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UNIDO PROJECT

XA/ERI/03/619 - Interated Program for Eritrea:
Component IV B-Food/Fish Sector. Sub-Contract (SC1)
Purchase Order No.: 16000534. Contract No.: 2003/194

Final Report

Assignment in Eritrea from 28 November to 18 December 2003

Consultant Ms. Ulla Jensen, Højmarklaboratoriet a/s, Denmark

Edition 1. (Final)
Date 29 December 2003
Audit at QCL Massawa December 2003

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Annex 1 : Additional list of equipment
1. Introduction

1.1 Background
The Fish Control Laboratory in Massawa (QCL) started in 2001 and since then it has developed into a well function testing laboratory. A more detailed presentation is coming in part 1.4.

1.2 Proposal
The Laboratory is in the final phase where they in near future wants to meet the EU requirements for accreditation and this assignment is meant to provide the services to help them accomplish this goal.

1.3 Working programme

The audit was performed during a visit at QCL Massawa from 29 November to 15 December 2003.

During this mission the Massawa QCL's complete quality system was audited and the equipment situation was audited, due to additional request for new equipment to be required, before the final accreditation. Furthermore the chemistry tests were audited and training programs for testing chemistry methods and equipment were implemented during the mission. In addition to the audit findings some suggestions are made in this report and it is up to the QCL to fulfil the audit findings in a proportional way.

In addition to the audit two laboratory customers were visited. (ERI Fish Product in Massawa and the Aqua production compound for shrimp)

From 15 December to 17 December 2003 a visit in Asmara.

Briefing to UNIDO Program Officer Ms. Mimi Groenbech

Visit at the Eritrean Standards Institution with a meeting with Mr. Mussi and General Manager Mr. Abraham Kubrom about the needs of a accreditation of the Calibrations Laboratory especially the needs of calibrated thermometers and balances in the food industry.

Visit at the Fish Industry Eritrean Marine Product Co.
1.4 Presentation of Quality Control Laboratory in Massawa, Eritrea

The Quality Control Laboratory (QCL) has been established in the year 2001 under a project, Marine Products Export Pilot Project, funded by the Agency for French Development (AFD, Djibouti). The Laboratory was operational independently since September 2001. Completion of this laboratory has fulfilled a major requirement of the Competent Authority of the Ministry of Fisheries of The State of Eritrea in their compliance to the EU directives on sanitary and hygiene condition of the fish and fishery products being produced and exported from Eritrea. The Laboratory is situated at Ghibi, a fish-landing centre, at Massawa. In 2003 around 400 samples of water and fish products were tested for around a total of 1819 parameters in the chemistry and microbiology laboratory.

Staff members are at present the following.

Director and Chief Microbiologist: Dr. T.S. Shetty
Quality Assurance Manager and Microbiologist: Mr. Giorgis Zekristo (QAM)
Microbiologist: Mr. Essayas Haile
Chemist: Mr. Michael (New staff member)

French and other European consultants have trained the staff members during the establishment of the lab for the last 2 years. Due to that training they have made a Quality Manual and implemented a quality assurance system.

At present the QCL is performing analysis of water and fish products using the following parameters. All methods used in the QCL have reference to international standard methods.

Fish Products - Microbiology

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count 30°C</td>
<td>ISO 4833</td>
</tr>
<tr>
<td>Total Coliforms</td>
<td>ISO 4832</td>
</tr>
<tr>
<td>Fecal Coliforms</td>
<td>NF V08-060</td>
</tr>
<tr>
<td>E. coli</td>
<td>NF V08-053 ISO 7251</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>NF V08-057-1</td>
</tr>
<tr>
<td>Suphite reducing clostridia</td>
<td>XP V08-061</td>
</tr>
<tr>
<td>Salmonella/Shigella</td>
<td>NF EN 12824</td>
</tr>
<tr>
<td>Vibrio cholerae</td>
<td>ISO 8914</td>
</tr>
</tbody>
</table>

Fish Products – Chemistry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMA</td>
<td>Decision 95/149/EC</td>
</tr>
<tr>
<td>TVB-N</td>
<td>Decision 95/149/EC</td>
</tr>
<tr>
<td>Histamine</td>
<td>TLC semi-quantitative method</td>
</tr>
<tr>
<td>Sulfite</td>
<td>BS-EN-1988-1</td>
</tr>
</tbody>
</table>

