INIS-XA--555

Establishment of External Quality Assurance Procedures for use with the FAO/IAEA ELISA kits

Report of an FAO/IAEA Consultants Meeting organized by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture and held in the Vienna International Centre

JOINT FAO/IAEA DIVISION
OF NUCLEAR TECHNIQUES IN FOOD AND AGRICULTURE
Animal Production and Health Section
&
AGENCY'S LABORATORIES
FAO/IAEA AGRICULTURE AND BIOTECHNOLOGY
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1. BACKGROUND

As part of the programme of support to scientists in developing countries, the Joint FAO/IAEA Division has developed and distributed ELISA kits for detecting both the causative agent and the immune response of animals to a number of the major diseases affecting livestock. In many cases these kits are now being used as part of national and international control and/or eradication programmes (e.g. for rinderpest, trypanosomosis, foot and mouth disease, brucellosis) and are likely to form the basis for establishing a country's freedom from particular diseases (e.g. rinderpest) at the national and international level.

To further encourage international trade in livestock and livestock products, and to assist in the regional or global control and eradication of a number of the major diseases affecting livestock, there has been a strong move towards international standardization for animal disease diagnosis. Central to this is the need for internal and external quality assurance procedures to ensure that a standardized approach is being adhered to and that the results can be relied upon.

In 1992, an FAO/IAEA consultants meeting was convened to define and establish for the ELISA, standards for internal quality control of reagents and procedures and for the expression of results. The recommendations of that meeting have now been incorporated in all FAO/IAEA ELISA kits and have been adopted by the OIE (Office International des Epizooties). The primary function of the internal quality controls is to ensure that the assay is performing within defined limits. Equally important, is an assurance to all outside interested bodies (national veterinary authorities, international organizations, donor organizations, trading partners) that the results being provided by a laboratory are valid. The procedures for ascertaining this assurance would form the basis of an external quality assurance programme (EQAP). Between 1990 and 1993, as part of establishing an EQAP, laboratories using the FAO/IAEA ELISA kits for rinderpest sero-monitoring in Africa were sent a panel of 40 sera to assess the proficiency of each laboratory on an annual basis. The results were compiled to indicate to managers of the Pan African Rinderpest Campaign that results from these laboratories could be relied upon.

In September 1994, an FAO/IAEA consultants meeting was convened with the aim of extending and further improving this EQAP for veterinary laboratories in developing countries utilizing FAO/IAEA ELISA kits. The meeting focused on establishing procedures that would recognize veterinary laboratories as competent in utilizing FAO/IAEA ELISA kits for specific diseases and tasks. In adopting the approach that is detailed below it is hoped that the system can be expanded to form the basis of a wider system that can encompass a variety of diagnostic procedures and laboratories. It is intended to seek OIE endorsement for this EQAP and it is anticipated that such an approach should improve the quality of reports being submitted to OIE.

2. APPROACH

2.1. The Application and Assessment of Quality Assurance Systems in Veterinary Laboratories

A quality assurance system is the sum total of a laboratory's activities aimed at achieving an acceptable level of proficiency. A quality assurance system within a laboratory includes the application of quality assurance principles to factors such as staff training, administrative procedures, management structures, auditing, process control and the final output of results. In the establishment, maintenance and improvement of total quality assurance within a laboratory, internal quality control (IQC) and external quality assurance, in particular proficiency testing, are critical components.

For the external recognition of a laboratory's capabilities, it is necessary not only to ensure that essential procedures are in place, but also that these procedures are regularly monitored and their efficiency and

effectiveness measured. An external quality assurance programme coordinated by an independent third party is an internationally recognized approach for the implementation of such quality systems in laboratories.

2.2. Key Elements of a Quality Assurance Programme

To provide confidence in an individual laboratory's competence in the conduct of specific diagnostic or certification assays, it is necessary to implement a formal accountable system for recognizing their performance capabilities. An assessment of the laboratory's capabilities, based on sound scientific principles, would therefore provide the basis for formal recognition.

