with the tests, their purpose, and the analysis of test results;

h) have technical management that has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources;

j) appoint backups or deputies for key managerial personnel such as the quality manager.

NOTE: In laboratories with a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.2. Quality system

4.2.1. The laboratory management shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and volume of testing it undertakes. The laboratory management shall document its policies, systems, programmes, procedures and instructions to enable the laboratory to ensure the quality of the test results and diagnostic interpretations it generates. Documentation used in this quality system shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2. The laboratory management shall define and document the policies and objectives to be achieved by implementing the quality system. The laboratory management shall ensure that these policies and objectives are documented in a quality manual. The overall objectives shall be set out in a quality policy statement in the quality manual, stating the standard of performance to be achieved and maintained. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) a statement of the laboratory management's intentions with respect to the standard of service it will provide;

b) the purpose of the quality system;

c) a requirement that all personnel concerned with testing activities within the laboratory familiarise themselves with the quality documentation and implement the policies and procedures in their work;

d) the laboratory management's commitment to good professional practice and quality of its diagnostic services to its client;

e) the laboratory management's commitment to compliance with this Standard.

NOTE: The quality policy statement and manual should be concise.

4.2.3. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.

4.2.4. The quality manual shall define the roles and responsibilities of technical management and the quality manager including their responsibility for ensuring compliance with this Standard.

4.3. Document control

4.3.1. The document control system shall ensure that only the current version of the correct document is in use in the laboratory, and that documents needed for staff to perform their work are available at the work location.

4.3.2. The laboratory shall have documented policy, procedures, and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived, and discarded. Procedures shall be reviewed and approved by authorised, qualified staff.

4.3.3. Amendments to documents shall be identified clearly in the text and reviewed and approved by authorised, qualified personnel having access to pertinent background information concerning the change.

4.3.4. Documents shall be uniquely identified and accurately cross referenced.

NOTE: In this context 'document' means any information or instructions, in any format or medium, that have direct bearing on or affect the quality of test results, and includes not only the quality manual, policy, procedures, and instructions, but also test methods, worksheets, forms, international standards, and regulations.

4.4. Review of request, tender or contract

4.4.1. The laboratory shall have documented policy and procedures that describe how the laboratory ensures that it is capable of doing particular testing. The procedures shall ensure adequate review of the proposed work with laboratory staff and the client. The laboratory shall keep a record of the review and of client agreement.

4.4.2. The review shall also cover any work that is subcontracted by the laboratory.

4.5. Subcontracting of test services

The client shall be informed of and agree to any subcontracting of work.

4.6. Purchasing services and supplies

The laboratory shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results. These procedures shall include a description of the criteria for selection, evaluation, use, handling, and storage of materials and reagents having an effect or potential effect on test results.

4.7. Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.8. Control of nonconforming testing and test results

4.8.1. The laboratory shall have a policy and procedures that ensure that nonconforming testing (conditions that exist that have or could adversely affect the reliability of test results) is detected and promptly corrected. The laboratory shall have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client. These procedures shall describe who has the authority to withhold test results, implement corrective action, and authorise resumption of work.

4.8.2. When a serious issue or a risk to the quality of test results is identified, the laboratory shall ensure that the corrective action procedures given in 4.9. shall be implemented promptly.

4.9. Corrective and preventative action

4.9.1. The laboratory shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure:

a) designation of appropriate authorities responsible for implementation of corrective action(s);

b) investigative procedures are implemented to determine the root cause(s) of the problem;

c) upon identification, appropriate corrective action(s) are implemented;

d) documentation of any required changes to operational procedures;

e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem;

f) when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11.

NOTE: Special internal audits need only be initiated when a serious issue or risk to the quality of test results or integrity of the quality system has been the subject of corrective action.

4.9.2. The laboratory shall identify potential sources of nonconformance and potential needs for improvement, either technical or with the quality system. Preventative action procedures shall include:

a) identification and evaluation of potential nonconformance or improvement;

b) development and implementation of an action plan, including appropriate controls;

c) monitoring of effectiveness in reducing likelihood of nonconformance or in addressing specific needs for improvement;

NOTE: Preventative action is a pro-active process. Identification of specific technical areas requiring preventative action often involves the ongoing monitoring and review of the validity of the test methods and the competence of the laboratory.

4.10. Records

4.10.1. General

The laboratory shall have a records management system.

