Guidelines for Establishing Quality Systems in Veterinary Diagnostic Testing Laboratories

Report of an Joint FAO/IAEA Consultants Meeting/Workshop organized by the
Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, FAO/IAEA Agriculture and Biotechnology Laboratory and Department for Technical Co-operation

Vienna International Centre
4-8 September 2000

(Version 1.02, 17 May 2002)

Foreword to the *Version 1.02, from 17 May 2002*:

This document was edited after a consultants meeting in September, 2000 and is meant to be updated at least once a year.

During a follow-up meeting in Onderstepoort, South Africa in July, 2001 the usefulness of the guidelines were discussed and comments and further chapters such as 1) Estimation of Measurement Uncertainty and 2) Occupational Health and Safety (OH & S) were included. The latter ones are not part of the OIE standard but are recommended as part of good laboratory practice ("glp").

Statements in italics are either advisory in nature or are provided as examples to the primary body of text.

An updated version of this document is available under:
http://www.iaea.org/programmes/nafa/d3/public/guidelines.pdf

An interactive web-based training programme is available under:
http://www.aplactraining.asn.au

Summary

A training course/ workshop entitled: "**Developing Standardized Training Material To Assist FAO/IAEA Member States To Establish Quality Systems For Veterinary Diagnosis Laboratories**" was held in Vienna 4-8 September, 2000.

The purpose of this training course/ workshop was to produce working documents which are crucial to assist veterinary testing laboratories to develop and implement a quality system based on the OIE Standard "Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases".

Furthermore this report gives an example-oriented overview of the structure and contents of critical documents and procedures such as Quality Manual (QM), Standard Operating Procedures (SOPs), etc. inherent to a quality system and describes the different stages in the implementation of the OIE Standard.

For that reason it can be used as a practical guide not only for the production of necessary documents but also as a help to determine the status of a laboratory during its journey towards establishing a Quality System.

In addition to the discussion a number of formal presentations were made (see attached agenda):

CONTENTS

Abbreviations

AAHL	Australian Animal Health Laboratory, Victoria, Australia
AGID	Agar Gel ImmunoDiffusion
APU	Animal Production Unit, Austria
c-ELISA	Competitive - Enzyme Linked Immunosorbent Assay
CPD	Continuous Professional Development
CSIRO	Commonwealth Scientific and Industrial Research Organization, Victoria, Australia
EA	European Accreditation service
EQAP	External Quality Assurance Programme
EQC	External Quality Control
FAO	Food and Agriculture Organization, Rome
glp	good laboratory practice as generally conducted in a laboratory (should not be confused with the GLP standard)
HAI	Haemagglutination Inhibition
GLP	Good Laboratory Practice (the “Standard”)
IAEA	International Atomic Energy Agency, Vienna
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission, Geneva
ILAC	International Laboratory Accreditation Co-operation
IQC	Internal Quality Control
ISO	International Organization for Standardization, Geneva
ISO/IEC	International Organization for Standardization / International Electrotechnical Commission, Geneva
NAAL	Nuclear Application in Agency’s Laboratories, Vienna
NATA	National Association of Testing Authorities, Victoria, Australia
NVSL	National Veterinary Service Laboratory, New York
OH & S	Occupational Health and Safety
OIE	Office International des Epizooties, Paris
OIE – Standard	Office International des Epizooties – Quality System Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases
QA	Quality Assurance
QC	Quality Control
QM	Quality Manual
QS	Quality System
SOP	Standard Operating Procedure
UKAS	United Kingdom Accreditation Service

VNT	Virus Neutralization Test
WI	Working Instructions

1. CONCLUSIONS AND *RECOMMENDATIONS*

(Statements in italics are either advisory in nature or are provided as examples to the primary body of text.)

1.1 The Food and Agriculture Organization/International Atomic Energy Agency (FAO/IAEA) External Quality Assurance Programme (EQAP) for Animal Disease diagnosis as described in the 1994 Consultants Report [1] has achieved its purpose in creating a Quality Assurance (QA)/Quality Control (QC) environment in the laboratory and should maintain its central elements.

Where appropriate equal emphasis should now be placed on quality management and operations as well as on Internal Quality Control (IQC) analysis, charting methods and proficiency testing.

1.2 The OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases (OIE Standard [2]) needs to be evaluated by an external accrediting organization for its applicability to the accreditation of veterinary testing laboratories under international quality standards.

To fulfill conclusion 1.2), and as a preliminary filter, the OIE Standard should be submitted to NATA, Australia, for review, with the expected outcome of providing credibility toward ISO acceptance.

1.3 An IAEA project will be crucial for the successful implementation of a Quality System (QS) in selected laboratories and for the final preparation of standardized training material.

A project proposal should be prepared and submitted accordingly.

1.4 National and Institute commitment to QS for veterinary diagnostic laboratories is essential.

The Agency should seek confirmation of national commitment from workshop participants.

1.5 Essential guidelines and basic information to implement QS were successfully developed and provided to workshop participants.

Assistance should be provided to workshop participants to implement a quality system in their laboratories. This assistance may be financial or otherwise.

1.6 Further or continued support to workshop participants is required if they are to successfully implement QS in their laboratories.

- *Training material should be provided to aid in implementation of the QS.*
- *The Agency should investigate the availability, procurement and distribution of QS training material.*
- *On-site assistance by external experts is needed.*
- *Fellowships for QA training and visits to accredited veterinary laboratories is essential.*
- *Training material should be made available on the web.*

1.7 A time-frame for the establishment of QS is essential.

The time-frame is contingent upon the implementation of the recommendations under 1.4 to – 1.6 above. Demonstration of progress by workshop participants *will be by submission of reports to IAEA.*

1.8 Establishing QS in veterinary diagnostic laboratories in other developing countries will require assistance and advice.

It is anticipated that workshop participants will act as advisors to establish QS in other laboratories in their region.

2 INTRODUCTION

PRINCIPLE : "QUALITY IS A JOURNEY, NOT A DESTINATION."

2.1 Purpose

The purpose of this report is to assist veterinary testing laboratories to develop and implement a quality system based on the OIE Standard "Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases" **[2]**.

The introduction to the OIE Standard states: "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[1] 17025:1999, *General requirements for the competence of testing and calibration laboratories* (as outlined in Annex B of ISO/IEC 17025 **[3]**). Accreditation bodies that recognize the competence of such testing laboratories may use this Standard as the basis for their accreditation."

The above statements may not yet be ratified by the ISO Standards.

This report gives an example-oriented overview of the structure and contents of critical documents and procedures such as Quality Manual (QM), Standard Operating Procedures (SOPs), etc. inherent to a quality system and describes the different stages in the implementation of the OIE Standard.

For that reason it can be used as a practical guide for the production of necessary documents and also to determine the status of a laboratory during its journey towards establishing a QS.

2.2 General considerations

The implementation of quality systems is becoming an international necessity more than just having in place standards for improving efficiency and accuracy. There is an increasing need for veterinary diagnostic laboratories to comply with international standards (e.g. ISO 9000 Series **[4]**) to improve accountability that can be accepted by third parties. This is of special importance for national laboratories involved in the control and eradication of major animal epizootics.

The preparation of the necessary documentation and the adaptation of the laboratory operational procedures leading to the establishment of quality systems and official accreditation is currently very difficult if not impossible for any given QA coordinator in veterinary diagnostic laboratories in developing countries due to the vast and usually confusing standards, prerequisites and interpretations to the existing international standards.

1 International Organization for Standardization / International Electrotechnical Commission

2.3 Development of the FAO/IAEA External Quality Assurance Programme

Over the last five years the Animal Production and Health Subprogram through its FAO/IAEA External Quality Assurance Programme has facilitated the implementation of principles of QC, QA and documentation in developing countries. In its role as the FAO/IAEA Central Laboratory for ELISA and Molecular Techniques in Animal Disease Diagnosis and as a Collaborating Center of "Organization International des Epizooties" (OIE) and "World Health Organization" (WHO), the Animal Production Unit (APU) in close collaboration with the Animal Production and Health Section has expanded its participation in the development of international guidelines for the performance of diagnostic tests. The guidelines relate to the standardization of international reference reagents, the establishment of internationally acceptable IQC and External Quality Control (EQC) procedures, laboratory management practices for QA and QC, the standardization of data expression, and the standardization of diagnostic validation procedures.

The major outcome of a FAO/IAEA consultants meeting entitled: "The FAO/IAEA EQAP and Movement Towards a Generic Veterinary Diagnostic Testing Laboratory Accreditation Scheme" held in February, 1998 was a set of "Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases". This document has been accepted, recognized and adopted by the OIE as the "OIE Standard" and it contains the specific requirements unique for these types of laboratory.

The dissemination of this information but more importantly, understanding it is crucial for the implementation of an adequate laboratory QS. The Department for Technical Cooperation and the Animal Production and Health Subprogram have designed a multi-regional project to facilitate the implementation of a QS, which may eventually lead to the accreditation of veterinary diagnostic laboratories in developing countries. It is envisaged that this will be achieved within the regions using QA coordinators trained by IAEA.

The purpose of this Joint consultants' meeting/workshop was to bring together a group of experts in QS, accreditation procedures and experience in veterinary diagnostic laboratories in developing countries to prepare: **a**) 'generic' documents in accordance with the new OIE Standard from which laboratory QA coordinators can develop their own material, and **b**) through a continuous process, initiate discussions on training material to be used by the 'IAEA trainers' while guiding and monitoring the establishment of QS in veterinary diagnostic laboratories in the different regions.

Six QA coordinators or trainers (two from each region, e.g. Africa, Asia, and Latin America) from leading laboratories participated in the meeting to become familiar with the reasons, purpose, relevance and technical details of the material under preparation while strengthening their knowledge on managing QC and QA and documentation issues. They will assist in the development of the training material allowing for regional needs and conditions.

It is expected to extend these activities through interregional workshops in which the QA coordinators will discuss the adaptation and dissemination of generic documents and training material within their laboratories, the status of implementation and the constraints encountered. Based on their experiences other suitable laboratories in each region will be identified to implement QS.

3 GUIDANCE IN THE PREPARATION OF A LABORATORY QUALITY MANUAL

3.1 The concept

The Quality Manual (QM) will allow the development and implementation of a Quality System (QS) that complies with the OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases (OIE Standard) produced by the Standards Commission of the OIE.

This chapter will help guide laboratory personnel in the preparation of a laboratory Quality Manual (QM) as required by the OIE Standard under section 4.2 **[5, 6]**.

It must be emphasized that this document is a guide only and it may be necessary for the contents to be modified to suit the individual laboratory's unique circumstances. Useful information on this topic can be obtained from the International Laboratory Accreditation Cooperation (ILAC) e.g. ILAC-14:1996 "Guidance Documents Available from Accreditation Bodies for the Preparation of Laboratory Quality Manuals" (http://www.ilac.org).

The laboratory is only required to produce one QM. If it becomes necessary to modify elements within the QM to suit requirements set by different agencies and approval bodies the modifications can be documented separately. These changes should be cross-referenced to the relevant elements in the QM.

To be an effective working document a laboratory QM should provide the basic policies and practices under which the laboratory functions. It should also link and provide cross-references to the Standard Operating Procedures (SOP's), resource information and records used in the laboratory.

The **aim of the QM** is to allow:

- actual laboratory practices being carried out to be described;
- the laboratory's policies, procedures, commitment to good laboratory practice (glp) and quality of calibration/testing services to be communicated to management and laboratory staff;
- all laboratory staff to understand the extent of their own duties and responsibilities;
- the laboratory's management to audit actual working practices against those considered necessary for the laboratory's proper operation;
- the elements of the QM to be carried out by the laboratory on a daily basis enabling an effective QS;
- efficient laboratory management.

Ideally the QM should be prepared by a senior member of staff assisted by all laboratory staff. The responsible person should have, as a minimum requirement, a thorough technical background with several years of technical experience at the laboratory bench together with managing a section/department. The person should be computer literate to a level that will allow the confident use of a computer and word processor such that a document can be typed, securely saved electronically, formatted and printed. In addition the person should be apolitical, be able to negotiate at various levels and be sympathetic to the possibility that staff may resist change as they might feel the introduction of a QS is there to check their work! It may be appropriate to give the person a title synonymous with their new function (e.g. Quality Manager).

If the laboratory is large, with many sections or departments, it may be necessary to form a committee consisting of section/department heads.

The size of the QM is determined by the user and the quantity of documented procedures to be included. The size usually reflects the complexity of the laboratory, the related Organization and nature of the work/business (i.e. the more complex the laboratory the larger the QM). The format of the QM is also the choice of the user but once decided should be applied to all the elements of the QM.

Before undertaking the task of producing a QM and developing a QS, it is important to realize that the activities will be demanding of staff in terms of time (i.e. QS work load will be in addition to their normal work load) and capability. Therefore, the task can only be achieved if there is a strong will to succeed and a sustained commitment over several years from all staff, but most especially from senior management.