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Water – Microbiology

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate Count 22°C and 37°C</td>
<td>NF EN ISO 6222</td>
</tr>
<tr>
<td>Total and Heat Resistant Coliforms</td>
<td>NF T 90-474</td>
</tr>
<tr>
<td>Intestinal Enterococci</td>
<td>NF EN ISO 7899-2</td>
</tr>
<tr>
<td>Spores of Anaerobic Sulfito Reductor</td>
<td>NF T 90-415</td>
</tr>
<tr>
<td>Total and Heat Resistant Coliforms</td>
<td>NF T 90-413 (MPN)</td>
</tr>
<tr>
<td>Group D Streptococci</td>
<td>NF T 90-411</td>
</tr>
</tbody>
</table>

In addition to that, they perform a number of chemical water analyses like BOD, Nitrate, Nitrite, Ammonia and Phosphate.

1.4.1 QCL proposal for accreditation

In addition to be fully approved by the EU market for fishery products during 2004, the QCL want an accreditation for some parts of the laboratory work. They want the accreditation to cover the following parts.

Fish Products - Microbiology

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count 30°C</td>
<td>ISO 4833</td>
</tr>
<tr>
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<td>NF V08-053 ISO 7251</td>
</tr>
<tr>
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</tr>
<tr>
<td>Salmonella/Shigella</td>
<td>NF EN 12824</td>
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</tbody>
</table>

Water – Microbiology

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate Count 22°C and 37°C</td>
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</tr>
<tr>
<td>Group D Streptococci</td>
<td>NF T 90-411</td>
</tr>
</tbody>
</table>

Audit performed by UNIDO Consultant Ulla Jensen Højmarklaboratoriet, Denmark
2. Audit findings in the Quality Manual and quality system.

In this audit the Quality Manual and all sub procedures were audited against the ISO 17025:2000 General requirements for the competence of testing and calibration laboratories, and against its own requirements and in mind that the laboratory in near future want a accreditation. The findings are reported in the following.

The number in front is referring to the ISO 17025 clause and the next is referring to the number in the QCL Quality Manual.

2.1 Quality manual

2.1.1 ISO no 4.1.4 Organisation (QCL no 3.1)
The Lab needs to describe their role in the organisation Ministry of Fisheries to ensure their independency of influence from other departments in the large organisation. Description and a diagram.

2.1.2 ISO no 4.2.2 Quality policy (QCL no 1.1, 1.2)
Statement in quality policy should be signed personally by the manager and include the 4.2.2. a, b, c, d, e. It is important to describe that the QCL will follow the ISO 17025:2000 and exact what area the QCL want the accreditation to cover.

Example of accredited area
- Microbiology tests of fish products and foodstuffs
- Microbiology tests of water
- Sampling of fish products and foodstuffs
- Water sampling

2.1.3 ISO no 4.13 Internal audit (10.1)
A scheme is missing for the internal audit and advicely it has to be performed 2 times a year divided into 1 vertical audit and 1 horizontal. The QAM is in charge of planning the audit in fixed times (month) during the year. The auditor should be a staff member. The QAM is in charge of implementing the findings from the audit and keep the audit reports in archive system. The auditor has to verify that the quality system comply its own requirements and the ISO 17025:2000 requirements.

For every deviation the auditor will find there has to be made a deviation report no X and this report shall have the following information’s.

- Scope of deviation and date for the correct result to be achieved (internal auditor)
- Action to be performed to achieve the correct result of the deviation (QAM)
- Signature from the internal auditor to confirm the deviation result is implemented.

Audit performed by UNIDO Consultant Ulla Jensen Højmarklaboratoriet, Denmark
2.1.4 List of Methods
The list of methods should be an annex and the contents of non-accredited methods should be clearly marked. The list needs the following information's.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Sample matrix</th>
<th>Reference methods</th>
<th>Positive control</th>
<th>Proficiency testing</th>
<th>Detection limit</th>
<th>Standard deviation for repeatability</th>
<th>Standard deviation for reproducibility</th>
</tr>
</thead>
</table>

It is important to have the unique document edition.

