

**Access to Microfinance & Improved Implementation of Policy Reform
(AMIR Program)**

Funded by the U.S. Agency for International Development

**Laboratory Analytical Quality Assurance
Phase I**

Final Report

Deliverable for Policy Component, Task No. 4.6.5
Contract No. 278-C-00-98-00029-00

February/March, 2001

This report was prepared by John Weatherwax, in collaboration with Chemonics International Inc., prime contractor to the U.S. Agency for International Development for the AMIR Program in Jordan

CONTENTS

EXECUTIVE SUMMARY.....	1
INTRODUCTION AND BACKGROUND	2
TRAINING COURSE: LABORATORY ANALYTICAL QUALITY ASSURANCE (AQA).....	2
DRAFT AQA PROGRAM.....	3
TRAINING COURSE: MAINTAINING QUALITY IN ANALYTICAL METHODS.....	5
CONCLUSIONS AND RECOMMENDATIONS.....	6
ANNEX 1: LABORATORY AQA TRAINING PROGRAM AGENDA	8
ANNEX 2: LIST OF PARTICIPANTS FOR THE AQA TRAINING COURSE.....	9
ANNEX 3: TRAINING PRESENTATION (ANTHONY WHITEHEAD)	10
ANNEX 4: AQA TRAINING PRESENTATION (JOHN WEATHERWAX).....	11
ANNEX 5 :DRAFT AQA PROGRAM "FOOD TESTING LABORATORY- MINISTRY OF HEALTH" "AQABA, JORDAN"	12
ANNEX 6: PROPOSED CHANGES IN PROCEDURES	46
ANNEX 7: MAINTAINING QUALITY IN ANALYTICAL METHODOLOGY TRAINING PROGRAM AGENDA	47
ANNEX 8: LIST OF QUALITY IN ANALYTICAL METHODS TRAINING COURSE PARTICIPANTS.....	48
ANNEX 9: MAINTAINING QUALITY IN ANALYTICAL METHODS -TRAINING COURSE-	49
PRESENTATIONS (SLIDES AND OVERHEADS).....	49

EXECUTIVE SUMMARY

Analytical Quality Assurance (AQA) is a necessary activity in any analytical laboratory, especially those involved in national law enforcement such as the Ministry of Health (MOH) Food Testing laboratory in Aqaba, Jordan. In its simplest form, AQA is the procedure by which the laboratory establishes specific measures to control and improve analytical quality, and then provides a system to ensure that those quality control measures are being done. The net effect is not only reduction of analytical error, but overall improvement of analytical operations. A previous assessment of the MOH Food Testing Laboratory in Aqaba noted that the laboratory had no formal AQA program in place.

A training program on AQA was held from 25 February to 1 March 2001 in Aqaba. Participants included laboratory heads, analysts and technicians from MOH laboratories in Amman, Aqaba and Irbid, as well as Ministry of Agriculture (MOA) laboratories in Aqaba and the Jordan Institute of Standards and Metrology (JISM) laboratory in Amman. The course was designed to introduce the participants to AQA principles and then to involve them in the process of preparing an AQA Program.

On conclusion of the course, an AQA Program tailored to the needs of the MOH Food Testing Laboratory in Aqaba, was prepared by the consultant and critiqued by the participants. The Program included many of the suggestions and technical considerations put forward by the participants during the training course. It formalized many of the quality control procedures and requirements now in place and proposed means to assure their operation. It further detailed some proposed changes in procedures designed to improve overall operations and to assist the process of analytical data management needed for the risk-based system of import food control now being instituted at the Port of Aqaba.

A brief follow-up training course on Maintaining Quality in Analytical Methods was prepared and presented by the consultant on 12 and 13 March 2001. This included a discussion of analytical errors; the use of basic statistics to evaluate analytical data; proficiency testing of both individuals and the laboratory; and validation of new or modified analysis methods. Participants were again primarily from the Aqaba MOH laboratory, but included analysts from the MOH laboratories in Amman and Irbid.

The primary recommendation made was to adopt, at least in part, the proposed draft AQA Program. Much of the Program formalizes many of the quality procedures now done at the Food Testing Laboratory, or proposes internal quality control procedures that are of immediate use. These parts of the Program can and should be initiated as soon as possible. Those other parts of the Program dealing with proposals involving major changes should be adopted when the involved procedural changes are authorized.

The remaining report recommendations dealt with solutions to specific problems that were noted and discussed during the AQA training course and the preparation of the draft AQA Program.

INTRODUCTION AND BACKGROUND

On 15 February 2001, the Aqaba Special Economic Zone (ASEZ) was formally established. It includes the Port of Aqaba on the Red Sea and a surrounding 375 km² of land. This is a vitally important area as the Port is the only access for Jordan to world trade by sea. The ASEZ Authority is the governing body for the Zone and consists of six ministerial-level Commissioners, each of which is responsible for a major area of regulatory or operational activity. The Commissioner for Health and the Environment, Dr. Bilal Bashir, has among his responsibilities, the regulatory control of human health and the protection of the environment in the ASEZ. This includes ensuring the quality and safety of foods imported into the Zone. The Ministry of Health (MOH) Food Testing Laboratory in Aqaba provides laboratory analysis of samples of foods collected at the Port when offered for importation into the ASEZ. A previous assessment review¹ of that laboratory noted that there was no system or program in place to ensure high quality of analytical work. The report recommended establishment of an Analytical Quality Assurance (AQA) Program, to include appropriate training for the laboratory staff in AQA procedures.

An operating AQA program is an absolute necessity for a modern analytical laboratory, especially a government laboratory enforcing national food quality and safety laws. An effective AQA program not only minimizes analytical errors, it prevents their recurrence; it identifies training needs and operational deficiencies; it provides for cost savings in the long term (and often in the short term as well); and it provides a tracking record and documentation that can be referred to in the event of a dispute or to respond to inquiries.

The AMIR Program in Jordan is a USAID-funded activity and is committed to assisting Jordan in establishing a risk-based system of import food control, which would ensure food safety as well as provide for better access by Jordan to world markets. Improving the capability for laboratory testing of import foods is an important part of this system. It was therefore considered necessary to establish an AQA program for the MOH Food Testing Laboratory and to train the laboratory staff, as recommended by the previous assessment review.

TRAINING COURSE LABORATORY ANALYTICAL QUALITY ASSURANCE (AQA)

On arrival in Aqaba, the consultant visited the MOH Food Testing Laboratory and met with Dr. Damen Abbadi, Director of the MOH Directorate, Aqaba. Dr. Abbadi expressed his interest and support of the proposed training program in laboratory AQA. The consultant advised him that the training would be in both lecture and workshop format and that the goal was to prepare a draft AQA program for the Food Testing Laboratory, as the end product of the training course.

The AQA training course was established from 25 February to 1 March at the Crystal Ballroom, Aqaba Gulf Hotel, Aqaba. It was held from 1800 to 2200 hours each evening, to allow for necessary ongoing laboratory analytical work during the day. The AMIR Workshop Coordination Group in Amman arranged for an excellent sound system and simultaneous

¹ See Report of the Assessment Review of the Ministry of Health Food Testing Laboratory, Aqaba, Jordan, AMIR Program, September 2000

translation. The training course agenda is attached as Annex 1. Participants included laboratory heads, analysts and technicians from Aqaba, Amman and Irbid, representing both the Ministries of Health and of Agriculture, as well as the Jordan Institute for Standards and Metrology (JISM). A total of 21 persons participated. The list of participants is attached as Annex 2.

A welcome was given during the course opening ceremonies by Dr Bashir, who stressed the importance of assuring laboratory analytical quality in examining import foods. AMIR consultant Mr Anthony Whitehead was involved in the establishment of the risk-based import food control system for Jordan. Mr Whitehead provided the participants with an overview of that system and its ramifications for improved coverage of import foods at the Port. (A copy of the slides used in Mr Whitehead's presentation is attached as Annex 3).

As noted in the agenda, the first two evenings of the course introduced AQA principles and how to prepare an AQA program for a laboratory. (A copy of the slides used by the consultant for that presentation is attached as Annex 4). The third evening consisted of group discussions on the technical elements in AQA, including establishment of Standard Operating Procedures (SOPs). The final two evenings were in workshop format with the participants divided into work groups and assigned portions of proposed AQA program elements to discuss and to provide an outline of considerations for preparation of a draft AQA program.

