

Implementation of quality assurance in national foot and mouth disease laboratories, based on the guidelines of the Office International des Epizooties

K. De Clercq

Veterinary and Agrochemical Research Centre, Groeselenberg 99, 1180 Ukkel, Belgium

Summary

The final act of the Uruguay Round of the General Agreement on Tariffs and Trade, 1994, contains the Agreement on the Application of Sanitary and Phytosanitary Measures, which aims to reduce the negative effects of health barriers on international trade to a minimum. Therefore, the Office International des Epizooties (OIE) Regional Commission for Europe proposed that an accreditation system based on the EN 45000 standard should be applied to achieve international recognition of certificates and testing laboratories. To this end, the OIE Standards Commission published a series of guidelines for the evaluation of laboratory quality and proficiency testing. In 1995, the Food and Agriculture Organization European Commission for the Control of Foot and Mouth Disease recommended that the OIE proposal should be applied in all foot and mouth disease (FMD) diagnostic laboratories in Europe. This review summarises the EN 45001 standard and the OIE guidelines, and proposes that these guidelines should be taken as a basis for the implementation of a quality assurance programme in FMD laboratories.

Keywords

Certificates – Foot and mouth disease – International trade – Laboratories – Proficiency testing – Quality assurance – Quality evaluation – Sanitary and Phytosanitary Agreement – Standards.

Introduction

In the past, international trade in animals has always been constrained by the fear of importing epizootic or zoonotic diseases. As a consequence, the importation of animals was certified following tests performed in national laboratories. More recently, within the European Union (EU), there has been free movement of animals and importing countries have had to rely on certificates from the exporting countries. The need for reliable and comparable tests between national laboratories has therefore become urgent.

As many countries sought access to other markets, the pressure for free trade became greater and was no longer limited to the EU or other closed trade regions. The General

Agreement on Tariffs and Trade (GATT) – now replaced by the World Trade Organization – played a very important role in opening up world markets and was responsible for the signing by 125 States of the 'Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations' in April 1994. This final act contains the 'Agreement on the Application of Sanitary and Phytosanitary Measures' ('SPS Agreement'), which aims to reduce the negative effects of health barriers on international trade to a minimum (8).

This agreement will only succeed if countries have confidence in the certificates and diagnostic test results of one another. Therefore, it was proposed at the 16th Conference of the Office International des Epizooties (OIE) Regional Commission for Europe, held in Stockholm from 28 June to 1 July 1994, that an accreditation system based on the

EN 45000 standard should be applied in future for the international recognition of certificates and testing laboratories. The OIE Standards Commission was asked to prepare guidelines to achieve this (7, 9).

At the 31st Session of the Food and Agriculture Organization (FAO) European Commission for the Control of Foot and Mouth Disease (FMD) in Rome, April 1995, it was recommended that standards of the EN 45000 series should be adopted to evaluate international veterinary certification and testing laboratories, as well as diagnostic procedures. It was also stated that, based on these recommendations, quality assurance (QA) programmes should be developed in all FMD diagnostic laboratories in Europe (7).

The Research Group of the Standing Technical Committee of the FAO European Commission for the Control of Foot and Mouth Disease also recommended, at a meeting in Vladimir (Russian Federation, September 1995), that national FMD laboratories should be encouraged to implement QA programmes which refer to the international standard EN 45000 in the International Organization for Standardization (ISO) 9000 series (6). The Group also recommended that certificates for international trade should be accepted only from laboratories which participate in international accreditation schemes (3).

In September 1995, the OIE Standards Commission published the 'OIE Guidelines for Laboratory Quality Evaluation' in a report (14), and the report of the Commission dated February 1996 included the 'Draft OIE Guidelines for Laboratory Proficiency Testing' (14). Both papers were intended to supplement the 'OIE Guidelines for the Evaluation of Veterinary Services' (12). These two documents, recently published as a single document (14), can be considered the catalyst for the establishment of QA programmes in the national FMD laboratories.

Quality standards ISO 9000 and EN 45000

Industries now operate under a standardised quality control system. In fact, it was the United States army, in 1963, which first asked that suppliers implement a QA programme in their respective organisations. The chosen system had to fulfil the rules laid down in the MIL-Q-9858 document, known as the American Military Standard (1).

