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23561

FINAL REPORT
UNIDO project XP/PAK/07/002 – Laboratory Accreditation service

All labs covered by this project have been visited on site (surveillance visits) according to the contract. Below please find description of results for each visit and the process of evaluation of corrective actions which led to continuation of the accreditations granted last year. The surveillance visits have not led to any changes in the scope of accreditation for any of the laboratories. The accreditation documents have therefore not been reissued.

TEST 212 Quality Control Centre, PSQCA, Karachi:

Surveillance visit dates: 14 and 15.12.2007. See enclosed reports. All NCs raised during the visit are closed but NC regarding calibration of balances and reference thermometers have to be followed up at the end of 2008.

Decision regarding continuation of accreditation for microbiological tests according to the scope has been taken.

TEST 213 Marine Fishery Department, Karachi:

Surveillance visit date: 17.12.2007. See enclosed reports. All NCs raised during the visit are closed but one of the NCs regarding calibration of balances was raised again during the extraordinary assessment (extension of scope with Chemical testing) visit performed in April 2008.

Decision regarding continuation of accreditation for microbiological tests according to the scope has been taken.

TEST 214 National Agricultural Research Centre, Grain Quality Testing Lab, Islamabad:

Surveillance visit dates: 21 and 22.01.2008. See enclosed reports. All NCs raised during the visit are closed but NC regarding calibration of balances and reference thermometers have to be followed up at the end of 2008.

Decision regarding continuation of accreditation for chemical and microbiological tests according to the scope has been taken.

TEST 215 National Water Quality Laboratories, PCRWR, Islamabad:

Surveillance visit dates: 17 and 18.01.2008. See enclosed reports. All NCs raised during the visit are closed but NC regarding calibration of balances and reference thermometers have to be followed up at the end of 2008.

Decision regarding continuation of accreditation for chemical and microbiological tests according to the scope has been taken.

TEST 217 Southernzone Agricultural Research Centre, Karachi:

Surveillance vist dates: 14 and 15.01.2008. See enclosed reports. All NCs raised during the visit are closed but NC regarding calibration of balances and reference thermometers have to be followed up at the end of 2008.

Decision regarding continuation of accreditation for chemical tests according to the scope has been taken.

TEST 218 PCSIR, Karachi (only chemistry and microbiology laboratories):

Surveillance visit dates: 18 and 19.12.2007. See enclosed reports. All NCs raised during the visit are closed but several of the the NCs were raised again during the extraordinary visit to the chemical laboratory and the ordinary surveillance visit to the textile laboratory performed in April 2008. One of these NCs is about calibration of balances and reference thermometers which has to be followed up at the end of 2008.

Decision regarding continuation of accreditation for chemical and microbiological tests according to the scope has been taken.

Regarding all laboratories:
All laboratories have got an NC regarding lack of acceptable traceability for temperature and balances. NA has given a final deadline for correcting these NCs and all labs have to document that they meet this requirement within 01.12.2008. See also letter from NA dated 08.04.08 (enclosed).

Kjeller, 09.05.2008

Roald K. Nilsen

Project leader

Norwegian Accreditation (NA)

Appendices:

For each surveillance visit
- Lead assessors reports
- Technical assessors reports
- Summary reports
- NCs raised

Copy of letter from NA dated 08.04.2008

uncertainty has been calculated and the laboratories have participated in an inter laboratory comparison for these measurements.

Another issue that has been raised has to do with the calibration certificates. It is necessary to specify that you require accredited calibration of your equipment. This means that you must require calibration certificates which contain the logo of the accreditation body with the accreditation number/ ID of the calibration laboratory. Calibration certificates issued by organisations/ laboratories which are certified (e.g. to ISO 9000) are not accepted.

Laboratories which currently have open NCs regarding lack of acceptable traceability must as a minimum present a plan for how to solve this in a satisfactory way. Copies of calibration certificates must be sent to Norwegian Accreditation by 1 December 2008 at the latest.

Laboratories to be assessed in 2008 will receive NCs if traceability is not acceptable.

PNAC accredited laboratories (whether it is NPSL or other laboratories) will be accepted as soon as PNAC has signed the APLAC MRA.

Yours sincerely,

Inger Cecilie Laake

Inger Cecilie Laake
Technical Director
Norwegian Accreditation

Cc: Zawdu Felleke, Unido
Abdul Rashid, Director General/Pakistan National Accreditation Council
Technical officers in NA
Relevant NA technical assessors.