The following sections of this guide are designed to address all the required elements of a quality standard. The order in which the elements appear in the QM is a matter of choice.

Remember:
Laboratory Q Ms - effective laboratory management and operation cannot be achieved unless all members of the laboratory's staff are fully aware of the policies and operating procedures of the laboratory and the extent of their own duties and responsibilities.

For this to be achieved and maintained it is essential that all the laboratory's policies, procedures and practices be documented. This documented QS represents the basis of the operation of the laboratory and becomes the basis on which the laboratory's management can periodically audit the actual working practices against those considered necessary for the proper operation of the laboratory. Such a document becomes the Q M of the laboratory.

*The Q M is the **central controlling document** which lays down the basic policies and principles on which the laboratory functions, and provides the coordination links with (or cross references to) collections of operating procedures (i.e. test methods, internal audits, external QC, equipment calibration), resource information and records upon which the laboratory's QS depends.*

The Q M should be so written that a person who is technically proficient in your area of testing can, after reading your Q M (and the Procedures/Methods to which it refers) competently manage your laboratory.

- keep the QM **simple** and **appropriate** to your circumstances.
- the QM and all documents used within the QS, are subject to internal and external audit and are therefore controlled.

The QM can be prepared as an electronic and/or hardcopy copy. If an electronic copy is prepared systems must be in place enabling the document to be backed-up (copied) and be stored securely. If the QM is prepared from the start as an electronic copy it will allow for the laboratory up-dating its computer hardware/software as resources allow.

3.2 The Elements

3.2.1 Introduction

The introduction describes:
- The laboratory and its position in the parent organization or Dept/Ministry:

- That the QM is the property of the laboratory and by whom it has been created *-name the committee or individual responsible*.
- What is in the QM, i.e. the quality policies and/or documents and procedures that the laboratory will operate to comply with the quality standard.
- It will state how amendments to the QM can be approved and implemented - *name the committee or individual responsible*.
- There should be a comment on where and to whom the document is available *(e.g. the QM is an in-house document available to staff from the laboratory; it may or may not be a confidential document);*
- what Standard(s) is/are used?
- the scope of the QM, what does it cover (i.e. the whole laboratory or its sections/departments or particular tests), and how it relates to any other Manuals i.e. SOP Manual etc, if these are not included in the QM.
- structure of the QM;
- reason for the QM;
- mission statement;
- table of contents;
- distribution and control;
- writing amendments.

3.2.2 **Organization and Management** (OIE Standard section 4.1)

Shall include:
- tree chart for management, organization structure and personnel;
- quality policy statement **signed** by senior manager/management;
- describe responsible committee and/or organization related to the operation of QA system;
- human resources. This describes the staff structure of each section/department, including all those sections/departments that can or may affect the quality of the work produced from the laboratory (e.g. finance section, stores, occupational health and safety (OH & S), engineering, etc.);
- any changes to the QM should be checked by staff who may be affected by the changes before the changes are implemented;
- useful to include floor plan of the laboratory in the QM that should include room number and name of section/department or room. This will help with OH & S issues that may arise or may need to be assessed for risk analysis studies. The plan is also useful to understand how different sections or individual laboratory rooms inter-relate with each other and where potential problems may occur or where the audit process may identify potential problems.

3.2.3 **Document Control** (OIE Standard section 4.3)

Policy

- *The laboratory shall operate a document control procedure which meets the requirements of the OIE Standard/ISO17025 Standard.*
- *The laboratory shall appoint an appropriate member of staff, if so they wish, to carry out the duties of Document Controller for the QS.*
- *The Document Controller shall be responsible for the maintenance, security and integrity of all documents within the quality system.*

Procedures

- Identify the Document Controller, or staff who are responsible for document control.

It should not be the Quality Manager.

The person(s) is/are responsible for:
- the safe keeping of documents within the QS;
- uniquely identifying each document;
- identifying who is responsible and has authority for creating and/or making changes to the document;
- ensuring the QM, test methods and operating procedures are available, updated and if extracts of the QM are required in areas where computers cannot be held (e.g. Pathology, sample reception, etc.). These extracts will require authorization;
- all staff training documents are maintained to identify that training has taken place. In addition, ensuring that training appears on staff records.
- ensuring out-of –date documents are removed and that only current documents are in use.

3.2.4 **Management reviews** (OIE Standard section 4.12)

Policy

- Management will review the QS and test related activities at least annually, in accordance with the requirements of the OIE Standard.
- The annual Management Review will examine all elements of the QS and will be documented.
- Actions arising from the annual Management Review will be addressed.

Procedure

Describe how the Management Review will be accomplished (i.e. in December of each year the Quality Manager will prepare a report on the operation of the QS. This report will be submitted to the designated Management Review committee by the end of January of the following year.) Ensure the requirements of the quality standard are addressed.

- report on all aspects of the QS including all corrective actions, any system failures and any changes to documents following internal and external audits. This identifies any problems (e.g. procedures not carried out due to low staff numbers, suitability of the quality system, demonstrates quality improvement takes place because corrective action is documented);
  Note: *if during or after the preparation of the QM it is found that actual working practice(s) are incorrect; the practice(s) should be changed **before** the QM is changed.*
- review policy statement to ensure the scope is relevant to your laboratory;
- the review document may need to be sent to the responsible committee (if one exists) before sending to the Head of Laboratory.

3.2.5 **Internal audits** (OIE Standard section 4.11)

The importance of performing good internal audits cannot be over estimated.

Policy

- The laboratory will establish an internal audit process that meets the requirements of the OIE Standard.

- An Internal Audit Schedule will be created. All elements of the QS will be audited as prescribed in the Internal Audit Schedule. Reports will be made of all Internal Audits. Reports of Internal Audits will be controlled documents.

Procedures

The following are areas/activities for which procedures need to be created and documented.

- all elements of the QS are subject to internal audits at least annually;
- *decide on what type of audit will be carried out and when. There are two types, horizontal and vertical. Horizontal deals with one process or aspect (e.g. training, across different sections/ departments within a laboratory) and vertical deals with various process processes or aspects (e.g. training, SOPs, calibration, etc.) within a section/department examining them from the beginning to the end. Vertical takes longer to achieve*;
- identify who will undertake and manage the internal audit procedure and arrange for their training with an accreditation agency;
- *it may be appropriate to establish an Internal Audit Group of which the person selected as the internal auditor will be part;*
- *so that the process of internal audits is not interrupted make sure they are undertaken when relevant staff are at the laboratory;*
- *each laboratory section/department may be audited by following specimens taken at random (e.g. 2 or 3 specimens per laboratory section/department) through the entire diagnostic test procedure;*
- maintain an audit schedule status log and audit check list (Annex 2);
- use a template for report writing. An example of an internal audit report is provided in Annex 3 ;
- produce internal audit report and submit to Internal Audit Group for review;
- following the Internal Audit Group review, list any corrective action(s) taken and follow the progress of the implementation of the corrective actions (Annex 4*). If necessary give time limit on when actions should be taken to correct "corrective actions".*

3.2.6 **Quality Control, QC** (OIE Standard section 5.9)

Internal QC Policy

- All test methods shall be subject to internal QC procedures and all results will be logged in compliance with the OIE Standard.
- Internal QC procedures for each Test Method will be described (i.e. individual Test Method Protocols).
- Internal QC results will be regularly reviewed by the appropriate staff member, and the review documented.
- Procedure(s) for action in response to internal QC failure(s) will be documented.

Internal QC Procedure

- All diagnostic tests shall be subject to internal QC procedures. These procedures need to be described **[7]**.
- a running log of internal QC should be established and maintained. This log should be reviewed periodically. The process needs to be described and documented;
- diagnostic tests shall be controlled using standard reagents. Traceability of all standard reagents will be documented. Provide an explanation of how the procedure is performed.

External QC Policy

- The laboratory shall participate in appropriate external QC/QA programmes whenever possible and practicable.
- All test methods shall be subject to external QC procedures *whenever possible and/or practicable* and all results will be logged in compliance with the OIE Standard.
- *The Technical Manager (or equivalent responsible officer) shall decide on the appropriateness of participation in a particular external QC/QA system.*

External QC procedures

Diagnostic tests shall be subject to external QC procedures *whenever appropriate and available*. These procedures need to be described.

- A running log of external QC should be established and maintained. This log should be reviewed periodically. Describe and document the process that may be required of the laboratory when the laboratory is involved in an external QC assessment (e.g. the FAO/IAEA EQA Programme) and identify the responsible person.

Remember: *External auditors look at policy and procedures to ensure they comply to the Standard you are using.*

3.2.7 **Contract review** (OIE Standard section 4.4)

Do not accept work that you cannot achieve. If you subcontract the work to another laboratory they do not have to be compliant to the OIE Standard, but the customer must know this and agree to using the subcontractor.

Policy

- A review of all contracts and requests for diagnostic testing shall be undertaken as required under the OIE Standard. *This review shall be documented.*

Procedures

- Document who decides if the laboratory can undertake the testing requested. Document how the requests will be recorded and filed.

3.2.8 **Corrective and Preventative action** (OIE Standard section 4.9)

Policy

- Corrective action shall be initiated in response to any non-conformance or failure in the quality system.
- *Corrective action will also be initiated when an opportunity for improvement is identified.*

(Note: non-conformance means any failure to comply with a documented QS procedure or requirement.)

Procedure

- *Staff should be encouraged to initiate corrective action. The benefit to staff to do so is reflected in their performance appraisal. Describe how a corrective action is initiated. How are the actions documented (the use of a Corrective Action Request Form is useful)? Where and how are documents logged and filed. Who is responsible for following up corrective actions? Corrective actions may be initiated in response to internal/external QC/QA failures, internal/external audits, annual Management Reviews, customer complaints, equipment failures, etc, and/or as a way of documenting updates to Test Methods, staff records or other operating procedures.*

Remember*: undertaking corrective actions is a POSITIVE process, not a NEGATIVE one. (some organizations refer to this as "An Opportunity for Improvement" ! Rather than corrective action)*

3.2.9 **Staff and Training** (OIE Standard section 5.2)

Policy

- The laboratory shall ensure that all staff have the necessary training and experience to carry out the work assigned to them.
- The Technical Manager is responsible for ensuring that diagnostic work is only carried out by staff appropriately trained and approved.
- Records will be maintained of staff training and experience.
- Include induction process when beginning career at laboratory, further training or continuous professional training (CPD) and training in new techniques.

Procedures

- Describe the training procedure and show that it is compliant with the OIE Standard.
- *Refer to any staff recruitment procedures the laboratory operates, and any education requirements associated with particular positions in the laboratory (these may be procedures held by the Personnel Dept, etc. Don't rewrite them. Just refer to them).*

Staff records
This shall include job descriptions (Annex 5), line of responsibility, and training records (Annex 6). *It is important to define responsibilities and authorities.*

3.2.10 **Accommodation and environment conditions** (OIE Standard section 5.3)

Policy

- State that the laboratory and its environment shall not adversely affect results and shall be compliant with National Standards (if they exist) and the OIE Standard.

Procedures

- Document who is responsible for ensuring that the policy is met and maintained, and how this will be assessed.

3.2.11 **Equipment (inventory, calibration and maintenance)** (OIE Standard section 5.5)

Policy

- State that the equipment is appropriate for the use to which it will be put. That staff are trained in its use and maintenance, and where appropriate, the equipment is maintained and calibrated in accordance with the OIE Standard. Equipment Manuals, shall be listed providing location and a unique number, and be available to staff as required.
- Appropriate records will be maintained.

Procedures

- All equipment shall be given a unique inventory number, *and it is useful to create a complete (Master) list of equipment. The list can contain information on the maintenance and/or calibration requirements for each item of equipment, (i.e. temperature range for refrigerators, +/- limits for pipettes), and the location of each item. Define responsibility for creating, maintaining and amending this list.*

- Produce a maintenance/calibration schedule and record for each piece of equipment (an example is provided in Annex 7).
- Ensure the maintenance and calibration date, and the date due is recorded on a label fixed to each piece of equipment.
- Provide an explanation of the procedure undertaken if equipment fails.

3.2.12 **Equipment calibration and Performance checks** (OIE Standard section 5.5)

Policy

- Equipment shall be calibrated and maintained in a manner assuring the quality of the test performed.

Procedures

Two types of procedure exist:
- external by calibration laboratory (e.g. metrological institutes);
- internal by own laboratory **[16]**.

In each case there will be different calibration intervals and performance checks. Annex 7 provides general guidelines to calibration intervals and performance checks for equipment commonly used in veterinary laboratories and therefore should be used as a guide only. It should be noted that where equipment has not been used for sometime then it should be checked and calibrated prior to use.
- escribe documentation procedures.