For a laboratory to operate at an internationally acceptable standard, a number of key quality elements must be in place. The level of conformity to these key elements is measurable and therefore forms the basis of any subsequent evaluation of a laboratory's performance. These key elements comprise:

- The presence of staff with the requisite skills and abilities to undertake the required diagnostic testing
- The use of a laboratory information management system
- Regular maintenance and calibration of equipment to approved and accepted standards
- The use of approved standard operating procedures.
- The application of internal process controls (internal quality control).

The EQAP's function is to ensure that these factors are in place within laboratories, that they are effectively utilized and that data are available both to determine performance and identify areas for improvement. Satisfactory performance in these elements would therefore provide the framework for international recognition of a laboratory's capabilities.

2.3. Components of an External Quality Assurance Programme

An EQAP for veterinary laboratories should be based on proof of the presence of systems for implementation and conduct of QA/QC, the continual satisfactory performance of processes and output, and the use of external quality control procedures. These three critical elements are detailed below:

2.3.1 Survey Questionnaire

A questionnaire-based survey of individual laboratories can be utilized to provide a regular system for monitoring for the presence of the key quality elements (Section 2.2.). It is a mandatory requirement that all laboratories participating - in the EQAP should complete and return such a questionnaire (Appendix A). The satisfactory presence of the relevant key elements will be determined by the third party coordinator and will form a major part of the assessment and recognition of the laboratory.

2.3.2 Internal Quality Control (IQC)

It is mandatory that laboratories fulfill the requirements for internal quality control as specified in the designated standard method. These include the use of appropriate reference and control sera, the application of test acceptance criteria, the monitoring of test performance through the use of control charts and the provision of relevant data for third party assessment.

In the initial stages of the EQAP, it is acceptable for laboratories to provide relevant IQC data to the coordinator for evaluation. The consistent performance of the assay will be determined by the coordinator from the use of *cusum* and other statistical tools. However, laboratories should implement the regular use of these

control charts as a component of the routine internal monitoring of test performance. Furthermore, it should be the long term objective for laboratories to generate suitable control charts for assessment by the coordinator. It may be necessary for the appropriate software and training to be provided to the laboratories in order to achieve this requirement.

2.3.3 External Quality Control (EQC)

External quality control involves proficiency testing and the conduct of statistical analysis of inter and intra laboratory internal quality control data. EQC can be used to:

- determine the competence of participating laboratories for the designated test and monitor the consistency and comparability of the laboratory's test data.
- assist in the resolution of inter-laboratory differences.
- assist in monitoring the calibration of equipment

2.4 Inter-laboratory Proficiency Testing

Proficiency testing schemes involve inter-laboratory comparisons between groups of two or more laboratories. For inter-laboratory proficiency testing each laboratory will conduct the designated test method on a defined panel of test antisera, the EQC panel. Identical panels of test samples will be dispatched simultaneously to participating laboratories for concurrent testing. Satisfactory completion of proficiency tests provides evidence of that laboratory's ability to produce reliable test results

2.4.1 Purpose of the EQC panel

1. To assign a score (pass or fail) to each participating laboratory.
2. To quantitatively assess the performance of individual laboratories including the identification of real and potential sources of error.
3. To provide a quantitative measure of repeatability within laboratories and reproducibility between laboratories.
4. To achieve fairness in assessing laboratories with respect to assigning positive or negative status to individual samples.
5. To ensure that the test system is sufficiently robust to be used for its intended purpose.

2.4.2 Composition of EQC Panel

There should be a minimum number of five samples. These should comprise:

- one sample which will produce an unequivocal negative result
- one sample which will produce an unequivocal weak positive result
- one sample which will produce a medium to strong positive result

The remaining two test samples may be selected from any combination of the above three categories. Final decision on the inclusion of suitable samples should be based on individual test requirements for additional evaluation of assay performance.

For an individual test sample to be acceptable for inclusion in the EQC panel, it should, as far as is practicable, meet the following criteria:

- derived from a single animal
- undiluted *(However, if the above are not possible, then a positive test sample should be prepared by diluting a stronger positive sample in the sample that is used to prepare the negative sample)*
- not lipaemic
- not haemolyzed (for sera)
- should not contain secondary clots (for sera)
- not contaminated
- have not been repeatedly frozen and thawed
- free from infectious agents with respect to the requirements of the country concerned
- be supplied to participating laboratories in a volume sufficient to perform at least one repetition of the test in question. Normally 100 ul should be sufficient for ELISAs.
- initial assignment of weak positive should ensure that the sample does not give equivocal results
- all aliquots of a given sample must be derived from a single batch

Test samples should be allocated unique identity codes. Ideally, individual test samples sent to different laboratories should be given different identities to reduce the potential for collusion between laboratories.