4.10.1.1. The laboratory shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews, as well as, corrective and preventive action records.

4.10.1.2. All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE: Records may be in the form of any type of media, such as hard copy or electronic media.

4.10.1.3. All records shall be held secure and in confidence.

4.10.1.4. The laboratory shall have procedures to protect and back-up data held on computers at all times and to prevent unauthorised access to or amendment of data on computers.

4.10.2. Technical records

4.10.2.1. The laboratory shall retain for a defined period of time, original observations, derived data, calibration records, staff records, a copy of each test report issued, and any other information necessary to recreate the activity. The records for each test shall contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.

4.10.2.2. Observations, data and calculations shall be clearly and permanently recorded and identifiable to the specific test at the time they are made.

4.10.2.3. When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible nor deleted), and the correct value entered alongside. All such alterations to records shall be dated, signed or initialled by the person making the correction. In the case of computer-collected data, similar measures shall be taken to avoid loss or change of original data.

4.11. Internal audits

4.11.1. The laboratory shall periodically and in accordance with a predetermined schedule and procedure conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit programme shall address all elements of the quality system, including testing activities. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

NOTE: In laboratories with a small number of personnel, effective internal audits may not be feasible. In such cases, it may be appropriate for two or more laboratories to cooperate in auditing each other.

4.11.2. When audit findings cast doubt on the effectiveness of the operations or on the quality of

the laboratory's test results, the laboratory shall take timely and effective corrective and preventive action, and shall notify clients in writing if investigations show that the laboratory results may have been affected (see 4.8.).

4.11.3. The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these corrective actions are discharged within an appropriate and agreed time-frame.

4.12. Management reviews

4.12.1. The quality system and test related activities shall be reviewed by management at least once per year. The review shall take into consideration:

a) suitability of policies and procedures;

b) reports from managerial and supervisory personnel;

c) reports of recent internal audits;

d) corrective and preventative actions;

e) assessments by external bodies;

f) results of interlaboratory comparisons or proficiency tests;

g) changes in the volume and type of work;

h) client feedback;

i) complaints;

j) other relevant factors, such as quality control activities, resources and staff training.

4.12.2. Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed time-frame.

4.12.3. This review and subsequent activities shall ensure the continuing suitability and effectiveness of the quality management system and shall ensure the introduction of necessary changes and improvements.

5. Technical requirements

5.1. General

5.1.1. Many factors can affect the reliability of test results. The extent to which these factors contribute to the reliability of test results differs between tests. The laboratory shall take account of these factors in developing or adopting test methods and related procedures for routine use, in the training and qualification of personnel, in the selection and calibration of equipment, and in the assessment of materials and reagents to be used in testing.

5.2. Personnel

5.2.1. The laboratory shall ensure the initial and ongoing competence of all laboratory personnel to do their assigned work.

5.2.2. The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and diagnostic interpretation, and the management shall authorise only staff who are documented as qualified and competent to do testing and related work.

5.2.3. The laboratory shall have a system that ensures the establishment and maintenance of a training programme relevant to the present and anticipated needs of the laboratory.

5.3. Accommodation and environmental conditions

5.3.1. Laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of tests. The laboratory shall ensure that the environment does not invalidate the results or adversely affect the required quality of any testing activity.

5.3.2. The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, radiation, humidity, airflow, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Test activities shall be stopped when the environmental conditions jeopardise the test results.

5.3.3. There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4. Access to and use of areas affecting test results shall be controlled.

5.4. Test methods

5.4.1. General

5.4.1.1. The laboratory shall use appropriate test methods and related procedures for all infectious animal disease diagnostic testing activities. Consideration shall be given to all factors that impact on the relevance of the test method and test results to a specific diagnostic interpretation or application. These factors include the suitability of the test method, its acceptability by the scientific and regulatory communities, its acceptability to the client, and its feasibility given available laboratory resources. To the extent possible, test methods shall be chosen from those endorsed or published by reputable technical organisations or sources.

5.4.1.2. Test methods shall be approved for use by qualified, authorised personnel, according to established procedures.

5.4.1.3. Tests shall be appropriately controlled.

5.4.1.4. The laboratory shall have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment, and the collection, handling, transport and storage of specimens and preparation of samples for testing.

5.4.1.5. Laboratories using test methods prepared by national and international standards-setting bodies and other external technical organisations shall have a system that ensures that they automatically receive updates of these methods in a timely manner.