Describe who is responsible for carrying out maintenance and calibration on equipment (i.e. in-house, off-site contractors), and the process by which this will occur. NOTE: This information may be part of a separate operating procedure, if so, it will need to be referred to under this section.

3.2.13 **Methods** (OIE Standard section 5.4)

Policy

- Methods used in the laboratory will be approved for use by competent staff.
- Wherever possible the laboratory shall use Internationally approved diagnostic test methods as prescribed in the OIE Manual of Standards for Diagnostic Tests and Vaccines and/or by recognized Reference laboratories.
- In house methods shall be fully validated as prescribed in the OIE Manual of Standards for Diagnostic Tests and Vaccines.
- Test Methods will be written according to the approved format and reference should be made to where the format is available.
- Approved Test Method protocols will be controlled documents.
- The supervisor is responsible for ensuring that staff have the latest version of the Test Methods available as required.

Procedures

- Provide method on how the test methods are approved to the OIE Standard and identify a staff member, closely linked to the laboratory (e.g. project leader), who will be responsible for maintaining records (a tree chart of managing records is provided in Annex 8). Also provide a procedure for how the methods are up-dated, how the records are numbered and who is responsible for record disposal.
- Use standard format for method and document under procedures.

- It is advised that there is an agreement on the diagnostic test acronyms to be used in all documents and throughout the laboratory, and they are documented (e.g. AGID, HAI, VNT, c-ELISA, etc.).

Staff list

- List the staff approved as test operators, the staff who have performed the test, whom could deputize at short notice and those staff capable of performing the test. (NOTE: this information should also be recorded on the staff records under section 3.9.3).

Test methods used

- List test methods performed at the laboratory.

3.2.14 **Sample management** (OIE Standard section 5.8)

Policy

- The laboratory will have documented procedures for accepting, logging, identifying, protecting, retaining and discarding specimens, samples or items for testing in accordance with the requirements of the OIE Standard.
- The procedures will be approved by the Technical Manager or equivalent.
- Advice to specimen submitters on the type of specimen required for a particular diagnostic investigation, its storage and safe transportation, will be provided by the laboratory.
- Responsibility for ensuring that Sample Management procedures are followed will be delegated to an appropriate member of staff (e.g. Technical Manager or equivalent).

Procedures

Receiving specimens:
State how specimens are received and given accession numbers, and the procedures undertaken when specimens are received in poor condition or if leakage occurs through packaging. State who is responsible. Describe the procedure for receipt of specimens outside of office hours (if you have one.)

- *Distributing specimens*: provide procedure for distributing specimen submissions, ensuring appropriate handling and storage.
- *Specimen retention*: provide procedure for specimen retention.
- *Referring specimens*: provide procedure for referring specimens to other laboratories, how it is recorded and who is responsible.
- *Disposal of specimens* *provide procedure for the disposal of specimens and the recording of the disposals.*
- *Responsible staff*: list those responsible and what they are responsible for.

3.2.15 **Records** (OIE Standard section 4.10)

Policy

- All records shall be maintained and archived in an appropriate manner and in compliance with the requirements of the OIE Standard. *Record here if the laboratory has a policy regarding record keeping with which you also need to comply*. *Detail which records will be kept.*

Procedure

- State how records are created and maintained, and the procedure used. Who is responsible for ensuring the procedure is carried out, who will create the records, file them, sign for them and archive them.

***Remember**: "Records" includes the original laboratory test readings/results such as ELISA results, or VNT observations, as well as such items as Internal Audit Reports and Management Review Reports, etc. You may need to describe different processes for the different types of Records. It may be possible to state that this section/department deals only with laboratory result reports, and that other Records are dealt with in the appropriate sections/departments (In Annex 8 the results related part is bold).*

- If laboratory results are recorded electronically describe the system here. Details such as back-ups, who is responsible, who has permission to add and edit data, etc. should be provided in a SOP.

3.2.16 Reports (e.g. diagnostic reports to customers) (OIE Standard section 5.10)

Policy

- All reports of diagnostic testing will be in writing, and signed by an approved member of staff in compliance with the requirements of the OIE Standard.
- Staff will be approved for signing diagnostic reports.
- All Reports will be filed in compliance with the requirements of the OIE Standard. Reports of diagnostic testing will be regarded as confidential by all staff

.

Procedure

- Include how reports are created and stored. A staff member could be allocated the responsibility of document controller. Include how reports are forwarded to customers/clients. All reports shall be signed by authorized personnel. Describe how amendments to reports will be made when necessary. If a fee is charged for testing, describe how this is carried out.

3.2.17 External resources (purchasing and subcontractors) (OIE Standard sections 4.5 & 4.6)

Note: This may include off-site calibration/maintenance of equipment and the forwarding of samples to other laboratories.

Policy

- All materials that have an effect on the outcome of the test shall be specified. The quality required of supplied materials (i.e. ELISA plates, conjugate, reference reagents), will be specified and monitored.

Procedure for sub-contracting

- Identify suppliers and determine if their products, reagents, etc. will provide consistent results.

Customer agreement should be sought before using a sub-contractor.
Use, or refer to, any existing laboratory procedures for sub-contracting.

Procedure for purchasing

- *Use, or refer to, any existing laboratory procedures for purchasing. There may be Departmental or Ministry requirements covering purchasing by the laboratory.*
- Specify materials used in tests and how purchases made. It may be appropriate to obtain purchasing information from the purchasing officer.

The quality required of supplied materials (i.e. ELISA plates etc) can be specified in the Test Methods.

- The performance of suppliers should be reviewed periodically.

3.2.18 **Complaints** (OIE Standard section 4.7)

Policy

All complaints will be dealt with by (insert name of responsible person) and documented, with a record of action taken documented

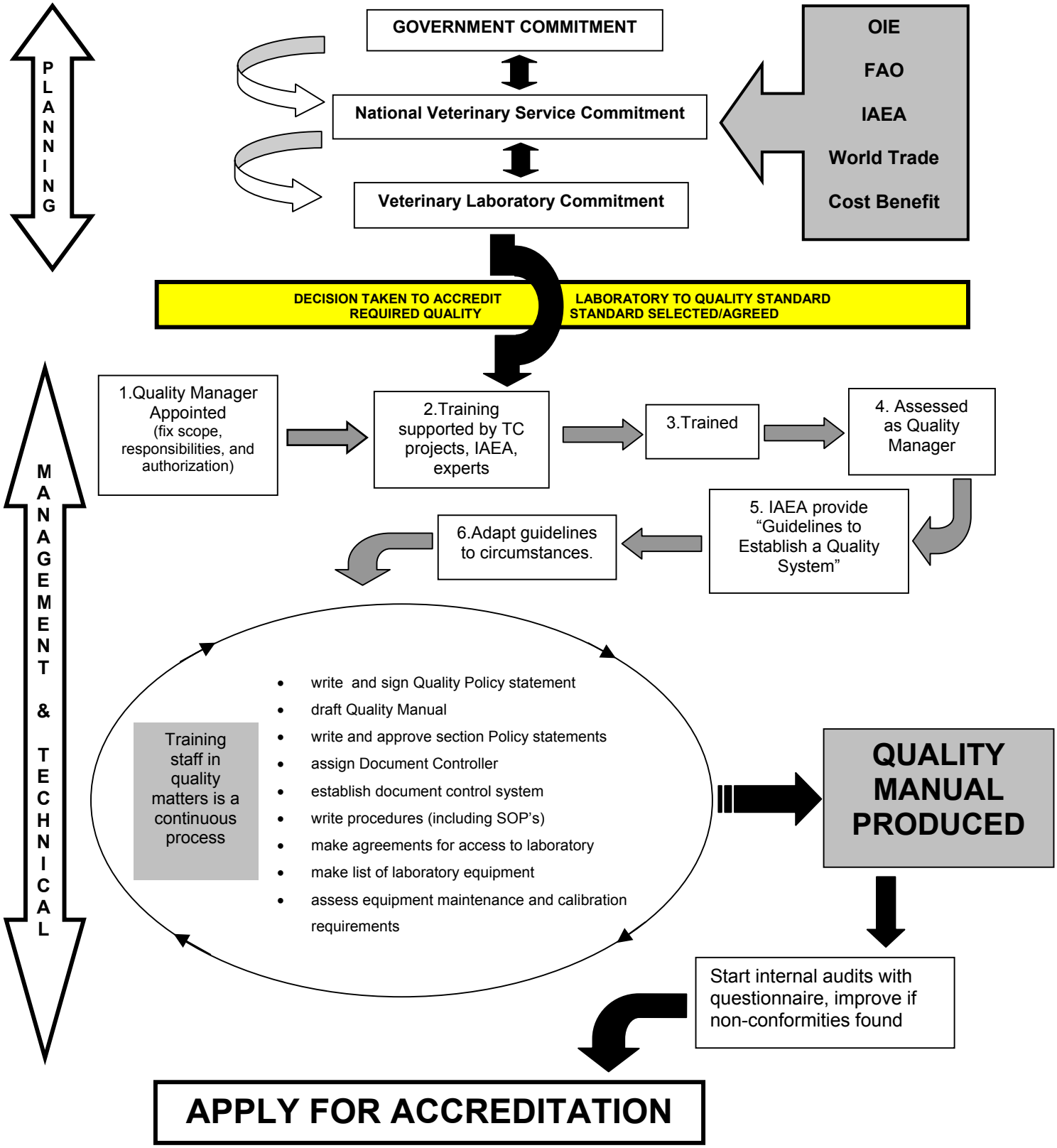
.

Procedure

Provide method to deal with complaints and their correction. It may be necessary to appoint a complaints officer. Produce a hardcopy template for recording complaints.

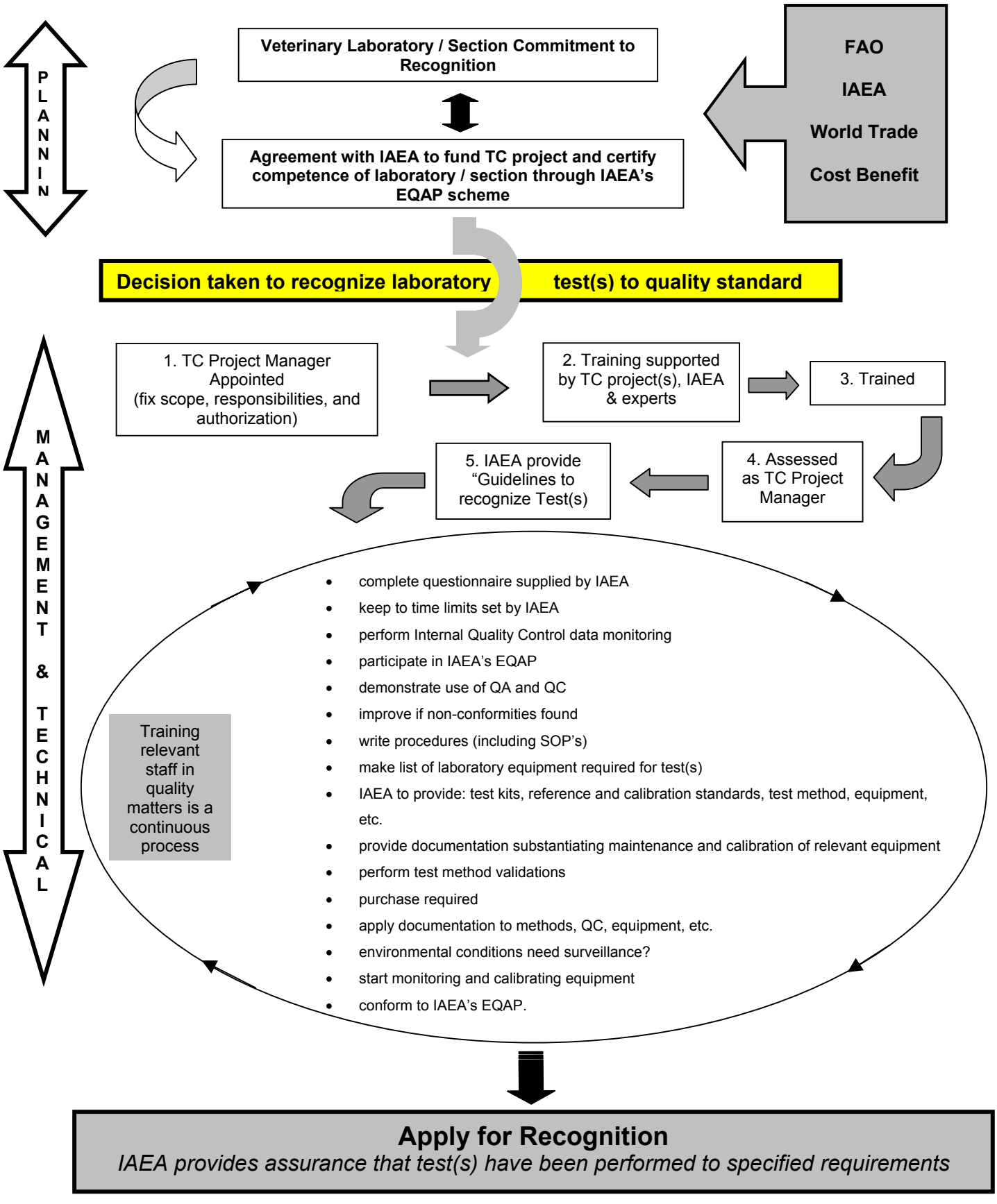
4. STAGES IN THE IMPLEMENTATION OF THE OIE STANDARD

The flowchart, below, of this element should be read in conjunction with the logical framework (Annex 8a) and GANTT Chart (Annex 9).