2.4.3 Determination of Sample Status

For the purpose of selection of the sample for inclusion into the panel, the initial assignment of the status of a sample will be based on the reactivity determined by the coordinator. The final determination of the status of the sample will be based on the results of testing by the participating laboratories. This status will be determined only when over 80% of the laboratories obtain the same result. If this does not occur then results pertaining to that particular sample are disregarded for the purposes of laboratory recognition.

2.4.4 Logistics of Proficiency Testing

The proficiency testing should be carried out at least twice a year. Shipment time should be coordinated with the activities of the participating laboratories whenever possible. A set time limit of one month is allowed for the conduct of the assay and the return of the results to the coordinator. Such a period will commence from the date of confirmation of receipt of the panel of test samples by the participating laboratory.

To facilitate the operation of this system, the third party coordinator will notify the participating laboratory by fax or telex of the date of dispatch of the EQC sample panel. It is the responsibility of the participating laboratory to notify the third party coordinator of the date of receipt of the samples within three weeks of the time of dispatch by third party coordinator. In the event of no such notification is received by the coordinator, a follow-up investigation will be conducted by the coordinator to determine the reasons for the delay.

2.4.5 Statistical Analysis

For inter-laboratory comparison it is essential that appropriate statistical analysis is completed on EQC panel data. The following types of analyses are proposed:

- frequency analysis demonstrating the distribution of laboratory results
- measurement of intra- and inter-laboratory variance through repeatability and reproducibility indices
- determination of systematic and random error through Youden plot analysis

2.5. Laboratory Recognition

In order to pass a proficiency test a laboratory must obtain the expected results on all samples in the EQC panel, except for samples. declared ineligible (see Section, 2.4.3).

Laboratories may be granted one of two levels of **recognition**:

1. Recognized laboratory

Criteria: the laboratory has successfully fulfilled all of the requirements of the EQAP for the designated assay including passing two most recent proficiency tests

2. Provisionally Recognized Laboratory

Criteria: a newly participating laboratory has successfully fulfilled all of the requirements of the EQAP for the designated assay including passing its first proficiency test

or

the laboratory has successfully passed the last two or more proficiency tests but has not fulfilled other requirements of EQAP.

or

a recognized laboratory has failed the most recent proficiency test.

Recognition will be withdrawn if a laboratory fails to meet the necessary EQAP requirements for the designated assay. Laboratories not fulfilling the requirements of EQAP will not be granted recognition.

2.6. Requirements for Confidentiality

For EQAP reporting purposes laboratories will be identified only on the basis of unique code numbers. Laboratories obtaining provisional or full recognition will be identified by their full name and will be included on the approved list of recognized laboratories. All samples for proficiency testing will be handled in a confidential manner.

3. IMPLEMENTATION OF AN EQAP BY FAO/IAEA

In the FAO/IAEAs' Programme of activity it has been clearly identified that the operation of an External Quality Assurance Programme (EQAP) for the FAO/IAEA ELISA kits is the responsibility of the FAO/IAEA Central Laboratory for ELISA and Molecular Techniques in Animal Disease Diagnosis, itself a part of the Animal Production Unit of the IAEA's Laboratory, Seibersdorf. However, in implementing such a programme it is essential that the Centre liaise closely with technical officer of the Animal Production and Health Section of the Joint FAO/IAEA Division. Furthermore the decision to award recognition status to a laboratory should be made by a panel comprising the Head of the ELISA Centre, the Head of the Animal Production and Health

Section and the appropriate technical officers, taking into account all information obtained through the operation of EQAP.