The result was the beginning of all subsequent QA systems. The concept was adopted by several industrial sectors, such as the nuclear power and pharmaceutical industries. These sectors adapted the norms to their needs. Later, in the 1970s, national quality standards were developed.

Owing to the development of a large number of different standards, assessment by potential customers or government agencies became difficult. Therefore, the ISO developed the ISO 9000 series of standards (2, 5, 10). These were officially published in 1987. As the EU considered national standards to be a barrier to free trade, the EU and the European Free Trade Association (EFTA) adopted the ISO series in their directives. This ISO 9000 series was translated into the EN 29000 series by the European Committee for Standardisation.

The EN 45000 series was specifically developed to promote confidence in laboratories able to conform to these standards. In developing the EN 45000 series, existing standards such as those of the ISO and International Electrotechnical Commission (IEC) (1) were taken into account. An overview of the most important standards is given in Appendix I. The EN 45000 series covers items such as assessment, certification and accreditation, and serves as the reference standard. A list of several EN 45000 standards is given in Appendix II. Most countries have a national organisation which is responsible for awarding accreditation to laboratories and which must itself conform to the EN 45003 standard. In the EU, these organisations are members of the European co-operation for Accreditation of Laboratories (4).

Certification of a QA system using the ISO 9000 series involves only consideration of the way in which an organisation applies that system. Accreditation by EN 45000 involves evaluating not only the implementation of a QA system, but also the ability (proficiency) of the laboratory to perform specific tests, such as those laid down in the OIE *Manual of Standards for Diagnostic Tests and Vaccines*, hereafter referred to as the OIE *Manual* (13).

Specifications of the EN 45001 standard

The EN 45001 standard describes the technical criteria which must be fulfilled and guidelines to be followed by testing laboratories applying for accreditation. In general, the standard deals with the following subjects (1):

- scope and field of application
- definitions and references
- legal authority and recognition
- impartiality, independence and integrity
- technical competence
- collaboration
- duties due to accreditation.

Several of these subjects are examined in further detail below.

Impartiality, independence and integrity

It is logical that all such laboratories should be independent. However, it is also stated that the salaries of laboratory

personnel should be independent of the numbers of tests performed and their results. The responsibilities of staff involved in manufacturing products (e.g. laboratory kits) for sale should be clearly distinguished from those of staff controlling the quality of those products.

Technical competence

Organisation and management

A document describing the organisation and different responsibilities within the testing laboratory must be freely available and regularly updated. A technical manager should have overall responsibility for the technical aspects of all operating procedures within the laboratory. Adequate supervision should be provided by staff familiar with the QA system and all laboratory procedures.

Personnel

There must be a sufficient number of personnel and they must have the necessary qualifications and experience. Training must be organised, regularly updated and recorded. Employees should be free from inducements which might adversely influence test results.

Environment and equipment

Environment

The environment must be protected against any outside influences. When necessary for the test, there must be a calibrated control system to record the environmental conditions (e.g. a cold room).

Entrance to, and use of, the testing environment must be controlled. Admission requirements for people from outside the testing environment must be clearly described.

Equipment

Every item of equipment necessary to perform the test must be available, together with its unique label, identification record, maintenance and calibration procedures and service records. Defective or suspect equipment must be taken out of service until repaired, retested and recalibrated (e.g. centrifuge, micropipette).

A calibration programme must be used so that results can be referred to international standards. If this is not available, the testing laboratory must deliver proof of the accuracy of test results by taking part in inter-laboratory testing at regular intervals.

Working procedure

Test methods and procedures

Well-documented instructions must be available for all equipment used, as well as for storage and testing of the samples. Reference can be made to an accepted standard test, e.g. as given in the OIE *International Animal Health Code* (11).

Each chemical or biological reagent used in the test should be appropriately labelled and its history should be documented. Documentation should include information on the following:

- origin of the reagent
- date of receipt
- date of preparation for use
- storage conditions
- expiry dates, where applicable.

Quality system

A technical manager must be appointed within the laboratory. This manager must have available a high-quality manual containing all the standard operating procedures which must be applied to guarantee the quality of the tests performed at all times. An important feature in this manual is a procedure for tracing back and taking corrective action when a malfunction is discovered or when a complaint is made. The QA programme must be controlled by regular internal audits.