Norsk Akkreditering

To NA accredited and applicant laboratories in Pakistan

Deres ref./Your ref.	Vår ref./Our ref.	Dato/Date
		08.04.08

Requirements for measurement traceability

In October 2007 it was communicated to all NA accredited test laboratories that to comply with the ILAC, EA and NA policy on measurement traceability, balances, thermometers and other important equipment used in accredited methods would have to be calibrated by

- A laboratory which is accredited by an accreditation body which is a signatory to the ILAC/ EA/ APLAC MRA

or

- By a national metrology institute which has signed the BIPM MRA.

NA's policy is described in NA Doc. 25/31, which has been made available to all NA accredited laboratories. This policy has been enforced in all NA accredited laboratories both in Norway and abroad. In Pakistan, laboratories were given some time to comply with this policy, as acceptable traceability is not easily available.

During the surveillance visits in December 2007 and January 2008 it became clear that several laboratories have still not obtained acceptable measurement traceability for their equipment. This mainly relates to balances and thermometers.

By this letter, all NA accredited laboratories are informed that failure to comply with the policy for measurement traceability by the end of 2008 will result in suspension of the methods for which the equipment is relevant. We do understand that this requires some economical effort, but as an EA MLA signatory NA is obliged to enforce this policy.

In this situation, the simplest solution for calibration of thermometers may be to purchase new thermometers which have been calibrated by an accredited laboratory abroad.

For balances, it is currently necessary that an acceptable calibration laboratory (according to the policy mentioned above) calibrate the balances on-site in Pakistan. Some laboratories have asked if it is acceptable to purchase weights which are calibrated by an acceptable laboratory and then they would perform the calibrations of the balances themselves. The answer to this is that internal calibrations are only accepted after an application has been received and assessed by NA's assessors, measurement

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Lead assessor's report

Name of organisation	Pakistan Standards and Quality Control Authority (PSQCA), Quality Control Centre (QCC)				
Director General:	Abdul Ghaffar Soomro				
Accreditation no.:	Test 212	Applicant no.:	-	Date(s) of assessment:	14/ 15 December 2007
Geographical sites assessed:		Karachi			

1 Assessment

This report concerns the first surveillance visit. The initial assessment to this laboratory was carried out in January 2007. An extraordinary assessment visit was carried out in June 2007 to close out the non-conformities raised during the initial assessment.

The assessment team

Name	Position
Inger Cecilie Laake	Lead assessor
Anne Grændsen	Technical assessor

Personnel interviewed

Name	Position
Dr. Tahira Zaheer	Quality Manager
Ms. Gul Sanober	Deputy Director (vertical audit only)
Azmat Yar Khan	Store Officer and Deputy Quality Manager
Sadia Naz	Systems Analyst

Participants in the concluding meeting:

Name	Position
A.G. Soomro	Director General PSQCA
Mohammad Iqbal	Director QCC
Dr. Tahira Zaheer	Quality Manager
Azmat Yar Khan	Store Officer/ Deputy Quality Manager
Ms. Gul Sanober	Technical Manager Microbiology Laboratory
Ms. Amna Khatoon	Deputy Technical Manager
Mr. Nazir Hussain	Director Laboratories
Dr. Ali Abbas Qazilbash	Observer, Unido
Mrs. Anne Grændsen	Technical assessor, Norwegian Accreditation
Mrs. Inger Cecilie Laake	Lead assessor, Norwegian Accreditation

The deadline for correction of non-conformities is: **4 February 2008**

2 Non-conformities

Categorisation of non-conformities is described in NA Dok. 55 and on NA's web-page (www.akkreditert.no).

3 Results from the evaluation of compliance

The results from the assessment/ evaluation of compliance between the international standard NS-EN ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories) and the applicant's management system, equipment, personnel and premises are given below.

4	Management requirements
4.1	Organization

Description/ evaluation:

The Quality Control Centre is a part of Pakistan Standards and Quality Control Authority (PSQCA). The organization was established in 1951. PSQCA is owned by the Ministry of Science and Technology, i.e. it is a governmental body. QCC has approximately 150 employees. Accreditation has been granted for testing of water quality. The accredited activities are performed in the microbiology laboratory.

In addition to microbiology, QCC has several other sections dealing with the following types of testing:
- Chemical analysis
- Physical and mechanical testing
- Building materials testing
- Textile testing
- Testing of electrical products.

None of these activities are accredited.