2.1.5 ISO no 4.3 Documents identification
All documents in the quality system have to be uniquely identified also all separate documents in the manual have to be identified. Here documents can be policy and procedures.

Suggestion

<table>
<thead>
<tr>
<th>QM X.Y</th>
<th>X is the first part of this document Y is the next</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edition Z</td>
<td>Z is the actual edition</td>
</tr>
<tr>
<td>Revised by: XX</td>
<td>XX person who made the revision.</td>
</tr>
<tr>
<td>Rev. date: xx.xx</td>
<td>xx.xx month and year for the revision.</td>
</tr>
<tr>
<td>Approved by</td>
<td>Read and approved by Lab. Manager</td>
</tr>
<tr>
<td>Xxxxxxxxxxxxxxxxxxx</td>
<td>Manager signing</td>
</tr>
<tr>
<td>Lab Manager</td>
<td></td>
</tr>
<tr>
<td>Effective: xx.xx.xx</td>
<td>Day, month, year</td>
</tr>
<tr>
<td>Issued: xx.xx</td>
<td>Issued first time month, year</td>
</tr>
<tr>
<td>Issued by:</td>
<td>Person who issued the document the first time</td>
</tr>
</tbody>
</table>

Other documents in the quality system

<table>
<thead>
<tr>
<th>Part X.Y.V</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Edition Z</td>
<td></td>
</tr>
<tr>
<td>Effective from: xx.xx.xx</td>
<td></td>
</tr>
<tr>
<td>Revised by: XX</td>
<td></td>
</tr>
<tr>
<td>Approved by: XX</td>
<td></td>
</tr>
<tr>
<td>Issued: xx.xx</td>
<td></td>
</tr>
</tbody>
</table>

Contents document in all files should include edition number and date the document is effective from and signature.
2.1.6 ISO no 4.1.5 b, c. Staff members
All staff members should sign a document to ensure their independence from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work and to ensure the protection of the clients' confidential information.

2.1.7 ISO no 5.2 Personnel
All staff members should sign job descriptions and responsibilities personally. The Lab should keep a list of methods where staff members approved for every single method are listed with name and the date they were approved for the method.

2.1.8 ISO no 5.10.3 Test reports.
The Lab needs clearly identification of the sample. Example water or fish products.
Remarks (opinions 10.4): Procedure for remarks including which kind of remarks and conclusions and which persons are responsible.
Statement: The test report shall not be reproduced except in full, without written approval of the laboratory.
Test methods might be listed as original reference in service for the client. An example can be if the sample batch is exported and tested again in another laboratory and the test results are deviating from QCL’s. In this situation it can be important to ensure the exact reference methods.

Reception of samples.
The exact temperature must be noted when the sample is received together with date and time. The number of the thermometer should be noted.

2.1.9 ISO no 4.4 Requests, tenders and contracts
Subcontractor: The Lab needs a policy and procedure for the use of subcontractors like calibration laboratories, test laboratories and proficiency test laboratories.

2.1.10 ISO no 4.10 Corrective actions
The Lab needs policy and a procedure for corrective actions. Documentation should be kept in a separate file.

2.1.11 ISO no 4.11 Preventive actions
The Lab should make a statement about preventive action, like participating in proficiency testing, using reference materials and positive and negative control.

2.1.12 ISO no 4.8 Complaints (10.3)
The Lab needs a list of all complaints listed in numbers and with date, report number and explanations of the errors and filed with hard copies of all documents. Errors may be found inside the Lab and the same procedure must be followed.
If the error is severe, procedures for correction must be followed.
2.1.13 ISO no 4.6 Purchasing (5.4)
The Lab needs a procedure for purchasing the right quality of equipment, chemicals and media. The person who is responsible for the use of this chemical, media or equipment must approve the standard of quality before all purchasing.
Example
The quality of the chemicals must be specified as “technical quality” or “analytic standard” and approved by the responsible person by signing before purchasing.

2.1.14 ISO no 4.14 Management reviews
Reports from Management reviews meetings are not complete and according to new time schedule procedures it should be kept in separate files.