5. STAGES IN APPLYING FOR RECOGNITION

The flowchart, below, of this element should be read in conjunction with the NATA flowchart (Annex 8b).



6 REFERENCES

1. IAEA, Establishment of external quality assurance procedures for use with FAO/IAEA ELISA kits, Report of an FAO/IAEA Consultants Meeting, IAEA, FAO/IAEA Animal Production and Health Subprogramme, Vienna, 12-16 September 1994.
2. OIE Manual of standards for Diagnostic Tests and Vaccines, Chapter 1.1.2. Quality Management in Veterinary Diagnostic Laboratories, 8-14, Standards Commission of the OIE, 2000.
3. ISO/IEC 17025 (1999). General requirements for the competence of testing and calibration laboratories. International Organization for Standardization (ISO), Geneva, ed. 1.
4. ISO Standards Series – International Organization for Standardization (ISO), Geneva:

ISO 9000 : 2000	Quality Management systems - Fundamentals and vocabulary
ISO 9001 : 2000	Quality Management systems – Requirements
ISO 9004 : 2000	Quality Management systems – Guidelines for performance improvements
HB90.0 : 2000	The ISO 9001 Comparison 2000 vs 1994

5. National Association of Testing Authorities (1995). Quality management in the laboratory – Quality system and it's documentation.
6. Australian/New Zealand (1996). Guidelines for developing quality manuals – AS/NZ ISO 10013. Joint Standards Australia and Standards New Zealand. ISBN 0 7337 0360 7.
7. Rebeski, D.E., Winger, E.M., Ouma, J.O., Kong Pages, S., Büscher, P., Sanogo, Y., Dwinger, R.H., Crowther, J.R., 2001. Charting methods to monitor the operational performance of ELISA method for the detection of antibodies against trypanosomes. Vet. Parasitol. 96, 11-50.
8. Cornell University, Suggested Format for Writing of Standard Operating Procedures, produced by the Task Force on Quality Assurance (1999).
9. National Association of Testing Authorities (1995). Documenting your laboratory quality system – System procedures.
10. National Association of Testing Authorities (1995). Guide to the development of a quality system for a laboratory.
11. Nuclear Application in Agency's Laboratories, Vienna I
12. National Association of Testing Authorities (1995). Quality management in the laboratory – Staff resources and responsibilities.
13. Co-operation on International Traceability in Analytical Chemistry (1995). International guide to quality in analytical chemistry – An aid to accreditation. CITAC CG1, ed. 1, 12/95, ISBN 0 948926 090.
14. International Organization of Standards (1992). Quality assurance requirements for measuring equipment – Part 1 and Annex A.
15. Crowther, J.R. (2000). The ELISA Guidebook. Methods in Molecular Biology, vol. 149. Humana Press, New Jersey.
16. Lunt, R. (1997). Pipette Calibration: colormetric method for verifying pipette delivery volume for use with pipettes dispensing volumes of up to 250 microlitres. Australian Animal Health Laboratory Disease Diagnosis Project.
17. Garfield, F. (1997). Quality assurance principles for analytical laboratories – Appendix C: instrument performance check. AOAC International, ed. 5. ISBN 0 935584 46 3.
18. Wiggins, S. and Shields, D. (1995). Logical framework – clarifying the 'logical framework' as a tool for planning and managing development projects. Project Appraisal, 10, 1. Beech Tree Publishing, UK.
19. Burke, R. (1999). Project Management – Planning and Control Techniques. 3rd ed., J. Wiley & Sons Ltd, UK

COUNTRY	ORGANIZATION	WEBSITE
-	European Accreditation Service (EA)	http://www.european-accreditation.org
-	International Accreditation Forum (IAF)	http://www.iaf.nu
-	International Laboratory Accreditation Co-operation (ILAC)	http://www.ilac.org
Argentina	Organismo Argentino de Acreditacion (OAA)	http://www.oaa.org.ar/Informacion/informacion.htm
Australia	National Association of Testing Authorities (NATA) ***An interactive web-based training programme is available***	http://www.nata.asn.au http://www.aplactraining.asn.au
Austria	International Atomic Energy Agency (IAEA)	http://www.iaea.org
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
France	Office International des Epizooties (OIE)	http://www.oie.org
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
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.nitg.go.kr)	http://kolas.ats.go.kr/
Malaysia	Standards & Industrial Research Institute (SIRIM) and Skim Akreditasi Makmal Malaysia (SAMM)	http://www.sirim.my/
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/qrc/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
United Kingdom	UK Accreditation Service (UKAS)	http://www.ukas.com
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

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APPENDIX 1: AGENDA OF FIRST CONSULTANTS MEETING/WORKSHOP

JOINT FAO/IAEA DIVISION
OF NUCLEAR TECHNIQUES IN FOOD AND AGRICULTURE
INTERNATIONAL ATOMIC ENERGY AGENCY
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Joint Consultants Meeting/Workshop
on
"Developing Standardized Training Material To Assist FAO/IAEA Member States To Establish Quality Systems For Veterinary Diagnosis Laboratories"

4-8 September, 2000
Vienna International Centre, Austria
(Room B 0545, Tel. 2600-21450)

AGENDA

MONDAY, 4 SEPTEMBER

09.00 – 09.15	Opening Remarks Oswin Perera *(Acting Head, Animal Production and Health Section, Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture)*
09.15 – 09.30	Opening Remarks (Contd.) *Jorge Morales, Mokdad Maksoudi, Carlitos R. Aleta (Regional Coordinators, Department of Technical Cooperation)*
09.30 – 10.15	The FAO/IAEA EQA programme: Past, present and future *Axel Colling, Mario Garcia, Martyn Jeggo (AP unit and AP&H Section)*
10.15 – 10.45	Coffee
Session 1	**Current views and trends of Quality Systems in Veterinary Diagnosis Laboratories** *Chairperson: Richard Jacobson*
10.45 – 11.30	The Role of the Office International des Epizooties in Developing Diagnostic Laboratory Quality Assurance Programs *Jim Pearson (OIE, France)*
11.30 – 12.15	Experiences with the implementation of a Quality System at the IAEA Laboratories *Ales Fajgelj (Quality Assurance Supervisor, IAEA Laboratories)*
12.15 – 14.00	Lunch
Session 1 (Contd.)	**Current views and trends of Quality Systems in Veterinary Diagnosis Laboratories** *Chairperson: Jim Pearson*

14.00 – 14.45	Laboratory Accreditation: Experiences in Germany *Brigitte Thoms (AKS, Germany)*
14.45 – 15.30	Establishing Quality Systems and Laboratory Accreditation: Experiences in Australia and developing countries *William J. Doughty (CSIRO, Australia)*
15.30 – 16.00	Coffee
16.00 – 16.45	Principles of assay validation *Richard Jacobson (University of Cornell, USA)*
16.45 – 17.30	Data Recording Management Systems for Veterinary Laboratories in Developing Countries *Ian Gumm (University of Reading, U.K.)*
18.00	Cocktail reception

TUESDAY, 5 SEPTEMBER

Session 2	**Current situation of Quality Systems in Veterinary Diagnosis Laboratories in developing countries** *Chairperson: Brigitte Thoms*
09.00 – 09.30	Status and needs of Quality Systems in Veterinary Diagnosis Laboratories in Cote d'Ivoire *Emmanuel Couacy-Hymann (Cote d'Ivoire)*
09.30 – 10.00	Serodiagnostic activities and quality control measures of diagnostic assays at OVI *Janusz Paweska (South Africa)*
10.00 – 10.30	Status and needs of Quality Systems in Veterinary Diagnosis Laboratories in Peru *Ana Maria Espinoza (Peru)*
10.30 – 11.00	Coffee
Session 2 (Contd.)	**Current situation of Quality Systems in Veterinary Diagnosis Laboratories in developing countries** *Chairperson: Ian Gumm*
11.00 – 11.30	Status and needs of Quality Systems in Veterinary Diagnosis Laboratories in Colombia *Olga Mariño (Colombia)*
11.30 – 12.00	Status and needs of Quality Systems in Veterinary Diagnosis Laboratories in the Philippines *Blesilda Verin (Philippines)*

12.00 – 12.30 Status and needs of Quality Systems in Veterinary Diagnosis Laboratories in Malaysia
Mohamed Naheed (Malaysia)

12.30 – 14.00 Lunch

Session 3 **Review of the OIE Standard**
Chairperson: William Doughty

14.00 – 16.00 The OIE standard: practical aspects

16.00 – 16.30 Coffee

16.30 – 18.00 (Contd.) The OIE standard: practical aspects

WEDNESDAY, 6 SEPTEMBER

Session 4 **Identification of Tasks for Group Work**
Chairperson: Richard Jacobson

0.9.00 – 10.30 Quality systems and accreditation in veterinary diagnosis laboratories of developing countries:
- The structure of a convenient pathway: a stepwise approach
- Basic, important and recommended requirements
- Generic documentation and training material
- National commitment and IAEA inputs
- Accreditation bodies in developing countries

Assignment of participants to working groups

10.30 – 11.00 Coffee

11.00 – 12.30 Group work to develop the assigned tasks

12.30 – 14.00 Lunch

Session 5 Preparation of QA Programme and training material
Chairperson: William Doughty

14.00 – 16.00 Group work to develop the assigned tasks

16.00 – 16.30 Coffee

16.30 – 17.30 Presentations by group leaders and discussion

17.30 - 18.00 Evaluation of progress, selection of QA material to be drafted and reformulation of working groups

19.30 Social gathering
Restaurant Bamkraxler, Kahlenberger Str. 17, A-1190 Wien
Tel. 3188800

THURSDAY, 7 SEPTEMBER

Session 5 (Contd.)	**Preparation of QA Programme and training material** *Chairperson: Brigitte Thoms*	
09.00 – 10.30	Group work to develop the new assigned tasks	
10.30 – 11.00	Coffee	
11.00 – 12.30	Presentations by group leaders and discussion	
12.30 – 14.00	Lunch	
14.00 – 16.00	Consultants: Workshop participants:	Preparation of QA material Work plan, timetable and commitment for implementing QS towards accreditation
16.00 – 16.30	Coffee	
16.30 – 18.00	(Contd.) Consultants: Workshop participants:	 Preparation of QA material Work plan, timetable and commitment for implementing QS towards accreditation

FRIDAY 8 SEPTEMBER

Session 5 (Contd.)	**Preparation of QA Project Document and training material** *Chairperson: Ales Fajgelj*	
09.00 – 10.30	Preparation of QA material	
10.30 – 11.00	Coffee	
11.00 – 12.30	Plenary group: Evaluation of progress and identification of further tasks to be completed by the AP&H Sub-programme	
12.30 – 14.00	Lunch	
Session 6	**Conclusions and recommendations** *Chairperson: Ian Gumm*	
14.00 – 16.00	Conclusion and recommendations	
16.00	Closure of meeting	

ANNEX 1 FORMAT FOR WRITING STANDARD OPERATING PROCEDURES (SOP)
FOR CALIBRATION AND MAINTENANCE

(This Standard Operating Procedures is taken as an example from the Quality Manual of the Animal Production Unit of the IAEA Laboratories, Seibersdorf.)

1. Title: **Calibration, maintenance and use of pH/conductivity meters**

2. **Purpose:** This instruction describes the steps used to calibrate, maintain, and use pH and conductivity meters under the control of the Unit.

3. **Scope:** This instruction applies to only those pH and conductivity meters that are kept and used within the Unit's laboratory rooms.

4. **Definitions:** none

5. **References:** Manufacturer's instruction manual with each meter.

6. **Responsibilities:** It is the responsibility of all Unit staff to follow this instruction when calibrating, performing maintenance, and/or using a pH or conductivity meter in the conduct of Unit activities.

7. **Prerequisite:** The staff member shall have a working knowledge of the concepts of ions, acids, bases, pH units.

8. **Precautions:** The solutions used for pH or conductivity calibrations and pH titration of solutions can be dangerous. Appropriate clothing (e.g., lab coat, gloves, etc.) and eye-protection shall be used while performing any part of this instruction.