Reporting

Each report must have a unique number. In addition to the results, it must contain all data about the sample (e.g. identification, date of sampling and testing), signatures of the staff involved in testing and the supervisor, and a correct interpretation of the results.

Registration and record-keeping

All reports (e.g. testing, results, calibration) must be kept in such a way that the whole procedure can be repeated.

Handling samples

An identification system must be established so that any confusion about the samples and results is excluded. The identification code must guarantee a blind testing procedure. Clear rules must govern the reception, storage and discarding of each type of sample and assay.

Confidentiality and safety

Documented procedures must be available to ensure the protection of proprietary rights and confidential information.

Sending out samples

Sending out samples to another laboratory, if a specified test is not performed at the laboratory to which the samples have originally been sent, is allowed only when the other laboratory fulfils the same criteria.

Collaboration

Collaboration guidelines cover the following subjects:

- collaboration with clients
- collaboration with laboratory accreditation bodies
- collaboration with other laboratories and committees dealing with standards.

Duties due to accreditation

An accredited laboratory must fulfil all the necessary criteria at any given time. If not, the laboratory is obliged to inform its clients immediately. The accreditation of the laboratory

should not be used to mislead clients. Thus, the laboratory must not pretend that the entire laboratory is accredited if only some of the testing procedures fulfil all the criteria. Changes in procedure which might influence the status of the laboratory should be reported immediately to the national organisation which is responsible for according accreditation.

Aspects of the ‘OIE Guidelines for Laboratory Quality Evaluation’

The ‘OIE Guidelines for Laboratory Quality Evaluation’ (14) are based on the ISO 9001 and EN 45001 standards. They include the subjects examined below.

Introduction

Purpose

This document provides guidelines for the evaluation of the quality of a laboratory.

Scope

This document covers guidelines for the evaluation of laboratories which perform tests to qualify animals and animal products for international trade. This could include the use of proficiency testing (inter-laboratory test comparison; see ‘Proficiency testing’ below) for specific assays.

Formal accreditation

Accreditation to ISO 9000 or EN 45000 standards should provide sufficient reassurance of the competence of a testing laboratory. Nevertheless, it is recognised that, in many circumstances, such a high level of accreditation may be difficult to achieve. Accordingly, the present guidelines have been prepared to promote acceptance of test results between countries. An improvement in confidence in, and therefore acceptance of, the results of another country, based on a demonstrable, concerted improvement in testing standards, should lead to the safe removal of trade barriers.

Laboratory organisation and management

See EN 45001 (Section 3).

Environment

See EN 45001 (Section 3).

The laboratory should provide effective separation of areas in which incompatible activities may adversely affect the outcome of the test.

Human resources

See EN 45001 (Section 3).

A member of staff with appropriate skills should be nominated to supervise the day-to-day running of the laboratory in the absence of the technical manager.

Equipment

See EN 45001 (Section 3).

Sample-handling

See EN 45001 (Section 3).

Any abnormalities in the condition of the sample on arrival at the laboratory should be recorded. If the condition of the sample casts doubt on the validity of the test, samples should be taken from the animal again and an unequivocally negative result obtained before further action, such as export, can proceed.

Biological containment procedures should take into account both human and animal health hazards.

Guidelines for the transport, handling and storage of samples are provided in the *OIE Manual* (13).

Test methods and procedures

The *OIE Manual* provides the principal source of standard methodologies for tests performed under these guidelines (13). When such methodologies are modified by an individual laboratory, or when tests are used which do not appear in the *Manual*, they must be fully documented and validated, and the laboratory should have this information available if requested.

A demonstrable internal quality control programme, designed to ensure that the test complies with the guidelines, should be documented and used for each assay. Documentation should include the following:

- detailed bench protocol
- work sheets
- sample data
- positive and negative cut-off criteria
- internal quality control data.

Record-keeping and reporting

See EN 45001 (Section 3).

External recognition

Wherever possible, the laboratory should participate in national and international programmes which recognise laboratory diagnostic proficiency. This usually requires participation in external check sample programmes or in other inter-laboratory comparisons.

