French Ministry
of Foreign Affairs

Ehiopian Ministry
of Agriculture

Mission in Ethiopia

July 14 – 23 2003

QUALITY ASSURANCE INFORMATION AND ASSESSMENT IN EARO LABORATORIES

Ethio-French Project on Quality and
Sanitary Aspects of Animal Products in Ethiopia

Emmanuel Albina
CIRAD – Département Emvt

ERRATUM

Page 3:

- 1st paragraph: «In the framework of the "Ethio-French project on quality and sanitary aspects of animal products in Ethiopia", a **workshop** on quality assurance (QA) was conducted at the National Animal Health Centre (NAHRC) in Sebeta. This **workshop** consisted of an evaluation of QA at NAHRC, a visit to the Quality and Standards Authority in Ethiopia (QSAE), the organisation of a workshop at NAHRC and the definition of quality objectives and work-programme for NAHRC. »
- 5th paragraph: « It has a central edifice of **1426** m2 (**905** m2 for the lab sections) and various other building facilities for personnel, animal husbandry and stores. These facilities are relatively recent (**10** years).»

Page 5:

- 8th paragraph: « Although conducting research and reference activities on major animal diseases on the request of the Ministry of Agriculture, NAHRC has no organic link with this Ministry: it is only **accountable to** the Ethiopian Agricultural Research Organisation (EARO **under the Ministry of Rural Development**). »
- 14th paragraph: « The site map of NAHRC is provided in annex 2. The central laboratory building is about **1426** m^2 (**905** m^2 for the lab sections, see annex 3). It was built in **1990**. A new administrative building is almost finished. The administrative personnel of the main building are expected to move very soon to this new building. This moving will release new offices for scientists and technicians. »

Page 7:

- Under item 2.4 Equipments: « The laboratory has all the necessary equipments to achieve its research and routine diagnostic work. However, the maintenance of the equipment is almost absent. Several deep freezers are out of service and there are no clear perspectives of restoration: this is particularly crucial since it may cause disruption in the laboratory capacity to ensure secure storage of samples for testing. There are no individual equipment files in the laboratory containing the instruction book and data sheets on inventory, maintenance, checking and whenever necessary on calibration. There is no short instruction notice displayed close to the equipment to ensure proper use of the equipment. **For each equipment, a person from the laboratory staff should be appointed as responsible for regular checking, calibration, usual maintenance and for taking out first measures in case of malfunction. A second person should be identified as substitute.** »
- Under item 2.5 Building facilities : « The laboratory is **10** years old and has probably not received very much attention for maintenance. Thus, the laboratory shows several signs of insufficient upkeep (roof leakages, deficient cleansing, paint deterioration…). Repair of roof leakages and refreshment of inner painting are highly desirable. In addition to the general improvement of the laboratory conditions, it will also give to the visitors (or auditors) an indication on the level of commitment to "Quality" . »

Page 9:

- Key action 10: « Set up an access control to the laboratory: entrance shall be restricted **to** the laboratory staff. Entering staff shall wear specific laboratory overcoats that will not leave the laboratory except for cleaning. »

Page 10:

- 5th paragraph: « Secondary consumable stores should be better assigned. Specific rooms can be allocated for that purpose (see annex 7). **At the time of the visit, some consumables were temporarily laying down in the laundy, which is not acceptable: if these consumables are to be used by the laundry staff, they should be stored in a specific cabinet, if not they should be stored elsewhere.** »

Contents

Summary

In the framework of the "Ethio-French project on quality and sanitary aspects of animal products in Ethiopia", an expertise on quality assurance (QA) was conducted at the National Animal Health Centre (NAHRC) in Sebeta. This expertise consisted of an evaluation of QA at NAHRC, a visit to the Quality and Standards Authority in Ethiopia (QSAE), the organisation of a workshop at NAHRC and the definition of quality objectives and work-programme for NAHRC.

During the evaluation of NAHRC, the following observations were made:

Main positive points:

- NAHRC is doing reference activities (research and diagnosis) on diseases of the lists A and B of the Office International des Epizooties (OIE)
- It has a central edifice of 220 m2 (150 m2 for the lab sections) and various other building facilities for personnel, animal husbandry and stores. These facilities are relatively recent (15 years).
- It has recent and suitable equipments
- One laboratory section (protozoology) is advanced in the establishment of a quality assurance system

Main points to be improved:

- The laboratory has no defined QA policy and procedures
- Its mandate and objectives are not clearly and accurately defined and advertised
- The laboratory access is not under control, thus security and confidentiality are not ensured
- Although relatively recent, the laboratory shows several signs of insufficient maintenance (deficient cleansing, paint deterioration...). Electric power supply should be better secured. Internet and phone connections are often out of service.
- Many equipments are out of service with no clear perspectives of restoration: this is particularly crucial for freezers since it may disrupt the capacity of the laboratory to store securely the samples to be tested
- Equipments present for a long time in the laboratory have never been put into first service
- Laboratory consumables or equipments and desks are sited at the laboratory entrance or in corridors
- There is no clear separation between office activities and lab activities
- The laboratory has important stocks of biological or sterile products that have exceeded the expiry date. However, there are no internal procedures or records ensuring that they have characteristics that still meet the laboratory specifications for testing

QA objectives for NAHRC, as agreed during the workshop, were defined as follows:

- Set up a quality assurance programme to ensure the quality of testing and research
- QA for testing will refer as much as possible to the ISO/17025
- QA for research will benefit from the implementation of ISO/17025 and will also rely as much as possible on good laboratory practice (GLP)

The work-programme for NAHRC was then defined:

1. Quality policy statement by laboratory manager (identifying lab section(s) and activities concerned)
2. Appointment of a quality manager and training (3-4 weeks)
3. Appointment of a metrology manager and training (3 months)
4. QA information to all staff
5. Procedure for documentation structure and identification
6. New organization of laboratory (modification of room assignment and equipment position)
7. Improvement of testing traceability (unique identification for test demand and samples)
8. Standard operating procedures (SOP) for laboratory supplies
9. Selection of the laboratory section that will be first concerned by QA
10. Set up an access control to the laboratory
11. Organisation of internal audits by quality manager to follow QA progression: ½ day each 4th month

This work-programme shall be undertaken by NAHRC in the next 12 months and independent evaluations of progress shall be made by external audits: one in mid-term and one at the end of period (July 2004)

Programme

Monday 14th of July:
Travel from Montpellier to Addis Ababa through Paris and Francfurt. Welcome at Addis Ababa by **Dr Berhe Egzabhier** from National Veterinary Institute (NVI) at Debre Zeit and **Dr Agnès Poirier**, Technical Assistant and Project leader on "Quality and sanitary aspects of animal products in Ethiopia) at the National Veterinary Services of Ethiopian Ministry of Agriculture (MoA)

Tuesday 15th of July:
Meeting with **Mrs Zinash Sileshi**, Head of the Animal Science Research at Ethiopian Agricultural Research Organization (EARO) and **Dr Sintayehu Abditcho**, Head of National Animal Health Research Centre (NAHRC) at Sebeta: introduction and presentation of the objectives of the mission
Meeting with **Dr Jean-Luc François** (SCAC, French Embassy): introduction and presentation of the objectives of the mission, and discussion on the current projects related to virology
Meeting with **Dr Sileshi Zwedie**, Head of the National Veterinary Services (MoA) and **Dr Alemayehu Mekonnen**, National Coordinator: introduction and presentation of the objectives of the mission, discussion on the foot and mouth disease research project at NAHRC (Sebeta) in cooperation with CIRAD
Meeting with **Dr Bayleyegn Molla**, Associate Professor at Faculty of Veterinary Medicine (FVM) in Debre Zeit: introduction and discussion of the organization of the next virology course to be held at Debre Zeit in December; Visit of the FVM
Meeting with **Dr Berhe Egzabhier** from NVI: visit of the Institute

Wednesday 16th July:
Working day at NAHRC (Sebeta) with **Dr Laike Mariam Yigesu**, Scientist: Visit of NAHRC, evaluation of laboratory supplies management

Thursday 17th July:
Working morning at Sebeta with **Dr Laike Mariam Yigesu**: evaluation of laboratory traceability from samples to final result reports
Meeting with **Dr Sileshi Zwedie** to complete the file for FMD project acceptation
Meeting with **Mrs Almaz Kahsay**, Head of Quality and Standards Authority of Ethiopia (QSAE): visit of the microbiology and metrology sections

Friday 18th July:
Working morning at Sebeta with **Dr Laike Mariam Yigesu**: evaluation of staff management and budget facilities
Preparation of the workshop

Saturday & Sunday 19-20th July:
Discovering Ethiopia…
and arranging the last details for the workshop

Monday 21st July to Wednesday 23rd July:
Workshop (see programme in annex 1)

1- Description of NAHRC and of its objectives (research, diagnosis and quality assurance)

The National Animal Health Research Centre (NAHRC) was established in 1995 with the following objectives:

1. Identify and prioritise major animal health constraints
2. Undertake applied and basic researches on prioritised animal health problems with high economic and/or public health importance
3. Provide diagnostic and referral service
4. Provide national animal health information through disease monitoring and surveillance systems and networks
5. Co-ordinate national research programme on animal health

Although conducting research and reference activities on major animal diseases on the request of the Ministry of Agriculture, NAHRC has no organic link with this Ministry: it is only dependent on the Ethiopian Agricultural Research Organisation (EARO, Ministry of Research). This situation has to be improved rapidly since the absence of official commitments between NAHRC and the Ministry of Agriculture upon questions related to the control of notifiable animal diseases may become the source for potential conflicts. A general agreement or specific agreements between both structures should therefore clarify:

1. The objectives and services pursued by each part and the connections between them
2. The responsibilities and duties of each part
3. The resources offered by each part to achieve the objectives

The quality assurance settlement at NAHRC requires a clarification and a formalisation of the connections with the Ministry of Agriculture. Besides the implementation of QA at NAHRC, **the Ministry of Agriculture should officially recognise NAHRC as the national reference laboratory for the animal diseases concerned.**

The site map of NAHRC is provided in annex 2. The central laboratory building is about 220 m² (150 m² for the lab sections, see annex 3). It was built in 1985. A new administrative building is almost finished. The administrative personnel of the main building are expected to move very soon to this new building. This moving will release new offices for scientists and technicians.