DRAFT AQA PROGRAM

The consultant prepared a draft AQA program following the course and included the information developed during the closing session discussions. It was tailored to the MOH Food Testing laboratory in Aqaba, but could be adapted to any other laboratory if desired, simply by adjusting the elements to fit the requirements of the new laboratory. The draft AQA program is attached as Annex 5.

Discussions by the group during the training course, especially in the workshop portion, were lively and a number of innovative ideas to improve laboratory analytical quality were aired. Some of these, unfortunately, were simply not practical, but others were quite useful and were included in the program. The draft program prepared by the consultant, formalizes many procedures which are or have been used (but which were not previously documented) and proposes a number of new procedures. The new procedures as well as those problems or difficulties which need to be addressed, are discussed below in the order they appear in the draft AQA program:

Housekeeping – A laboratory can be a very hazardous place to work for those who have no scientific training. Laboratory workers involved in cleaning and housekeeping operations need additional training in avoiding specific hazards such as contact with toxic or dangerous chemicals, including cleaning and disinfecting compounds. Also, more and better cleaning equipment is needed (e.g. mechanical floor scrubber).

Safety – The Food Testing Laboratory does not have a safety program and has almost no safety equipment. A safety program needs to be implemented as soon as possible, along with obtaining the necessary equipment and supplies. The latter includes fire extinguishers, portable eyewash stations, first aid kits, face shields, etc. The laboratory does have dust masks for use in the Aflatoxin sample preparation area.

Hazardous waste handling and disposal –Special plastic bags that will survive autoclaving are needed so that they can be used to collect pathogen-contaminated glassware or food material for sterilization. There is also a need for metal cans (about 20-liter size) for collection of toxic solvent waste for later disposal in an appropriate land fill (one where ground water would not be affected) or by incineration, if available.

Quality concerns – air quality – The window air conditioning units presently direct air at bench top level, which can create problems for microbiological examinations.

Quality concerns – fume hoods – An air flow meter to measure fume hood exhaust rate is needed for routine checking of the hoods to ensure their proper operation.

Sample receipt and assignment – This section of the draft program contains the largest number of proposed procedural changes. Most of these changes reflect and are dependent on the new sample collection procedures proposed for food imports into the ASEZ. A listing of the changes proposed in the AQA program, along with how it is now done, is attached as Annex 6. The key issues are:

- ◆ Smaller sample size due to portion sampling (avoiding the present incredibly large sample sizes of up to 300 kg and more);
- ◆ Separate samples for each lot production code sampled (simplifying the laboratory handling and final data entry for the risk-based system);
- ◆ Use of a unique sample number assigned at the time of collection (rather than by the laboratory) and a sample collection report tailored to the data needs of the risk-based system;
- ◆ Elimination of the storage and later return of the analyzed sample remainder to the importer (not necessary with small sample sizes and makes more laboratory sample storage space available);
- ◆ Use of a proposed Laboratory Analysis Results sheet as an assignment control document; as a summary document for a compilation of final results; and as a data entry document for the risk system.

Instrument performance – Uninterruptible Power Supply (UPS) units are needed for all computers and those instruments having computer components (such as data systems). A UPS device provides for continuous instrument or computer operation for up to 15 minutes following a power failure. This permits the computer or instrument to be shut down with no loss of data, until the power resumes.

Reference standards – As noted in the program, primary reference standards of chemicals and other substances, are the most desirable as their purity is certified by a national standards organization or other acceptable certifying organization. There is no certification of primary reference standards in Jordan, even by JISM. Therefore, any primary standards must be purchased from foreign sources. At the present time the Food Testing Laboratory has no primary standards and uses only what the program defines as secondary or “other” standards.

Identification of approved methods – One of the suggestions to improve quality that were brought up by the participants, was to prepare a flow chart showing steps in the analysis for specified analytical methods. This would include critical points in the analysis and places

where the test could be stopped overnight if needed. The consultant heartily endorses this procedure and included it in the AQA program.

Analytical worksheets – preparation and use – Pre-printed worksheet forms are very useful for many reasons, among which are:

- ◆ Recording of analytical data is much easier and faster, and preparation error is reduced.
- ◆ Training a new employee in use of the form is simplified.
- ◆ Review of the data is both easier and faster as the reviewer knows where to look on the form.

At present, such forms are used only to a limited extent by the Food Testing Laboratory. The consultant strongly urges the preparation and use of pre-printed analysis worksheets as much as is possible. This was stressed by the consultant during the training, but is not directly referred to in the AQA program.

There is one issue that became obvious during the training course, but cannot be covered in an AQA program. It appears that there is no direct communication on new laboratory requirements or standards between the MOH in Amman and the outlying laboratories such as in Aqaba and Irbid. These laboratories must get any new requirements or other information from the main MOH laboratory in Amman. It would seem reasonable that the laboratories should be treated equally regardless of size when new information is distributed.

During the AQA training course itself and during the critique of the prepared draft AQA program, the consultant stressed to the participants that much of the draft program can be implemented now because much of it represents what is actually being done, presented as formal procedures with reporting requirements. Those portions of the draft program that propose fairly radical changes in procedure (notably the sample receipt and assignment section) can only be implemented as procedural changes are authorized by the MOH. In a true sense, therefore, the draft AQA program serves as a goal. Also, programs such as this are dynamic and subject to change and revision as circumstances warrant.

TRAINING COURSE MAINTAINING QUALITY IN ANALYTICAL METHODS

As a follow-up to the AQA training described above, the consultant prepared and presented a two-day training course in Maintaining Quality in Analytical Methods. This was held 12-13 March 2001, also at the Aqaba Gulf Hotel and also from 1800 to 2200 hours. As with the AQA training, the evening sessions were held to permit normal work at the Food Testing Laboratory during the day. The agenda is attached as Annex 7. The participants were again primarily from the Aqaba Food Testing Laboratory, with representatives from the Amman and Irbid MOH laboratories. A list of the participants is attached as Annex 8. Four key areas related to quality in analytical methodology were covered. These were:

- ◆ Analytical error – what it is and does - A discussion of accuracy and precision in analysis, as well as random and systematic errors and what can be done to reduce the latter.

- ◆ An introduction to statistical evaluation of analytical data – A presentation of some basic statistical tools that can be used to evaluate groups of analytical data to detect systematic errors and serious random errors, and to identify trends.
- ◆ Proficiency testing – intra- and inter-laboratory – A discussion of ways to test the analytical proficiency of individual analysts, the laboratory as a whole and the laboratory as it relates to other laboratories.
- ◆ Validation of analytical methods – The need for validation of new or changed analysis methods and approaches that could be used in designing the validation procedure.

Copies of the slides and overheads used by the consultant in the training course are attached as Annex 9. One change was made in the schedule of the final day. By mutual agreement of the consultant and the other AMIR consultants, Anthony Whitehead and John Parker, the Food Inspectors being trained by Mr Parker were invited to join the laboratory participants during the last part of the final laboratory training session. Some individual inspectors and analysts were socially acquainted and were generally aware of each other's work. They had never met as a group, however, to discuss how they could better work together. This joint meeting provided that opportunity. Each consultant made a presentation on the interrelationship of the food inspectorate and analytical services in import food control. Ms Rima Za-Mut, Director, Food Control Division, ASEZ Authority, outlined the functions of the ASEZ Authority and the import entry procedures to be used by ASEZA Customs under the risk-based system. This was followed by a general discussion. The consultant believes it was a valuable and productive joint meeting.

CONCLUSIONS AND RECOMMENDATIONS

The proposed AQA Program for the Food Testing Laboratory in Aqaba (see Annex 5) formalizes many of the quality control requirements and procedures already in place, with some proposed changes and improvements, especially in documentation and reporting. It further proposes other changes and new procedures which are not presently being done but which are needed to ensure quality and to integrate the laboratory into the data processes of the risk-based import food control system. Some of these new procedures are dependent upon corresponding changes in the import sample collection process. It is therefore strongly **recommended** that, as an initial step, the MOH Food Testing Laboratory in Aqaba adopt those portions of the proposed draft AQA Program (Annex 5) that do not involve or depend on procedural changes in sample collection at the Port. Especially important are the assessment review protocols described in Chapter 10 of the Program, to assure that control of quality is being done.

