

FAQ

FAO/IAEA External Quality Assurance (EQA) Programme for Veterinary Diagnosis Testing Laboratories in Developing Countries

****Italics and bold means cross-reference***

What are the objectives of the FAO/IAEA EQA programme?

- a) develop reference data for the assessment of new FAO/IAEA diagnostic assay performance in the field
- b) determine the user's general QA status and specific assay proficiency
- c) enhance the user's QA awareness and culture
- d) provide reference data to help identify and solve systematic and random errors in FAO/IAEA diagnostic assay application, and
- e) provide an organized and transparent mechanism to enhance the national and international credibility of the user's laboratory.

In addition, the data developed through the FAO/IAEA EQA programme can be used from a programmatic perspective as baseline data for

- a) the development of appropriate intervention strategies
- b) monitoring project implementation, and
- c) evaluation of project impact during and after the project's conclusion.

What is the FAO/IAEA External Quality Assurance programme (EQA) made of?

The FAO/IAEA External Quality Assurance programme consists of three pillars:

- 1) *a questionnaire* which monitors the presence and use of key quality elements, administrative matters, infrastructure and quality assurance/ quality control and management.
- 2) *Monitoring of Internal Quality Control (IQC) data* to assess the repeatability and precision of the test conducted in that particular laboratory. These data can be used by the test operator to detect trends and shifts in test performance, also.
- 3) *External Quality Control (EQC)*, involving proficiency testing; i.e., interlaboratory comparisons between two or more laboratories. For interlaboratory proficiency testing, each laboratory conducts the designated test method on a defined panel of test samples, the EQC panel. Identical panels of test samples are dispatched to the participating laboratories for concurrent testing.

How many EQA rounds were undertaken up to now and what are the results?

Since 1995 14 EQA rounds were carried out (4 rounds with the competitive Rinderpest ELISA, 7 rounds with the indirect brucellosis ELISA, 1 round with the Trypanosomosis Ag ELISA and 2 rounds with the FMD ELISA (1 round with the Ag and 1 round with the Ab ELISA) with an average number of approximately 30 participants worldwide. FAO/IAEA Recognition was granted more than 22 times. Good results were obtained from the proficiency tests e.g. most of the laboratories correctly identified the test panel. Information provided through the questionnaire indicated that maintenance and calibration procedures and checks of laboratory equipment need more objective criteria concerning frequency and technical interventions. The analysis, monitoring and charting of internal quality control ELISA sera and troubleshooting procedures merit more attention from the test operator and further training in this area is a priority. Specific literature (Rebeski et al.), training material (word documents or pdf. Files) and Excel worksheets (Excel worksheet for DDD and SDD charts) can be obtained from A. Colling@iaea.org.

What is in it for me?

The EQA programme can be regarded as a bridge to establish quality control, quality assurance and quality management and documentation in the developing country laboratory. Successful participation in the EQA programme leads to FAO/IAEA "Recognition". "FAO/IAEA "Recognition" means that the laboratory has provided evidence that a specific test e.g. FAO/IAEA indirect brucellosis ELISA was performed within preestablished limits and that the laboratory additionally has responded to the questionnaire. "Recognition" must not be confounded with "Accreditation" or "Certification". Participation in the EQAP is of special importance for developing countries, where no national accreditation/certification body exists.

Who can participate and what is the scope of the FAO/IAEA EQA programme?

In the past participation was restricted to laboratories which had a Technical Cooperation or Research Contract and which used an FAO/IAEA ELISA. To overcome this limitation and based on the experience and mandate of the Animal Production and Health subprogramme the EQA programme has extended its assistance into establishing quality systems in veterinary testing laboratories. The basis for this new approach is the new "***OIE Standard For Management and Technical Requirements For Laboratories Conducting Tests For Infectious Animal Diseases.***" "***Guidelines***" <http://www.iaea.org/programmes/nafa/d3/public/guidelines.pdf> were developed to establish a Quality System following this standard and can be downloaded from this site. The subprogramme is promoting the implementation of this standard in veterinary testing laboratories through an interregional TC project entitled: "Establishing Quality Systems in Veterinary Testing laboratories".