9. **Procedure:**

9.1) The electrode shall be stored according to the specifications of the manufacturer's instruction manual.

9.2) Calibration of the meter shall be done according to the procedures of the manufacturer's instruction manual. If the meter cannot be calibrated properly, it shall be taken out of service until it is repaired and shown to be operating properly.

9.3) Routine maintenance of the meter and electrode shall be done according to the procedures of the manufacturer's instruction manual.

9.4) The meter shall be used according to the procedures of the manufacturer's instruction manual.

10. **Records:** A record of the meter used and the calibrations done for any procedure shall be kept by the responsible staff member with the notes for that procedure in the laboratory record. Routine maintenance and any repairs shall be documented by the responsible staff member in an equipment log book that is kept with the manufacturer's instruction manual for each meter.

11. **Appendix:** List of pH and conductivity meters.

List of pH and conductivity meters

Room	IAEA number (other)	Brand
DM 04	none (M1138)	Mettler Delta 350
DM 09	none (54673)	Schott
LW 14	15652	WTW Multilab 540

ANNEX 1 CONTD: FORMAT FOR WRITING STANDARD OPERATING PROCEDURES (SOP) **FOR TESTS**

The following provides guidance to the content and format of a SOP for a test procedure. The information in *italics* describes what is meant by the name of the SOP section/sub-section and the type of information that would be required [**8, 9**].

Title page	*Include: **1**. concise test title in full, **2**. name of disease or condition, **3**. Type of test or assay used, **4**. name of Authority (e.g. Department of Agriculture), **5**. name of country, **6**. abbreviation of test title.*
Revision page	*Include: **1**. previous versions, **2**. author, **3**. authorization, **4**. Date.*
Table of Contents	
1. Introduction	
1.1 Disease	*Concise description of disease or condition that is under investigation*
1.2 Assay	*Name and concise description of assay(s) or test(s) used in the investigation*
1.3 Results	*Describe briefly how results are calculated and expressed*
1.4 References	*Include all references to the assay or test*
1.5 Abbreviations	*Define abbreviations and terms used in the text that are either not common, have not been defined in the QM or their meaning is specific to the procedure.*
2. Equipment	*List all equipment used in the investigation, including manufacturer, model and room where equipment kept (e.g. Class II cabinet in isolation room no.)*
3. Reagents	
3.1 Chemicals	*List all chemicals and/or biologicals used in the investigation, including make, manufacturer, batch number and storage conditions. It may be necessary to refer to other SOPs if such material (e.g. cell cultures) are prepared using methods that are already described by other SOPs.*
3.2 Biologicals	
4. Preparations	
4.1 Preparation of samples	*Include type of sample, how did samples arrive and in what condition. What method(s) were used if samples arrived in an unexpected condition (e.g. clotted blood instead of serum). How were samples treated or prepared prior to testing and how were they stored.*
4.2 Staff training and approvals	*Do the relevant staff, have the necessary training and therefore authority to undertake the work. State their name, position and type of training they have received, and what special procedures they are familiar with (e.g. microbiological spills). Can the work be carried out under the required conditions? If appropriate, are the staff vaccinated.*
5. Test Performance	
5.1 Pre-conditions	*What, if any, are the safety considerations and other issues relevant to the SOP being used in a responsible manner.*
5.2 Assay or test procedure	*Describe where the test or assay is carried out and state if these are approved for such work.* *Provide a step-by-step sequence (e.g. flowchart or actions that are bulleted or numbered) of the actions required to achieve the purpose of the procedure. Also provide details of what is to be done, and when, where and how it is to be done.*
6. Results	
6.1 Calculations	*If appropriate include how results are calculated. If computer usage is required provide name of software used and where the relevant file(s) are located.*
6.2 Readings	*If appropriate include how reading the test or assays are read, and where and how they are recorded.*
6.3 Acceptance	*State what is or are the criteria for accepting a valid result (e.g. what result should the positive and negative controls give). Also state what system is in*

	place for re-running a test if the controls do not pass control checks
6.4 Interpretation	*State what is or are the criteria for interpreting the result (e.g. the controls should show a certain level of reaction between predefined limits). Indicate if any degree of caution should be exercised regarding related diseases or conditions.*
6.5 Recording	*Samples are recorded as positive, negative or otherwise (e.g. uncertain) by recording on worksheets on the basis of the criteria given in the results and interpretation. When making the recording it may be necessary or useful to link the result(s) and interpretation in a spreadsheet.*
6.6 Reporting	*State procedures for reporting result(s), to whom they are reported.*
7. Specimen Retention	
7.1 Retention record	*State where, at what temperature and for how long are the specimens stored. It may be necessary to itemize where different specimens are kept, (e.g. sera at –20^{o}C, viruses at –80^{o}C. Specimens shown to be negative may be stored differently to specimens that are positive).*
7.2 Disposal of samples	*State how, where and when the specimens were disposed. Reference can be made to another SOP that describes the disposal procedure).*
8. Quality Assurance	*State how is the performance of the assay or test monitored. If the information does not appear as an appendix to the SOP where is it kept.*
9. Appendices	*Appendices may include test cover sheets that can include: **1**. criteria for accepting test results, **2**. sample records, **3**. results sheets, and **4**. details of how media, stains, viruses, bacteria, etc. are prepared and worked with. In some cases (e.g. ELISA) it may be necessary to include allowing the progressive monitoring of test performance indicators.*

ANNEX 1 CONTD: FORMAT FOR WRITING STANDARD OPERATING PROCEDURES (SOP) **IN DETAIL [8]**

1. Title page (first page)

Name and short address of laboratory, and logo (*if applicable*)	**Page 1 of….**	
	Quality Manual	*Insert version number of manual*
	SOP	*Insert unique number that will allow this particular SOP to be distinguished from the other SOPs.*
	Number of updates	*Insert number*

*NOTE: The information above should be included in the **header** of **each** page of the SOP.*

Test title in full

Name of disease or condition

Type of test or assay used

Name of Authority (e.g. Department of Agriculture)

Name of country

Abbreviation of test title

NOTE: The following table and information should be included in the footer of each page of the SOP:

Author	*Insert name(s) in this column*	*Insert date(s) in this column*
Authorized by		
Published by		

If this document is printed it becomes an UNCONTROLLED VERSION. Please refer to the …(*add here where the SOP is stored electronically)* for the latest version.

---

2. Revision page (second page)

REVISION PAGE

Previous Versions	Author	Authorization	Date

---

3. Table of Contents page (to include page numbers)

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4. The technical content of the **subsequent pages** of the SOP will follow the table of contents, above.

ANNEX 2 EXAMPLE OF AN INTERNAL AUDIT CHECK LIST

Note: Internal Audits are the laboratory's own process for monitoring the correct implementation of its quality system. Internal audits are used to demonstrate that the laboratory's documented quality system processes are being followed.

1. Title:	**INTERNAL AUDIT CHECK LIST [10]**
2. Purpose:	This working instruction gives guidance for internal auditors in performing internal audits and supports the Internal Audit Procedure **[10]**.
3. Scope:	This working instruction is to be used only by internal auditors at the laboratory (state where or provide address).
4. Definitions:	Provide definitions as appropriate
5. References:	Provide references if applicable
6. Responsibilities:	The internal audit team leader is responsible for performing the task according to these instructions and to take care that the relevant records will be submitted as described in Section/Element 3.3.
7. Precondition:	This instruction applies only when internal audit date is announced and agreed in advance **[9]**.
8. Precautions:	This checklist is not exhaustive and it only provides a basic guide to the auditors.
9. Procedure:	Check list provided below:

a) Staff

i) Staff have the appropriate blend of background, academic or vocational qualifications, experience, and on-the-job training for the work they do.
ii) On-the-job-training is carried out against established criteria, which are objective. Up-to-date records of the training are maintained.
iii) Tests are only carried out by authorized analysts.
iv) The performance of staff carrying out analyses is observed by auditor.

b) Environment

i) The laboratory environment is suitable for the work carried out.
ii) The laboratory services and facilities are adequate for the work carried out.
iii) There is adequate separation of high and low level work.
iv) The laboratory areas are sufficiently clean and tidy to ensure the quality of the work carried out is not compromised.
v) There is adequate separation of sample reception, preparation, clean-up, and measurement areas, to ensure the quality of the work carried out is not compromised.
vi) Adherence to safety regulations is consistent with the requirements of the quality management standard.

c) Equipment

i) The equipment in use is suited to its purpose.
ii) Staff are trained in the use of equipment as necessary.
ii) Major instruments are correctly maintained and records of this maintenance are kept.
iii) Appropriate instructions for the use of equipment are available.
iv) Traceable equipment (e.g. balances, thermometers, glassware, timers, pipettes, etc.) are appropriately calibrated, and the corresponding certificates or other records demonstrating traceability to national (international) measurement standards are available.
v) Calibrated equipment is appropriately labeled or otherwise identified to ensure that it is not confused with uncalibrated equipment and to ensure that its calibration status is clear to the user.
vi) Instrument calibration procedures and performance checks are documented and available to the users.
vii) Instrument performance checks and calibration procedures are carried out at appropriate intervals and show that calibration is maintained and day-to-day performance is acceptable. Appropriate corrective action is taken where necessary.
viii) Records of calibration, performance checks and corrective action(s) are maintained.
ix) Manufacturer's Manuals are controlled and available to staff as necessary.

d) Methods and Procedures

i) In-house methods are fully documented, appropriately validated, and authorized for use.
ii) Alterations to methods are appropriately authorized.
iii) Copies of published and official methods are available.
iv) The most up-to-date version of the method is available to the analyst.
v) Test procedure inserts from Test Kits are controlled and available to staff.

vi) Analyses are (observed to be) following the methods specified.
vii) Methods have an appropriate level of advice on calibration and quality control.

e) Chemical and Physical Measurement Standards, Certified Reference Materials and Reagents

i) The measurement standards required for the tests are readily available.
ii) The measurement standards are certified or are the "best" available.
iii) The preparation of working measurement standards and reagents is documented.
iv) Measurement standards, reference materials and reagents are properly labeled and correctly stored.
v) New batches of measurement standards, and reagents critical to the performance of the method are compared against old batches before use.
vi) The correct grade of materials is being used in the tests.
vii) Where measurement standards or reference materials are certified, copies of the certificate are available for inspection.

f) Quality Control

i) All Internal and External QC procedures are documented.
ii) There is an appropriate level of quality control for each test.
iii) Where control charts are used, performance has been maintained within acceptable criteria.
iv) QC check samples are being tested by the defined procedures, at the required frequency and there is an up-to-date record of the results and actions taken where results have exceeded action limits. QC results are subject to appropriate review.
v) Results from the random re-analysis of samples show an acceptable measure of agreement with the original analyses.
vi) Where appropriate, performance in proficiency testing schemes and/or inter-laboratory comparisons is satisfactory and has not highlighted any problems or potential problems This process is documented, results are filed and subject to review.
Where performance has been unsatisfactory, corrective action has been taken.

g) Sample Management

i) There is an effective documented system for receiving samples, uniquely identifying samples against requests for analysis, showing progress of analysis, issue of report, and fate of sample.
ii) Samples are properly labeled, handled and stored, and sample retention procedure is documented.
iii) The documented procedures are being followed.

h) Records

i) Notebooks/worksheets or other records show the date of the test, analyst, analyte to be measured, sample details, test observations, quality control, all rough calculations, any relevant instrument traces, and relevant calibration data.
ii) Notebooks/worksheets are completed in ink, mistakes are crossed out rather than erased or obliterated, and the records are signed by the analysts.
iii) Where a mistake is corrected the alteration is signed by the person making the corrections.
iv) The laboratory is complying with its procedures for checking data transfer and calculations.

i) Test Reports

i) The information given in reports is consistent with the requirements of the relevant quality management standards, and reflects any provisions made in the documented

method.

ii) Test Reports are being signed by approved staff.

iii) Reports are being sent to the correct addresses (see Client Complaints)

iv) Test Reports are being filed appropriately.

v) Client confidentiality is being maintained.

j) Miscellaneous

i) Documented procedures are in operation to handle queries and complaints and system failures.

ii) The Laboratory Quality Manual is up-to-date and is accessible to all relevant staff.

iii) There are documented procedures for sub-contracting work,

iv) Vertical audits on random samples (i.e. checks made on a sample, examining all procedures associated with its testing from receipt through to the issue of a report) have not highlighted any problems.

10. Records:

i) See Procedures **[9]** for details on records.

Note : The observations of the Internal Audit should be reported on the appropriate form (see Annex 3)
Corrective actions arising from Internal Audits should be documented on the appropriate form (see Annex 4)

ANNEX 3 AUDIT REPORT

[9]

Auditor:	**Audit No**.:
Area/Activity Audited:	
Comments on Audit Findings:	
Corrective Action Request Raised: …….. …….. …….. …….. **…….. …….. …….. …….. …….. …….. ……** Copies of relevant Corrective Action Requests are attached	
Auditors Signature: ……..	Date: ……./……./…….
Audit Program Manager: …….	Date: ……./……./…….