It is further **recommended** that the Food Testing Laboratory prepare additional Standard Operating Procedures (SOPs) and assessment review protocols as needed, using as guides the SOPs and protocols now included in the Program.

The remaining recommendations will deal with problems and difficulties noted during discussions of the AQA process during the training course and during preparation of the draft AQA Program. These will be listed under the headings used in the body of this report.

Housekeeping – The laboratory cleaning staff need additional training to acquaint them with laboratory hazards encountered during cleaning operations and it is **recommended**

that such training be given. It is further **recommended** that consideration be given to purchase of mechanical cleaning aids such as floor scrubbers.

Safety – The laboratory has no safety program and very little safety equipment or supplies. It is strongly **recommended** that a safety program be developed and adopted and that necessary safety equipment and supplies be purchased. (Note – The consultant is scheduled to return to the Aqaba laboratory to conduct training on new instruments and methodology. At that time, the consultant will provide a proposed safety program and list of needed equipment and supplies, for consideration by the laboratory).

Hazardous waste handling and disposal – At present, all waste to be disposed of is placed in the trash if solid and flushed down a sink if liquid. Containers are needed for hazardous waste handling and disposal. It is therefore **recommended** that plastic bags that are autoclavable be purchased for sterilization of glassware and foods that are contaminated with pathogenic bacteria. It is further **recommended** that metal cans (about 20 liter size) also be purchased to allow for collection and later disposal of toxic solvent waste.

Quality concerns – air quality and fume hoods – It is critical that air drafts at bench-top work surfaces are at a minimum so as to avoid contamination of plates in microbiological examinations. It is therefore **recommended** that laboratory window air conditioning units be adjusted so that air does not blow on the bench surfaces. The exhaust rate of fume hoods is also important and it is **recommended** that an inexpensive air-flow meter be purchased to monitor hood exhaust rates.

Sample receipt and assignment – Use of the proposed new procedures outlined in this section is dependent upon proposed changes in the methods of sample collection. It is **recommended** that the provisions of this section be implemented as soon as new inspection and sample collection procedures are adopted. The proposed Laboratory Analysis Results sheet or a similar document prepared by the laboratory should, however, be considered for immediate implementation.

Instrument performance – Power failures are fortunately not a frequent occurrence in Aqaba, but they do occur from time to time. Computers and laboratory instruments with computer data components are sensitive to loss of power as data can be lost without possibility of retrieval. It is **recommended** that Uninterruptible Power Supply (UPS) units be purchased for each computer and instrument with computer components. UPS units will supply uninterrupted power during a power outage, so that computers and instruments can be shut down without loss of data, until power resumes.

Reference standards – The Food Testing Laboratory has no primary chemical standards as there is no certifying agency or organization in Jordan for primary standards (this includes JISM). Such standards are needed as a reference point to confirm the purity and quality of existing secondary and other standards now in use in the laboratory. It is therefore **recommended** that selected primary standards be purchased from foreign sources, until such time as local primary standards are available.

Analytical worksheets – The consultant strongly **recommends** the preparation and use of pre-printed worksheet forms by the laboratory. Some are in use presently, but there are a number of analyses that would benefit from the use of such forms. They also tend to reduce preparation error and are much easier to review.

ANNEX 1

LABORATORY ANALYTICAL QUALITY ASSURANCE TRAINING PROGRAM

Venue – Crystal Ballroom, Aqaba Gulf Hotel, Aqaba, Jordan

Dates – 25 February-1 March 2001

Time – 1800-2200 hours

Lecturer – John Weatherwax, AMIR Consultant

AGENDA

25 February

- 1800 – 2000 Welcome – Dr B. Bashir, ASEZ Commissioner for Health and Environment
Opening remarks and introductions – J. Weatherwax
A Risk-based System of import food control, an overview – A. Whitehead
The role of the laboratory in a Risk-based System of import food control – J. Weatherwax
- 2000- 2030 Coffee/tea break
- 2030- 2230 Analytical quality assurance (AQA) – an introduction

26 February

- 1800- 2000 Preparation of a laboratory AQA program
- 2000- 2030 Coffee/tea break
- 2030- 2230 Preparation of a laboratory AQA program (continued)

27 February

- 1800- 2000 Technical elements to include in a AQA program – group discussion
- 2000- 2030 Coffee/tea break
- 2030- 2230 Standard operating procedures (SOPs) – group discussion

28 February

- 1800 – 2200 Developing a draft of a AQA program for the Ministry of Health Aqaba Food Testing Laboratory – (the participants will be divided into small work groups with assigned program elements to discuss and prepare an outline of considerations for later group discussions in plenary session)
(There will be no formal break, but coffee/tea will be available at 2000 hours)

1 March

- 1800 – 2200 Group discussion in plenary of the comments and considerations prepared by the individual work groups. Development of a final draft AQA program.
(Again, no formal break, but coffee/tea will be available)
Closing remarks – J. Weatherwax

ANNEX 2: List of Participants
In the
ANALYTICAL QUALITY ASSURANCE
Training Course: “Laboratory Participants”

Name	Organization *	Position
Ashraf Abu- Hassan	MOH, Amman	Agricultural Engineer
Hanan Musad	MOH, Amman	Laboratory Technician
Rajab Najar	MOH, Amman	Veterinarian
Maha Hamdan	MOH, Irbid	Food Technician
Nada Bitar	JISM, Amman	Head of Food Laboratory
Ahmad Abu- Syam	MOA, Aqaba	Plant Technician
Randa Hawash	MOA, Aqaba	Laboratory Technician
Maysoun Al- Sharif	MOA, Aqaba	Laboratory Technician
Mahmoud Mustafa	MOH, Aqaba	Head of Food Laboratory
Atef Abu- Syam	MOH, Aqaba	Agricultural Engineer
Ayoub Al- Reyalat	MOH, Aqaba	Veterinarian
Amjad Hussein	MOH, Aqaba	Veterinarian
Ashraf Daradkeh	MOH, Aqaba	Agricultural Engineer
Mohammad Abdullah	MOH, Aqaba	Food Technician
Nihal Khader	MOH, Aqaba	Laboratory Technician
Mai Abdullah	MOH, Aqaba	Agricultural Engineer
Ali Tawaha	MOH, Aqaba	Agricultural Engineer
Alia Hassan	MOH, Aqaba	Laboratory Technician
Ruwaida Hassan	MOH, Aqaba	Agricultural Engineer
Hadeel Hamed	MOH, Aqaba	Agricultural Engineer
Ehab Nussair	MOH, Aqaba	Veterinarian

* - Key: MOH = Ministry of Health
 MOA = Ministry of Agriculture
 JISM = Jordan Institute for Standards and Metrology

Annex 3
Training Presentation (Anthony Whitehead)

Attached

Annex 4
AQA Training Presentation (John Weatherwax)

Attached

Annex 5

Draft AQA Program
Food Testing Laboratory
Ministry of Health
Aqaba, Jordan

Date prepared: 1 March 2001

Approved by:

Signature

Date

CONTENTS

Chapter 1 – Introduction and background

- Quality policy and responsibilities
- Scope of laboratory duties and expertise
- Organization and personnel

Chapter 2 – Laboratory facilities and environment

- Housekeeping and pest control
- Safety program and procedures
- Hazardous waste disposal
- Quality concerns

Chapter 3 – Sample handling and accountability

- Sample receipt and assignment
- Sample storage
- Sample disposal

Chapter 4 – Instruments and equipment

- Instrument performance
- Equipment calibration
- Maintenance and repair

Chapter 5 – Reagents and media

- Ordering and inventory maintenance
- Storage and handling procedures
- Quality concerns

Chapter 6 – Reference standards

- Ordering, storage and handling procedures
- Quality concerns

Chapter 7 – Analytical methods

- Identification of approved methods
- Performance testing
- Validation requirements and procedures

Chapter 8 – Analytical worksheets.....

- Preparation and use
- Reporting requirements
- Review and acceptance

Chapter 9 – Records and reports.....

- Scope of coverage
- Files maintenance and archiving

Chapter 10 – Program assessment and documentation.....