Responsibility for day-to-day management of QCC rests with the Director, Mr. Mohammad Iqbal. He reports to the Director General of PSQCA. Dr. Tahira Zaheer is appointed as Quality Manager (QMR) for the laboratory which has been assessed. She is also the QMR for the whole of QCC. Ms. Gul Sanober is appointed Technical Manager of the microbiology laboratory. This position is not indicated in the organisational chart. However, it is stated in the quality manual that Section Heads/ Deputy Directors are the Technical Managers.

Appointment of deputies is described in the quality manual chapter 4.1.11.

Conflict of interest is discussed in the quality manual.

Job-descriptions are prepared for relevant personnel. A special form has been prepared for this purpose. Job-descriptions for the quality manager, the deputy quality manager/ store officer, the systems analyst and the technical manager were all dually signed by the person reviewing the content and the person approving the document. All the job-descriptions looked at during the assessment contained relevant information as to the responsibilities attached to the corresponding position. The Director of QCC approves all job-descriptions except the one for the Quality Manager. This is approved by the Director General.

Since the extraordinary visit in June 2007, the Deputy Technical Manager of the microbiology laboratory has left the organisation. To cover up for this and the increased amount of samples being analysed (approximately 300 samples are being analysed each year), QCC is in the process of hiring 2 additional microbiologists. Remark: when key personnel leave the organisation, QCC is required to inform Norwegian Accreditation in advance (if at all possible).

QCC holds regular meetings with the relevant regulatory bodies. To ensure appropriate communication internally, circulars are circulated whenever needed.

	NC no.	-				
	In compliance	X	Not in compliance			

4.2 Management system

Description/ evaluation:

The management system has undergone few changes since the initial assessment. The version of the Quality Manual submitted to Norwegian Accreditation is dated 28 August 2007. Is has been given a new revision number (03). In addition to the Quality Manual, the management system consists of several procedures, work instructions, test methods and forms.

The Quality Policy has been revised and is satisfactory in relation to ISO 17025. The policy contains the commitments to comply with ISO 17025 and to continuous improvement of the system. Also the requirement for personnel to familiarise themselves with the management system and to implement it in their work has been included in the policy. No evaluation of the degree of fulfilment of the Quality Policy had been performed at the time of the extraordinary visit in June 2007. This was done during the Management Review performed in November 2007.

	NC no.	-				
	In compliance	X	Not in compliance			

4.3 Document control

Description/ evaluation:

A copy of the master list of all documents was provided during the assessment. This list contains internal QCC documents (name and ID, issue date, revision number, revision date and issue number). **Remark**: QCC should include important external documents in the list, e.g. NA Dok. 25/31 and 14 and standard test methods.

The procedure for document control, P-01/01, defines the lay-out and structure of all controlled documents. The form F-01/05 indicates who is responsible for approval of the different documents. The quality manual is approved by the Director General of PSQCA, while all other documents are approved by the Director of QCC.

The original and signed version of the quality manual and other documents belonging to the management system is stamped "MASTER COPY". Controlled copies of the documents in the management system shall bear the stamp: "CONTROLLED DOCUMENT". Furthermore the procedure states that documents that have restricted access are marked "CONFIDENTIAL". This is not done in practise (**minor non-conformity**).

The document control procedure does not allow for handwritten changes to controlled documents.

Responsibility for distribution of documents rests with the quality manager.

The electronic archive of documents is used for back-up purposes. The system analyst has given access for a restricted number of personnel to the PCs. This is OK since all documents are found on paper. However, the list of passwords is not kept in written form. It is recommended that this practise is reconsidered since it could create problems if the systems analyst is not present.

	NC no.		Minor NC , see summary report NA-S23			
	In compliance		Not in compliance	X		

4.4 Review of requests, tenders and contracts

Description/ evaluation:

QCC's customers are regulators. The regulators collect samples which are then sent to QCC for analysis. The regulators are also part of the PSQCA. The regulators pay an annual fee for the analyses performed.

A vertical audit was carried out by the two assessors together. Receipt of samples and clarification of the tests to be performed is satisfactory. See also the report from the technical assessor, Mrs. Anne Grændsen.

NC no.	-				
In compliance		X	Not in compliance		

4.5 Subcontracting of tests and calibrations

Description/ evaluation:

QCC has described in the quality manual that the organisation does not use sub-contractors. It was clarified that should it become necessary in the future, the sub-contractor needs to be an accredited laboratory.