2.1.15 Statistic control / Training
Every 3 month a counting control after the procedure NMKL Report no 5 2nd edition 1994 page 45 should be performed for all staff members working in microbiology laboratory. A statistic report is made and discussed with the staff members.
Standard deviation for the repeatability must be performed every year for every method using results from double determination or results from reference material.
The Lab. needs reference material for microbiology testing and there are recommendations mentioned where to buy it in the list of equipment and chemicals in Annex 1.

2.2 Equipment control program

2.2.1 Thermometers
The QCL needs an accredited calibrated reference thermometer (liquid glass) and working thermometers (liquid glass) for all incubators, baths, fridges, ovens and freezers.
The QCL needs data loggers to check the stability of the temperature in incubators, baths, fridges, ovens and freezers and to make check of the characteristics for loads/cycles in autoclaves.
The QCL needs maximum thermometers to check the exact temperature in every batch in the autoclave, and for checking the temperature in the oven.

2.2.1.1 Reference thermometer,
Calibrated reference thermometer (glass) with certificate from 0 to 100 °C. Control points will be the temperature the thermometers are used for. Example.

\[
\begin{align*}
0,00^\circ C & \quad \text{accept } \pm 0,10 \text{ by calibration} \\
30,00^\circ C & \quad \text{accept } \pm 0,10 \text{ by calibration} \\
42,00^\circ C & \quad \text{accept } \pm 0,10 \text{ by calibration} \\
80,00^\circ C & \quad \text{accept } \pm 0,10 \text{ by calibration}
\end{align*}
\]

Requirements for full traceable re-calibration have to be done by an accredited calibration laboratory every 5 years for a liquid in glass thermometer.
Calibrated reference thermometer (electronic) with certificate from 0 to 600 °C. Control points

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Acceptance ± °C by Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°C</td>
<td>0 ± 0,5 by calibration</td>
</tr>
<tr>
<td>120°C</td>
<td>120 ± 1 by calibration</td>
</tr>
<tr>
<td>170,0°C</td>
<td>170 ± 1 by calibration</td>
</tr>
<tr>
<td>410,0°C</td>
<td>410 ± 1 by calibration</td>
</tr>
<tr>
<td>550,0°C</td>
<td>550 ± 1 by calibration</td>
</tr>
</tbody>
</table>

Requirements for full traceable re-calibration have to be done by an accredited calibration laboratory every 3 years for a thermocouples (electronic) thermometer.

For single point annually as ice-point check made as in-house check
Check single point 0°C in ice water. The temperature is read after 10 min in 50 % ice water.

2.2.1.2 Working thermometers liquid in glass and thermocouples
All working thermometers should be checked against reference thermometer at ice point and working temperature range annually.

Check single point 0°C in ice water. The temperature is read after 10 min in 50 % ice water.

And annually do checking the temperature of the working thermometers against the reference glass-liquid thermometer in a water bath at the actual working temperature for 24 hours. Read the thermometers after they have been placed directly besides the reference thermometer for 10 min.

Deviation max 0,1 or 0,2 depending on the thermometer scale. Otherwise QCL have to do the procedure again and if there is still a deviation then mark the thermometers for the deviation.

2.2.1.3 Maximum thermometers
Maximum thermometers from autoclaves must be checked against a calibrated thermometer by 121 °C. Deviation ± 2°C. Check procedure in oil or sand (Protein destruction equipment)

2.2.1.4 High temperature working thermometers
Working thermometers for different ovens and destruction equipment must be checked against a calibrated thermometer by the actual temperature. Deviation ± 2°C. Check procedure in oil or sand (Protein destruction equipment or furnace).

All thermometers should be marked with a number as unique identification and for tracebility.

2.2.1.5 Temperature stability
Data logger with temperature probe can be used for checking the stability of the temperature during 24 hours in incubators, baths, fridges, ovens and freezers. Check of characteristics for loads/cycles in autoclaves. Control procedure every 2 years or after repair/modification.

Remember Checking procedure before use and when new thermometers are purchased.
2.2.2 Incubators
Check the temperature every day
Working thermometers should be placed in about 25 ml glycerol inside the incubators.