- Assessment review schedule
- Correction of deficiencies and documentation

Annexes

1. Organizational chart
2. Laboratory Analysis Results sheet

Standard Operating Procedures

1. Instrument performance criteria
2. Equipment calibration

AQA Assessment Review Protocols

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Instruments and equipment 2. Reference standards 3. Analytical worksheets | <p>Instrument</p> <p>Reference</p> <p>Analytical</p> |
|--|--|

CHAPTER 1

INTRODUCTION AND BACKGROUND

Quality policy and responsibilities

The Food Testing Laboratory of the Ministry of Health, Aqaba, Jordan, is committed to the establishment and maintenance of high quality laboratory analytical work. This Analytical Quality Assurance (AQA) Program is designed to assist and to further that commitment. The Program identifies key operational and functional areas in the laboratory in Chapters 2 through 9, and describes how quality is to be controlled in those areas. Chapter 10 outlines the scope and scheduling of those assessment reviews necessary to assure that the quality control activities in the laboratory are being done in a proper and timely manner. This includes a listing of the required reports and other documentation. It further includes the procedures for follow-up corrective action when deficiencies are found during the reviews.

The Director of the Ministry of Health Directorate in Aqaba has the overall responsibility for the establishment and direction of a quality policy for the Food Testing Laboratory. He is the approving authority for the present AQA Program and any future revisions to that Program. The Head of the Food Testing Laboratory is responsible for the day-to-day administration of the AQA Program within the Laboratory. He will appoint a Quality Coordinator from among the laboratory staff. The duties and responsibilities of the Quality Coordinator include, but are not limited to:

- Scheduling and conducting assessment reviews.
- Preparation of necessary AQA records and reports
- Archiving those records and reports for future access
- Noting deficiencies found during reviews and recommending corrective actions
- Following up on corrective actions to ensure the deficiency is corrected and is unlikely to recur
- Providing advice and guidance to laboratory staff in AQA matters
- Providing training in AQA principles and procedures for new laboratory staff
- Advising the Laboratory Head and suggesting changes or improvements in the AQA Program
- Preparing revisions and up-dates to the AQA Program as needed

Individual staff members in the Laboratory have the responsibility to become familiar with the AQA Program and its quality control requirements and to implement those requirements in their daily analytical work. The staff will promptly and accurately complete logbooks or other records that are required to be prepared or maintained. An effective AQA Program is dynamic and subject to change and improvement. The laboratory staff is encouraged to suggest such changes and improvements as the need arises.

Scope of laboratory duties and expertise

The Food Testing Laboratory in Aqaba is one of three Ministry of Health facilities that examine imported as well as domestically produced foods. The Food Testing Laboratory is essentially completely involved in import food testing, with less than 1% of its analytical

work devoted to domestic foods. The import foods examined are exclusively those entering the Aqaba Special Economic Zone (ASEZ), primarily through the Port of Aqaba.

The Laboratory is qualified to examine, and conducts analytical tests for, a wide variety of food quality and safety issues. These include, but are not limited to, the following:

Chemical examinations

- Colors in foods
- Metal residues
- Food contaminants (e.g. Aflatoxin, bromide residues)
- Food additives
- Various tests and indicators which indicate product quality

Microbiological examinations

- Various pathogenic organisms found in food (*Salmonellae* spp; enteropathogenic *Escherichia coli*; *Bacillus cereus*; *Vibrio parahaemolyticus*; *Vibrio cholerae*; and *Clostridium perfringens*)
- Indicators of bacterial quality (total aerobic plate count; *Staphylococcus aureus*; *Escherichia coli*; *Coliforms* spp; and *Streptococcus faecalis*)
- Bacterial toxins (*Staphylococcus aureus* enterotoxin)
- Yeast and mold
- Incubating low-acid canned foods and examining the contents of any swollen cans following incubation

Physical examinations

- Insect and other filth in foods
- Examination of can seam and container integrity for canned foods
- Examination of other packaging for integrity
- Examination of labeling
- Examination of fish for parasites
- Various visual and organoleptic examinations

The Laboratory also provides analytical expertise for any investigation of local food poisoning outbreaks, especially those suspected of being microbiological in origin. When requested, the Laboratory provides scientific advice and guidance on the analytical examination of foods.

Organization and personnel

A chart showing the location of the Food Testing Laboratory within the structure of the Ministry of Health is attached as Annex 1. The Laboratory itself is organized into four analytical groups, each dealing with specific analytical areas, as follows:

Chemistry Group – All chemical and physical testing of foods, except parasites in fish
Aflatoxins Group – All Aflatoxins residue testing. (Other mycotoxins will be included as training and new instrumentation are received)

Microbiology Group – Microbiological pathogen and quality testing for foods other than meat and fish

Meat and Fish Group – All microbiological and physical testing (including parasites in fish) for fresh, refrigerated or frozen meat and fish

Laboratory analytical staff in Chemistry, Aflatoxins and Microbiology is rotated among those three groups on a regular basis. The Meat and Fish Group are primarily veterinarians and are exempt from this rotation.

Each Laboratory staff member is expected to be:

Knowledgeable in the analytical procedures that they are required to perform

Aware of the scope and limitations of their duties

Familiar with AQA requirements and the application of AQA to their work

When new analysts are hired to join the Laboratory staff, they are assigned for training to a senior staff member. They are made acquainted with laboratory administrative procedures (rules, forms used, analysis requirements, etc.) and are trained in the specific analysis methods used. As noted above, the AQA Coordinator provides training in AQA principles and procedures.

Individual experienced staff members are encouraged to maintain and improve their technical knowledge by attending seminars, workshops, etc. and by self-study. Management provides specific training opportunities when and where possible. The Laboratory Head maintains a Training Record for both new employees and experienced staff. This documents completion of formal training as well as providing information on individual staff member areas of study, experience, training and expertise. The Training Record is restricted and may only be accessed by the individual and by management.

CHAPTER 2

LABORATORY FACILITIES AND ENVIRONMENT

Housekeeping and pest control

The building housing the Food Testing Laboratory is *located in Aqaba city. The structure has two floors with the Laboratory occupying converted office space in most of the upper floor. The process of housekeeping encompasses all cleaning and related activities to maintain the Laboratory in a neat, orderly and clean condition. Order and cleanliness are necessary for effective and efficient laboratory operation.*

The Laboratory has four workers who serve as cleaning staff. Two of these are men who also move samples from Receiving to the analysis area, and provide other lifting and carrying services as needed. Floor cleaning of the laboratory rooms and corridors is performed daily. The workers also clean bench space not in current use. There are many hazards in a laboratory and the cleaning of bench areas in use should only be done by persons who are aware of those hazards and how to cope with them. Therefore, the analyst cleans bench space in use and any spillage occurring during analysis.

Insect pests are a constant problem in older buildings, especially where food is stored and handled. A pesticide compound is sprayed in the Laboratory at two-month intervals to control insect pests. The Laboratory Head maintains a record of these spray treatments, which includes the pesticide used, the date applied, and the means of application. If insects are noted in a given laboratory area between spray applications, then that area receives immediate spray treatment with a note made in the record.

Safety program and procedures

(The Food Testing Laboratory does not have a formal safety program at present. A program is being developed and when adopted, it will be detailed in this section).

Hazardous waste disposal

The Laboratory must dispose of hazardous waste material in a safe manner. This includes foods and glassware that are contaminated with microbial pathogens. The Laboratory collects pathogen-contaminated food and glassware in plastic bags that are then sterilized by autoclaving. Sterile waste material is disposed of in the trash and reusable glassware is cleaned.

Biological toxins such as Aflatoxin are detoxified chemically before disposal of the container or material. Aflatoxin may be destroyed by application of common household hypochlorite bleaching solution.

Waste chemical solvents that are not water-miscible (e.g. chloroform, diethyl ether, etc.) are to be destroyed by incineration or by collection in metal containers and disposing in a suitable land fill (where no ground water can be contaminated).

Quality concerns

Air quality – Microbiological analytical operations such as plating and culture transfers are presently done on the open bench. In order to monitor the air quality in the microbiology work areas, a petri dish containing a non-selective general-purpose media is exposed to the air for 15 minutes and then incubated and a colony count made. If more than 15 colonies are found, the microbiological quality of the air in that area is considered unsuitable. This is done once every two weeks and is in addition to routine negative controls done at the time of analysis. A record of this check is maintained by the Microbiology Group, which conducts the testing.

Freezers/refrigerators – It is important that freezer and refrigerator units that are used to store samples are operating at the proper temperature. A check is made at least once daily during work hours, that they are at the correct temperature, and a notation is made in a record kept in the room where the units are located. Any discrepancy in temperature is immediately brought to the attention of the Laboratory Head.