ANNEX 4 CORRECTIVE ACTION REQUEST
[9]

No.: ……

☐ Int/Ext Audit	☐ Supplier Failure	☐ Customer Complaint	☐ Internal Failure	☐ Improvement Opportunity

Description of Problem: Signature: ……. Date: ……/……/…...
Action Requested to Correct Problem: Signature: ……. Date: ……/……/…...
Main Cause of Problem: Signature: ……. Date: ……/……/…...
Corrective Action Required to Eliminate Main Causes of Problem: Signature: ……. Date: ……/……/…...
Action Taken to Verify Effectiveness of Corrective Action: Signature: ……. Date: ……/……/…...
Changes to Documentation Completed: Signature: ……. Date: ……/……/…...

ANNEX 5 CONTENTS OF A JOB DESCRIPTION
[11]

1. **State the job title**: Does it describe the job accurately? Will it be understood inside and outside the organization?

2. **State to whom responsible**: Who deputizes for the superior?

3. **State who is supervised**: Record the next level down only.

4. **State the overall purpose of the job**: Define the primary objective in a brief statement.

5. **State the key task areas**: A key task area is a part of the person's work that substantially contributes towards reaching the primary objectives of the job.
   - State the key tasks as simply as possible using active terminology.
   - Distinguish between direct responsibilities (what he/she actually does him/her self) and managerial responsibilities (what he/she ensures that others do).
   - Do not overlook important subsidiary functions.

6. **State what control information is required**: State how and when the person will report on his/her areas of activity and responsibility.

7. **State the limits of authority**: It is often simpler to state what the person is not allowed to do.

8. **Job descriptions may also include**: Standard of work required (e.g. presentation, accuracy, deadlines) and conditions of employment (e.g. salary, hours, leave, etc.)

Duty Statements
If the organization is large it may be necessary to include separate duty statements that:
- list specific short-term objectives to be achieved by each person;
- are used as goal setting and performance appraisal.

For smaller organizations the staff structure may, by necessity, need to be more flexible allowing:
- staff to do more than one function (these staff may experience conflict with competing priorities);
- functions to be moved from one person to another as staff, workload and relative importance of functions change.

In this case separate duty statements may help to:
- draw together all tasks performed by one person;
- transfer the task from one person to another because workloads of each function have been identified.

Periodic Reviews
- job descriptions should be reviewed at least annually to ensure they continue to accurately reflect staff responsibilities;
- duty statements usually compiled annually in conjunction with staff appraisal;
- both the above are reviewed whenever significant changes are made.

ANNEX 6 EXAMPLE OF FORMAT FOR STAFF TRAINING RECORDS **[11]**

Name of Laboratory:

Name of Section/Department: **Section Manager**:

Name of staff member:

Date of birth: Grade: Date entered Section:

Previous experience:

Academic/professional qualifications with dates awarded:

(e.g. 1. MSc Analytical Chemistry, UMIST, 1993)
(2. BSc Hons Chemistry, London University, 1990)

Short courses and in-house training including dates:

(e.g. 1. 5 days ELISA workshop, Institute for Animal Health, 05/06/96)
(2. 1 day ELISA familiarization, internal, 03/07/96)

Training for specific tests/techniques:

(e.g.

Test details	Standard	Date	Authorization
PCR	A	02/07/95	XY
Electrophoresis	B, C	05/12/94	XY

(A = competent to carry out test, B = competent to report results, C = competent to train others)

ANNEX 7 GUIDE TO EQUIPMENT CALIBRATION INTERVALS AND PERFORMANCE CHECKS

[12, 13, 16, 17]

EQUIPMENT	EXTERNAL CALIBRATION INTERVAL*	INTERNAL CHECKING INTERVAL	PARAMETERS TO CHECK	TOOLS REQUIRED
Autoclaves		Daily	Visually, ability to achieve and sustain pressure	Pressure gauge, safety valve, presence of water ***Note**: autoclaves are difficult to check and calibrate. Usually should leave this to manufacturer or calibration laboratory.*
Balances	3 years	Weekly	Linearity, zero point, accuracy, visually inspect spirit level (if applicable), ensure vibration free	Calibrated reference weights
Biosafety cabinets Class I		Follow manufacturers recommendations	Hours used, air flow	Anemometer
Centrifuges		Continuous during use	Balance, speed of revolutions, temperature, timer	Calibrated balance, manufacturer
Controlled environment rooms		Continuous monitoring system preferred, or daily	Temperature, humidity	Thermometer, hygrometer
ELISA readers	1 year	Monthly	Source stability (e.g. lamp), fibre optics, plate carriage, filters and filter disc	1 year - calibration plate
Freezers		24 hour cycle	Visual investigation, calibration of temperature sensing system, thermal stability, reproducibility	Calibrated thermometer or pyroprobe
Incubators (general)		Daily	Temperature	Thermometer
Incubators (specific)		CO_2		Calibration kit
		O_2		
		N_2		
Micro-pipettes		Daily	Dust and dirt on external surfaces, and pipette tip cone for physical damage	70% ethyl alcohol [**14**, pp. 53]. If cone damaged send for repair
		Daily	Volume delivered and volume delivered at settings used	Graduated tips [**14**, pp. 53]
		Before use then every 3 months	Volume delivered and volume delivered at settings used	Colorimetric method [**15,16**], gravimetric method [**14**, pp. 54]

***** Please also refer to manufacturer and/or equipment manual.

EQUIPMENT	EXTERNAL CALIBRATION INTERVAL*	INTERNAL CHECKING INTERVAL	PARAMETERS TO CHECK	TOOLS REQUIRED
Microscopes		Daily or before use	Alignment, graticule calibration	Visually using standard documented procedures, reference graticule
pH meters		Daily	Electrode drift or reduced response	Check against two buffer solutions (ideally pH 4.0 and 10.0)
Pipette tip washer		Each day or week depending on frequency and number of tips used	Damaged tips, blocked tips, contaminated tips	Manually, discarding damaged/blocked tips. Written SOP required explaining washing method used and how performance of washed tips, relative to non-washed tips, is verified. ***Note**: Washing tips is not recommended but if absolutely necessary the method described in [**14**, pp. 56-57] should be used.*
Plate shakers		Each time machine used	Speed of rotation, correlation of rotation with control knob, temperature	Speed of rotation as recommended in ELISA protocol and/or "by eye" based on experience. Calibrated thermometer ***Note**: speed of rotation is more critical to the performance of an ELISA than temperature.*
Plate washers (automatic)		Each week	Tubing nozzles, pH of wash buffers, contamination of buffers, delivery of correct volume into each well	Manually check nozzles for blockages, fresh wash buffers, measure volume using pipette or "by eye" based on experience, pH meter
Plate washers (manual)		Each time machine used or weekly	Nozzles, pH of wash buffer, vacuum	Manually check each nozzle for blockages, fresh wash buffers and check vacuum sufficient to aspirate entire contents of each well, pH meter
Thermometers (digital)	1 year (calibration laboratory)	6 months	Check at ice point or at one point in the working range against a reference thermometer	Certified reference thermometer
Thermometers (liquid in glass)	10 years (calibration laboratory)	6 months	Check at ice point or at one point in the working range against a reference thermometer	Certified reference thermometer
Thermometers (reference)	10 years (calibration	Before use	Check at ice point	

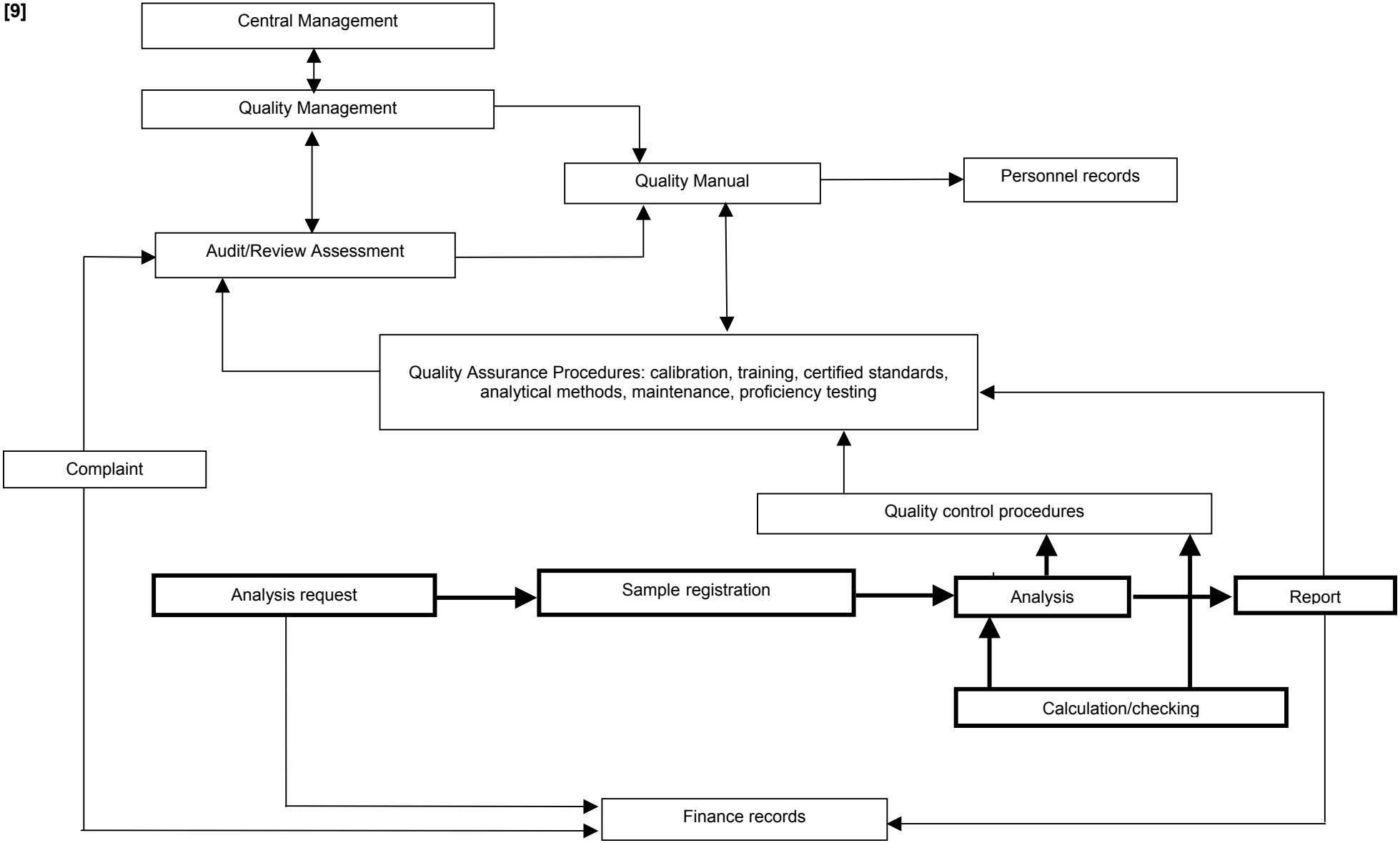
***** Please also refer to manufacturer and/or equipment manual.