NC no.	-				
In compliance		X	Not in compliance		

4.6 Purchasing services and supplies

Description/ evaluation:

Purchasing services and supplies is described in procedure P-03/01. A purchase committee has been established to review and approve purchases.

The QCC purchasing department maintains a list of approved suppliers. This list was made available during the assessment. It contains the following information about the suppliers:
- Name of the supplier
- Type of company
- Types of products they supply
- Name of QCC's contact person in the company
- Address of the company
- Remarks.

According to the procedure, suppliers are being evaluated using the following criteria:

- Quality and reliability of the product or service
- On time delivery
- Report from the laboratory
- Responsiveness in case of rejection
- After-sales service and support
- Price competitiveness.

A "Performance Monitoring Form" is prepared for the evaluation. However, this form does not include evaluation according to after-Sales service and support and price competitiveness, **see NC number 1.**

When answering to a tender, the organisations must pay 2-5 % of the value of their tender as "Earnest money" (security deposit). When the tender is awarded and the tender process is ended, the money is given back. This is said to be the process used by all governmental organisations in Pakistan.

NC no.	1				
In compliance			Not in compliance	X	

4.7 Service to the customer

Description/ evaluation:

Service to the customers is described in procedure P-04/02. Visitors in the laboratory are allowed by QCC provided confidentiality for other customers' samples is maintained.

A survey among QCC's customers is sent out with the test results. The customers who received the survey were customers in general, not only the microbiology laboratory's customers. The answers received from June until now indicate that customers are satisfied with the services of PSQCA. Internal training on how to behave when dealing with customers has been given to staff by the quality manager and the deputy quality manager.

NC no.	-				
In compliance	X	Not in compliance			

4.8 Complaints

Description/ evaluation:

Handling of complaints is described in procedure P-04/01. The procedure states that both verbal and written complaints are registered. All complaints are to be referred to the quality manager. She should acknowledge receipt of the complaint and forward the complaint to the Director of QCC. The quality manager is responsible for communication with the complainant.

A register of complaints has been established. However, even if the organisation has received complaints (customers who have told them that they are not happy with some parts of the work that QCC has done), no records of how this was dealt with is found in the register **(see NC number 2)**.

NC no.	2				
In compliance		Not in compliance	X		

4.9 Control of nonconforming testing and/or calibration work

Description/ evaluation:

See descriptions in procedures P-5/01 and P-06/01. A specific form has been taken into use for registration of preventive and correction actions, F-06/03. NCs are divided into 3 different categories (minor, essential and very serious). A root cause analysis is made by relevant personnel according to the nature of the NC.

In 2007, 7 internal NCs have been registered. A review of how these were handled, indicate that there is a tendency to close NCs rather early, i.e. before the effectiveness of the corrective action can be evaluated.

NC no.	-				
In compliance	X	Not in compliance			

4.10 Improvement

Description/ evaluation:

Handling of proposals for improvement is described in procedure P-14/01. A form for making proposals for improvement has been prepared, F-06/03. Proposals for improvement of the management system are reviewed during management reviews.

So far, only one proposal for improvement has been filed. QCC needs to implement the procedure and increase awareness of the importance of this among personnel. This should be followed up during the next surveillance visit.

	NC no.	-				
	In compliance		X	Not in compliance		

4.11 Corrective action

Description/ evaluation:

A review of the corrective actions performed indicates that they are in accordance with what the problem was. However, as mentioned under 4.9, QCC should allow sufficient time before the effectiveness of the corrective action taken is evaluated.

	NC no.	-				
	In compliance		X	Not in compliance		

4.12 Preventive action

Description/ evaluation:

The procedure for preventive action has been revised. The procedure is sound, but has not been implemented in the work of the laboratory. Several preventive actions are still being performed (e.g. participation in PTs, maintenance of equipment etc.). QCC should either implement the procedure or change it if they consider it not be a good procedure. This issue should be focused by QCC in the coming period, and also be followed up on by the assessment team during the next surveillance visit.

	NC no.	-				
	In compliance		X	Not in compliance		

4.13 Control of records

Description/ evaluation:

Procedure P-07/01 states the rules for record keeping in the laboratory. The following information about records is given in the attached form to the procedure:
- Name of records
- Record number
- Location
- Responsible persons
- Access
- Retention period
- Responsibility for disposition
- Retention period in the record room.

Records are generally kept for 1 year in the workplace and then for another 3 years in the records room.