Aspects of the ‘OIE Guidelines for Laboratory Proficiency Testing’

Aspects of these guidelines include the subjects examined below (14).

Introduction

Purpose

This document provides guidelines for evaluating the ability of a laboratory to conduct specific diagnostic tests.

Scope

These guidelines form part of the evaluation of laboratory quality.

Inter-laboratory test comparisons

Inter-laboratory test comparisons may be undertaken for a variety of reasons, including the following:

- a) determining the capability of a laboratory to conduct specific diagnostic tests
- b) checking or certifying the performances of individual operators
- c) checking or certifying the calibration of instrumentation
- d) harmonising existing test methods
- e) evaluating new test methods
- f) assigning values and ranges to reference materials
- g) resolving inter-laboratory differences.

Proficiency testing

Inter-laboratory test comparison which is conducted to determine the capability of a laboratory to perform specific diagnostic tests is referred to as 'proficiency testing'. Such testing is an integral part of laboratory accreditation programmes and is based on check sample panels.

Accreditation

Accreditation is a formal process of recognition by an independent authority of the competence of a laboratory to perform certain tasks, while meeting EN 45000 standards.

Before starting an accreditation procedure, laboratories are required to demonstrate an 'acceptable quality level (AQL)' (2). The OIE 'Guidelines for Laboratory Quality Evaluation' (14) were prepared to establish a minimum acceptable level of quality.

The second stage requires regular, scheduled proficiency testing to evaluate the ability of a laboratory to conduct specific diagnostic tests. Accreditation requires that laboratories successfully participate on a continuing basis, in order to maintain their recognised status.

Together with the OIE 'Guidelines for Laboratory Quality Evaluation' (14), these guidelines form an acceptable basis for a QA programme.

Authority and recognition

Accreditation programmes and proficiency testing schemes should be operated by an independent authority in order to prevent any bias in the awarding or denial of recognition. Such an authority for controlling FMD laboratories has yet to

be defined. Clarification should be sought from international organisations about the responsibility for establishing, running and financing an internationally recognised proficiency testing scheme for FMD diagnostic tests. Guidance is also needed on the official recognition and accreditation of FMD laboratories in recognised schemes.

The guidelines propose: first, that participation in an international accreditation programme and in proficiency testing schemes should be voluntary; and, second, that lack of participation or failure to achieve recognition should not prevent a laboratory from conducting diagnostic tests or a country from entering into trade agreements. However, these proposals appear to undermine the whole concept of accreditation and mutual acceptance of data, and to remove any incentive or need to participate.

Organisation and management

See EN 45001 (Section 3).

The organisation co-ordinating the proficiency testing scheme should be legally identifiable and have an internationally approved mandate to conduct such a programme. Both these requirements will need to be clearly defined in future.

Standard methods

The reference test should be calibrated against international reference standards for the antibody or antigen. Participating laboratories should also be encouraged to calibrate their own assays against the same international reference standards.

Selection and composition of check sample panels

Acceptance of test materials into the proficiency panel should be based on repeated testing by more than one analyst, and on conducting several runs of the test on different days.

The number of test samples in a panel depends on the numbers required to ensure statistical validity. A minimum of three samples should be included, as follows:

- an unequivocal strong positive
- a weak positive, indicating the lowest level which consistently gives positive results
- an unequivocal negative.

It would be advisable to add at least two more samples to the check sample panel, which could be varied from one round of proficiency tests to the next. This would prevent participating laboratories from anticipating the outcome.

Statistical analysis

Types of data

Quantitative data, such as end-point titres, and semi-quantitative data, such as percentage inhibition values, are

more flexible with respect to the types of statistical analysis possible than qualitative data, such as 'positive', 'negative' or 'suspicious'.

Assigned values

For the initial selection of test materials for the check sample panel, the producing laboratory should assign a preliminary value which has been verified by a series of tests. Moreover, it is proposed in the guidelines that, for qualitative data, at least 80% of the participating laboratories with an AQL (2) should obtain the same result in proficiency tests. For quantitative and semi-quantitative data, it is proposed that the assigned value should be recalculated after proficiency testing results have been submitted. In the case of semi-quantitative data, however, a minimum pass criterion should be set to avoid dilution of the reference standard.