Staff consists of 24 scientists (10 DVM, 14 MVSc: 3 are preparing a PhD graduation), 19 technicians and 49 administrative staff (including assistance, store and animal workers).

The laboratory is divided into four departments (Parasitology, Microbiology, Pathology and Pharma-toxico & Biochemistry) and 11 teams (including the epidemiology unit): the structure is shown in annex 4. Apparently there is no staff and no activity in the pharma-toxico & biochemistry department.

Current activities of NAHRC are dealing with the diagnosis and epidemiology of major diseases of animal: Rinderpest, peste des petits ruminants, contagious bovine and caprine pleuropneumonia, Rift valley fever, trypanosomosis and brucellosis. The diagnostic tools used are mainly ELISA. Several thousands analysis of sera are made each year. There is no activity in the field of classical virology or molecular biology. However, classical bacteriology, parasitology and entomology are done routinely.

The laboratory has two origins of budget resources: a budget from the government and a budget from specific projects funded by third-institutions (mainly foreign institutions). In 2002, the allocated budget was 793,419 Ethiopian birr from the government and 65,664 birr from specific projects (1 euro = 9.7 birr). However, for various reasons including the very long purchase process, only 581,184 birr and 57,670 birr were actually spent. In 2002, 144,900 birr were spent for the laboratory materials, chemicals & reagents: that is 2672 birr for each laboratory worker (275 euros a year for each lab worker).

In addition to this budget constraint, the reagent supply requires an extremely long process. It may sometimes take more than a year and a half to obtain consumables. This does not allow the laboratory to achieve its objectives within a reasonable period of time (time is crucial when it concerns highly contagious diseases). Furthermore, this tremendous delay does not fit in with the expiry dates of some biological

reagents used in the laboratory. The use of specific project budgets may sometime shorten the delay but not in a sufficient proportion to fulfil quality assurance requirements. The delay seems to result from an excessive administrative control (control before, during and after the process). For any expenditure using government funds, an official tender is also necessary. At last, when a purchase has to be made with foreign currencies, the process is again longer. These difficulties should be alleviated with a first priority rank: suggestion could be first to give the possibility to NAHRC to have a direct responsibility on consumable orders and purchases. Secondly, NAHRC should be able to hold a part of its national budget in foreign currencies (US dollars) through a specific commercial bank account. This budget shall enable the laboratory to make expenditures for a rapid supply of external biological reagents. **In conclusion, it is highly recommended to improve the purchase process of laboratory consumables and reagents with the aim to shorten the delivery delay lower than 3 months.**

2- Evaluation of QA at NAHRC

The following issues summarised the observations made during the first week and the results of the collective evaluation conducted by the workshop participants.

2.1- Sample handling and management of analysis requests

The situation regarding sample handling and management of analysis requests is heterogeneous among the different laboratory sections. The protozoology section seems to be the most advanced in this area since a unique identification system allows a complete traceability of samples up to the final result reporting. Under this condition, the ISO/17025 standard is fulfilled: [*the system shall be designed and operated so as to ensure that samples cannot be confused physically or when referred to in records or other documents (ISO/17025)*]. Standardised result reporting is also in use in this section, however, it should be revised against the ISO/17025 specifications (section 5.10.1, 5.10.2, 5.10.3 and 5.10.5).

Owing to its advanced position in this area and in others, **the protozoology section could be a pilot section for the completion of a QA system at NAHRC.**

In the other laboratory sections, the requirements for sample handling and analysis management are not achieved. Due to shortage of freezing equipments, the storage of serum and tissue samples is not ensured securely. On the other hand, the laboratory is storing a large amount of samples, which are probably not all interesting. A SOP for sample handling after analysis is necessary and should describe a duration limit for sample storage: important samples could be stored for a longer period, the others being destroyed 1 or 2 months after the completion of tests. The laboratory is also building a deep cold room (-20°C) that will help in the improvement of the conditions for sample storage.

2.2 Consumables

Purchase of consumables follows a complicated albeit standardised protocol. This protocol should be described in a SOP.

Outside the laboratory, there is a well-organised central store for all consumables. Procedures for storage and delivery to the laboratory sections are defined and should be now put in a written form. In the laboratory, the secondary stores are not organised and have no specific locations: thus consumables may be stored in corridors, in working rooms, etc...

However, the major problem with consumables is the delivery delay after ordering (see above section 1). The laboratory has big stocks of biological or sterile products that have exceeded their expiry date. However, there are no internal procedures or records ensuring that they have characteristics that still meet the laboratory specifications for testing. The current delay for consumable purchase is not compatible with a good management of the expiry dates of most biological reagents used in the laboratory. It is reminded here that **this major constraint represents a durable obstacle to the development of QA and the achievement of accreditation at NAHRC.**

Consumables prepared within the laboratory (buffers, solutions, dilutions...) are not properly identified: they should be labelled at least with the nature of the product(s) they contain, the date of preparation and whenever appropriate the expiry date.

2.3 Methods

The laboratory essentially uses commercial diagnostic reagents and follows the manufacturer instructions. For the quality documentation, a SOP front page should be prepared and should cover the manufacturer instruction. For in-house or laboratory-adapted methods, SOP have to be prepared referring as much as possible to previous published or acknowledged protocols.

2.4 Equipments

The laboratory has all the necessary equipments to achieve its research and routine diagnostic work. However, the maintenance of the equipment is almost absent. Several deep freezers are out of service and there are no clear perspectives of restoration: this is particularly crucial since it may cause disruption in the laboratory capacity to ensure secure storage of samples for testing. There are no individual equipment files in the laboratory containing the instruction book and data sheets on inventory, maintenance, checking and whenever necessary on calibration. There is no short instruction notice displayed close to the equipment to ensure proper use of the equipment. There is no personnel identified for the equipment and appointed for taking the first measures in case of malfunction.

2.5 Building facilities

The laboratory is 15 years old and has probably not received very much attention for maintenance. Thus, the laboratory shows several signs of insufficient upkeep (roof leakages, deficient cleansing, paint deterioration...). **Repair of roof leakages and refreshment of inner painting are highly desirable.** In addition to the general improvement of the laboratory conditions, it will also give to the visitors (or auditors) an indication on the level of commitment to "Quality".

Electric power supply should be better secured. The laboratory has its own generating set that is supposed to automatically compensate any disruption of the general electric power supply. However, this generating set should be permanently checked for service. Records of the maintenance and operations of this generating set should be made available.

Internet and phone connections are often out of service. This is surely affecting the quality of services delivered to the clients. At present, there are unfortunately no solutions to propose.

2.6 Personnel

The laboratory has standardised procedures for personnel recruitment and individual files for personnel management. Thus, the education, qualifications and training of the personnel can be monitored. However, the management of these files is not optimised. Many documents are not stored in a unique file at the same place. This impedes the retrieval of all necessary informations. To demonstrate the high level of laboratory commitment to "Quality", this point should be improved: it will also save time for the future external audits and will help in preserving the auditor patience. The laboratory strategy for personnel training does not appear to be defined accurately. This is particularly evident for the technician staff.

3- QA Workshop at Sebeta

The workshop was held on 21, 22 and 23rd of July. The programme is shown in Annex 1. All staff from NAHRC was invited to attend. Other participants were the head managers of the 11 Regional Veterinary Laboratories, one representative of the Faculty of Veterinary Medicine and one representative of the National Veterinary Institute (NVI, Debre Zeit). The list of participants is attached in annex 5 (40 persons, including the head managers of NAHRC and of the 11 Regional Veterinary Laboratories). All presentations are attached under annex 8.

A general QA information was given on Monday morning. Then, in the afternoon, a questionnaire made of 45 questions covering all aspects of QA was filled. This questionnaire was used for a rapid evaluation of QA progress in the different laboratories. The results of this survey are shown in Annex 6. The scores are probably over-estimated but the purpose of this exercise was not to set up an accurate evaluation of QA level in the laboratories, but rather to give the participants the opportunity of an interactive assessment of QA requirements. However, the scores show that NAHRC (more precisely, the protozoology section) and NVI are the most advanced. Other laboratories (Shola, the Faculty of Veterinary Medicine, Sodo and Bedelle) have a longer way to go for achieving QA.

Tuesday was dedicated to the definition of specific QA objectives for the Regional Veterinary Laboratories. A virology seminar was also organised followed by a practical approach to QA at NAHRC.

QA objectives for the Regional Veterinary Laboratories were identified as follows:

1. standardisation of equipment management
2. improvement of sample processing and test result reporting
3. assignment of tests to competent staff and management of personnel competence with individual record files
4. improvement of laboratory supply management and procedures
5. writing up procedures for testing

These objectives are considered as priority actions and should be clearly underlined in the quality policy statement of the laboratory head manager.

The virology seminar gave the opportunity to present CIRAD and its activities in this area and also to discuss the interest of researches carried out on major viral disease of ruminants.

The practical approach of QA at NAHRC relied on the realisation of four different audits concerning four different laboratory sections. After a general explanation and an agreement on the method, participants were split into four groups and asked to carry out an audit of one laboratory section. The lab sections concerned were Bacteriology, Serology, Parasitology & Entomology and Protozoology. Each auditing group had to investigate the sections on the following issues:

1. Samples and analysis handling
2. Equipment
3. Personnel
4. Consumables
5. Methods
6. Laboratory facilities
7. Result reporting

Audits lasted for 1 hour and a half and were followed by reports and discussion. The objective was not to provide a comprehensive evaluation of the laboratory sections but rather to give an opportunity to participants to test their recent knowledges in QA.

The following results were obtained:

1. The protozoology section is probably the most advanced in terms of QA. For instance, it has an operating sample identification system ensuring proper traceability of items, raw data and result reporting documents. It has also a rather good management of equipments including calibration of ELISA plate reader and pH meter and daily checking of freezers' inner temperatures. This section could be identified a pilot section for the rapid implementation of a quality system referring to ISO/17025. Other sections could secondarily follow the example to set up their own system.
2. Evaluation of the three other sections is summarised in table 1. It should be stressed that recurrent problems are encountered in all sections: insufficient staff training, lack of documentation and checking for equipment and no separate rooms for offices and laboratory manipulations.