NOTE: International, regional or national standards or other recognised specifications that contain sufficient and concise information on any of the above subjects do not need to be rewritten as internal procedures if these standards are published in a way that they can be used as published by the operating staff in a laboratory. Consideration may need to be given to providing additional documentation for optional steps in the assay or additional details. As with all test methods, they shall be subject to document control (see 4.3.).

5.4.2. Selection of methods

5.4.2.1. The client shall be informed of the test method chosen and, if required, the laboratory shall provide the client with the rational used in making this choice (see 5.4.1.1.).

5.4.2.2. Analysts shall have documented proficiency in the performance of the test. Proficiency shall be documented on an ongoing basis, at appropriate intervals. Assessment of proficiency shall be based on objective data, using blind samples of appropriate number and composition. These samples should be well characterised.

5.4.2.3. The laboratory shall perform tests only when the process can be demonstrated to be in statistical control.

5.4.2.4. The test method shall contain enough critical and descriptive information such that an experienced technician can properly perform the test within pre-established control limits without reference to other information sources. In addition, it shall include:

a) evidence of document and configuration control;

b) relevant references;

c) a description of intended analyse(s) (e.g. antibody) and any quantities or ranges to be determined (e.g. titre);

d) any reference standards or reference materials required (e.g. reference strains, reference standards for antibody);

e) a description of the appropriate matrix or specimen for testing, including species (e.g., bovine serum);

f) safety considerations, including biocontainment level needed;

g) a list of and specifications for equipment, materials, and reagents, including software;

h) conditions for acceptance of specimens as fit for testing;

i) conditions for specimen identification, collection, handling, transportation and storage;

j) conditions for sample preparation;

k) a description of the controls used and their acceptance limits;

l) checks to be made prior to beginning the test procedure (e.g. equipment checks and calibrations);

m) acceptance criteria for test results;

n) data to be recorded, and the method of analysis/transformation, presentation, and/or interpretation (e.g., how an absorbance reading is transformed and interpreted as a positive or negative result relative to a cut-off), and recording;

o) most current description of the test procedure.

5.4.2.5. The test method shall be validated before it is incorporated into the routine diagnostic activities of a laboratory. The same prerequisite applies to an existing assay that has been modified if the modification affects the performance characteristics of the assay (see 5.4.3.).

5.4.3. Validation of test methods

5.4.3.1. A test method, whether an international or national standard method, a harmonised method, or developed in-house shall be considered appropriate for routine diagnostic purposes only if it has been validated according to the principles outlined in the OIE *Manual of Standards for Diagnostic Tests and Vaccines* and other related OIE references. While it is preferred that all methods, developed in-house or drawn from reputable collections of standard methods, undergo an in-house validation using an appropriate number of samples from the population of interest, the user is not required to re-validate international or national standard methods, but shall be able to define, at least through reference to public or private documentation, the analytical sensitivity and specificity, accuracy and precision, diagnostic sensitivity and specificity and other parameters relevant to the use of the test method in the user's laboratory. The user shall provide documented evidence of data on and statistically valid assessment of comparative performance for those assays that are harmonised by interlaboratory comparison to an accepted and validated standard method. The user shall conduct a full validation on all test methods developed in-house as outlined in the OIE *Manual of Standards for Diagnostic Tests and Vaccines*.

5.4.3.2. Validation data, including all original observations, calculations, equipment monitoring and calibration records, and archived procedures used to formulate performance characteristics, shall be retained and updated by the laboratory for at least as long as the assay is used for routine diagnostic purposes and for at least seven years after the assay has been retired from use.

NOTE: Depending on client needs, the laboratory may be required to define other diagnostic performance indicators such as positive and negative predictive values of the test. Such indicators may be particularly relevant to certain diagnostic applications or test populations.

5.4.4. Control of data

5.4.4.1. The laboratory shall ensure, using appropriate procedures, that all data resulting from test validation and all data relating to test results are secure, retrievable, and approved for use by specified, qualified personnel

5.4.4.2. Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.4.3. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

a) computer software, modified or developed by the user, is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use, i.e. the laboratory shall implement and document changes to control procedures such that these activities can be recreated and an audit trail be established;

b) procedures are established and implemented for protecting the security, integrity, and retrievability of data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.

NOTE: Commercial software in general use within its designed application range may be considered sufficiently validated.