Since this EQAP is part of the support programme to scientists in developing countries it should be operated free of charge to participating laboratories. However, in implementing this programme, given current staff and funding resources, it will be necessary to adopt a stepwise approach dealing with each major disease at a time. It is proposed that in three years, systems should be operational for rinderpest, brucellosis, trypanosomosis and foot-and-mouth disease. It is proposed that at the end of three years an external review is conducted on the operation of EQAP to determine its effectiveness and the feasibility of extending its scope to other diseases and diagnostic systems.

In the earlier stages of developing this programme the agreement between a participating laboratory and the FAO/IAEA should be on an informal basis with enforcing arrangements kept to a minimum to ensure the operation of the programme. Even at this stage however, it will be of benefit if OIE is informed of FAO/IAEA recognized Laboratories. As the programme develops it may become necessary to formalize arrangements on a contractual basis to assure outside interested bodies of the value of the recognition status. The scope of such contractual arrangements should be determined during the third year review.

4. CONCLUSIONS

4.1. It is important for the liberalization of international trade in animals and animal products as well as for effective national and international disease control programmes that diagnostic laboratory tests are carried out using defined standards.

4.2. External quality assurance programmes (EQAP) for veterinary laboratories supplement internal quality control systems and provide an assessment of uniformity between laboratories. EQAP should be coordinated by a third party organization.

4.3. The authority of the third party coordinator should be endorsed by the OIE.

4.4. An EQAP should lead to recognition of individual laboratories for their competence in defined assays for specific diseases. The criteria and procedures for **recognition** have been defined.

4.5. An EQAP must include essential components by which a laboratory's capability and performance can be evaluated. These will include an evaluation of laboratory information management, the training and experience of staff, maintenance of equipment and the nature and volume of diagnostic activities. A key component of the programme is proficiency testing.

4.6. Proficiency testing is conducted by the distribution to all participants on a regular basis of external quality control sample (EQC) panels. Such panels should include as a minimum 5 samples comprising suitable negative and positive samples. It is appropriate for most types of assays that proficiency testing is conducted twice a year.

4.7. Before providing a certificate of **recognition,** the third party organization should be satisfied that a laboratory has fulfilled all the requirements. of the EQAP. The criteria for provisional and full recognition are defined within the EQAP.

5. RECOMMENDATIONS TO THE JOINT FAO/IAEA DIVISION

5.1. General

5.1.1. The Joint FAO/IAEA Division is in a position to start an EQAP, formulated for use with its own ELISA kits, for those veterinary diagnostic laboratories which participate in the programme of the Joint FAO/IAEA Division and in the IAEA's Technical Cooperation programmes. As such the EQAP will focus on developing countries. However, it is recommended that wherever possible internationally recognized Reference Laboratories for the particular disease should also participate in order to provide additional assurance.

5.1.2. The EQAP should not place unreasonable demands on participating laboratories bearing in mind the particular operational problems encountered in developing countries. Nevertheless it should provide sufficient assurance for national and international bodies to have confidence in the performance of individual recognized laboratories.

5.1.3. The Joint FAO/IAEA Division's EQAP should be restricted initially to those laboratories using the FAO/IAEA ELISA kits. Later, expansion may be considered to include other laboratories using alternative methodologies, but only where such methods have been standardized against recognized international standard reagents.

5.1.4. The EQAP should include an element of data gathering and analysis to facilitate the Joint FAO/IAEA Division's role in technical support and troubleshooting for participating laboratories.

5.1.5. The EQAP should comprise four key elements:

- Information on laboratory management and staff gathered by means of a questionnaire. This information will be updated twice yearly and supplemented by information from the Joint Division's technical officers.
- A data base designed to assess on consistency of ELISA kit performance provided by the internal control sample data from ELISA tests. This will require some additional computer programming and will not therefore be available at the start of the EQAP. A planned development of such a monitoring system should be incorporated into the EQAP and should include a training element to enable anticipating laboratories to make use of the data in day- to-day laboratory management.
- Proficiency testing by means of an external quality control sample (EQC) panel tested twice yearly for each assay by all participants.
- Recognition of laboratories by the issue of certificates of **recognition** to individual laboratories for specific assays, according to procedures outlined in this report.

5.2. EQC Panel

5.2.1. All samples in EQC Panel should be coded.

5.2.2. The EQC Panel should consist of 5 samples, including a negative, a weak and a strong positive. The other 2 should be duplicates selected from among these 3. Although single, undiluted samples are preferred it may be necessary to pool samples or to dilute positives in negative serum to achieve the desired panel.