After this collective evaluation work, QA objectives and key actions were identified for NAHRC.

4- QA objectives for NAHRC and key actions for the next 12 months

The following QA objectives were defined for NAHRC:

1. achieve ISO/17025 standards for animal disease diagnosis with beneficial consequences on research activities
2. meet "Good Laboratory Practice" standards for specific research programmes
3. obtain acknowledgement of technical and quality competence in the field of research and diagnosis of animal diseases through the official designation as a National Reference Laboratory by the Ethiopian Ministry of Agriculture

These objectives should be described in the quality policy statement of the NAHRC head manager. It should also mention the progression plan and identify the necessary resources for the objective achievement. A short, mid and long-term programme should be announced. Key actions and priority tasks should be identified, and the first laboratory sections concerned should be selected.

In order to start with QA at NAHRC, a series of key actions for the next 12 months were identified:

1. Quality policy statement issued by the NAHRC head manager (as described before, not more than 2 pages)
2. Appointment of a member of staff as quality manager and organisation of training for this personnel (3-4 weeks preferentially in a European structure). Hierarchically, [*the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources (ISO/17025)*]
3. Appointment of a member of staff as metrology manager and organisation of training for this personnel (1 week of theory preferentially in an European structure and 2 weeks of practice in the Quality and Standards Authority of Ethiopia, QSAE, see below). Hierarchically, the metrology manager shall only refer to the quality manager
4. QA information to all staff: one full day for all staff by a QA expert (this information day could be organised in December, by the author)
5. Procedure for documentation structure and document identification: this procedure shall be derived from a model coming from an accreditated European laboratory
6. New organisation of the laboratory (modification of room assignment and equipment position): this is put in more details in the next section
7. Improvement of testing traceability: ISO/17025 specifies that **[*the system shall be designed and operated so as to ensure that samples cannot be confused physically or when referred to in records or other documents (ISO17025)*]**. Suggestion could be the use of a unique code for each analysis request, mentioned on all samples and referred documents (client documents, registration books, raw data, result report...)
8. Standard operating procedures for laboratory supplies and storage: these SOP shall describe what is done and how expiry dates are managed (the problem of delivery delay shall be solved)
9. Selection of the laboratory section that will be first concerned by QA
10. Set up an access control to the laboratory: entrance shall be restricted the laboratory staff. Entering staff shall wear specific laboratory overcoats that will not leave the laboratory except for cleaning.
11. Organisation of internal audits by quality manager to follow QA progression: ½ day each 4th month

This work-programme shall be implemented by NAHRC in Sebeta, in the next 12 months and independent evaluation of progress shall be made by external audits: one in mid-term (possibly in December) and one at the end of the period (July 2004).

5- Specific proposals for the improvement of building and equipment organisation at NAHRC

In the near future, the administrative department of NAHRC, presently located in the right wing of the main laboratory building will be moved to another building. This is a unique opportunity for improving the functional organisation of the laboratory and its quality standards. The next proposals have been made taken into account this moving.

A general problem in the laboratory is the insufficient space available for offices and freezers, and the presence of non-organised stores for consumables. It is therefore proposed to move the scientist offices towards the administrative section (2 scientists by office). Then, offices in the laboratory sections could be reallocated to technicians in order to remove the tables actually present in the manipulation zone.

QA in a laboratory requires to separate activities that are not compatible. This is the case when a freezer containing serum or animal tissue samples is located in the room where sterile media are prepared. The laundry, the sterilisation room and the medium preparation room should not contain freezers with biological samples (except those that are sterile and used for medium preparation). Moreover, it is not recommended to accumulate freezers in the corridor: the corridor should not be considered as a manipulation zone and therefore should not contain biological samples. Then, it is highly desirable to site the freezers in the laboratory sections or to set up a specific air-conditioned room to house them. On the other hand, it is acceptable to use the corridor to store documents in closed bookcases provided that access control to the laboratory is efficient to preserve confidentiality.

It is not acceptable to store equipments in rooms where they have no specific use or even more may have incompatible use: for instance, high speed centrifuge for virology or bacteriology should not be present in the sterilisation or medium preparation room.

Non-infected cell lines are manipulated under a horizontal laminar flow cabinet (protecting only the items). This may represent a biosafety risk for the manipulator when certain cells, particularly cells originating from human or monkey, are in use. On the other hand, media which are sterile and safe are prepared under vertical laminar flow cabinet (protecting both the manipulator and the items). Therefore, it is recommended to make an exchange between the two cabinets.

Secondary consumable stores should be better assigned. Specific rooms can be allocated for that purpose (see annex 7). It is not acceptable to maintain anarchic stores of consumable, for instance in the laundry.

The entrance of the laboratory is cluttered up with tables and laboratory consumables. This gives to visitors a very bad first feeling on the laboratory. Tables should be removed and dividing walls should be built to enclose laboratory consumables (see annex 7).

At last, NAHRC is willing to set up a virology section and to develop the use of molecular biology. This will require specific room organisation. A proposal is made in the annex 7. The general idea is to better split the serology and the virology part. In the virology part, two cell culture rooms have to be identified (one non-infected and one infected). Therefore, it is proposed to put a dividing wall with a door between the serology part and the corridor going to the virology part. The current cell culture room for non-infected cell cultures should be maintained and access to the infected cell culture room should be improved by modifying the circulation through the corridor and the shower. At last, a molecular biology lab should be set up in the toxicology section that has actually no use. This molecular biology section would be made available to all sections (parasitology, bacteriology and virology).

All the above-mentioned modifications are represented on the map of annex 7.

6- QA and Metrology in the Quality and Standards Authority of Ethiopia (QSAE)

QSAE is an independent public authority performing different types of biochemical and biological analysis. It also provides metrology controls for other laboratories or companies. It is charging its services and therefore has developed a real client-supplier relationship. Under this framework, QSAE has developed a QA system. The author was given the opportunity to visit the bacteriology section of QSAE and its metrology department. In the bacteriology section, the visit allowed to see a QA system and its available documentation. This system is not completed but it is very well engaged. The metrology department is really impressive. It consists of a large air-conditioned room with controlled access, in which all necessary equipments are available for mass, length, volume, electric wavelength and temperatures calibration. National standards for each measurement are stored securely and working standards are used for calibration. Personnel skills in metrology and calibration appear to be excellent.

QSAE should absolutely become a partner for NAHRC in at least two directions: training of the NAHRC metrology manager and calibration of the working standards of NAHRC.

Conclusion and final recommendation

The head manager of NAHRC has expressed his interest in the development of QA in his Institute. QA progress in one section of this laboratory illustrates that achieving ISO/17025 standards is not unrealistic. A precise work-programme has therefore been identified to start the quality system. Meanwhile, considerable efforts have to be produced to solve the problem of consumable supplying and its consequence on the expiry dates. With little budget, the laboratory could be refreshed (new painting) and better organised (extension of offices and modifications in the virology and common molecular biology sections). These actions would improve the quality of the work carried out in this laboratory and would give a more favourable impression to the visitors. The success for QA is largely dependent on the personnel motivation. This motivation is obtained by a large involvement of the personnel in the strategy and in the definition of specific tasks. The importance of QA objectives must be exposed and agreed by all staff. It must be stressed that QA is a collective approach towards excellence.

Emmanuel Albina
Montpellier, 12th August 2003

Table 1: Main nonconforming points observed in four lab sections of NAHRC

QA issue	Bacteriology section	Serology section	Parasitology and entomology section	Protozoology section
Samples and analysis handling		Sample identification to be improved No timetable for sample disposal	No submission form for samples	
Equipment	No documents No instruction notices Problems of maintenance	No calibration Problems of maintenance Shortage of deep freezers	No calibration No instruction notices Problems of maintenance	No instruction notices Problems of maintenance
Personnel	Insufficient staff training		No information on staff experience and training	Insufficient staff training
Consumables		Problems with expiry dates	No reconstitution date for in-house consumables Problems with expiry dates	
Methods			Additional references required	
Lab facilities	No access control No checking of environmental conditions	No separate rooms for offices and lab manipulation	Insufficient space for lab manipulation No separate rooms for offices and lab manipulations	Insufficient space for lab manipulation No separate rooms for offices and lab manipulations
Result reporting	Different result reporting forms	No standardized result reporting		

Annex 1

Programme of the workshop

Ethiopian Agricultural Research Organization

National Animal Health Research Centre (NAHRC)