Statistical methods

Frequency analysis is a simple and meaningful method for participating laboratories to see where their performance stands in relation to the other laboratories in the proficiency testing scheme.

Measures of intra- and inter-laboratory variation through reproducibility indices often provide valuable information on the precision and robustness of the test methods.

Pass/fail criteria

The criteria for passing or failing a laboratory on a proficiency test should be clearly documented. These criteria must take into consideration a number of factors which may vary from one disease to another, and from one type of test to another, with respect to the relative risk and to the impact on trade.

In regard to false results, the draft guidelines make the following proposal: results which would potentially lead to a false negative classification of an infected animal would have to be weighed against those that would possibly lead to a false positive classification of a healthy animal. In most instances, the former type of error should not be tolerated as it indicates a problem with diagnostic sensitivity. Therefore, tests should be thoroughly validated and conditions adapted where necessary.

Frequency of proficiency testing

It is recommended that proficiency testing (see 'Proficiency testing' above) be performed on a bi-annual basis.

Laboratory recognition

The criteria for awarding, denying or withdrawing recognition should be clearly documented.

Logistics

Eligibility and acceptance

Eligible laboratories should be sent a comprehensive outline of the QA programme and the proficiency testing scheme. A form should be included which, when signed and returned to

the co-ordinating organisation, indicates the acceptance by the laboratory of the terms and conditions of the programme.

Notification and shipment of panels

Participating laboratories should be notified at least one month in advance of a pending proficiency test. Each should receive a panel with a unique set of codes to prevent collusion between laboratories. On shipment, the intended recipients should be informed of the relevant transport arrangements (such as the method of shipment, carrier, airway bill, etc.) in order to facilitate rapid retrieval and clearance of the shipment on arrival.

Testing and return of results

The panel may be tested more than once. However, only one set of results should be returned to the co-ordinating organisation for analysis. Under normal conditions, the person responsible for routinely running the test should be selected to run the check sample panel.

Results must be returned in the proper format and on time. Failure to do so could lead to omission from the round of proficiency testing, and loss or downgrading of recognition status.

Analysis and reporting

A general report summarising the results of all the analyses should be prepared for distribution to all participating laboratories. A code, randomly assigned to each participant, should ensure anonymity in the general report. Individual laboratories should be informed of their unique code for this run of proficiency tests.

These laboratories should also receive a summary of their own performance and their recognition status. This summary should indicate clearly all factors contributing to any change in their status. Where this status has been downgraded, it is especially important to indicate real or potential causes. In some instances, it may be pertinent to reissue a second identical but recoded panel after corrective action has been taken.

All data and results of analyses, as well as the recognition status of participating laboratories, should be kept in confidence at all times.

Disclosure

The primary purpose of these guidelines is to remove trade barriers, not to create them. It is expected that participating laboratories, having achieved full recognition status, may request that official verification of their status be made available to trading partners by the independent authority or co-ordinating organisation.

Conclusion

Owing to the increased movement of animals through international trade, a QA programme for laboratories which perform tests is essential. It is the only way to maintain confidence in results between different laboratories.

In the first instance, the system should help all laboratories to achieve a quality level which is high enough to pass proficiency testing. In the future, such testing should be performed on a regular basis. In contrast to the actual OIE draft guidelines outlined in the section entitled 'Authority and recognition' above, it is felt that lack of participation or failure should temporarily prevent that laboratory from testing animals or animal products for international trade. A regulatory system in which there are no consequences for non-compliance is likely to fail and would remove any incentive or need to participate.

It is clear that even this system will not provide a 100% assurance that everything is satisfactory between two proficiency testing or quality controls, but it will be a definite step forward. FMD laboratories will be obliged to comply if they want to maintain their credibility. Even so, there will still be a risk of disease in international trade as falsification of certificates and the substitution of animals could occur before or during transport.

Recommendations

1) FMD laboratories conducting diagnostic tests to qualify animals and animal products for international trade should

participate in a QA programme. This programme should at the very least include both laboratory quality evaluation and proficiency testing based on the OIE Guidelines for Laboratory Quality Evaluation and for Laboratory Proficiency Testing, respectively. Laboratories which comply with standards such as ISO 9000, ISO 9001, EN 29000, EN 45000 or EN 45001 (6) will have no difficulties in meeting these guidelines.