Check the stability of the temperature in the incubators for 24 hours, annually or at least every 2 years.

2.2.2.1 Check procedure for ventilation
3 agar plates placed inverted in different places in the incubator. Weight the plates before and after incubation. Incubation time 48 hours and the maximum acceptable loss of weight of the agar must not exceed 15%.

Check ventilation 2 times a year

2.2.3 Autoclaves
The Lab need maximum thermometers to check every use of the autoclaves and data loggers to check the characteristics for loads/cycles in autoclaves. Time check.

2.2.3.1 Maximum thermometers
In every autoclave load put in between the media bottle the maximum thermometer and after opening the autoclave note that the temperature was 121°C ± 2°C. Before use shake the scale below 118°C.

2.2.4 Balances
The laboratory needs accredited calibrated check weights and working check weights.

2.2.4.1 Check weight
Balance check every morning or before use. Check zero point and use a 1 or 2 g check weight and the deviation must be less than 0.005 g from the previous check weight. Note the weight data in the log book.

Daily used check weights must be checked against calibrated weights annually or check on balance immediately following traceable calibration.

2.2.4.2 Balances calibration
Check the balance with the calibrated check weights 1 g and 50 g (or similar) in between the annually full calibration. The deviation must be less than 0.005 g and 0.01 g from the previous check weight. Note the weight in the log book
Annually the balance must have a full traceable calibration by an accredited calibration laboratory.

2.2.4.3 Calibration weights
The calibrated weights must have a full traceable calibration every 5 years by an accredited calibration laboratory.
2.2.5 Dilumat (Gravimetric diluter)
The Lab needs procedure for daily check for sample weight and dilution rate.

2.2.6 PH meter
The Lab needs better quality in buffer solutions and a new electrode while the present is out of order.
Calibration must be performed every day or before use.
Note in the log book the batch number of the buffer solutions in every calibration.
(Note the slope value and deviation from the previous must be < 5%)
Check the buffer chemicals 4 and 7 they may not be open more than 6 month and buffer 9 only 3 month. Buffer solutions should be supplied with certificates. (Merck, Hamililton, Reagecon)
Check the old buffer against the new one just open. Make a calibration with the old buffer and check the values by measuring the new ones.
Check the temperature against a reference thermometer 2 times a year.
Example:
Calibrate on buffer 4 and 9 and after that make a control with the buffer 7. The deviation in the buffer 7 must be <0.02 from the theoretical value.
Keep the electrode in 3,5M KCl

Electrode control.
In buffer 7 the mV must be 0 ±20
In buffer 4 the mV must be 170 ±20
If there are problems try to keep the electrode in 1M HCl for 2 hours or in 0,1M HCl for 1 night.
Try the calibration procedure again.

2.2.7 Chemicals - medias
All chemicals and medias should be marked with
Date of receiving
Date of opening
Date of expiry (date given by the supplier)
After the expiry date all chemicals and medias must be removed from the stock.
Safety sheets for chemicals should be kept in the chemical lab

2.2.7.1 Media control
For the PH in the ready to use media maximum acceptable deviation is normally ±0,2
Storage condition and expiry date for stock solutions plates and tubes.
Extend the use of positive test culture to every batch of samples
Extend the use of negative control by use of uninoculated plates with every batch of samples

2.2.8 Distillation unit. (water supply)
The QCL needs a procedure for checking the ready to use water (distilled water)
Check procedure:
For conductivity weekly and limits <0.5 mS/m (5 μS/cm) use a conductivity-meter
For microbial contamination monthly <50 cfu/ml use PCA 30°C in 3 days

Audit performed by UNIDO Consultant Ulla Jensen Højmarklaboratoriet, Denmark
2.2.9 Stomacher
Time check once a year.

2.2.10 Water bath
The QCL needs a procedure for checking the temperature.
Working thermometer inside the water bath registration every day or when it is in use.
Calibration against calibrated reference thermometer like all working thermometers.
Check for temperature stability with temperature loggers in 24 hours. 1 – 2 times a year.
Water bath must be covered with plastic balls or a lid to reduce evaporation.