Workshop on Laboratory Quality Assurance

July 21-23/2003

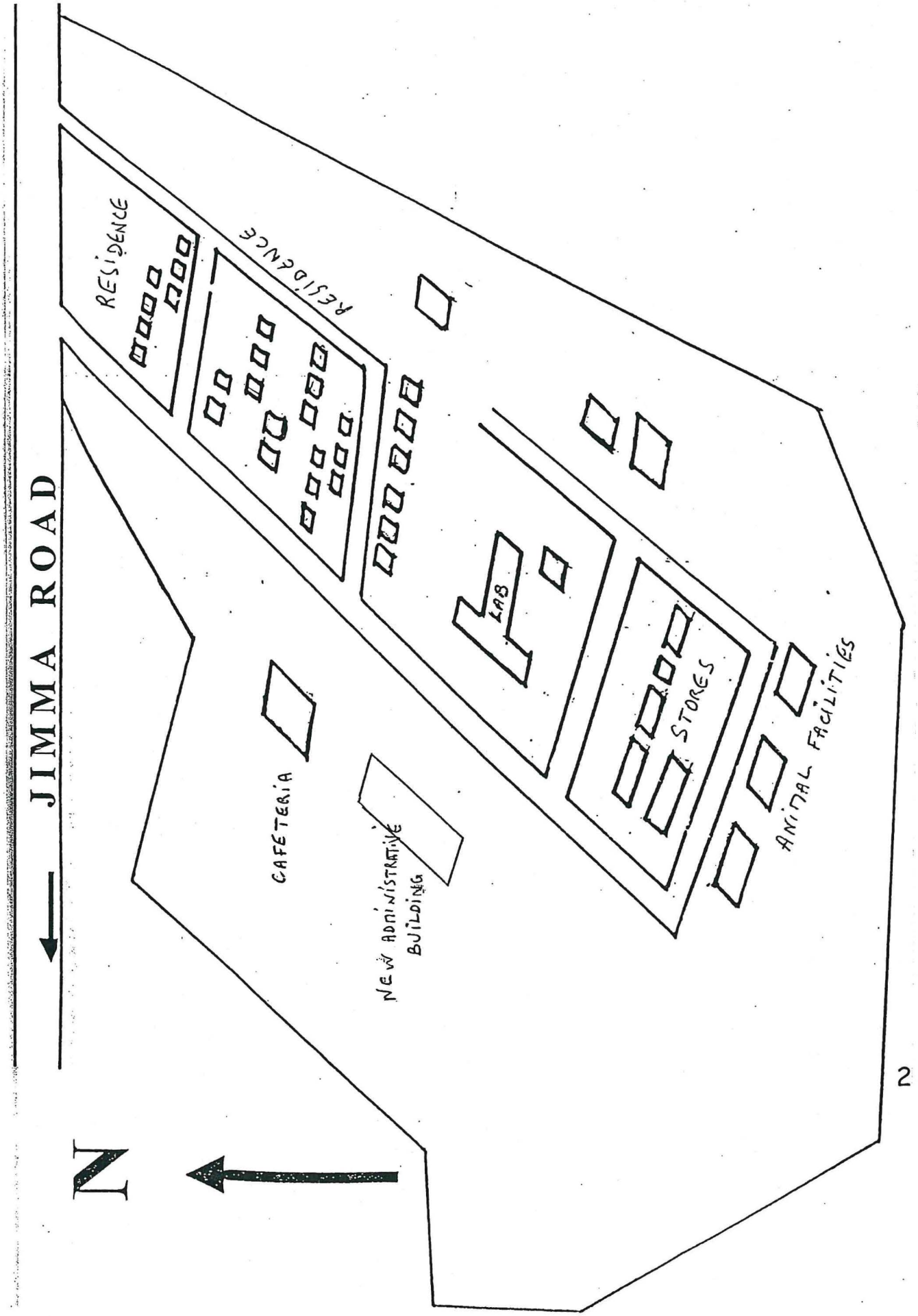
by

Dr. Emmanuel ALBINA (CIRAD)

Date	Time	Course Detail
21/07/03	9:00-10:30	Q.A. presentation
		General concepts
		ISO 17025
	10:30-10:45	***Tea break***
	10:45-12:30	Good laboratory practice (GLP)
		OIE Guidelines
	12:30-13:30	***Lunch***
	13:30-17:00	Evaluation of Q.A. in different laboratories (questionnaire & discussion)
22/07/03	9:00-10:30	Definition of Q.A. objectives in different laboratories
	10:30-10:45	***Tea break***
	10:45-12:30	Virology research in CIRAD: state of the art
	12:30-13:30	***Lunch***
	13:30-17:00	Q.A. of Sebeta (proposal)
23/07/03	9:00-10:30	Q.A. of Sebeta (proposal)
	10:30:10:45	***Tea break***
	10:45-12:30	General conclusion & recommendations

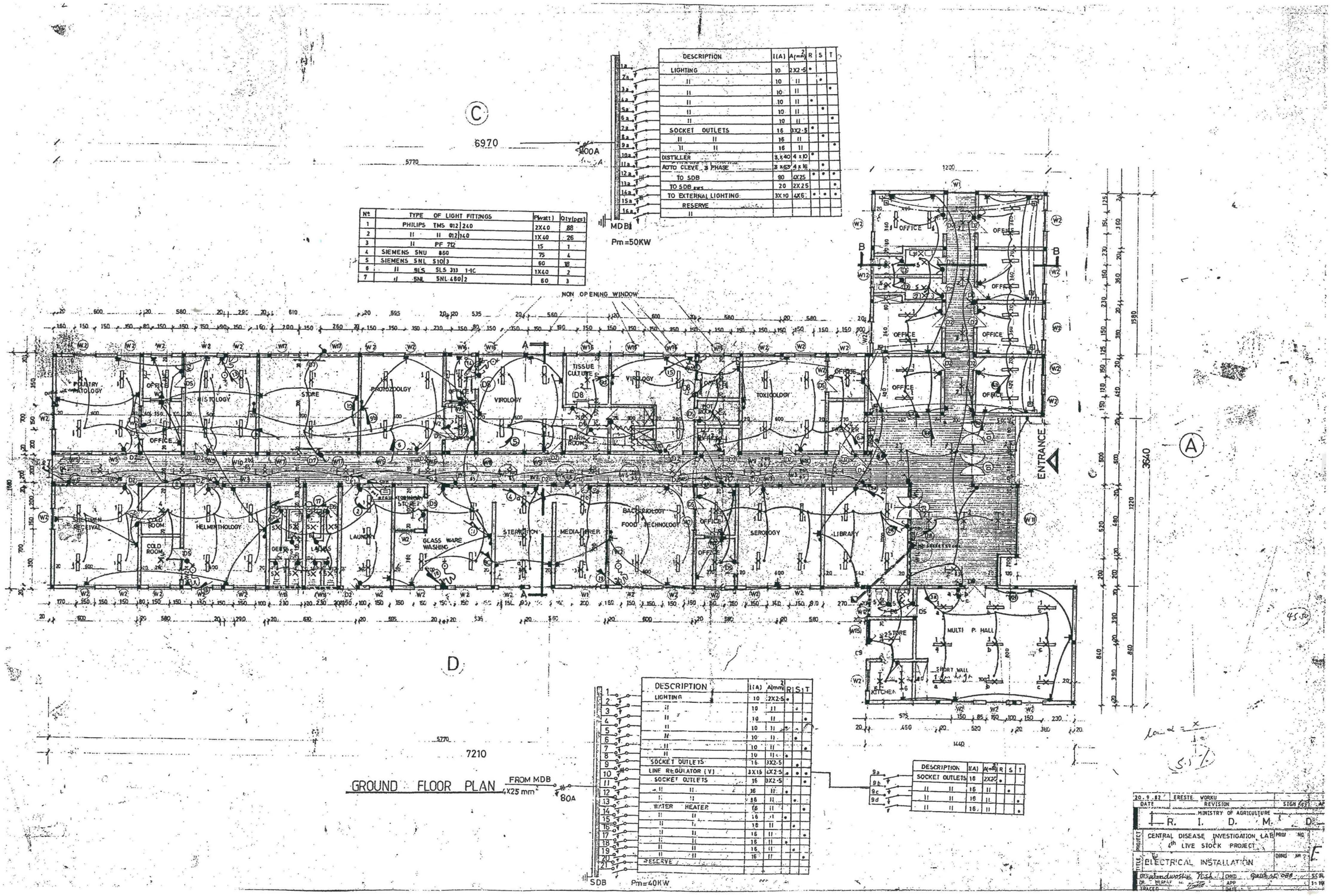
Annex 2

Site map of NAHRC



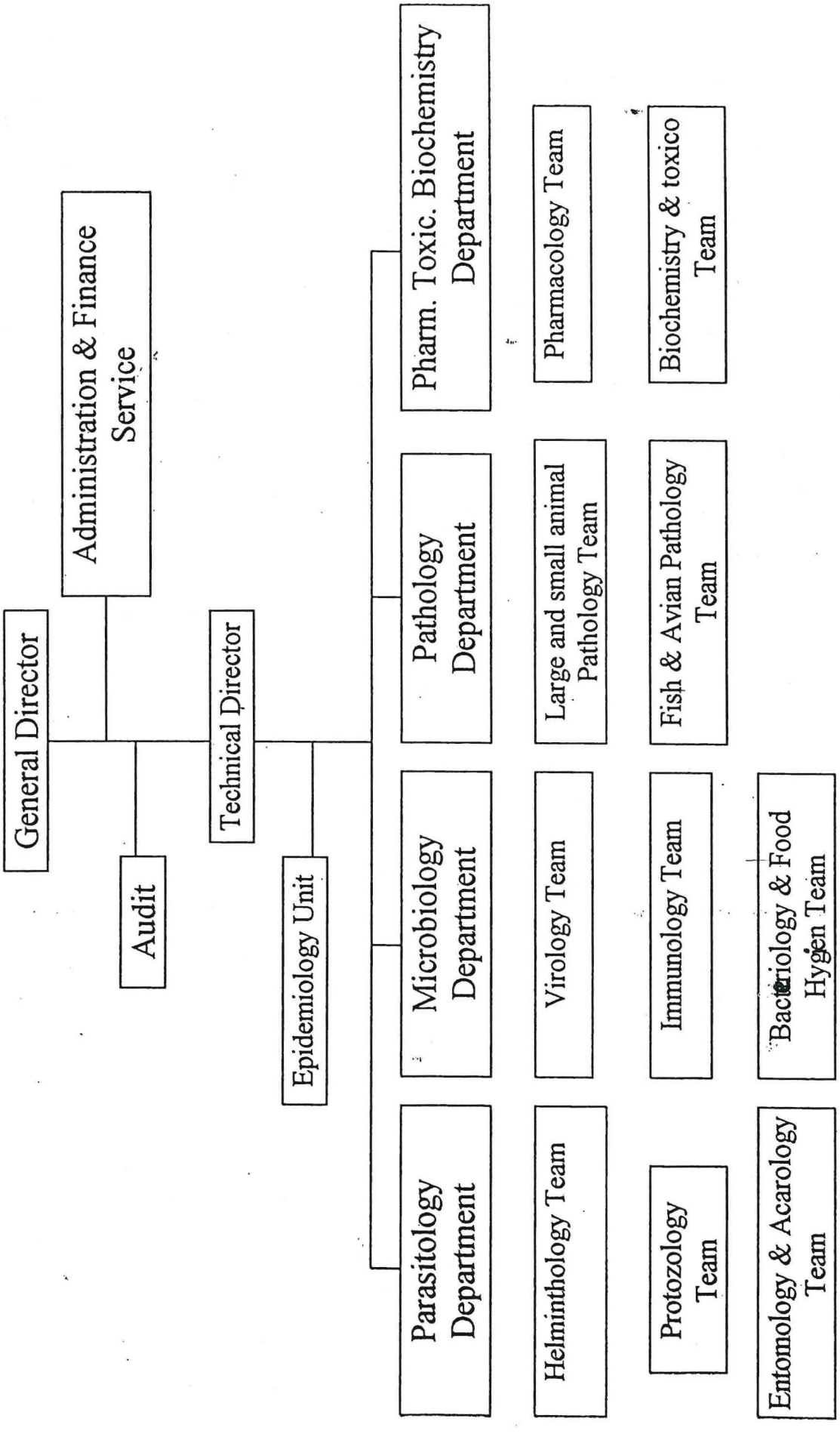
Annex 3

Map of the central laboratory building



Annex 4

Structure organisation of NAHRC



Quality Assurance Information

Sebeta

July 21-23/2003

*By Dr Emmanuel Albina**

List of workshop participants

Annex 5

Name	Organization	Signature		
		July 21/2003 QA information - Lab evaluation	July 22/2003 QA objectives – Sebeta proposals	July 23/2003 Sebeta proposals - Conclusion
Roman Tsuda	NAHRC			
Lakemariam Yigezu	"			
Dino Awel	"			
Night mesfenen	"			
Hailugeresh Adamu	"			
Abera Kebede	"			
Tefera Mulisa	"			
Abebe mesfenen	"			
Africa Tefera	"			
Dereje Shegu	"			