Fume hoods – Fume hoods in the laboratory must have an adequate airflow to operate properly and to prevent solvent and other fumes from entering the laboratory air. The air exhaust rate of each fume hood is checked daily when it is switched on. The hood front opening is closed to about 20 cm. There should be physical evidence of airflow into the hood. No record of this check need be kept. However, if there appears to be inadequate or no airflow, the Laboratory Head is to be advised immediately.

CHAPTER 3

SAMPLE HANDLING AND ACCOUNTABILITY

Sample receipt and assignment

All samples are received in the Laboratory Reception area. The sample is accompanied by a sample collection report and a sample number will have been assigned at the time of collection. The sample package is given a quick visual inspection on receipt to ensure there is no damage, leakage, etc. (If damage is noted, the sample is put aside without further processing and the Laboratory Head is notified). Any special storage requirements given on the collection report are noted and the sample is properly stored pending assignment. The storage location is noted on the collection report. Parts 1, 2, 3 and 7 of a Laboratory Analysis Results sheet (see Annex 2) are completed for each sample. The sample receipt information and storage location are entered into a Sample Register maintained in Reception. This Register includes the following information:

- Sample number
- Product
- Date and time received
- Condition (if damaged, the Laboratory Head is notified)
- Initial storage location
- Date sample is given to analyst
- Receiving analyst
- Date analyzed sample is returned for storage (if returned)
- Date of final disposal
- Method of disposal

The collection report, any accompanying documents as well as the partially completed Laboratory Analysis Results sheet are given to the Laboratory Head. The Head completes parts 4, 5, 6 and 12 (date assigned) of the Results sheet and assigns the sample. The collection report and any attached documents are given to the laboratory group assigned the sample. The Head retains the Results sheet as a control, until analytical results are received from the examining group. The group receiving the collection report with the sample assignment will contact Reception and arrange for delivery of the sample. The analyst receiving the sample will confirm that the sample matches the description on the collection report, as to product, total units or portions collected, etc. Any discrepancy is reported to the Laboratory Head.

If the sample is to be examined by more than one group (e.g. microbiology and chemistry), then one group is selected by the Head to receive the collection report with the assignment. The second group is given a portion of the sample for their analysis, by the first group.

During the analysis, the physical sample will be in the custody of an analyst of the group assigned the sample. This analyst is responsible for maintaining the integrity of the sample as well as for interim storage. Interim storage must be at the proper temperature and in a secure area.

Sample storage

The Laboratory has two sample storage rooms. One is used only for dry storage at ambient temperature and has metal shelving. The shelves are appropriately numbered so that samples stored in the room can be located easily. The second storage room contains four top loading freezers and one refrigerator, for frozen and refrigerated sample storage. The freezers are each identified and sections within each freezer are noted, so that samples stored in them can be easily located. The Sample Register initiated and maintained by Reception will indicate these storage locations.

Sample disposal

When the sample analysis is complete and the results reported to the Laboratory Head, the Head will attach the analysis worksheets to the Laboratory Analysis Results sheet and will complete parts 8-10 (results) and 13 (date completed). At that time, if a portion of the sample still remains, the Head will complete part 14 (sample disposition) and will instruct the analyst on disposition of the sample remainder.

If the remaining food sample is considered hazardous (contains a bacterial pathogen, a toxin, etc.) it will be disposed of as hazardous waste (see Chapter 2). If not, it may be disposed of by denaturing (making it inedible) and placing in the trash. Reception is notified of the disposal date and manner, so that the information can be entered into the Sample Register.

CHAPTER 4

INSTRUMENTS AND EQUIPMENT

(**Note:** For purposes of this AQA Program, ‘instruments’ are considered to be measuring devices – e.g. chromatographs, pH meters, balances, etc., and ‘equipment’ is considered to be for sample processing – e.g. ovens, baths, shakers, etc.)

Instrument performance

Where possible, the Laboratory keeps sophisticated instruments in an Instrument Room where the environment can be more closely controlled than in the open laboratory area. When this is not possible, instruments are placed in laboratory areas that are generally free of air drafts and have proper services (electric, water, etc.). At present the Laboratory does not have Uninterruptable Power Supply (UPS) units for its computer or for instruments with computer data. UPS units provide battery-operated power to the instrument for a short time, in the event of line power failure for the building. They are needed to prevent data loss and/or damage to sensitive computer components of modern instruments.

An individual log book is maintained for each of the following instruments and is kept with the instrument:

- Atomic absorption spectrometer
- Gas chromatograph
- High performance liquid chromatograph
- UV-visible recording spectrophotometer

Each logbook keeps a record of:

- Instrument name and accessories
- Date and results of performance tests (see below)
- Date and results of any calibrations done
- Date of any maintenance performed
- Date instrument is removed from service (inoperable with repairs needed)
- Date and type of repairs performed
- Date instrument is returned to service (after repair)

Checking performance of an instrument is an integral part of an AQA program. A periodic performance check provides assurance that the instrument is operating in a satisfactory manner and that the instrument results are usable for analytical reporting. A Standard Operating Procedure (SOP) has been prepared for instrument performance criteria, and is attached as SOP 1. The schedule for performance checking is given in Chapter 10.

Equipment calibration

The calibration of and checking that calibration is important for certain equipment, especially those devices that have set temperatures for operation. Examples are incubators, ovens and water baths. SOP 2, attached, covers equipment calibration and checking. The schedule for the checks is given in Chapter 10. The results of calibration or checking are included in one logbook covering all individual devices. The log book is kept in a laboratory area designated by the Laboratory Head, and includes the following information regarding each piece of equipment:

- *Name of equipment*
- *Date and result of any calibration*
- *Date and result of calibration checks (e.g. operating temperature)*
- *Date of any maintenance performed*
- *Date equipment is removed from service (inoperable with repairs needed)*
- *Date and type of repairs performed*
- *Date equipment is returned to service (after repair)*

Maintenance and repair

Where possible, instrument and equipment maintenance should be a routinely scheduled event. The Jordanian Scientific Society provides some maintenance (and repair) services. Manufacturers of the more sophisticated instruments often have service personnel available in the country or in the region. Any instrument or equipment maintenance or repair is recorded in the logbooks referred to above. Also if possible, the Laboratory Head should keep records of maintenance and repair costs. These may be later used to justify purchase of new or updated instruments or equipment.

CHAPTER 5

REAGENTS AND MEDIA

Ordering and inventory maintenance

Reagents (chemicals, solvents, etc.) used in chemical testing and media used in microbiological testing are critically important to the laboratory. There must be sufficient stock of the correct purity on hand, stored properly and available for immediate use. A system of supplies administration must be in place to ensure that these requirements are met.

The Food Testing Laboratory places an annual bulk order for needed reagents and media, with the Ministry of Health in Amman. The MOH maintains a stores unit in Amman for bulk stocks of reagents and media and orders sent there by the Laboratory are usually filled and returned in 1-2 days. The Laboratory keeps a minimum stocking level of two-week use, of all reagents and media on hand. When this reorder point is reached, the Laboratory places an order with the MOH stores. The Laboratory Head maintains a Supplies Logbook to control ordering, receipt, and inventory of reagents and media. This Book includes the following information regarding each item:

- Item name and description
- Container size
- Cost per unit
- Maximum stock level
- Minimum stock level (reorder point)
- Date and amount ordered
- Date received
- Expiration date on label (if any)
- Amount on hand and location in storage area
- Units removed for use – date and analyst
- Balance on hand

The ordering and inventory system used by the Laboratory is as follows:

- *A supplies order is placed with the MOH stores in Amman*
- *When the order is received it is checked for completeness, placed in the supplies storeroom (reagents) or the laboratory media storage area (media), and entered into the Supplies Log Book*
- *When a container of reagent or media is removed from storage for analytical use, the Laboratory Head is notified and he enters the information in the Supplies Log Book*
- *When the reorder point is reached, a supplies order is placed*

Storage and handling procedures

The Laboratory supplies storage is a room with shelving. It is air-conditioned to maintain a stable temperature, especially for solvents. It is locked with the key retained by the Laboratory Head.