5.2.3. The interpretation of the EQC Panel results should be based on inter-laboratory comparisons and a result considered correct when greater or equal to 80% of participating laboratories agree on that result.

5.2.4. Statistical analysis should be carried out by FAO/IAEA on the quantitative data (percent positivity or percent inhibition) arising from the EQC tests. This will provide information on the robustness of the assay and assist monitoring of laboratory performance. Suggested analyses include frequency distributions, Youden plots, and measures of variance.

5.2.5. The FAO/IAEA EQAP should be re-evaluated after 3 years of operation and any necessary alterations or enhancements introduced at that time.

5.3. Linkage with Existing FAO/IAEA Quality Assurance Programmes

The new EQAP system (based on 5 samples proficiency tests) will completely replace all other existing systems.

5.4. Level of Participation in the External Quality Assurance Programme

5.4.1. For those laboratories currently using FAO/IAEA designated diagnostic kits, participation in the External Quality Assurance Programme (EQAP) is obligatory and the supply of kits will be contingent upon the participation of individual laboratories.

5.4.2. **Recognized** laboratories failing to participate for one round of the EQAP will be downgraded to a **provisional recognition** status but will still receive the kit.

5.4.3. A failure to participate in two sequential rounds of the EQAP will result in the loss of the **recognized** status of the laboratory and may result in the cessation of further supplies of the kit.

5.4.4. These conditions of participation and the penalties of non-compliance will be documented and supplied to the supervisors of individual laboratories in the form of a contractual agreement. Inclusion of a laboratory in the EQAP and the supply of kits will be dependent upon the return of the signed agreement to the IAEA.

5.4.5. Laboratories not meeting the detailed requirements will be recorded as supplying a nil return against their relevant laboratory code number.

5.5. Eligibility for Inclusion in the EQAP

Currently the EQAP will .involve only those assays that are supplied in a kit format by FAO/IAEA. The inclusion of laboratories in this programme should be dependent upon the relevant FAO/IAEA guidelines (Section 5.1 - 5.4). The potential for the future global expansion of this programme and the likely inclusion of assays not supplied by the FAO/IAEA is foreseen and such developments may require the involvement of funding from third party donor organizations.

6. RECOMMENDATIONS TO OIE

6.1. The primary assurance of uniform standards in diagnostic laboratories is provided through the availability of international standard methods and reference reagents. **The activities of 0IE in these areas are therefore strongly supported.**

6.2. Additional assurance may be gained by the implementation of external quality assurance programmes. It is acknowledged that OIE does not have the resources to operate such programmes in its own right.

6.3. It is recommended that OIE develop guidelines for the implementation of external quality assurance programmes for veterinary diagnostic laboratories. Such programmes will –facilitate the evaluation of laboratory services which form an integral part of the "Evaluation of Veterinary Services" as adopted by OIE (1993) *(Rev Sc, Tech Off Int Epiz, 12: 1291-1313).*

6.4. In view of the recognition by GATT of OIE as the world organization for standardization in the animal health sector, **it is recommended that 01E should define a procedure for the accreditation of international quality assurance programmes In the area of animal disease diagnosis.** The proposals detailed above for the FAO/IAEA ELISA kits provides a model of one such programme.

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Appendix A
EXAMPLE
Questionnaire for laboratories participating in the External Quality Assurance Programme (EQAP) for the FAO/IAEA Rinderpest competitive ELISA kit.