* DVM, PhD, former head of the accredited swine virology and immunology laboratory (Afssa), currently head of the tropical virology section of animal health programme (CIRAD)

Name	Organization	Signature		
		July 21/2003 QA information - Lab evaluation	July 22/2003 QA objectives – Sebeta proposals	July 23/2003 Sebeta proposals - Conclusion
MELAKU SOMBO	NAHRC			
EJIGU ZEBEN	"			
Berhan Ayalew	"			
Lelebrhan Yemeregen	"			
Yeftusra Alkidan	"			
Genet Bogale	"			
TIBEBU H/SILLASSIE	"			
Ayelech Mulunch	"			
Getachew Nenguste	"			
Asmamaw Berhanu	"			
Mesfin Ademe	"			
Kassa Bayou	"			
Tadewos Kassa	"			
Tilahun Tekle	"			
Hassen Chalca	"			
Million Abera	"			
Tesfaye Ka Haile	"	—	—	

Quality Assurance Information

Sebeta

July 21-23/2003

*By Dr Emmanuel Albina**

Name	Organization	Signature		
		July 21/2003 QA information - Lab evaluation	July 22/2003 QA objectives – Sebeta proposals	July 23/2003 Sebeta proposals - Conclusion
Etsay Kebede	Mekele Regional Laboratory			
Tesfaye Kebede	Debre Zeit " "			
Girma Abeto	Kombolcha " "			
Legesse Tsegaye	Bahar dar regional vet. lab.			
Zewdu Dagne	Mizan regional Vet. Lab			
Tsega Alemayehu	Addis Ababa Vet. Lab.			
Hagos Ashenafi	Faculty of Vet. Medicine			
Mengistu Mekuria	Sodo Reg. Vet. Lab.			
Gelagay Ameleq	NVI			
Hailu Wondimagegn	Assela lab			
Ahmed Dawa	Harar RVL			

* DVM, PhD, former head of the accredited swine virology and immunology laboratory (Afssa), currently head of the tropical virology section of animal health programme (CIRAD)

Name	Organization	Signature		
		July 21/2003 QA information - Lab evaluation	July 22/2003 QA objectives – Sebeta proposals	July 23/2003 Sebeta proposals - Conclusion
~~Ahmed Ibrahim~~	~~Harar R/V/L~~			
Adugna Tadesse	Bedele Reg. vet Lab			
~~Zewdu Dagne~~ –	~~Mizan Reg vet lab~~			

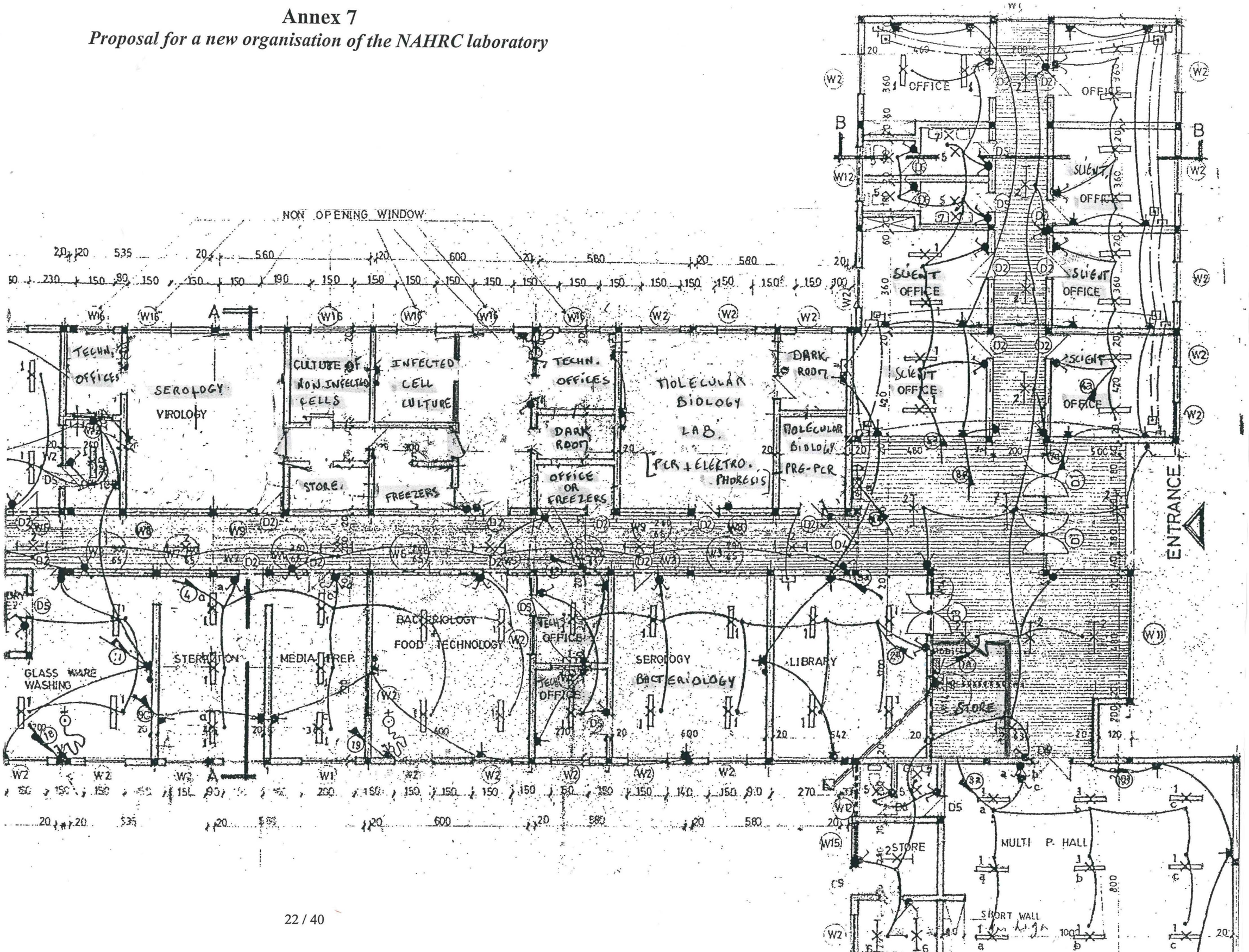
Annex 6

Results of QA evaluation in NAHRC and the Regional Veterinary Laboratories by using a questionnaire derived from ISO/17025 and covering all aspects of QA in the laboratory

Laboratory	Score (out of 45)
NAHRC (protozoology section)	34
Assela	24
Bahir Dar	21
Bedelle	16
Dire Dawa	29
Faculty of Veterinary Medicine	15
Hirna	22
Kembolcha	27
Mekele	28
Mizan	18
National Veterinary Institute	30
Shola	12
Sodo	16
Average	**22.5**

Annex 7

Proposal for a new organisation of the NAHRC laboratory



Annex 8

Copy of the presentations made during the QA workshop

Second step

- Implementation of a quality organization:
  - Appointment of a quality manager below the responsibility of the director
  - Appointment of a metrology manager below the responsibility of the quality manager
  - If necessary, appointment of local quality or metrology managers
  - Training plan for QA and metrology managers
  - Project schedule

Albina 2003

Third step: personnel and communication

- Involvement of personnel
- Information on quality assurance:
  - Quality assurance workshop with ALL staff
  - Interactive meetings of personnel sub-group for quality system definition
  - Written communication

Fourth step: progressive construction of the documentation system

- Each quality field needs collective evaluation, lab manager decision, action and evaluation (internal audit)
- The first action should be the definition of the documentation structure and of its identification (each document should be uniquely identified and linked to the documentation system)

Sebata qualities objectives in the next 12 months (1/3)

- Quality policy statement
- Appointment of a quality manager and training (3-4 weeks in an accredited laboratory)
- Appointment of a metrology manager and training (practice = 2 weeks in QSAE, theory = 1 week in ?)
- Information on quality assurance of all staff (local workshop for 2-3 days)
- Procedure for documentation structure and document identification

Albina 2003

Sebata qualities objectives in the next 12 months (2/3)

- New organization of laboratory:
  - Modification of room assignment (better division between offices and lab)
  - Modification of equipment position (removal of freezers from corridors)
- Improvement of testing traceability:
  - Unique identification for each analysis request: [*the system shall be designed and operated so as to ensure that samples cannot be confused physically or when referred to in records or other documents (ISO17025)*] Suggestion could be a unique code for each analysis request, labelled on samples and mentioned on all referred documents (client documents, registration books, raw data, result report...)