When an analyst receives a reagent or media from stock, he or she inspects the container, the cap or seal, and the product itself for any damage or abnormalities. Any such are immediately reported to the Head. The analyst also confirms that any expiration date given on the product label has not been exceeded. The analyst typically retains the container until the reagent or media is used up, or until the expiry date has been reached. Any expired product as well as the empty container, is disposed of by the analyst, who then notifies the Laboratory Head.

Quality concerns

Media performance – Before a new bottle of media is used in an actual analysis, it is tested to ensure that it will support growth of the microbes being analyzed for. This provides assurance that there will be no false negative results obtained with that media.

Media preparation – When petri dish plates are prepared of a given media, the plate top is marked with a felt-tip pen to indicate the day the plate should be discarded if not used.

Reagent purity - Generally, the Laboratory accepts the commercial purity statement of reagents. In those cases where ultra-pure material is required (certain solvents used in residue analyses, for example), the purity of the substance is confirmed by examining the material using the testing system to ensure that no interference in the analysis is found.

CHAPTER 6

REFERENCE STANDARDS

Ordering, storage and handling procedures

For purposes of the AQA program, a Reference Standard is a pure chemical or organic substance that may be used for comparison during the quantitative and/or qualitative analysis of a constituent or attribute of a food. Reference Standards may be divided into three categories:

1. Primary – Substances that have been analyzed and the purity certified by a national standards organization or other acceptable certifying organization.
2. Secondary – Substances whose purity is certified by analysis of commercial suppliers or organizations other than the above.
3. Other – All other reference standards which are considered acceptable by the laboratory, but which do not fall into the above two categories. These can include locally obtained materials that have undergone replicate analyses or have been compared to primary or secondary reference standards to calculate purity.

“Working” standards are dilute solutions of the above reference standards, prepared and used personally by individual analysts. Information on the preparation of working standards is recorded and retained in the individual analyst’s notebook.

The Laboratory obtains its reference standards from suitable sources and, on receipt, identifies each as belonging to one of the above categories. The label of the substance is then marked with its category. The received standards are placed in a special storage cabinet. They are then assigned to specified analysts in each laboratory group as needed. These analysts then assume responsibility for the proper storage and use of the reference standard. If the material has an expiration date, the analyst ceases to use it on that date and destroys the unused remainder. This and disposal of the empty container is reported to the Laboratory Head.

The Laboratory Head maintains a notebook record of all reference standards (by category). The notebook has entries for:

- Substance name
- Responsible analyst
- Purity (in % or other suitable designation)
- Source (where obtained)
- Date received by the laboratory
- Date of expiration (if any)
- Special storage requirements (refrigeration, freezing, storage in the dark, etc.)
- Date used up or destroyed

If deemed important, a description of the substance will also be included. For category 3 substances, the notebook will indicate how the purity was determined (e.g. comparison to a higher standard, comparison to an absolute value, etc.).

Quality concerns

Maintenance of purity – Great care must be taken to ensure that reference standards do not become contaminated or lose their purity. All standards (including working standards) are stored properly with attention to special storage requirements. When removed from storage for use, they are returned to storage as soon as is practicable. Care is taken when using a reference standard, to avoid contamination (e.g. using clean transfer utensils, etc.) and to prevent unnecessary difficulties (e.g. leaving a hygroscopic material uncapped and open to the air for longer than necessary).

CHAPTER 7

ANALYTICAL METHODS

Identification of approved methods

The Food Testing Laboratory uses analytical procedures from three primary sources in testing foods for quality and safety. The primary sources are:

- *AOAC International Book of Methods*
- *British Pharmacopoeia*
- *Ministry of Health procedures*

The Laboratory, however, can and has used other procedures, primarily from international sources such as the Codex Alimentarius or recognized national or regional methods such as those from the U.S. Food and Drug Administration or the European Union.

A file is maintained with copies of all methods approved for use in specified analyses or for specific food products. In order to assist analysts in applying the appropriate methods, flow-chart diagrams have been prepared and are on file, which show the analytical steps for commonly used methods or for those procedures which are very complex. These diagrams also indicate points during the procedure where extra care must be taken or where the analysis can be stopped overnight and continued the following day.

Performance testing

The analysis methods used by the Laboratory are primarily from international sources and many, if not most, have undergone collaborative or other testing to assess their consistency and usability in many different laboratories. This provides a measure of assurance that the methods in use are capable of providing accurate results when used in the Food Testing Laboratory.

This assurance, however, is not sufficient. It must be demonstrated that the method works and provides good quality results when used in the Laboratory. This is done by a system of performance testing of the methods generally used. A method performance test has the added benefit of providing a measure of the analytical skills of the analyst. The test is typically an examination of a sample containing a known amount of the analyte being tested for, or a blank sample to which the analyte has been added. The analyst performing the test should note and record any critical points in the analysis as well as noting stopping places during the analysis where it can be held overnight. This information can be used in preparing the analysis flow diagrams referred to previously. The analyst should further note any anomalies or difficulties encountered, and advise the Laboratory Head accordingly.

The Food Testing Laboratory performs a performance test for all new methods, and for the more commonly used older methods. A notebook is kept with the methods file which details the performance tests done. Information in the notebook includes:

- Name of method
- Date of performance test

- Analyst
- Result of performance test
- Remarks (observations by the analyst)

Validation requirements and procedures

From time to time, any given analytical procedure must by necessity be modified to accommodate changes in sample matrix, unusual interferences, etc. Any change proposed by the analyst, however, must have the approval of the Laboratory Head, and must also be validated by an appropriate recovery procedure.

The validation procedure used must be carefully selected. The simplest procedure is to simply add analyte to a blank sample and attempt a recovery. This, however, may not be satisfactory as it does not test the extraction of the analyte from the sample matrix. If a sample with a known level of the analyte is available, it should be used. There is also the possibility of running side-by-side tests using the modified method and a second procedure known to give good results. As a matter of policy, validation recoveries should be run in triplicate, to provide some information on the precision of the modified method.

The results of validation tests for modified methods are kept in the individual analysts notebook, but a brief summary of the modification and validation should be placed with the original method in the methods file.

CHAPTER 8

ANALYTICAL WORKSHEETS

Preparation and use

The analytical worksheet is the single most important document that an analyst prepares. It provides the means to make a final judgment on the legality of a lot of food – does it meet the standards or does it fail? All analytical worksheets, whether preprinted or not, share some common features and requirements, which are:

- *Sample number*
- *Product name*
- *Product description as received*
- *Analytical method used (with any modifications and validation noted)*
- *Date of analysis*
- *Analytical results*
- *Analyst(s) name(s) and signatures*

The above information would appear on the front of the worksheet. The back of the worksheet would have raw data and calculations hand-written in ink. (Use ink for a permanent record as pencil may be erased and written over). If an error is made in any data, calculations or other information on the back of the worksheet, then one line should be drawn through the error and a brief note made adjacent to the error to explain the strike-out. Some other information that is to be included on the back of the worksheet is:

- *Always record units of measure (g, ml, etc.) in raw data and calculations*
- *If an instrument such as a gas chromatograph or high performance liquid chromatograph is used, list the instrument parameters used for the analysis*
- *Chart recordings should be noted in the data, but the charts themselves should be stored in an area near the instrument*
- *When calculations are done, record the entire formula used in the calculation, not just the final answer*

Reporting requirements

As previously noted in Chapter 3, the Laboratory Head retains the Laboratory Analysis Results sheet for control purposes, when the analysis assignments are made. Each analyst examining the sample prepares a analytical worksheet which, when complete, is given to the Laboratory Head to attach to the Results sheet and be used in the final analysis summary. Before the analyst gives the completed worksheet to the Head, it is advisable to have the worksheet calculations checked by a colleague. The colleague would then initial the calculations as being arithmetically correct.

Review and acceptance

The Laboratory Head provides the final laboratory review and acceptance of the analysis worksheet and any other sample documents. It is his decision to recommend pass or fail to the MOH Directorate based on his acceptance of the analysis results.