Records stored on paper are only for back-up purposes. All valid originals of documents are on paper. Records were not assessed in detail during this visit, and should therefore receive more attention during the next assessment.

A minor non-conformity was raised by the technical assessor, see summary report NA-S23.

	NC no.		Minor non-conformity			
	In compliance			Not in compliance	X	

4.14 Internal audits

Description/ evaluation:

Procedure P-08/01 describes how internal audits are carried out in the laboratory. It is stated that a checklist taking into account ISO 17025, the quality manual and the quality procedures of QCC needs to

be taken into account.

The quality manager nominates the auditors to perform the audits. It is required in the procedure that auditors have received training in ISO/IEC 17025. The quality manager herself and the technical manager are the two persons approved as auditors. This authorisation should be formalised.

A plan for internal audits to be carried out in 2008 has been prepared on form F-08/01. However, this plan is very general and does not indicate specifically what areas and topics will be audited. There is a more specific plan prepared, but this is not a controlled document. **See NC number 3.**

Reporting from internal audits is done using the checklists mentioned in the procedure and a form for the summary report. The reports are not sufficiently detailed in terms of what was discussed, who participated/ who were audited/ interviewed and positive findings (**see NC number 3**). In 2007, the whole system has undergone auditing. In addition, an external auditor has audited issues related to confidentiality of records. During these audits, no NCs were registered.

It is recommended that training in conduct of internal audits is given to key personnel.

NC no.	3		
In compliance		Not in compliance	X

4.15 Management reviews

Description/ evaluation:

Conduct of Management review is described in procedure P-09/01. Records show that the procedure is implemented in practise. The last Management review was carried out on 29 November 2007. The minutes prepared for this meeting contains the following information:
- Personnel participating
- Topics discussed
- Decisions made during the meeting
- Allocation of responsibility
- Target date for completion of the action agreed.

NC no.	-		
In compliance	X	Not in compliance	

5 Technical requirements

5.2 Personnel

Description/ evaluation:
In general, the competence of personnel is good. According to her job-description, the quality manager has the responsibility for identifying training needs for the technical personnel and for reviewing the effectiveness of the training received. A training plan has been prepared for the period July 2007 to June 2008 in general. In addition, individual training plans have been prepared for the quality manager, the technical manager and the deputies for the quality manager and the technical manager. For other personnel it is stated that on-the job-training will is given as needed.

During the vertical audit, the assessors asked for records showing authorisation of S.M. Raza Haider. This was provided. Authorisation of personnel to perform specific tasks in the laboratory should be followed up on during the next surveillance visit. A **minor non-conformity** was raised regarding lack of information on dates for training activities in the CVs, see summary report NA-S23.

NC no.		Minor non-conformity	
In compliance		Not in compliance	X

5.3	**Accommodation and environmental conditions**
	Description/ evaluation: See the report from the technical assessor, Mrs. Anne Grændsen.
	NC no. | - |
	In compliance | X | Not in compliance | |
5.4	**Test and calibration methods and method validation**
5.4.1	**General**
	Description/ evaluation: The scope assessed is composed of standard methods. For more information, see the report from technical assessor Mrs. Anne Grændsen.
5.4.2	**Selection of methods**
	Description/ evaluation: See the report from the technical assessor Mrs. Anne Grændsen.
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/ evaluation: The microbiology laboratory of PSQCA/ QCC is accredited for standard methods only.
5.4.5	**Validation of methods**
	Description/ evaluation: See the report from the technical assessor Mrs. Anne Grændsen.
5.4.6	**Estimation of uncertainty of measurement**
	Description/ evaluation: See the report from the technical assessor Mrs. Anne Grændsen.
5.4.7	**Control of data**
	Description/ evaluation: See the report from the technical assessor Mrs. Anne Grændsen.
	Summary/Conclusion: An essential non-conformity related to lack of implementation of work instructions is raised by the technical assessor.
	NC no. | 6 |
	In compliance | | Not in compliance | X |