EQUIPMENT	EXTERNAL CALIBRATION INTERVAL*	INTERNAL CHECKING INTERVAL	PARAMETERS TO CHECK	TOOLS REQUIRED
	laboratory)			
Timers		Two years or less depending on use	Accuracy	***Note**: Timers with quartz/electronic movements are generally more accurate and stable than conventional mechanical timers and will require less frequent calibration.*
Volumetric glassware		Dependent on usage	Accuracy	Precision pipettes/burettes
Water baths		Daily	Temperature and correlation of temperature control knob with thermometer reading	Calibrated thermometer
Water purification (deionizer)		Continuous conductivity measurement preferred (if source water hard once a day)	Conductivity meter battery and conductivity	Conductivity meter, voltmeter
Water purification (glass distillation)		Each week (if source water hard once a day)	Conductivity, pH, sterility, hardness	Conductivity and pH meter, bacteriological culture, hardness testing kit

***** Please also refer to manufacturer and/or equipment manual.

ANNEX 8 RECORD MANAGEMENT IN A QUALITY SYSTEM

[9]



ANNEX 8a EXAMPLE OF A LOGICAL FRAMEWORK FOR IMPLEMENTING A QUALITY SYSTEM IN A VETERINARY LABORATORY

[18]

GOAL	**Veterinary Laboratory/Section Accredited to National and/or International Standards**				
PURPOSE	**Quality System (QS) implemented in laboratory**				
OUTPUTS	*SUMMARIZED ACTIVITY LIST*	*KEY RESULTS AREAS*			
	Management requirements:	**Responsible person(s)**	**Resources needed (e.g. human, organization, funds, equipment)**	**Time needed**	**Quantity**
1.0 Commitment to quality process	1.1 Obtain commitment to quality initiative; 1.2 Decision taken to accredit laboratory to quality standard.	*(Maybe identified by name, initial or position held)*	Internal FAO/IAEA, OIE *(Maybe identified by position held or department)*		
2.0 Organizational & Management aspects covered	2.1 Appoint Quality Manager; 2.2 Define & establish work area(s), responsibilities, authority; 2.3 Train Quality Manager; 2.4 Assess Quality Manager's capabilities; 2.5 Provide Quality System guidelines; 2.6 Adapt Quality System guidelines to suit requirement of laboratory.		Internal Internal FAO/IAEA FAO/IAEA FAO/IAEA Internal		

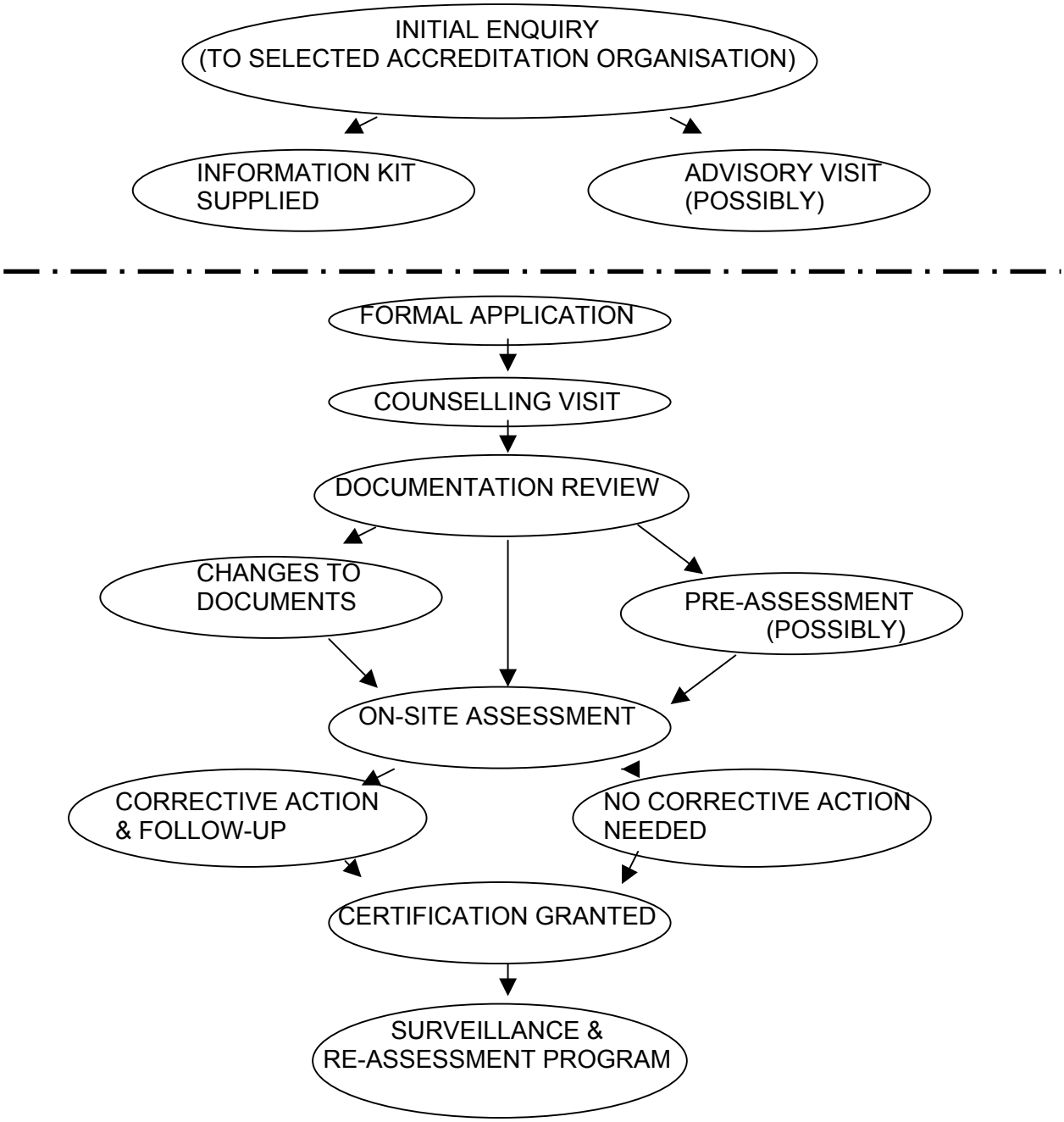
3.0 Organizational & Management aspects covered	3.1 Produce organizational tree chart of key personnel; 3.2 Attach job descriptions; 3.3 Optimize employee working conditions; 3.4 Establish supervision of diagnostic test staff; 3.5 Protect client's confidential information; 3.6 State Laboratory's legal situation correctly.			1 month 1week 3week 1 week 1week 1week	1 lab tree, 8 job descri's.
4.0 Internal quality system designed	4.1 Define and document management policies and objectives to achieve Quality System in a QM; 4.2 Communicate, be understood, be available and implement using appropriate personnel the documentation required for QM; 4.3 Regularly up-date QM; 4.4 Conduct internal audits periodically and with pre-determined timetable and questionnaire; 4.5 Conduct external audits periodically and with a predetermined timetable; 4.6 Record audits findings and corrective actions required.			2 months 1 month 1 day/ 6m 1day/1m/4m 2days/1m ?	
5.0 Documentation control system established	5.1 Write policy and working instructions for document control; 5.2 Review and up date document control instructions; 5.3 Documents uniquely identified and cross-referenced; 5.4 Ensure that only current versions of the documentation are used; 5.5 Signature and interpretation of analysis results by correct person.			1 month 1day/4m 1 week 1day/3m 1day/3m	
6.0 Relationship between laboratory and clients improved	6.1 Review proposed work and diagnostic capability with staff and clients; 6.2 Record the proposed work review and client agreement; 6.3 Review subcontracting laboratory work; 6.4 Write policy and procedures to follow in case of non-conforming testing of results; 6.5 Write policy and procedures to resolve clients or other parties' complaints; 6.6 Control quality of subcontracting work; 6.7 Inform the client about subcontracting work.			1.5 months 0.5 week 2 weeks 2 weeks 2 weeks 1 month ?	
7.0 Purchase and supplies activities controlled	7.1 State policy and procedures for selection and purchase of services and supplies; 7.2 Write procedures for purchasing, receipt and storage of consumable materials and reagents.			4 days 3 days	

8.0 Recording system controlled	8.1 Establish procedures for identification, collection, indexing, access, storage, maintenance, review and disposal of quality and technical records; 8.2 Establish retention times of records and appropriate storage conditions; 8.3 Ensure confidence and security of records; 8.4 Protect unauthorized access to computers and back-up data held on computers; 8.5 Record observation, data and calculations clearly and permanently; 8.6 Correct record mistakes crossed out and signed by the responsible person.			2 weeks 2 days 1 week 2 days Continuous Continuous	
	Technical requirements:				
9.0 Competence of laboratory personnel assured	9.1 Implement scheme for instruction and training of laboratory staff; 9.2 Appoint a Supervisor in absence of the Director; 9.3 Provide adequate supervision of unqualified personnel; 9.4 Establish staff motivation program; 9.5 Maintained current jobs descriptions and staff CV; 9.6 Authorize competent and qualified staff to perform the test; 9.7 Define level of competence required by the staff.			2 weeks 1 day Continuous 1 week Continuous 1 day 1 day	
10.0 Accommodation & working environment conditions regulated & controlled	10.1 Establish program to monitor, control and record appropriate laboratory environmental conditions and test performance; 10.2 Plan a logical flow of activities; 10.3 Define control of people access to laboratory; 10.4 Define control uses and accesses to test areas; 10.5 Observe National hygiene and security laws; 10.6 Ensure essential services; 10.7 Establish measures to control sample's transport service.			1 week 3 days 1 day 1 day 2 days 2 days 2 days	

11.0 Assays and related procedures documented	11.1 Document assay and procedures according to specific diagnostic activities & criteria; 11.2 Formally update assays based on National and/or International standards; 11.3 Write SOPs and maintain SOP rules; 11.4 Document proficiency of the technician; 11.5 Validate & document all assays under 'in-house' conditions and retain validation data 11.6 Validated new or modified assays; 11.7 Establish a program to quality control media, diluents and reagents; 11.8 Establish an Internal Quality Control system.			1 month 1 week 3 months 3 days 3 weeks Continuous 2 weeks 2 weeks	
12.0 Appropriate assay equipment procured	12.1 Identify and label appropriate equipment for each test; 12.2 Establish and record a maintenance program; 12.3 Identify and record the equipment spares and items; 12.4 Establish calibrations and calibration verification programs; 12.5 Ensure that authorized and qualified personnel operate equipment; 12.6 Document & make available the equipment maintenance & operating instructions; 12.7 Identify and properly store out-of-service equipment; 12.8 Design and keep records of equipment non-conforming to function; 12.9 Label equipment with calibration status and next calibration date; 12.10 Safeguard test equipment and related software & hardware correctly; 12.11 Perform cleaning and inspection of all equipment regularly.			2 weeks 1 week 2 days 2 weeks Continuous 1 week Continuous 2 days 1 day 2day Continuous	
13.0 Traceability measured	13.1 Measure traceability of results using SI units or other means; 13.2 Define instructions to handle, maintain and store reference equipment, standards or materials, in a correct manner; 13.3 Traceable Reference standards to SI units or OIE reference materials.			2 weeks 3days 3days	
14.0 Sampling procedures documented	14.1 Document and statistically validate specimen collection plan and procedures; 14.2 Record relevant data and operations related to specimen collection; 14.3 Ensure that sampling is carried out in accordance with OIE Standard.			1 month Continuous Continuous	

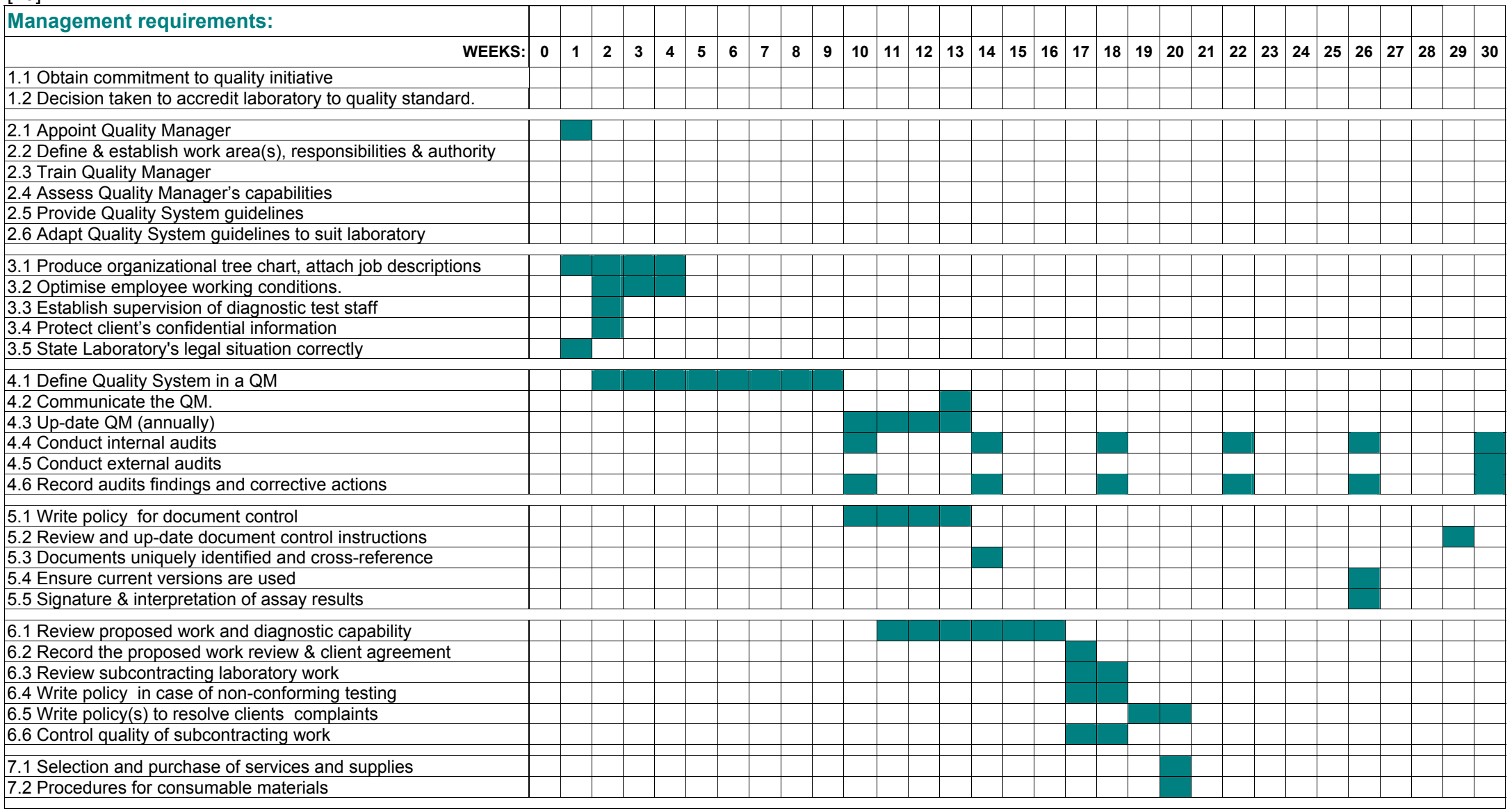
15.0 Specimen handling & transportation procedures established	15.1 Establish system to identify with unique number the specimen and related samples, and correctly link them with report; 15.2 Check at reception condition of samples and record any abnormalities; 15.3 Observe handling, preparation and storage of specimen conditions to avoid deterioration; 15.4 Observe biological & chemical safety.			2 days Continuous Continuous Continuous	
16.0 Quality of test results monitored	16.1 Established results monitoring program (e.g. proficiency testing)			1 week	
17.0 Test results correctly reported	17.1 Design accurate, clear, unambiguous, objective and specific reports; 17.2 Design a special report content for specimens received from clients and in–house sampling; 17.3 Document basis for interpreting results; 17.4 Clearly identify tests performed by subcontractors; 17.5 Keep reports transmitted by electronic means under confidential protection; 17.6 Identify report amendments clearly; 17.7 Identify report replacements uniquely and clearly linked to replaced report.			1 week 1 day 2 weeks 1 day 1 day Continuous Continuous	