2) FMD laboratories are encouraged to adapt their tests until they pass an evaluation for proficiency.

3) Lack of participation in or failure to pass proficiency testing by a laboratory should temporarily prevent that laboratory from testing animals or animal products for international trade.

4) Clarification should be sought from international organisations about the responsibility for establishing, running and financing an internationally recognised proficiency testing scheme for FMD diagnostic tests. Guidance is also needed on the official recognition and accreditation of FMD laboratories in recognised schemes.

Acknowledgements

The helpful comments of Drs A.I. Donaldson and R.P. Kitching, at the Institute for Animal Health, Pirbright, United Kingdom, are gratefully acknowledged.

Mise en œuvre de l'assurance qualité dans les laboratoires nationaux de la fièvre aphteuse, d'après les lignes directrices de l'Office international des épizooties

K. De Clercq

Résumé

L'acte final des négociations de l'Uruguay Round de l'Accord général sur les tarifs douaniers et le commerce (1994) inclut l'Accord sur l'application de mesures sanitaires et phytosanitaires visant à réduire au minimum les effets négatifs des barrières sanitaires sur les échanges internationaux. La Commission régionale pour l'Europe de l'Office international des épizooties (OIE) a donc proposé la mise en place d'un système d'accréditation basé sur la norme EN 45000 en vue d'une reconnaissance internationale des certificats et laboratoires d'analyse. À cette fin, la Commission des normes de l'OIE a publié une série de lignes directrices

pour l'évaluation de la qualité et des compétences d'un laboratoire. En 1995, la Commission européenne de lutte contre la fièvre aphteuse, relevant de l'Organisation des Nations unies pour l'alimentation et l'agriculture (FAO), a recommandé l'application de la proposition de l'OIE dans tous les laboratoires européens de diagnostic de la fièvre aphteuse. L'auteur présente une synthèse de la norme EN 45001 et des lignes directrices de l'OIE, et propose que ces mêmes lignes directrices servent de base à la mise en œuvre d'un programme d'assurance qualité dans les laboratoires de la fièvre aphteuse.

Mots-clés

Accord sanitaire et phytosanitaire – Assurance qualité – Certificats – Contrôle des compétences – Échanges internationaux – Évaluation de la qualité – Fièvre aphteuse – Laboratoires – Normes.

■

Aplicación de la garantía de calidad en laboratorios nacionales para la fiebre aftosa a partir de las directrices de la Oficina Internacional de Epizootias

K. De Clercq

Resumen

El acta final de la Ronda Uruguay del Acuerdo General sobre Aranceles Aduaneros y Comercio (1994) contiene el Acuerdo sobre la aplicación de medidas sanitarias y fitosanitarias, que busca reducir al mínimo los efectos negativos de las barreras sanitarias al comercio internacional. En esta misma línea, la Comisión Regional para Europa de la Oficina Internacional de Epizootias (OIE) propuso que se aplicara un sistema de acreditaciones basado en la norma EN 45000 con el objetivo de facilitar el reconocimiento internacional de certificados y laboratorios de diagnóstico. Para ello, la Comisión de Normas de la OIE publicó una serie de directrices para la evaluación de la calidad y el nivel de capacidad de los laboratorios. En 1995, la Comisión Europea para la Lucha contra la Fiebre Aftosa de la Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO) recomendó que en todos los laboratorios de diagnóstico de la fiebre aftosa de Europa se aplicara la propuesta de la OIE. El autor hace una exposición resumida de la norma EN 45001 y de las directrices de la OIE, y propone que se adopten esas directrices como punto de partida para implantar un programa de garantía de calidad en los laboratorios de diagnóstico de la fiebre aftosa.

Palabras clave

Acuerdo sobre medidas sanitarias y fitosanitarias – Certificados – Comercio internacional – Control de calidad – Examen del nivel de capacidad – Fiebre aftosa – Garantía de calidad – Laboratorios – Normas.