- **The questionnaire should be filled out by the officer responsible for the diagnosis and serological monitoring of rinderpest.**
- **The information will be handled confidentially, and not divulged to a third party.**
- **If you have any comments on this questionnaire or useful additional information concerning Quality Assurance, please use the space at the end of the questionnaire.**
- **Your co-operation is highly appreciated. The information provided by you, combined with the information from other participating laboratories, will be essential for successful implementation of the EQAP.**

A.1.
Name and address of your Institute:
Name:_____

_____

Address:_____

_____

Tel:_____ Fax:_____Telex:_____

A.2.
If your Institute has no fax machine, are you sending/receiving faxes through your local UNDP?
Yes / No

A.3.
Name of the officer completing this questionnaire:
Mr/Ms/Dr._____

_____

Position/rank within the Institute :_____

_____

B.1.
Which laboratory techniques are used for the diagnosis and serological monitoring of rinderpest in your laboratory? Please indicate with a check (√) mark:

for Ag detection		for virus isolation		for Ab detection	
Agar gel test		Cell Culture		Competitive ELISA	
Antigen-capture ELISA		Inoculation of susceptible cattle or buffalo		Serum neutralisation test (SNT)	
Immunoperoxidase techniques					
Molecular-based techniques e.g. PCR, DNA probes					

B.2
How many samples per year, are tested for the diagnosis and serological monitoring of rinderpest in the laboratory?

< 5000		5000-15000		15000-25000		>25000		.....	

B.3
For what purpose are you testing for Rinderpest?

Import		Export		Surveillance / Monitoring		Outbreak investigation	

B.4.
Please specify other diseases being diagnosed by the Institute by filling in this table?

Disease	Using which laboratory technique(s)?	Using a FAO/IAEA ELISA kit? yes / no	Testing for: import / export / surveillance / outbreak investigation
Peste des petits ruminants (PPR)			
Foot and mouth disease (FMD)			
Infectious Bovine Rhinotracheitis (IBR)			
Bluetongue			
Brucellosis			
Contagious bovine pleuropneumonia (CBPP)			
Trypanosomiasis			
Babesiosis			
Other:			

B.5.
Are you or other people within your institute establishing a serum bank as described in the Rinderpest ELISA Manual? Yes / No. If yes, how many serum samples are stored at this point in time?
±_____

C.1.
How are the serum samples stored in your laboratory, before being tested with the FAO/IAEA competitive ELISA kit?

in the refrigerator, at + 4°C	
at 0°C	
at - 20°C	
at - 80°C	
in liquid nitrogen	
.....	

using cryopreservation vials	
using cryopreservation vials in combination with Nalgen® storage system	
using micronic tubes	
using serum storage plates (Polypropylene)	
using vacutainers	
others:	

Do you have access to a - 80°C freezer for sample storage? Yes/ No
Do you have access to liquid nitrogen for sample storage? Yes / No

C.2.
Do you have a source of purified water?
Yes / No If yes, please specify:

Deionized		Distilled		Double distilled	

Are the filters or columns regularly changed? Yes / No
How often?_____

C.3.
Do you have problems with your power supply?
Yes / No
If yes, please indicate duration, frequency and type of power interruption

period:		frequency:		type:	
< 1 hour		every day		no power	
< 6 hours		every week		unsteady voltage	
< 12 hours		every month		low voltage	
> 12 hours		irregular		.....	
irregular		.....		.....	

C.4.
In case of unsteady/low voltage, is the equipment connected through a stabiliser? Yes / No
In case of a power cut (no power), is there an automatic emergency power supply installed to run the freezer and/or refrigerator? Yes / No
Do you have easy access to a generator? Yes / No

C.5.
Is the laboratory where the rinderpest competitive ELISA is performed equipped with a functional air conditioner? Yes / No
What is the average daytime temperature, humidity in the laboratory? ±_____
_____

C.6.
Is the FAO/IAEA manual for the competitive rinderpest ELISA easily available to you or your staff? Yes / No
Is **all** the equipment specified in this manual available? Yes / No
If you are missing certain items, please specify:
_____
_____
_____

C.7.
Which type of pipettes, tips and ELISA reader are you using?

Pipettes:					
Biohit proline®		single channel 5-50µl		multi channel 5-50µl	
Finnpipette®		single channel 50-250µ		multi channel 50-250µl	
Titertek®		single channel 250-1000µl		multi channel 250-1000µl	
Gilson Pipetteman®					
.....		.....		.....	

Tips:		ELISA reader:	
Micronic ®		Multiskan MCC/340	
Biohit proline®		Multiskan Plus Mark II	
.....		BDSL Immunoskan Plus	
		.....	