5.5. Equipment, including computers and software

5.5.1. The laboratory shall be furnished with all items of test and related equipment required for the correct performance of the tests. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this Standard are met.

5.5.2. Equipment and its software used for diagnostic activities shall be capable of achieving the accuracy required and shall comply with specifications relevant to the procedures concerned. Calibration programmes shall be established for key equipment where these properties have a significant affect on the results.

5.5.3. Equipment shall be operated by authorised, qualified personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4. Each item of equipment used for test activities significant to a test result shall be uniquely identified.

5.5.5. Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:

a) identity of the item of equipment;

b) manufacturer's name, type identification, and serial number or other unique identification;

c) verification that equipment complies with the specification;

d) current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration or calibration verification;

g) maintenance carried out to date and the maintenance plan;

h) damage, malfunction, modification or repair to the equipment.

5.5.6. Maintenance procedures shall be established.

5.5.7. Equipment calibrations shall be performed by qualified personnel using procedures appropriate to intended use, accuracy and precision required, and at appropriate intervals as historical data indicate.

5.5.8. Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service, clearly labelled or marked, and appropriately stored until it has been repaired and shown to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and shall institute the 'Control of nonconforming work' procedure (4.8.).

5.5.9. Whenever practical, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration or verification and the date when the next calibration or verification is due.

5.5.10. When, for whatever reason, equipment goes outside the direct control of the laboratory for a period, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.11. When computers or automated testing equipment are used for the collection, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that the requirements of 5.4.4.3. are met.

5.5.12. Test equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the test results.

5.6. Measurement traceability

5.6.1. Where indicated and when possible, the laboratory shall have traceability of all measurements, including the calibration of equipment, to SI units.

5.6.2. Where traceability to SI units of measurement is not possible, the best available means for providing confidence in the results shall be applied such as:

a) the use of suitable reference standards or materials certified to give a reliable characterisation of the material;

b) mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned;

c) participation in a suitable programme of interlaboratory comparisons or proficiency testing.

5.6.3. Reference equipment, standards or materials used in conjunction with testing activities shall be handled, maintained, and stored in a manner that ensures proper performance and/or accuracy.

5.6.4. Biological reference materials shall, where possible, be traceable to accepted international standards or to OIE reference materials (e.g. International Standard Sera).

5.6.5. Checks needed to maintain confidence in the status of working standards and reference materials shall be carried out according to defined procedures and schedules.

5.6.6. The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.7. Specimens

5.7.1. General

The laboratory shall have procedures for the collection of specimens to ensure that they are both appropriate to the test being undertaken and suitable for testing.

5.7.1.1. The laboratory shall have procedures for the collection, processing where indicated and preservation of specimens. Collection and related procedures shall be available at the location where collection is undertaken.

5.7.1.2. The laboratory shall have procedures for recording relevant data and operations relating to specimen collection that forms part of the test that is undertaken, whether the collection is performed by laboratory staff or by the client. Records shall include the collection procedure used, identification of the collector, environmental conditions (if relevant) and diagrams or other means to identify the collection location as necessary (e.g. in the case of tissue specimens) and, if appropriate, the statistics that sampling procedures are based upon.

5.7.1.3. If responsible for the collection, the laboratory shall have a statistically defined and documented sampling plan for the collection of specimens from the population under test or investigation. The plan shall be available at the location where collection is undertaken.

NOTE: While the laboratory may provide relevant scientific and/or statistical input into the development of sampling plans for the testing of animal populations, the development of these plans does not fall within this Standard.

5.8. Handling of specimens

5.8.1. The laboratory shall have procedures that ensure the integrity of specimens. These shall include transportation, receipt, handling, protection, retention and/or disposal of specimens.

5.8.2. The laboratory shall have a system for identifying specimens that ensures no confusion between specimens or derived samples. The identification shall be retained throughout the life of the specimen and its derived samples in the laboratory, and linked to the test report (5.10.).

5.8.3. Upon receipt of the specimen, any abnormalities or departures from normal or specified conditions, as described in the relevant test method, shall be recorded. If there has been a departure from specifications, then the samples should not be considered fit to test.

5.8.4. When there is any doubt as to the suitability of a specimen for testing purposes, or when a specimen does not conform to the description provided, or if the test method required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the facts and results of the discussion.