■

Appendix I

Principal standards taken into account in developing the EN 45000 series

ISO/IEC Guide 2: General terms and their definitions concerning standardisation and related activities

ISO/IEC Guide 25: General requirements for the technical competence of testing laboratories

ISO/IEC Guide 38: General requirements for the acceptance of testing laboratories

ISO/IEC Guide 43: Development and operation of laboratory proficiency testing

ISO/IEC Guide 45: Guidelines for presentation of test results

ISO/IEC Guide 49: Guidelines for the development of a quality manual for a testing laboratory. ■

Appendix II

Some standards from the EN 45000 series which are important to laboratories

EN 45001: General criteria for the operation of testing laboratories

EN 45002: General criteria for the assessment of testing laboratories

EN 45003: General criteria for laboratory accreditation bodies

EN 45011: General criteria for certification bodies operating product certification

EN 45012: General criteria for certification bodies operating quality assurance certification

EN 45013: General criteria for certification bodies operating certification of personnel

EN 45014: General criteria for the declaration of conformity from a supplier. ■

References

1. Beltest (1991). – Algemene criteria en leidraden voor de beproevingslaboratoria die zich kandidaat stellen voor een accreditatie. Document L1/N-REV.0. Beltest, Brussels, 1-48.
2. Breitenberg M. (1992). – Questions and answers on quality: the ISO 9000 standard series, quality system registration, and related issues. International Organization for Standardization (ISO) Standards Code and Information Program. ISO, Geneva, 975-4040 (<http://www2.umassd.edu/SWPI/iso/isoques.html>).
3. De Clercq K. (1995). – Diagnostic aspects of international trade – personal experiences and opinions. In Report of the Research Group of the Standing Technical Committee of the European Commission for the Control of Foot and Mouth Disease. Vladimir, Russian Federation, 20-22 September. Food and Agriculture Organization (FAO), Rome, 42-44.
4. European Co-operation for Accreditation of Laboratories (EAL) (1998). – EAL: European Co-operation for Accreditation of Laboratories. SWEDAC, Borås, Sweden, 1-24 (<http://www.european-accreditation.org/>).
5. International Organization for Standardization (ISO) (1995). – ISO 9000 compendium: ISO 9000 international standards for quality management, 5th Ed. ISO, Geneva, 1-49.
6. Leforban Y. (1995). – Assessment of needs of national FMD laboratories for quality assurance for FMD diagnosis. In Report of the Research Group of the Standing Technical Committee of the European Commission for the Control of Foot and Mouth Disease. Vladimir, Russian Federation, 20-22 September. Food and Agriculture Organization (FAO), Rome, 61-73.

7. Leforban Y. (1995). – Quality assurance in FMD national laboratories: role of the World Reference Laboratory. In Report of the 31st Session of the European Commission for the Control of Foot and Mouth Disease. Rome, 5-7 April. Food and Agriculture Organization (FAO), Rome, 57-59.
8. Leforban Y. (1995). – Risk assessment. In Report of the 31st Session of the European Commission for the Control of Foot and Mouth Disease. Rome, 5-7 April. Food and Agriculture Organization (FAO), Rome, 66-75.
9. Leforban Y. (1995). – Trading guarantees and certification within Europe. In Report of the 31st Session of the European Commission for the Control of Foot and Mouth Disease. Rome, 5-7 April. Food and Agriculture Organization (FAO), Rome, 76-77.
10. Mendes A.S. (1993). – International perspectives in certification and accreditation. *J. AOAC int.*, **76** (1), 1-3.
11. Office International des Epizooties (OIE) (1992). – International animal health code: mammals, birds and bees, 6th Ed. OIE, Paris, 550 pp.
12. Office International des Epizooties (OIE) (1993). – Guidelines for the evaluation of Veterinary Services. In Risk analysis, animal health and trade (R.S. Morley, ed.). *Rev. sci. tech. Off. int. Epiz.*, **12** (4), 1291-1313.
13. Office International des Epizooties (OIE) (1996). – Manual of standards for diagnostic tests and vaccines, 3rd Ed. OIE, Paris, 723 pp.
14. Office International des Epizooties Standards Commission (1998). – Guidelines of the Office International des Epizooties for laboratory quality evaluation, for international reference standards for antibody assays and for laboratory proficiency testing. In Veterinary laboratories for infectious diseases (J.E. Pearson, ed.). *Rev. sci. tech. Off. int. Epiz.*, **17** (2), 600-609.