C.8.
Is the rinderpest competitive ELISA conducted **exactly** as described in the FAO/IAEA manual?
Yes / No
If no: which changes have been made?_____

_____

_____

_____

C.9.
When did you receive the last FAO/IAEA rinderpest kit?_____
Batch no.:_____ (see fact sheets) When were the last serum samples tested using the rinderpest competitive ELISA kit?_____

D.1.
Are there documented instructions (i.e. manuals) on the use and operation of all relevant equipment? Yes / No
If yes, are these easily available to the staff? Yes / No

D.2.
In case the pipettes, ELISA reader or other equipment items are not working properly:
Where do you send them for repair;

Pipettes	ELISA reader	Other items	
			You repair them yourself
			The equipment is repaired by other people within the laboratory
			There are local possibilities for repairmen outside the laboratory
			The equipment is sent to the IAEA for repair
			other:

D.3.
Are the pipettes and the ELISA reader calibrated on a regular basis?
Yes / No
If yes, please specify:

Equipment:	calibrating procedures:	date of last calibration
Pipettes		
ELISA reader		

E.1.
Are you using the EDI (ELISA Data Information) computer programme for reading and calculating the test results? Yes / No
If yes, which version?

EDI RPEIA 1.01		EDI RPEIA 1.03		EDI 2.11		.....	

If no, how do you read and calculate the test results?_____

_____

_____

E.2.
Are you using a computerised system, i.e. SID (Serum Information Data), EPI-info., to relate the ELISA test results with other details concerning the source of the serum sample such as animal number, age, sex, area of collection etc.?
Yes / No, If yes, please specify which computer programme you use: _____

_____

If no, which procedures do you use to relate the ELISA results with other details concerning the source of the serum sample?

_____

_____

_____

_____

E.3.
Could you specify the type of computer you are using for reading (and calculation) of the test results?

CPU 286		CPU 386		CPU486		Pentium		.....	

CPU = Central Processing Unit
Available RAM memory:_____
Available space on the Hard Disk:_____

If you are using a different computer for data storage (as asked in E.2.), could you please specify the type?

CPU 286		CPU 386		CPU486		Pentium	

CPU = Central Processing Unit
Available RAM memory:_____
Available space on the Hard Disk:_____

F.1.
If the EDI programme is used for reading and calculations of the ELISA plates, the Internal Quality Control data are automatically stored in a separate file (see the Rinderpest kit manual).
In case you are **not** using the EDI programme, how do you store the IQC data derived from each ELISA plate?

_____

_____

_____

F.2.
Do you use IQC data to monitor ELISA kit performance?
Yes / No
If yes, how do you monitor ELISA performance using the IQC data?_____

_____

_____

_____

F.3.
Approximately what proportion of the ELISA plates have invalid data because the IQC data are outside limits?_____
Are the samples on these plates always repeated? Yes / No
If no, why are they not repeated?_____

_____

G.1.
What is the name of the analyst(s) conducting the FAO/IAEA rinderpest competitive ELISA on a routine basis?
Mr / Ms / Dr.:_____

What is his/her current position?_____

G.2.
Could you indicate his/her highest technical qualification?

Certificate Subject:		Diploma Subject:		Degree Subject:	

How many years of experience does the analyst have in performing ELISA?

G.3.
Did the analyst receive additional training in running the rinderpest competitive ELISA?
Yes / No
If yes, please specify:

Participated in FAO/IAEA training course		On the job training by visiting FAO/IAEA experts	
On the job training by local experts		Other training (e.g. fellowship):	

G.4.
Do you and/or the analyst require further training in rinderpest diagnosis? Yes / No
If yes, please specify on which aspect of the ELISA extra training would be useful?

H.1.
Are there documented quality assurance/control procedures in use within the laboratory?
Yes / No
If yes, could you please summarise those procedures or enclose a copy?_____

H.2.
Is your institute involved in other quality assurance/quality control programmes?
Yes / No
If yes:
Name of the Quality Assurance Programme:_____

Organised by:_____

Thank you for filling in the questionnaire!

When all results of this questionnaire, together with the results of the External Quality Control panels are processed, we will send you an interim report. The information you provide will be completely confidential; collaborating laboratories will be identified only on the basis of code numbers.