5.9. Ensuring the quality of test results

The laboratory shall have procedures for monitoring the validity of test results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) internal quality control schemes using statistical techniques (e.g. control charts);

b) where applicable, use of international reference reagents for preparation of national and/or working standards for internal quality control;

c) when practical, replicate tests using the same or different methods;

d) correlation of results for different characteristics of a specimen or sample;

e) re-testing of retained specimens or samples;

f) participation in interlaboratory comparison or proficiency testing programmes.

NOTE: The validity of test results is influenced by both technical competence and assay performance characteristics. If the validity of test results is called into question, it is important to be able to distinguish between the two. A test may demonstrate appropriate process control but poor diagnostic performance or vice versa.

5.10. Reporting test results

5.10.1. The results of each test performed by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test method or contract.

5.10.2. Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:

a) a title (e.g. ‘Test Report’);

b) name and address of laboratory, and, if different, the location where the tests were performed;

c) unique identification (see 5.8.2.) at the beginning and on each page of the test report to ensure that the page is recognised as a part of the test report, and a clear identification of the end of the report;

d) name and address of the client placing the order;

e) description and unambiguous identification of the specimen(s) tested;

f) unique identification of the test method(s) used, including the version number;

g) date of receipt of specimen(s) and date(s) of performance of the test where relevant to the validity and application of the results;

h) test results;

i) reference to specimen collection procedures used by the laboratory or by the client where these are relevant to the validity or application of the results;

j) where appropriate and needed, opinions and diagnostic interpretations of the test results;

k) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorising the test report;

5.10.3. Where applicable, the test report shall also include:

a) date of specimen collection;

b) unambiguous identification of specimen source;

c) location of collection, including any diagrams, sketches or photographs;

d) reference to sampling plan used (see 5.7.1.3.);

e) details of any environmental condition during collection that may affect the interpretation of the test results;

f) identification of the collection procedure or technique.

5.10.4. When opinions and diagnostic interpretations are included in the test report, the laboratory shall document the basis upon which the opinions and interpretations have been made.

NOTE: When the results of a battery of tests are considered in formulating an opinion or making a diagnostic interpretation, it may be necessary to describe, for the client, the rationale behind the sequence of testing and the decision making process (e.g. presumptive vs definitive tests or screening vs confirmatory tests).

5.10.5. When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

5.10.6. In the case of transmission of test results and/or interpretations by telex, facsimile or other electronic or electromagnetic means, the requirements of this Standard shall be met.

5.10.7. The report format shall be designed to accommodate each type of test carried out and to minimise the possibility of misunderstanding or misuse.

5.10.8. When a battery of tests are to be performed and results reported as available, interim test reports shall be issued to the client. These reports shall indicate tests completed and tests pending. Such reports shall be uniquely identified as interim test reports, shall contain a reference to any and all preceding interim reports and shall meet all the requirements of this Standard.

Upon completion of all testing, a final test report shall be issued that is uniquely identified and shall contain a reference to any and all interim reports that it replaces.

5.10.9. When a material amendment to a test report that has been issued is necessary, a supplement to the test report shall be issued to the client. Such amendments shall be uniquely identified as a supplement, shall contain a reference to the original test report and shall meet all the requirements of this Standard.

5.10.10. When it is necessary to issue a new test report, it shall be uniquely identified and shall contain a reference to the original that it replaces.

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7. ISO 10011-1, *Guidelines for auditing quality systems – Part 1: Auditing*.
8. ISO 10011-2, *Guidelines for auditing quality systems – Part 2: Qualification criteria for quality system auditors*.
9. ISO 10011-3, *Guidelines for auditing quality systems – Part 3: Management of audit programmes*.
10. ISO 10012-1, *Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation for measuring equipment*.
11. ISO Guide 30, *Terms and definitions used in connection with reference materials*.
12. ISO Guide 34, *Quality systems guideline for the production of reference materials*.
13. ISO Guide 35*, Certification of reference materials – General and statistical principles*.
14. ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes*.
15. ISO/IEC Guide 43-2, *Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*.
16. ISO/IEC Guide 58, *Calibration and testing laboratory accreditation systems – General requirements for operation and recognition*.
17. ILAC[14]-G2, *Traceability of measurements*.
18. ILAC-G5, *Calibration and Maintenance of Test and Measuring Equipment*.
19. ILAC-G6, *Guidelines on Assessment and Reporting of Compliance with Specification*.

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