CHAPTER 9

RECORDS AND REPORTS

Scope of coverage

This AQA program does not encompass all records and reports of the Food Testing Laboratory, but does include those considered to be important in controlling quality. Those records and reports generated by the AQA program and referred to in the preceding chapters as well as the final chapter, are (note that records can be documents, logbooks or notebooks):

- *Staff training*
- *Pest control program*
- *Air quality monitoring*
- *Freezer/refrigerator temperature monitoring*
- *Sample register*
- *Laboratory Analysis Results sheet (Annex 2)*
- *Instrument logbooks*
- *Equipment logbook*
- *Supplies logbook*
- *Reference standards notebook*
- *Analysis worksheets*
- *Standard Operating Procedures*
- *AQA Review Protocols*

In addition to the above, a file of all approved analytical methods is maintained, and the Laboratory Head keeps a index list and file of all new requirements issued by the Ministry of Health. He sends an inquiry to Amman every few months to ensure that that index list and file are as current as possible. Further, the Quality Coordinator maintains a file of all assessment reviews and follow-up activities.

File maintenance and archiving

The various records and reports noted above are maintained and kept in locations noted in this Program. The Laboratory Analysis Results sheet is used for data entry into the computer information system that in turn is part of the overall risk-based system for import food control.

Archiving will be a future activity. When it becomes necessary to archive files, records or reports, the Laboratory Head will determine the archiving procedure and location.

CHAPTER 10

PROGRAM ASSESSMENT AND DOCUMENTATION

Assessment review schedule

Any and all areas in this Program which define analytical quality, are potentially subject to AQA assessment review to determine if the quality control measures taken are in fact being implemented and if not, what can be done to correct the situation. Three key areas under this Program were selected for initial assessment review. These are:

- *Instruments and equipment*
- *Reference standards*
- *Analytical worksheets*

AQA Assessment Review Protocols were prepared for each of these and are attached to this program. Each Protocol includes the review criteria, the schedule, the acceptable level of quality and the report format.

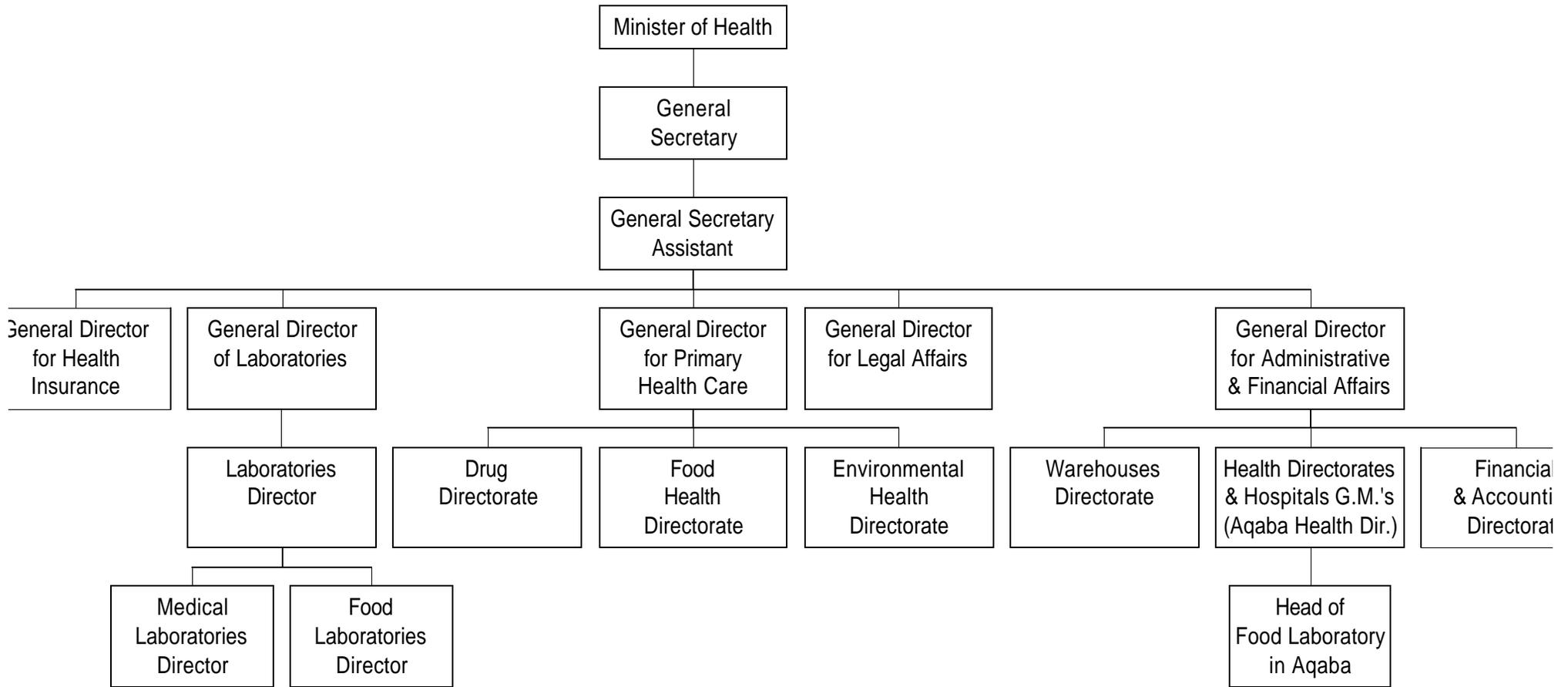
Correction of deficiencies and documentation

The Quality Coordinator conducts AQA Assessment Reviews on a pre-determined schedule. Any deficiencies noted during a given Review are reported to the Laboratory Head with a recommendation on ways to correct the problem. The Head makes the decision regarding the corrective action and it is implemented. The Quality Coordinator follows up in a reasonable time to see if in fact the correction has been done and the results. These are reported to the Head and a notation is made in the original Assessment Review report, for future information. The Quality Coordinator maintains all files related to the Assessment Reviews and any follow-ups.

ANNEX 1

Organizational Chart

Ministry of Health
Organization Chart



ANNEX 2

Laboratory Analysis Results Sheet

Laboratory Analysis Results		1. Product		2. Sample Number	
3. Date Received		4. Assigned to Chemistry Microbiology Meat and Fish		5. Labeling None Review	
				6. Net Contents Not applicable To be determined	
7. Description of the Sample					
Summary of Results					
8. <u>Chemical</u>		Pass Fail		10. Microbiological	
Colors				Pass Fail	
Metals				Aerobic plate count	
Mycotoxins				Total coliforms	
Other _____				E-coli	
9. Physical				Staph. aureus	
Labeling				Strept. faecalis	
Net contents				Yeasts and molds	
General condition				Salmonella spp	
Macroscopic filth				B. cereus	
Can defects				V. parahaemolyticus	
Parasites in fish				C. perfringens	
Other _____				V. cholerae	
				Y. enterocolitica	
				Other _____	
12. Date assigned			13. Date completed		
Chemistry _____			Chemistry _____		
Microbiology _____			Microbiology _____		
Meat and Fish _____			Meat and Fish _____		
14. Sample disposition					
15. Remarks					
15. Signature and date					
Director, Aqaba Food Laboratory					

Standard Operating Procedures

1. Instrument Performance Criteria

The following criteria should be used to check the performance of the indicated instruments. As new instruments are received, they should be added to this list. Additional or different criteria can be developed for each instrument from specifications given by the manufacturer. Check instrument performance once every three (3) months.

UV -visible spectrophotometer

Wavelength accuracy

- UV -Use benzene vapor and a 10 cm path. A sharp peak occurs at 260.0 \pm 0.4 nm
- Visible -Use didymium filter. Peak maxima occur at 441 \pm 2 nm, 529 \pm 2 nm and 685 \pm 2 nm.

Photometric accuracy

Prepare a solution of 60 \pm 0.25 mg potassium dichromate in 1 litre of 0.01N sulfuric acid. (This solution is very stable and may be used for up to one year). Scan this solution in a 1 cm cell from 210 to 450 nm. The following absorbances (\pm 1% of full scale) should occur at the indicated wavelengths:

Wavelength (nm)	Absorbance
235	0.747
257	0.869
313	0.293
350	0.644
351	

Atomic absorption spectrophotometer

Stability

.Aspirate a metal solution of known concentration, three consecutive times. The absorbance readings should not vary more than \pm 0.005 absorbance units.

.Record the baseline with flame operation only (no aspiration) for five (5) minutes. The baseline should not vary more than \pm 0.005 absorbance units.

Graphite furnace

- Inject a metal solution of known concentration, six consecutive times. Compare the sensitivity and reproducibility against previous injections of the same solution. The reproducibility should be within 10%. (Note -change the graphite cell when the instrument fails to hold a pre-set atomizing temperature).