Albina 2003

Sebata qualities objectives in the next 12 months (3/3)

- Standard operating procedures for laboratory supplies and stocks:
  - Describe what is currently done
  - Solve the problem of expiry dates

Albina 2003

Evaluations

- Internal audits:
  - periodicity: every 4 months
  - Duration: half a day
- External audits:
  - One at mid-term and one at the end of period

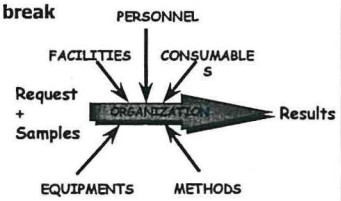
Albina 2003

NAHRC Participative Evaluation Method (1/2)

- Who?
  - Workshop participants
- What?
  - Participative evaluation of NAHRC
- Why?
  - To provide participants of the workshop with a practical approach on QA assessment
- Where?
  - Sebata, NAHRC laboratory, in 4 different sections:
- When?
  - July 22/07/2003

Method (2/2)

- How?
  - Visit of lab sections, interview of staff, record of at least 1 good point and 1 point to be improved on the following issues: sample and analysis receipt, building facilities, consumables, personnel, equipments, methods, result reporting
  - Duration: 1h30
  - 4 groups for 4 sections:
  - Debriefing after tea break



Development of Quality Assurance in NAHRC Sebeta

Proposals

First step

- Quality policy statement: made by the director
- Contents (ISO/17025):
  - Director's commitment to good professional practice, quality of testing and calibration
  - Director's statement of the lab services
  - Objectives of the quality system
  - Requirement for personnel engagement on quality assurance and implementation of quality policies and procedures
  - Director's commitment to compliance with existing appropriate standards

Quality policy statement

- Should not exceed 2 pages
- Should reflect the commitment of lab management to Quality Assurance
- Should identify sections and activities concerned
- Should identify resources for the project success
- Should be distributed to each staff member
- Should engage the lab towards the acquisition of an accreditation within a specified delay

Answering to the objectives of the quality policy statement

- Selection of reference guidelines to be applied (ISO/17025, GLP...)
- Definition of laboratory fields of activities concerned by accreditation
- Definition of work methods:
  - Work sub-groups
  - Document creation: assignment of tasks
  - For each document, use of the 5W method [who, what, why, where, when and how]

Test and calibration methods and method validation (2/2)

- Do you document any amendment of standards that will be under regular use in your laboratory?
- Have you estimated uncertainty of your measurement?
- Do you apply systematic control of calculations and data transfers?

Albina 2003

Equipment

- In your laboratory, do you calibrate or check equipments before first come into service?
- Are instructions on equipment use readily available for use?
- Are balances labelled with indications on their calibration status?

Albina 2003

Measurement traceability

- In your laboratory, do you have traceable working standards for the control of your balances?

Albina 2003

Handling of test and calibration items

- Do you have a procedure for receipt, handling, storage and disposal of samples?
- Do you have a system of sample identification that is retained throughout the sample life in your laboratory?

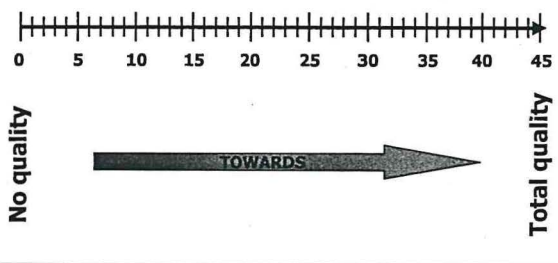
Albina 2003

Reporting the results

- In your laboratory, do you produce standardized result reports?
- Do result reports include name and address of « client », date of sample receipt and date of test performance?

Albina 2003

Results of evaluation



Internal audit and management reviews

- In your laboratory, Do you have internal evaluation of your activities and of the conformity of your results?
- Do you organise annual meetings with relevant staff for activity feedback and future plans?

Personnel (1/2)

- In your laboratory, do you ensure that persons performing tests have required competence and skills?
- Are technicians regularly trained in their field of competence (at least once every two years)?

Personnel (2/2)

- In your laboratory, do you maintain for each individual, a current job description specifying qualification and experience, tasks, responsibilities, duties and training history?
- Do you guaranty that short- term contracted personnel or students will not perform testing unless internal training and formalized evaluation of competence have been carried out before?

Accomodation and environmental conditions (1/2)

- In your laboratory, do you have separate rooms for bacteriology, parasitology, serology, virology, samples receipt and storage, consumables storage, preparation and sterilization of consumables?
- Is your laboratory organized to prevent cross-contaminations (one way progress) ?
- Do you have archive facilities to ensure secure storage and retrieval of documents?

Accomodation and environmental conditions (2/2)

- In your laboratory, do you control environmental conditions as required by relevant methods or procedures (e.g. control of room temperature when ELISA test performing requires 18-25°C)?
- Do you control access to rooms where testing is performed (including access control of lab personnel who is not directly working in the lab part)?

Test and calibration methods and method validation (1/2)

- Whenever methods for testing are not clearly specified by the « client », do you consult the « client » for an agreement on methods to be used?
- Whenever inappropriate methods are specified by the client, do you consult the client for an agreement on alternative methods?

Review of requests, tenders and contracts

- When « clients » address or modify their request by phone, is phone discussion recorded?
- Are there defined criteria for serum inclusion/exclusion into testing?

Purchasing supplies

- In your laboratory, Do you have a standardized process for purchasing lab supplies?
- Are purchased supplies checked for conformity before use?

Complaints

- Do you have records of client complaints?

Control of non conforming testing

- In your laboratory, Do you use systematically controls or standards for testing, thus allowing detection of nonconforming results?
- Do you have policy to determine the cause of nonconforming results?
- Do you participate to interlaboratory comparison tests?

Corrective and preventive action

- Are all nonconforming tests and their possible causes recorded?
- When equipment malfunction is detected, are investigations undertaken to evaluate the consequence of this event on previous testing?

Control of records

- Are raw data all recorded accurately and appropriately archived?
- Are raw data checked and initialled by the person responsible for their production?
- Are all lab result reports uniquely identified (with a serial number)?
- Are result reports easily retrieved from archives?
- Are mistakes crossed out and not erased, and the correct values entered alongside?

Evaluation of Quality Assurance

Questionnaire

Procedure

- Who?
  - Sebata and Regional laboratories
- What?
  - Evaluation questionnaire
- Why?
  - Assessment of QA level
- Where?
  - Sebata QA workshop
- When?
  - July 21/07/2003
- How?
  - By answering a questionnaire established from ISO/17025 requirements
  - By scoring answers and adjusting total score on a scale

Procedure details

- 45 questions referring to all aspects of ISO/17025
- Answer YES or NO (when uncertain, report NO)
- For YES attribute score 1
- For NO attribute score 0
- Report total score

CIRAD Albina 2003

Organization of the lab

- When appointed, does personnel sign a job description leaf-let delineating tasks, responsibility and duties?
- Has a member of staff been appointed as quality manager?

CIRAD Albina 2003

Quality system

- In your laboratory, Do you have quality objectives?
- Is personnel familiarized with standard operating procedures?

CIRAD Albina 2003

Document control

- Is document distribution controlled through a master list or an equivalent control document?
- Are document pages numbered and total number of pages indicated on each page?

CIRAD Albina 2003

Contents

- OIE Standard for management and technical requirements for laboratories conducting tests for infectious diseases (same contents as ISO/17025)
- OIE Guide 1: Validation of diagnostic assays for infectious diseases
- OIE Guide 2: International reference standrads for antibody assays
- OIE Guide 3: Laboratory proficiency testing

ISO 7218 Microbiology of food and animal feeding stuffs - General rules for microbiological examinations

- Contains specifications on:
  - Building facilities
  - Materials and equipments
  - Personnel
  - Preparation of materials
  - Preparation and sterilization of culture media and reagents
  - Samples for laboratory
  - Testing and result reporting

Equipments

- Incubator:
  - Requirement = X±1°C
  - Homogeneity of inside temperatures
  - Temperature checked daily with min/max thermometer
  - Cleaning and disinfection

Equipments

- Refrigerator:
  - Requirement = **-3±2°C**
  - Temperature checked daily with min/max thermometer
  - Cleaning and disinfection
- Freezer:
  - Requirement **< -18°C**, preferably = **-24±2°C**
  - Temperature checked daily with min/max thermometer
  - Cleaning and disinfection

Equipments

- Oven for sterilization:
  - Requirement = **170-180°C/1 hour**
  - Homogeneity of inside temperatures
- Biosafety cabinet:
  - Efficacy control once a year
  - Cleaning and disinfection after use
  - Periodical check of surface contamination

Equipments

- pH-meter:
  - Requirement = **X±0.1**
  - Each day before use, verification with at least two buffered solutions
- Balance:
  - Periodical verification with mass standards
  - Cleaning the weighing plateau once a day
  - Annual verification

OECD Principles of good laboratory practice

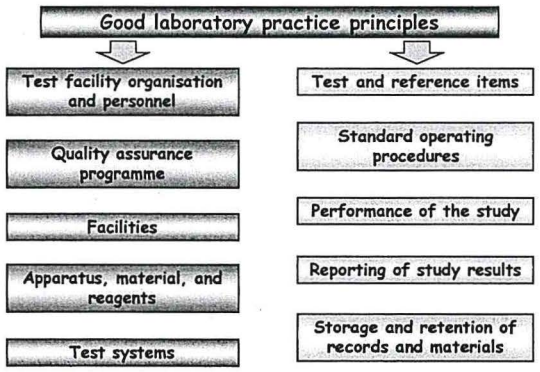
ENV/MC/CHEM(98)17
Unclassified
(01-26-98)

Analysis

- GPL specify requirements for the safety evaluation of chemicals contained in pharmaceutical, pesticide and cosmetic products, veterinary drugs, food additives and industrial chemicals
- GLP are less informative than ISO/17025 regarding quality assurance system
- However, GLP are more appropriate for the design of study protocol and its follow up

Contents

- Section 1: Introduction
  - Scope
  - Definitions of terms
- Section 2: Good laboratory practice principles



OIE quality standard and guidelines for veterinary laboratories: Infectious diseases

ISBN 92-9044-575-0

Analysis

- OIE guidelines provide an interpretation of the ISO/17025 guidelines in the context of veterinary laboratories working with infectious diseases: this interpretation does not modify the requirements
- It also provide three additional guides for the validation of diagnostic assays, the production of international reference standards and laboratory competence testing

ISO 17025

General requirements for the competence of testing and calibration laboratories

First edition (1999-12-15)

Albina 2003

DEFINITIONS

- Quality assurance : All the planned and systematic activities implemented within the quality system and demonstrated as needed.
- *Accreditation* : a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
- *Laboratory accreditation* : the formal recognition of the competence of a laboratory to carry out specific tests or specific types of tests", are specific to the use of ISO/IEC 17025.