What is the “OIE Standard on Management and Technical Requirements For Laboratories Conducting Tests For Infectious Animal Diseases”?

It describes the international standards for management and technical competence that serve as the basis for accreditation of laboratories that conduct diagnostic tests for infectious animal diseases. It is based mainly on ISO 17025 and other relevant Standards.

Accreditation bodies that recognize the competence of such laboratories may use this Standard as the basis for their accreditation. Section 4 specifies the requirements that a laboratory must meet in order to demonstrate sound management. Section 5 specifies the requirements needed to demonstrate technical competence for the diagnostic testing activities it undertakes.

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 diagnostic testing for infectious animal diseases, can operate a quality system that is compliant with ISO 9001 or ISO 9002 as well as with this Standard. Therefore, care has been taken to incorporate the requirements of ISO 9001 and ISO 9002 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.

What is the scope of the OIE standard?

This Standard specifies the general requirements a laboratory must meet if it is to be recognized as competent to perform diagnostic 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 standardized methods and methods not covered by international standards, including in-house developed methods.

This Standard is applicable to all laboratories conducting diagnostic 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.

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.

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 recognizing the competence of laboratories.

Certification, Accreditation: Where to start?

Websites from some international and national organizations regarding certification and accreditation are listed below:

National Accreditation/Certification bodies and International Organizations

List of webpages of international and national accreditation bodies. Useful references:

COUNTRY	Organization	WEBSITE
Int. Organization	European Accreditation service (EA)	http://www.european-accreditation.org
Int. Organization	International Accreditation Forum (IAF)	http://www.iaf.nu
Int. Organization	International Laboratory Accreditation Co-operation (ILAC) (Member countries and internet addresses see under directories) ISO/IEC homepage	http://www.ilac.org
Int. Organization	- gives an overview on International Accreditation Bodies & Standards Organizations, National Accreditation Bodies, Accredited Calibration & Testing Laboratories etc.	http://www.microserve.net/~iso25/
Int. Organization	International Atomic Energy Agency (IAEA) Animal Production and Health Subprogramme	www.iaea.org http://www.iaea.org/programmes/nafa/d3/index.html
Int. Organization	Office International des Epizooties (OIE)	http://www.oie.org
Int. Organization	Food and Agriculture Organization (FAO)	www.fao.org
Argentina	Organismo Argentino de Acreditacion (OAA)	http://www.oaa.org.ar/Informacion/informacion.htm

Australia	National Association of Testing Authorities (NATA)	http://www.nata.asn.au
Brazil	National Institute for Metrology Standardization and Industrial Quality (INMETRO)	www.inmetro.gov.br/
China	China National Accreditation Committee of Laboratories (CNACL)	http://www.chinaiso.com/iso-EN/shiyanshi/shiyanshi.htm
Germany	German Accrediting System for Testing	http://www.dap.de
Hong Kong	Laboratory Accreditation Scheme (HOKLAS) (Cr. Lay Har NG: hoklas@id.gcn.gov.hk)	http://www.info.gov.hk/id/ewww/aboutus/function/quality/hkas/index.htm
Iran	C/o Institute of Standards & Industrial Research of Iran P.O. Box 31585 Karaj, Iran Hovsep Sarkissian Telephone: 98-261-243-887 Fax: 98-261-225-015 ISO 9000, ISO 14000	
India	NATIONAL ACCREDITATION BOARD FOR TESTING & CALIBRATION LABORATORIES	http://mst.nic.in/dst/autoinst/natbord.htm
Indonesia	Badan Standardisasi Nasional (BSN) and Komite Akreditasi Nasional (KAN)	http://www.bsn.go.id/41P.HTM