2.2.11 Microscope
The QCL needs a procedure for checking the light, phase contrast and the condensor
Follow the check procedure in NMKL Report no 5 2nd ed. 1994, page 17-18
Light control (Köhlers light) 2 times a year.
Phase contrast and Condensor control regularly.

2.2.12 Pipettes / pipettors – volumetric control
The QCL needs a procedure for checking the accuracy and the precision in glass ware.
The QCL needs a Pipette washer.
Annually check the micropipettes for accuracy and precision (adjusting)
When purchasing volumetric glass ware make a volumetric control on 10 % or >5 pieces.
Annually make volumetric test on 10 % of the glassware
Check procedure performed gravimetric with glass ware and distillate water temperate at 25°C
Pipettes are checked for outlet volume value and measurement flask are checked for inside volume
Checking procedure before use when new volumetric glass ware are purchased. Take more than two pieces in every batch and for large batch around 10%.
The QCL might use cotton in the dilution pipettes to prevent cross contamination.

2.2.13 Distillation equipment for TVB-N and Protein
The QCL needs a procedure for checking the equipment.
Before analysing sample check the equipment by a standard solution 50 mg N/100g.
Standard solution: Ammonium Chlorid NH4Cl
Weight 1,9104 g NH4Cl into 1,00 litre flask.( 0,3821 g into 200,00 ml flask.)
Perform the distillation by 20.00 ml of this solution.

Audit performed by UNIDO Consultant Ulla Jensen Hojmarklaboratoriet, Denmark
2.2.14 Test cultures
The QCL need a schedule for subcultering the reference test cultures and a plan for specific tests on
the test cultures when they are subcultured.

2.2.15 Spectrophotometer
Control procedure for wavelength should be performed 2 times a year.

Procedure:
Dilute 40 mg Potassium-chromat in 1,00 litre 0,05 N KOH (2,805 g KOH pr. Distilled water litre)

Make measurement between 367 and 378 nm, at each nm and note all the belonging absorbance
(abs.) measurements.

The maximum abs. should be at 372 nm (+/- 5 nm) and the abs. 0,99 (+/- 0,02)

Note the max. abs. and the belonging nm.

2.2.16 Destruction unit for protein analysis
Temperature control in the test tubes.
Fill in sand in the tubes for around 5 cm accurately the same in all tubes. Turn on the heater 410°C
and make a measurement with the calibrated thermometer after 1,5 hour. Temperature should be
>400°C in all the tubes. Difference between the tubes < 10°C.

In every use of the destruction unit analyse 2 blinds and 2 standards.
Standard material: Acetanilid contains 10,36% Nitrogen.
Weight 0,3xxx g in every tube and follow the method.
Blind: Only chemicals.

2.2.17 Oven for moisture test
Every month make a temperature check with a maximum thermometer. Place the thermometer in a
cold oven and turn it on. After 2 hours check the thermometer and the temperature should be 105°C
± 3°C.

Standard solution for dry matter (moisture) 5 % (5g / 100g) dry matter
Dry around 30g NaCl in the oven at 105°C for 24 hours.
Weight 25,00g dried NaCl and dilute to 500,0 ml with distilled water.

Use 5,xxxx g for the test and proceed with the normal procedure.

2.2.18 International references
The following references were discussed with the staff members and used during the visit for
elaborating new procedures and for auditing the Quality System.
Reference materials chemistry
LGC Promochem (Sweden)
www.lgcromochem.com  se@lgcromochem.com

Reference material microbiology.
2003:1 Parameters
Livsmedelverket
Box 622
751 26 Uppsala
Sweden
Fax: 00 46 18 17 14 94
E-mail lngela.tillander@slv.se

Proficiency testing Microbiology and chemistry
FAPAS, FEPAS in UK
www.FAPAS.uk

Accreditation Body in Denmark
DANAK www.DANAK.dk

EA- European accreditation www.European-accreditation.org

International laboratory accr. Ilac www.ilac.org

Analytical Methods and assurance procedures
NMKL - www.nmk1.org

EA-04/10 Accreditation for Microbiological Laboratories

CITAC / EURACHEM GUIDE. Guide to Quality in Analytical Chemistry.
An Aid to Accreditation.