Albina 2003

Analysis

- ISO/17025 specifies requirements for laboratories carrying out tests and/or calibration, including sampling
- It covers activities performed using standard, non-standard and laboratory-developed methods
- It covers many aspects of ISO 9001 and 9002 (1994) but has also several technical competence requirements that are not covered by ISO 9001 and 9002
- ISO/17025 is more informative on quality assurance and quality system than GLP

Albina 2003

Contents

- Scope
- Normative reference
- Terms and definitions
- Management requirements
- Technical requirements
- Annexes
- Bibliography

Albina 2003

Management requirements

- Organization
- Quality system
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints
- Control of nonconforming testing
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

Technical requirements

- General
- Personnel
- Accomodation and environmental conditions
- Test calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results
- Reporting results

Metrology

- Process by which the performances of an equipment used for quantitative measurements (determination of mass, volume, temperature, pH...) are determined and regularly controlled
- Any measure should be provided with its uncertainty:

$$X = y \pm u$$

where: X is the quantity to be determined
y is the value measured by the equipment
and u is the uncertainty of the measurement

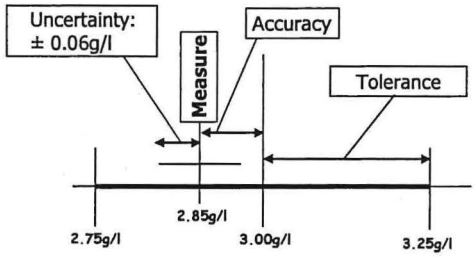
- U is determined by calibration

The 10 requirements of Metrology

- Identify measurement equipments
- Establish their control leaf-lets
- Define your minimum requirements for calibration
- Establish operating procedures for calibration
- Trace with national or international standards
- Determine environmental conditions
- Calibrate your equipments (results on control leaf-lets)
- Certify equipment capability
- Protect your equipment and avoid risk of adjustments
- Establish procedure for equipment exclusion

Important parameters in metrology

- **Accuracy:**
  - Measures the capacity of a measurement to give an exact value
- **Uncertainty:**
  - Measures the deviation of a measurement from expected result: corresponds also to the confidence interval of a measurement
- **Tolerance:**
  - Measures the acceptable deviation of a measurement in a given test



Uncertainty should be lower than ¼ of tolerance
Tolerance should be higher than 3 x accuracy

Conclusion on metrology

- Metrology is a necessary tool for quality assurance
- Needs serious training
- Sometimes considered as tedious
- Should be however set up with pragmatism
- Starting from the real needs in terms of measurements (official requirements, specific agreements...)
- Determining corresponding uncertainty through calibration procedures in connection with international standards

Other equipements requiring specific controls

- **Laminar flow cabinets:**
  - **In-house control:**
    - Decontamination of the working surface before and after each manipulation
    - Decontamination of all accessible surfaces once a week
    - Control or air flow (start manipulation 10 to15 minutes after switching on)
    - SOP for this control (what, why, who, when, how, results ?)
  - **External control:**
    - Once a year by an independent company

Controlling measurements

- Initial validation of equipments in 4 steps:
  - Validation of expected characteristics: *equipment must meet lab specification requirements*
  - Validation of installation procedure: *manufacturer and/or official specifications for installation must be fulfilled*
  - Validation of operating procedure: *equipment must operate properly*
  - Validation of performances: *equipment performances must be checked or calibrated*

⇒ Metrology

Controlling measurements

- Periodical verification of equipments:
  - Based on standard operating procedures (SOP)
  - Using written reports and storing records in the file dedicated to each measurement equipment
  - Leading to acceptance or exclusion of equipment (SOP)

Examples of periodical verifications

- Balances:
  - In-house checking:
    - Control of accuracy with calibrated mass (internationally certified)
    - SOP for this control (what, why, who, when, how, results ?)
  - External checking:
    - Once a year by an independent company

Examples of periodical verifications

- Micropipettes:
  - In-house checking:
    - Control of precision with calibrated balances and serial weighing of defined water volumes :
      - Example : for a 50-100 µl micropipette, weigh 10 pipetting at 50 µl and 10 pipetting at 100 µl, then check that deviation does not exceed your uncertainty specification
    - SOP for this control (what, why, who, when, how, results ?)
  - External checking:
    - Once a year by an independent company

Examples of periodical verifications

- Incubators (-80°C ⇒ + 56°C):
  - In-house checking:
    - Each equipment must have a thermometer inside or an electronic probe connected to a computer: in the former case, temperatures must be checked manually once a day
    - Thermometer should be calibrated and traceable with national or international standards
    - SOP for this control (what, why, who, when, how, results ?)

Examples of periodical verifications

- Autoclaves:
  - In-house checking:
    - Control of temperature by internal controls (« stericontrol »)
    - Permanent monitoring of temperature, pressure and time (printer required or manual records of important phases)
    - SOP for this control (what, why, who, when, how, results ?)
  - External checking:
    - Once a year by an independent company: control of equipment performances and security, control of thermal probes

Qualification requirements

- Technical manager qualification:
  - Graduation:
    - Doctor in biology (Human medicine, veterinary medicine, biochemistry...)
    - Doctor in Philosophy with biology specialization
  - Experience:
    - Several years of practice

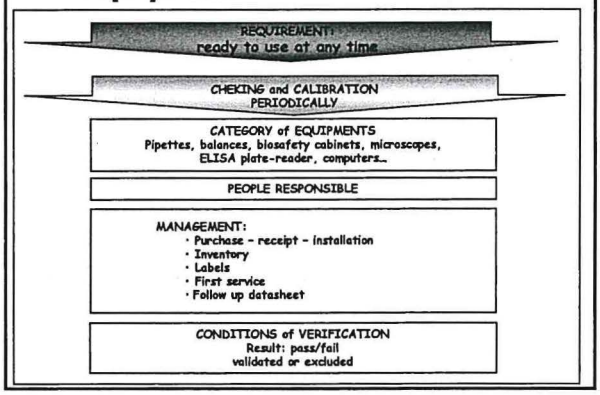
Albina 2003

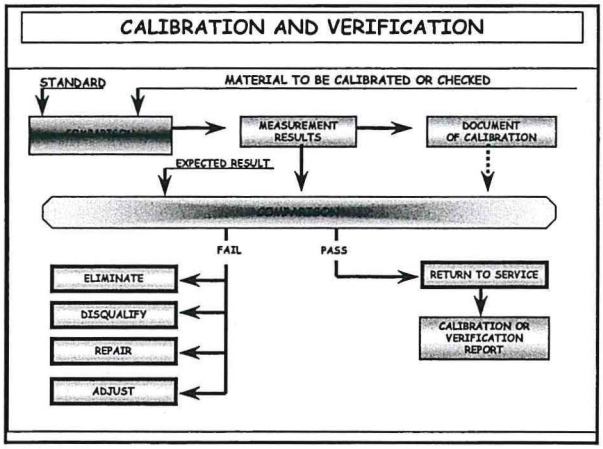
Internal qualification of the personnel performing the analyses

- Verification of initial graduation
- Training plan and knowledge evaluation
- Technical qualification:
  - Minimum number of analyses performed yearly (> 1000 for a given SOP)
  - Once a year, participation to an interlaboratory comparison test
  - In case of unsatisfactory results, tutorial completion of a testing with a qualified person

Albina 2003

Equipments





Quality assurance costs

- Costs of quality:
  - Salary of quality manager
  - Time for document working out
  - Calibration, certification with national or international standards
  - Building modifications and equipment purchase
  - Purchase of national or international guidelines
  - Accreditation costs
- Costs of no-quality:
  - 5 to 30% of the lab income
  - Errors, delays, loss of clients...

Albina 2003

Reference guidelines

- General requirements:
  - ISO 17025: General requirements for the competence of testing and calibration laboratories
  - ISO 9001: Quality systems – Model for quality assurance in design, development, production, installation and servicing
  - ISO 9002: Quality systems – Model for quality assurance in production, installation and servicing
  - ISO 7218: Microbiology of food and animal feeding stuffs – General rules for microbiological examinations
  - Good laboratory practice (GLP, OECD guidelines)
  - OIE guidelines
- Specific requirements:
  - For bacteriology, virology, serology... (national guidelines)
  - For biosecurity confinement level: OIE guidelines

Albina 2003

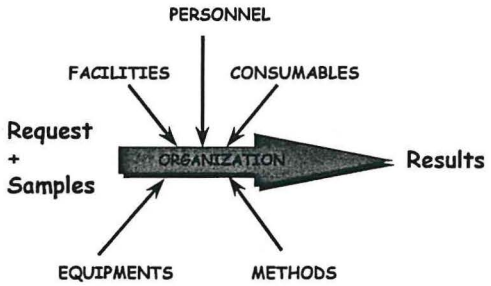
Document archives

- The quality manager is responsible for the document archives:
  - Identification of documents to be distributed and archived
  - Archive of all original documents
  - Definition of the archive duration and form (paper or computerised data)
  - Definition of the archive conditions (protection against fire or deprivation)
  - Maintenance of an historical file of all documents
  - Definition of the master list for distribution of documents
  - Archives by test or by field activity
  - All data regarding one testing should be traceable back from the archives

Quality assurance in a laboratory

- In addition to quality controls, a lab must ensure appropriate:
  - Internal organization
  - Facilities
  - Competent personnel
  - Procedure for sample reception, handling, registration, storage and preparation
  - Equipments
  - Materials and reagents
  - Methods
  - Procedure for results presentation, interpretation and transmission

The different components that may have an impact on results



Personnel

- Organization:
  - Sufficient number of qualified personnel
  - Appropriate ratio of Scientists/Technicians
  - Appropriate ratio of Technicians/SOP
  - Appropriate ratio of permanent/non permanent staff
  - Each personnel shall be well informed about his responsibilities and clearly understanding the functions he has to cover

Personnel

- Competence:
  - Technical manager:
    - Qualified and regularly trained
    - Having technical and general expertise
    - Experienced
    - Aware of methods and procedures
    - Ensuring that specified methods and procedures are followed and assessing the impact of any deviation
    - Ensuring that all raw data are fully recorded
    - Validating results
    - Signing and dating the final report

Personnel

- Competence:
  - Authorized Technicians:
    - Initial qualification and regular training
    - Apply SOP and commit themselves to comply with the instructions given in these documents
    - Record raw data
    - Follow internal and external evaluations and validations (intra or interlaboratory comparison tests)

Quality manual contents

- Document control
  - Description: definition of each category of documents
  - Identification of documents
  - List of current documents
  - Dispositions for distribution: master list
  - Archives
- Corrective and preventive actions
  - Amendments: definition and management procedure
  - Nonconforming testing and complaints: definition and management procedure
  - Internal audits: subject, organization (frequency, method...)
  - Management reviews: subject, organization (frequency, method...), feedback on deviations, nonconforming testing and complaints and on internal audits

CIRAD Albina 2003

Amendment and nonconforming testing

- Amendment: deviation from procedure which is proposed before testing and submitted to written authorisation
- nonconforming testing: unexpected deviation from normal process
- Amendment and nonconforming testing shall be managed: specific leaf-let, records, follow-up...