Korea	Korea Research Institute of Standards and Science (KRISS) and Laboratory Accreditation Scheme (KOLAS) (Mr. Jung-Heui KO: jungheui@mail.nitq.go.kr)	http://kolas.ats.go.kr/
Malaysia	Standards & Industrial Research Institute (SIRIM) and Skim Akreditasi Makmal Malaysia (SAMM)	http://www.sirim.my/
Mongolia	Mongolian National Center for Standardization and Metrology (MNCSM)	MNCSM@magicnet.mn
Myanmar (no national accreditation body but agreement)	Brunei Darussalam, Republic of Indonesia, Lao People's Democratic Republic, Malaysia, Union of Myanmar, Republic of the Philippines, Republic of Singapore, Kingdom of Thailand and Socialist Republic of Vietnam are Member States of the Association of Southeast Asian Nations and have signed ASEAN Framework Agreement on Mutual Recognition Arrangements in Vietnam, December 1998	http://www.aseansec.org/accsq/sqmain.htm
Philippines	Bureau of Product Standards Laboratory Accreditation Scheme (BPSLAS)	http://www.dti.gov.ph/bps/
Singapore	Productivity and Standards Board (PSB), Singapore Accreditation Council and Singapore Laboratory Accreditation Scheme - (SINGLAS) (Ms. Barbara VOON, bvoon@sac.sci.org.sg)	http://www.np.edu.sg/~tankc/grc/sislab.htm http://www.sac-sci.org.sg/
South Africa	National Metrology Lab (NML), South African National Laboratory Accreditation Service (SANAS)	http://www.sanas.co.za/
Switzerland	International Organization for Standardization (ISO)	http://www.iso.ch

Taiwan	Chinese National Laboratory Accreditation Program (CNLA), (Mr. Nigel Jou: 780255@cms.itri.org.tw)	http://itrinews.itri.org.tw/english/techs/measure.htm
Thailand	Thai Industrial Standards Institute, Thai Laboratory Accreditation Scheme (TLAS)	http://www.tisi.go.th/lab/tlas.html
Turkey	Scientific and Technical Research Council of Turkey National Metrology Institute (UME)	http://www.tubitak.gov.tr/ http://www.ume.tubitak.gov.tr/engmain.htm
Ukraine	State Committee of Ukraine for Standardization, Metrology and Certification (DSTU)	dstu@niafs.ukrpak.net
United Kingdom	UK Accreditation Service (UKAS)	http://www.ukas.com
USA	US National Institute of Standards and Technology (NIST)	http://www.nist.gov/
Vietnam	Directorate for Standards and Quality (STAMEQ), Vietnam laboratory Accreditation Scheme (VILAS)	http://home.vnn.vn/tcvn/home_en.htm http://home.vnn.vn/tcvn/lab_en.htm

What is Accreditation?

Accreditation is the title, which officially proves to comply with **ISO/IEC 17025**. It is applied to laboratories and test methods. It proves **technical competence** to the client.

The issuing organization is an accreditation body.

Advantages: It provides information about proficiency and competence and technical requirements.

Disadvantage: It is not flexible since it refers to the method of testing at the moment of accreditation.

What is Certification?

Certification is the title, which officially proves that management and general **production processes** comply with **ISO 9000 series**. The certifying body must be accredited. The person who certifies is an auditor.

Advantage: universal applicability

Disadvantage: formal frame, no information about proficiency and skills

What is GLP?

GLP stands for Good Laboratory Praxis and is a guideline developed by OECD. It is applied in testing agencies e.g. for research on new substances such as pharmaceuticals. GLP compliance is issued through an inspector of a state agency.

Advantages are security, laboratory standard and general acceptance.

Disadvantages are costs and work and its focus on documentation of results (not on their quality).

Other related websites:

a web-based interactive training programme about ISO/IEC 17025 can be found on the Nata homepage under <http://www.aplactraining.asn.au>

A. Colling
Animal Production Unit
IAEA, Vienna
e-mail: A.colling@iaea.org