Quality Assurance Guidelines for Microbiological Laboratories. NMKL Report no 5 2nd ed. 1994

ISO 17025:2000 General requirements for the competence of testing and calibration laboratories

2.3 General observations

In the Quality Manual there are good descriptions and procedures but improvement could be done in specifying where to find the exact procedure, in what file and where the file is kept.

Procedures are in general well implemented in the lab quality system, but some parts needs some improvement as described in this report. The procedures are well described but has to be followed and documented.
The municipal water supply is at present insufficient but some improvement has started. Electricity supply is in general sufficient but a generator would be appreciated.

There is in this audit found some lack of equipment necessary for the future accreditation and there is in Annex 1 an additional list of equipment. The list is additional to the list Annex 4 in TOR (Sb1).

2.4 Training

The staff members were during this visit trained in using computer (excel) programs to statistic calculations. The programs were made for determination of standard deviations for repetability and reproduceability in the testing methods and in addition some programs were made to control the daily use of reference materials and standards in control chart like X an R charts.

Besides the audit findings new procedures were in corporation with staff members made for quality assurance in some test methods in chemistry like TVB-N, Moisture and Protein. New procedures for calibration and control for a number of equipments were made along with the audit findings like PH-meter, Oven, Autoclaves, Spectrophotometer, Distillation unit, Destruction unit, Water distillation, Balances, Thermometers, Incubators and glass ware.

3. Recommendations

Due to that fact that the QCL want to be an accredited laboratory in near future they should immediately start implementing the advice from this report and follow all their already performed procedures. In the first month of 2004 they may contact an European accreditation body and make some arrangement like financial and time schedules for the accreditation process.

It is very important to the general quality work in QCL that the staff is well trained and stable due to that fact it is important to keep the already trained staff members. The number of staff is absolute minimum right now so if there is improvement in number of samples in chemistry the QCL need one more chemist with some experience in testing food samples.

It is important for the future accreditation process that the QCL will receive all equipment listed in this Annex 1 and the original list from TOR (SB1) Annex 4.

If the QCL in the nearest future want to test food samples for the most common nutrients and energy compounds (KJ) like Protein, Fat, Ash and Moisture they need additional equipment like soxlet for fat test and furnash oven for ash.

The QCL will need additional training in the new procedures and in the use of the new coming equipment.

The QCL may need an experienced accreditation consultant with in the coming accreditation process as a link between the accreditation body and the laboratory staff in order to facilitate the process.
4. Final conclusion

The QCL already has a high range quality assurance system implemented in their laboratory and to meet the requirements for an accredited laboratory they will need some adjustments as mentioned in this audit report and some additional equipment, before they can apply for the final accreditation.
ANNEX 1

Additional to Annex 4 from TOR Sub-Contract (SC1)

List of additional required equipment made during audit December 2003

1. Reference thermometer (glass liquid) with accredited certificate 0 - 100°C scale 0.1°C
2. Tubes for distillation unit. Length 29.6 cm and diameter inside 3.8 cm 6 pieces
3. Reference thermometer with accredited certificate (electronic) 0 - 600°C
4. Working thermometers (electronic) 0 - 600°C
5. Maximum thermometers for checking autoclaves h:6 cm range 80-130°C. 4 pieces
6. Fume hood for acid fumes including water and drain
7. Data logger for checking temperature stability and autoclave cycles -20 to 150°C with software
8. Volumetric flask 1.00 litre
9. Acetanilid (Standard for protein) 10.36% Nitrogen
10. Buffer 7 with certificate traceable to NIST
11. Glycerol 2 litres
12. Conductivity meter with range 0-2000 μS/cm resolution 1-2 μS/cm
13. Calibration solution for the Conductivity meter
14. Barometer
15. Hygrometer
16. PH electrode combination glass electrode single junction, refillable Hanna Instruments HI 1131B
17. Refilling solution for HI 1131B PH electrode
18. Pipette washer automatic h:75 d:16
19. Pipette jar cylinder h:65 d:16
20. Pipette basket h:70 d:13
22. Microbiology Reference material 2003:1 parameters. Livsmedelverket, Box 622, 751 26 Uppsala Sweden. Fax 00 46 18 17 14 94.