CIRAD Albina 2003

Internal audits

- Evaluation of the laboratory situation with reference to a quality objective
- Performed by a trained person with no implication in the inspected area
- Allows a fair evaluation of quality procedures and practices and identifies improvement actions

CIRAD Albina 2003

Quality Work-programme(s)

- Definition: Document(s) describing the procedures and associated resources undertaken by the laboratory in order to assure the quality of testing
- Should specify procedures, resources, personnel and delays used by the lab for a given testing
- Should contain the list of quality documents

CIRAD Albina 2003

Document management

- At any time, the complete list of applicable documents must be available
- Regular revision of documents is necessary (at least once a year) :
  - Each version should be incremented and the current version identification specified on all pages of the document (each page of the document should have a number out of total number of pages: example, 2/15)
  - Modifications in the new version should be summarised at the beginning of the document and then clearly identified within the document
  - A master list for distribution must be established and the obsolete version collected back to avoid co-existence of different versions

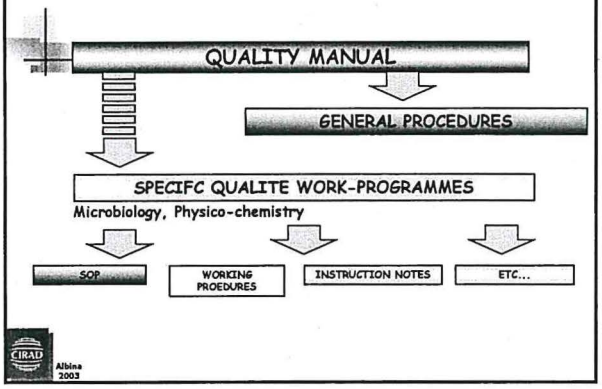
CIRAD Albina 2003

Other documents produced by the laboratory

- Results
- Final reports
- Ordering forms
- Invoices
- All have to be managed, recorded and archived as well

CIRAD Albina 2003

STRUCTURE OF THE DOCUMENTATION SYSTEM



Albina 2003

Quality manual

- **Definition:**
  - General dispositions undertaken by the lab to assure the quality of testing
- **Double objective:**
  - Internal use: give organizational description and functional rules to staff
  - External use: give clear and precise view of the organization and activities of the lab to potential clients and inspectors

Albina 2003

Quality manual contents

- Quality policy and strategy statement (written and signed declaration of lab director)
- Presentation of the manual
  - Presentation of the lab (activities and structure)
  - Subject of the manual (lab sections and activities concerned)
  - Definitions and guidelines referred to
  - Establishment of quality work-programmes and description of lab responsibility
- Personnel
  - Organization and management (organigramme...)
  - Detailed description of functions (example: quality manager, metrology manager...)
  - Current job descriptions and task assignment
  - Recruitment dispositions
  - Staff training and information

Quality manual contents

- Measurement and analysis equipments
  - Listing of different equipment categories: equipments for volume, temperature, mass measurements...
  - Description of interventions: initial checking or calibration, periodical checking, international standard traceability for measurement equipments
  - Organization: designation of equipment managers and deputies, duties of the metrology manager
  - Management: registry of equipments, equipment identification, individual equipment files containing records of inventory description, maintenance and control datasheets and manufacturer instruction use
  - Calibration and control: referring to contents of calibration operating procedures
  - Guidelines for equipment purchase, installation and first service

Albina 2003

Quality manual contents

- Laboratory facilities
  - General description: dated map with room assignment, conception and arrangements
  - Maintenance and cleaning
  - Access control and confidentiality measures
- Consumables
  - Listing of different categories: plastics, chemicals, biological reagents...
  - Supplying dispositions
  - Stock management: identification of products, inventory, minimal stock, expiry dates...

Albina 2003

Quality manual contents

- Test samples
  - List of sample categories: organs, sera, food stuff...
  - staff responsibility for receipt, handling, registration, storage and preparation of samples
  - General procedures for receipt, handling, registration, storage and preparation of samples
  - Checking procedure on accompanying documents
- Test demand
  - Process and documents used: identification, registration, analysis of the demand and test decision, test delays...
  - Conditions for test realization: responsibility for testing, checking raw data...
  - Result report: contents, responsibility for edition, checking, validation, approval, signature and sending

Albina 2003

Accreditation

- Official acknowledgment of the lab capacity to perform specific testing and to generate reliable results
- Accreditation authority: Organism managing a system of laboratory accreditations and deciding for specific laboratory accreditation

In France:

COMITE FRANCAISE D'ACCREDITATION
(COFRAC)
37, rue de Lyon
75012 PARIS
Tel: (33)1 44 68 82 20
w.w.w.cofrac.fr

cofrac

European co-operation for Accreditation (EA)

www.european-accreditation.org

Accreditation process

- Laboratory demand for accreditation
- Administrative examination of the demand (compliance of accompanying documents)
- Technical evaluation: method for evaluation, quality manual of the lab, reference guidelines...
- Visits: (1) initial audit, (2) validation audit, (3) extension audits
- Accreditation decision: after visit (1)

Quality documents

- The description of the quality system requires several documents:
  - Quality manual
  - General procedures
  - Quality work-programme(s)
  - SOP, working procedures, instruction notes...
- Each of these documents must be:
  - Uniquely identified: code, date, version number
  - Approved for use
  - Conveniently archived
  - Properly spread
  - Reviewed and Upgraded

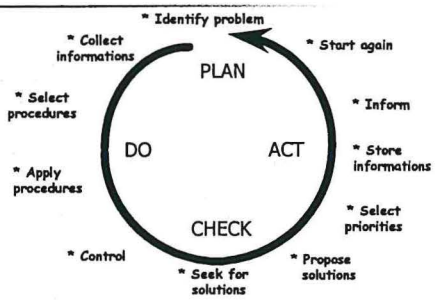
Definition of the quality documentation system

- Efficacy of quality system relies on efficacy of documentation system
- The first document should be the procedure describing:
  - The documentation structure of the lab
  - The form of the documents
  - The management of the quality document

A good documentation system should be:

- Well managed (easily reviewed and transmitted)
- Applicable and applied
- Reflecting at any time the reality

Quality assurance for solving problems



Albina 2003

The ultimate goal is total quality But not totalitarian quality !!!

- The quality system should tend to demonstrate the:
  - Quality of objectives
  - Quality of competences
  - Quality of attitudes
  - Quality of operations
  - Quality of results and products
  - Quality of communication

Albina 2003

The different phases of the development of a Quality system

- Why do you need to launch a QA system?
- Define the field of your QA needs
- Evaluate the existing dispositions
- Define QA policy and objectives
- Select reference guideline(s)
- Prepare your development strategy
- Build your QA system
- Maintain and improve your system
- Advertise

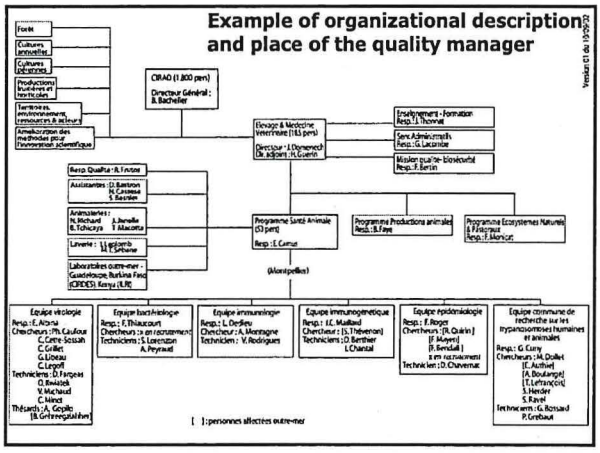
Albina 2003

Quality assurance: general requirements

- A quality policy and strategy statement must be carried on by the director
- A defined organization with a quality manager
- A quality manual defining quality system policies and objectives and listing the general organization and dispositions of the quality system
- A quality work-programme outlining the structure of documentation and listing the general procedures
- Specific standard operating procedures (SOP)
- An evaluation procedure: internal evaluation (audit) to verify that the lab still complies with requirements
- External evaluation for accreditation

Albina 2003

Example of organizational description and place of the quality manager



Albina 2003

Why is quality assurance desirable?

- Need for laboratory competence and result reliability
- Internal benefits:
  - Improvement of efficacy
  - Decrease of retesting
  - Increase of personnel responsibility and motivation
- External benefits:
  - National and/or international reference laboratory
  - Official designation
  - Accreditation

Albina 2003

QUALITY ASSURANCE
At The LABORATORY LEVEL

Emmanuel Albina
CIRAD-Emvt
July 2003

Contents

Principles of Quality and Confidence

- A Challenge:
  - Work together
  - Produce quality results
  - Fitting in with requirements (local, national or international)

« Confidence is achieved through collective reliability »
« Confidence gives feelings of assurance and security to the one who depends on the honesty and integrity of the other »

General considerations

- First objectives of quality assurance:
  - Writing what is done
  - Doing what is written
- Then, check if requirements are fulfilled
- if not, apply corrective action or modify requirements in order to improve traceability and reliability of results and confidence of clients

Quality concepts

- Prevent errors or deviations, limit corrective actions: collect data, analyse, improve procedures
- Do right since the very beginning, for the satisfaction of good work with no calculation
- Then avoid losses of:
  - Human forces
  - Materials
  - Power and water supplies
  - Means
  - Time...

Continuous improvement of confidence in the analysis