High Performance Liquid Chromatograph

Fluorescence detector

- Sensitivity -Record the Raman-scatter peak for distilled water. The peak should be at 397 nm \pm 10 nm. Peak height should be 30- 70% full scale at an attenuation of 16.
- Wavelength accuracy -Check the excitation and emission monochromators as given in the operating manual. Wavelength accuracy should be \pm 10% of the nominal value.
- Xenon lamp -After 500 hours of operation, check the noise level of the xenon lamp every 100 hours, as given in the operating manual. Replace the lamp if the noise exceeds 5% of full scale

Spectrophotometric detector

- Noise level -Record the baseline for methanol at 250 nm with full scale set at 0.0025 absorbance units. Flow rate should be 1 ml/min. Noise should not exceed 1.5% of full scale.
- Light intensity -Record the intensities of both the sample and reference light, using the same conditions as in the above noise level check. The intensity of both the sample and reference light should exceed 0.4. If the sample light intensity is below 0.4, the cell may need cleaning. If the reference light intensity is below 0.4 and the noise level is high, change the deuterium lamp.

STANDARD OPERATING PROCEDURE

2. Equipment Calibration

The following checks are to confirm that the equipment tested is properly calibrated (i.e. operating at the correct temperature, or having the correct accuracy). If the values found are significantly different from expected, notify the Laboratory Head as recalibration may be necessary. These checks should be done twice yearly.

Heating devices (e.g. ovens, incubators, water baths)

Check with calibrated thermometer or thermocouple and record in the appropriate notebook. Temperature variation should be within manufacturer's specifications.

Top-loading balances

Check with accurate weights at the low, middle and high range of the balance and record in the appropriate notebook. Accuracy should be within manufacturer's specifications.

Analytical balances (accurate to 0.1 mg)

Check with accurate weights at five ranges, from low to high. Accuracy should be within manufacturer's specifications.

AQA ASSESSMENT REVIEW
Protocol for
Instruments and Equipment

Schedule: Every four months.

Protocol: Review the notebooks for each major instrument as well as the notebooks maintained for equipment and minor instruments, and confirm the following:

- ◆ All notebooks have been properly maintained with correct entries and annotations.
- ◆ Instrument performance and equipment calibration checks have been made as scheduled. Any problems noted have been promptly referred to the Laboratory Head and follow-up actions are recorded, along with re-check data to confirm proper operation following correction.
- ◆ Any maintenance or repair of a given instrument or equipment is properly recorded in the appropriate notebook. A record confirming satisfactory operation after repair is also included in the notebook.

Any deviation from the above is considered a deficiency.

Deficiencies noted: (Attach a second sheet if necessary)

Recommendations:

Reviewer _____

Date _____

AQA ASSESSMENT REVIEW
Protocol for
Reference Standards

Schedule: Every four months.

Protocol: Review the reference standards record book and conduct a physical check of the reference standard storage cabinet as well as any other standards storage areas. Confirm the following:

- ◆ The record book has been properly maintained with correct entries and annotations.
- ◆ Storage areas are properly maintained and standards are correctly stored in accordance with any special storage requirements.
- ◆ Standards containers show no obvious defects and closures are satisfactory. A physical check of several standards at random show no obvious physical changes (e.g. discoloration) or contamination.
- ◆ No standard is beyond its expiration data and the record book notes destruction of those that have expired.

Any deviation from the above is considered a deficiency.

Deficiencies noted: (Attach a second sheet if necessary)

Recommendations:

Reviewer _____

Date _____

AQA ASSESSMENT REVIEW
Protocol for
Analytical Worksheets

Schedule: Every two months.

Protocol: Select six (6) analytical worksheets at random from the previous two-month period. Three (3) of these should be microbiological analyses and the remaining should be chemical analyses. Review each worksheet and confirm that each of the following criteria have been met:

- ◆ Sample number, product and any product codes are recorded.
- ◆ The proper analytical method was used.
- ◆ Any method modifications were approved and validated.
- ◆ Reference standards used and controls are reported where necessary.
- ◆ Only ink is used for recording. There are no notations in pencil.
- ◆ All strike-outs are explained.
- ◆ Calculations are complete and correct, including the calculation formula.
- ◆ The analyst has signed and dated the worksheet.

Any deviation from the above is considered a deficiency.

Deficiencies noted: (Attach a second sheet if necessary)

Recommendations:

Reviewer _____

Date _____

ANNEX 6

PROPOSED CHANGES IN PROCEDURES

Item or activity	Now	Proposed
Total sample size	Often very large – up to 300 kg + (due to unit sampling)	Small – usually 2-4 kg (due to portion sampling)
Sampling of one entry having several production codes	All codes are sampled and included under one sample number	Each code is sampled separately with its own sample number
Sample number	Assigned by laboratory. Sequential – may not be unique between years	Assigned at time of collection. Unique between and among years
Delivery to the laboratory	By importer representative	By Food Inspector
Receipt to importer for sample	Prepared by laboratory sample reception	None – notice of sampling given by Food Inspector
Sample remainder returned to importer after analysis	The importer is given the remaining sample of certain foods 7 days after sampling and analysis	Not necessary as sample sizes will be small and only used for analysis
Samples are recorded as received	Reception enters sample information into a log sheet	Reception enters (different) information into a Sample Register
Sample records are forwarded to the Laboratory Head	Reception forwards the collection document to the Laboratory Head	Reception prepares the initial entries on a Laboratory Analysis Results sheet for each sample received, and forwards to the Laboratory Head along with the sample collection report
The sample is assigned for analysis	The Laboratory Head assigns the sample and notes the assignment on a log sheet	The Head assigns the sample and notes the assignment on the Laboratory Analysis Results sheet, which he retains for control until all analyses have been completed

ANNEX 7

MAINTAINING QUALITY IN ANALYTICAL METHODOLOGY TRAINING PROGRAM

Venue – Crystal Ballroom, Aqaba Gulf Hotel, Aqaba, Jordan

Dates – 12-13 March 2001

Time – 1800-2200 hours

Lecturer – John Weatherwax, AMIR Consultant

AGENDA

12 March

1800-2000 Opening remarks and introductions

Analytical error – what it is and does

2000-2030 Coffee/tea break

2030-2200 An introduction to statistical evaluation of analytical data

13 March

1800-2000 Proficiency testing – intra- and inter-laboratory

2000-2030 Coffee/tea break

2030-2200 Validation of analytical methods
Closing remarks

ANNEX 8

List of Quality in Analytical Methods Training Course Participants

Laboratory Participants

Name	Organization *	Position
Rima Aqrabawi	MOH, Amman	Laboratory Technician
Nihaya Samour	MOH, Amman	Laboratory Technician
Nazeih Khalileh	MOH, Irbid	Veterinarian
Ahmad Abu-Syam	MOA, Aqaba	Plant Technician
Randa Hawash	MOA, Aqaba	Laboratory Technician
Maysoun Al-Sharif	MOA, Aqaba	Laboratory Technician
Mahmoud Mustafa	MOH, Aqaba	Head of Food Laboratory
Atef Abu-Syam	MOH, Aqaba	Agricultural Engineer
Ayoub Al Reyalat	MOH, Aqaba	Veterinarian
Amjad Hussein	MOH, Aqaba	Veterinarian
Ashraf Daradkeh	MOH, Aqaba	Agricultural Engineer
Mohammad Abdullah	MOH, Aqaba	Food Technician
Nihal Khader	MOH, Aqaba	Laboratory Technician
Mai Abdullah	MOH, Aqaba	Agricultural Engineer
Ali Tawaha	MOH, Aqaba	Agricultural Engineer
Majed Turad	MOH, Aqaba	Laboratory Technician
Ruwaida Hassan	MOH, Aqaba	Agricultural Engineer
Hadeel Hamed	MOH, Aqaba	Agricultural Engineer
Ehab Nussair	MOH, Aqaba	Veterinarian
Wafa Amro	MOH, Aqaba	Laboratory Technician
Ashraf Bani Younis	MOH, Aqaba	Laboratory Technician

* - Key: MOH = Ministry of Health
MOA = Ministry of Agriculture

ANNEX 9

Maintaining Quality in Analytical Methods Training Course Presentations (slides and overheads)

Attached