If you have any comments on this questionnaire, or you have additional information concerning Quality Assurance within your laboratory, please indicate:

_____

_____

_____

_____

_____

_____

_____

_____

_____

Date:_____ Name:_____

Signature:_____

Please return to:

Name of your FAO/IAEA Technical Officer : .....

Animal Production and Health Section
Joint FAO/IAEA Division
I.A.E.A.
P.O. Box 100
1400 Vienna
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(Fax: ++.43.1.20607)

APPENDIX B

DEFINITIONS

Accreditation (of a testing laboratory): A formal statement of competence of a laboratory by a third party. The scope of accreditation will define precisely the range of activities for which the laboratory has been accredited. Ibis must be as precise as possible so that all parties concerned know accurately and unambiguously the range of tests and/or analyses covered by the laboratory's accreditation.

Accuracy: The degree of agreement between test results and the accepted reference value.

Coordinator. Person or body which coordinates all the activities associated with a proficiency programme.

Certification: Procedure by which a Third Party gives written assurance that a product, process or service conforms to specified requirements.

External Quality Control (EQC) Panel: A set of standardized samples that is tested by laboratories performing an assay in order to provide data to ascertain the relative agreement in results among laboratories and/or to provide a mechanism for diagnostic laboratory certification/accreditation/recognition, and/or v provide a mechanism for troubleshooting by the Reference laboratory.

Internal Quality Control (IQC): The set of procedures undertaken by a laboratory for continuous monitoring of operations and results used to determine whether the results are reliable enough to be released; IQC primarily monitors the batch to bitch accuracy of results using quality control samples and precision on independent replicate analyser of test samples.

Quality Assurance Programme: The sum totes of a laboratory's activities aimed at achieving the required standard of analysis. While IQC and proficiency testing are very important components, a quality assurance programme must also include staff training, administrative procedures, management structure, auditing etc.

Inter-laboratory Test Comparisons: Organization, performance and evaluation of test on the same or similar samples by two or more different laboratories in accordance with pre-determined conditions.

Negative Sample: A sample that consistently gives a reaction below a pre-determined diagnostic threshold.

Positive Sample: A sample that consistently gives a reaction above a pre-determined positive diagnostic threshold.

Precision: The degree of agreeement between independent test results obtained under prescribed conditions.

Procedure: Specified way to perform an activity.

Proficiency Testing: Methods of checking laboratory testing performance by means of inter-laboratory tests.

Quality: The sum of characteristics of an entity teat bears on its ability to satisfy stated and implied needs. The term "quality" should not be used m a single term to express a degree of excellence in a comparative sense, nor should it be used in a quantitative sense for technical evaluations. To express these meanings a qualifying adjective should bye used.

Quality Assurance: All the planned and systematic activities implemented within the quality system and demonstrated as needed to provide adequate confidence that the requirements for quality are being fulfilled. Internal quality assurance provides a measure of testing proficiency and confidence to the laboratory management; external quality assurance provides a measure of testing proficiency and confidence to those outside the laboratory.

Quality Control: Operational techniques and activities that are used to fulfil requirements for quality.

Quality Management: All activities of the overall management function that determine the quality policy, objectives and responsibilities.

Reference Laboratory: Laboratory that provides reference values on a test item within a known level of certainty.

Reference Sample: A substance with one or more properties which are sufficiently well characterised to be used for the calibration of an apparatus, the assessment of a measurement, or for assigning values to materials.

Repeatability: That characteristic of a test that enables it to give similar results when performed more than once in the same laboratory under similar conditions (within laboratory comparison).

Reproducibility: That characteristic of a test that enables it to give similar results when the test is performed in different laboratories but under similar conditions (a between laboratory comparison).

Testing Laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of submitted samples.

Test Method: A defined technical procedure to determine one or more specified characteristics of a material or product.

Test Result: The value of a characteristic obtained by completely carrying out a specified measurement method, once.

Third Party: The person or body that is recognized as being independent of the parties involved with the issues in question. The parties involved are usually the testing laboratory ("first party") and those routinely receiving the test results and for whom the test was conducted ("second party")

nb. The definitions above have for the most part been derived from the appropriate ISO Guide (nos. 2, 20, 25, 43 and 8402).