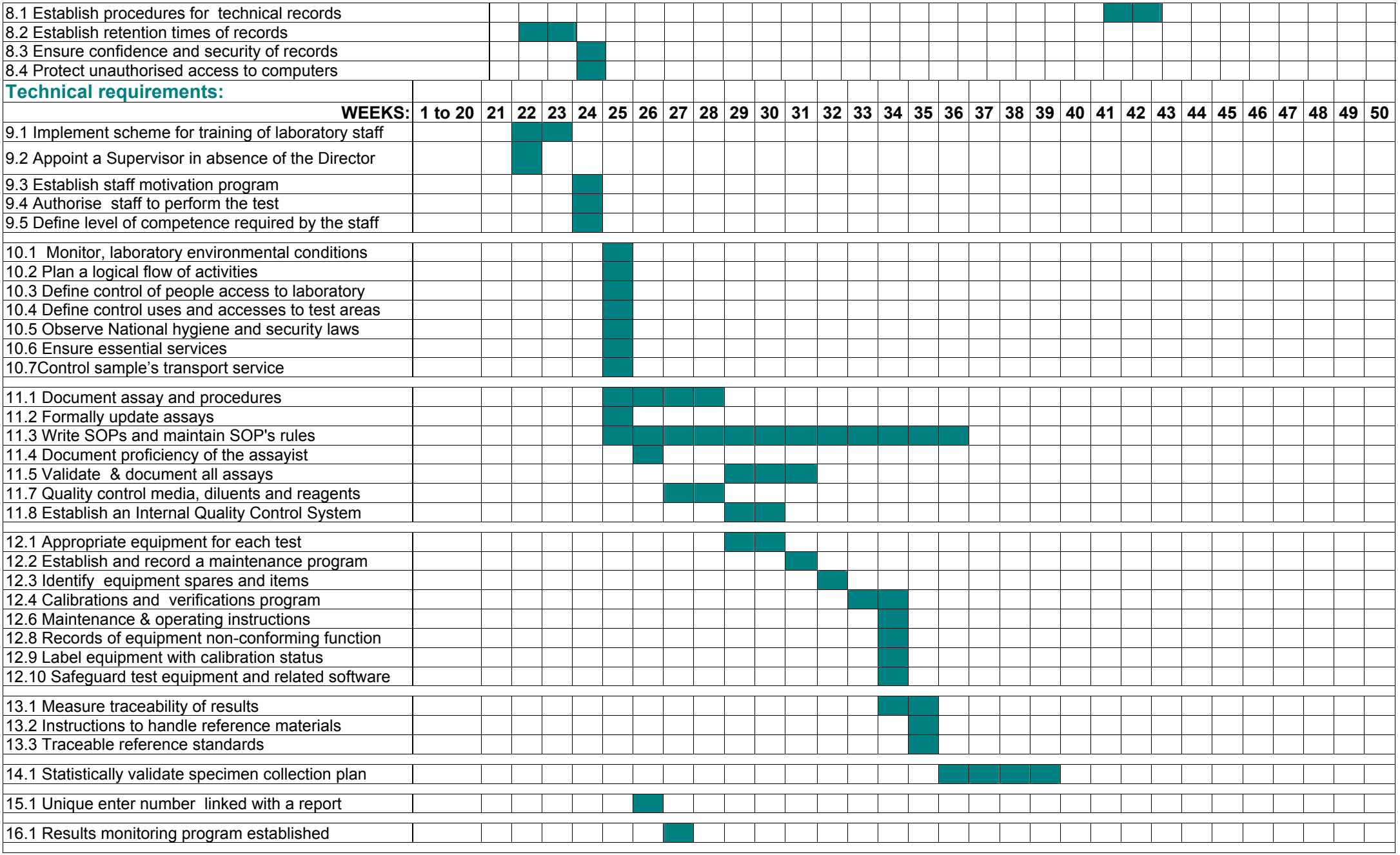
ANNEX 8b EXAMPLE (TAKEN FROM NATA) OF A FLOW CHART FOR APPLYING FOR CERTIFICATION IN A VETERINARY LABORATORY



ANNEX 9 EXAMPLE OF A GANTT CHART FOR IMPLEMENTING A QUALITY SYSTEM IN A VETERINARY LABORATORY

[19]




8.1 Establish procedures for technical records
8.2 Establish retention times of records
8.3 Ensure confidence and security of records
8.4 Protect unauthorised access to computers
Technical requirements:
WEEKS: 1 to 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
9.1 Implement scheme for training of laboratory staff
9.2 Appoint a Supervisor in absence of the Director
9.3 Establish staff motivation program
9.4 Authorise staff to perform the test
9.5 Define level of competence required by the staff
10.1 Monitor, laboratory environmental conditions
10.2 Plan a logical flow of activities
10.3 Define control of people access to laboratory
10.4 Define control uses and accesses to test areas
10.5 Observe National hygiene and security laws
10.6 Ensure essential services
10.7Control sample's transport service
11.1 Document assay and procedures
11.2 Formally update assays
11.3 Write SOPs and maintain SOP's rules
11.4 Document proficiency of the assayist
11.5 Validate & document all assays
11.7 Quality control media, diluents and reagents
11.8 Establish an Internal Quality Control System
12.1 Appropriate equipment for each test
12.2 Establish and record a maintenance program
12.3 Identify equipment spares and items
12.4 Calibrations and verifications program
12.6 Maintenance & operating instructions
12.8 Records of equipment non-conforming function
12.9 Label equipment with calibration status
12.10 Safeguard test equipment and related software
13.1 Measure traceability of results
13.2 Instructions to handle reference materials
13.3 Traceable reference standards
14.1 Statistically validate specimen collection plan
15.1 Unique enter number linked with a report
16.1 Results monitoring program established

17.1 Design accurate, objective and specific reports																															
17.2 Report for specimen from client and 'in–house'																															
17.3 Document opinions and interpretation of results																															

ANNEX 10 ESTIMATION OF MEASUREMENT UNCERTAINTY

Testing laboratories shall apply procedures for estimating “uncertainty of measurement”. Uncertainty of measurement comprises many components. Some of these may be evaluated from the statistical distribution of the results of a series of measurements and can be characterised by standard deviations. Other components are evaluated from assumed probability distributions based often on experience.

Due to the nature of the test, it may not be possible to calculate measurement uncertainty using metrologically and statistically valid calculations. In such cases the laboratory shall attempt to identify all the components of uncertainty so that a reasonable estimate can be made. This should be based on knowledge of the performance of the method and the measurement scope, and should make use of previous experience and validation data. Sources that may contribute to uncertainty include: reference standards and materials, methods and equipment used, environmental conditions, properties and condition of the item under test, and the operator.

Normally when estimating uncertainty the predicted long-term behaviour of the tested and/or calibrated item need not be taken into account.

Measurement of uncertainty shall be performed by staff familiar with the test(s) and understand the limitations of the measuring equipment and the influences of external factors, e.g. the environment. Staff shall take into account all uncertainty components considered important to the test(s) in the given situation using appropriate methods of analysis.

Documentary evidence will be filed as defined under “Records” as given above . The documents will show the assumptions made and the sources of information used to estimate the component uncertainty values, e.g. calibration certificates, previous data, behaviour of relevant materials.

References:

- ILAC/LLC(00)006 Guidance for accreditation to ISO/IEC 17025 & what evidence to look for, 11 August 2000.
- EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:1999), March 2000
- EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurement, Second Edition, QUAM:2000.P1.

ANNEX 11 OCCUPATIONAL HEALTH AND SAFETY

The following is not a requirement of the OIE Standard, but should be performed in the laboratory as part of “good laboratory practice” (glp).

Veterinary laboratory work should be undertaken without risk to staff health. The types of risk associated with laboratory health and safety include infection, and physical and chemical injuries. Risks from infection can be reduced by the containment of micro-organisms, by undertaking good laboratory practice and providing adequate facilities. Containment and storage of micro-organisms should provide protection to humans as well as animals. In order to assess risk it is important to assign a particular pathogen to a risk group, recognize if the pathogen causes death, disease or inconvenience and understand the epidemiology of the pathogen.

There are four risk groups associated with micro-organisms numbered Group 1 to Group 4.

- **Group 1** covers organisms that are unlikely to cause human disease.
- **Group 2** covers organisms that may cause human disease but are unlikely to be spread in the community and effective prophylaxis and treatment are available, e.g. influenza, Orf, Campylobacter, Salmonella.
- **Group 3** covers organisms that can cause severe human disease and may spread to the community but for which there is usually effective prophylaxis and treatment, e.g. rabies, anthrax, brucella.
- **Group 4** covers organisms that can cause severe human disease, may represent a high risk of spread in the community and for which there is usually no effective prophylaxis or treatment.

Once the level of risk is decided it is then possible to provide appropriate containment facilities. Details for each Group including suitable safety cabinets are provided in various texts on Health and Safety given in the References below . In addition, guidelines, standards and regulations for individual countries should also be consulted.

Risks to staff health from physical hazards, e.g. syringe needles, scalpel blades, glass, gas flames, hot solids, irradiation, and from chemical hazards which may be toxic and/or carcinogenic, e.g. chemical liquids and vapours, flammable chemicals, can be minimised if appropriate precautions are taken as indicated below. It should be remembered when working with chemicals that if the dose is sufficient even apparently harmless substances can be toxic.

The types of requirements for work with potentially hazardous and infectious agents are listed below:

- cleanliness and ease of cleaning;
- restricted personnel access;
- protective clothing, e.g. gloves, face mask, boots, breathing apparatus;
- ventilation;
- no food, drink, or smoking in laboratory;
- no mouth pipetting;
- minimise aerosols
- provision of effective disinfectants;
- safe disposal of chemical and physical waste;
- record and report accidents;
- provision of safety equipment;
- personal hygienic practices;
- staff training and appointment of safety officers;
- recording the use of hazardous materials or chemicals.

In addition there should be emergency control procedures that cover first aid, spillages, fires, fire fighting and evacuation of premises.

Healthy working conditions for all laboratory staff will be achieved if high standards of laboratory safety are provided and maintained.

References

- Office International des Epizooties (2000). Manual of Standards for Diagnostic Tests and Vaccines, 4th edition, Paris.
- World Health Organisation (1993). Laboratory Safety Manual, 2nd edition; Geneva.
- National Research Council (1981). Prudent practices for handling hazardous chemicals in laboratories. National Academy Press, Washington, DC.
- Garfield, F. (1996). Quality assurance principles for analytical laboratories. Association of Official Analytical Chemists, USA. ISBN 0-935584-46-3.
- Office of Biosafety, Laboratory Centre for Disease Control, health and Welfare Canada (1990). Laboratory Biosafety Guidelines. Ministry of Supply and Services, Canada, cat. No. MR21-1/1990.
- Rayburn, S.R. (1990). The foundations of laboratory safety (a guide for the Biomedical; Laboratory). Springer-Verlag, New York.