Lead assessor's report

5.5	**Equipment**				
	Description/ evaluation:				
	See the report from the technical assessor Mrs. Anne Grændsen. An essential non-conformity is raised concerning the thermometer used in the incubator.				
	NC no.	4			
	In compliance		Not in compliance	X	
5.6	**Measurement traceability**				
	Description/ evaluation:				
	Measurement traceability for balances and thermometers currently in place in the laboratory is not acceptable, ref. letter from NA dated 28 September 2007. However, it is acknowledged that new thermometers with calibration certificates from a UKAS-accredited laboratory have been ordered.				
	NC no.	5			
	In compliance		Not in compliance	X	
5.7	**Sampling**				
	Description/ evaluation:				
	Not relevant.				
	NC no.				
	In compliance		Not in compliance		
5.8	**Handling of test and calibration items**				
	Description/ evaluation:				
	See the report from the technical assessor Mrs. Anne Grændsen.				
	NC no.	-			
	In compliance	X	Not in compliance		
5.9	**Assuring the quality of test and calibration results**				
	Description/ evaluation:				
	See the report from technical assessor Mrs. Anne Grændsen.				
	NC no.	-			
	In compliance	X	Not in compliance		
5.10	**Reporting the results**				
	Description/ evaluation:				
	See the report from the technical assessor Mrs. Anne Grændsen. This should be looked in more detail during the next surveillance visit.				
	NC no.	-			
	In compliance	X	Not in compliance		

5.10.5	**Opinions and interpretations**					
	Description/ evaluation: Not relevant.					
	NC no.					
	In compliance		Not in compliance			
5.10.7	**Electronic transmission of results**					
	Description/ evaluation: Not relevant.					
	NC no.					
	In compliance		Not in compliance			

4 Other requirements

NA dok 14	**Conditions for use of NA's logo in accreditation marks and for making reference to accreditation**					
	Description/ evaluation: The accreditation mark is at present only used on test reports. QCC has faced problems when trying to write the accreditation number directly under the accreditation logo. NA will send the logo to QCC in word format. The accreditation number (TEST 212) shall be placed directly underneath "NORWEGIAN ACCREDITATION").					
	NC no.	-				
	In compliance	X	Not in compliance			
NA dok 25/31	**Accreditation conditions**					
	Description/ evaluation: A satisfactory description of the communication with Norwegian Accreditation and QCC's duty to inform Norwegian Accreditation in case of important changes in the laboratory has been included in the quality manual. The quality manager is responsible for the contacts with Norwegian Accreditation.					
	NC no.	-				
	In compliance	X	Not in compliance			
NA dok 26a	**Requirements for calibration and control of balances for accredited test laboratories**					
	Description/ evaluation:					

	Balances have been calibrated by an organisation which is not acceptable according to the policy for measurement traceability, see §5.6.					
	NC no.	5				
	In compliance		Not in compliance	X		
NA dok 26b	**Requirements for calibration and control of thermometers for accredited test laboratories**					
	Description/ evaluation Thermometers have been calibrated by an organisation which is not acceptable according to the policy for measurement traceability, see §5.6.					
	NC no.	5				
	In compliance		Not in compliance	X		
NA dok 50	**Flexible scope (if relevant)**					
	Description/ evaluation: Not relevant.					
	NC no.					
	In compliance		Not in compliance			
NA dok 52	**Calculation of measurement uncertainty in calibration**					
	Description/ evaluation: Not relevant.					
	NC no.					
	In compliance		Not in compliance			

5 Implementation of corrective actions to non-conformities found during the previous assessment

The non-conformities noted during the initial assessment in January 2007 and the extraordinary assessment in June 2007, have been satisfactorily closed.

6 Recommendation regarding accreditation

It is recommended that accreditation Test 212 is maintained under the condition that satisfactory corrective actions to the non-conformities raised are submitted to Norwegian Accreditation within 4 February 2008.

7 Recommendation regarding suspension

Not relevant.

8 Recommendation regarding scope of accreditation

It is recommended that the scope of accreditation is maintained as it is. If QCC applies for extension of the scope, as notified during the assessment, an application must be sent to Norwegian Accreditation with a description of the extension.

9 Recommendation regarding administrative/geographical units/ locations

Activities performed by the Microbiology laboratory of QCC in Karachi have been assessed and is covered by the recommendation referred to in point 8 above.

10 Changes since the previous visit

Ms. Shagufta Jabeen has left QCC. No other major changes have been made.

11 Right to complain

The organisation has the right to complain about factual mistakes in the report. Such a complaint must be submitted no later than 3 weeks after having received the report/ the report has been sent to the laboratory by Norwegian Accreditation.

Other issues

None.

The undersigned confirms that the report is not in conflict with NA policies and procedures.

Karachi/ Pakistan, 15 December 2007

Inger Cecilie Laake, lead assessor/
Norwegian Accreditation

Karachi/ Pakistan, 15 December 2007

Anne Grændsen, Norwegian Accreditation

13 References

Agenda for the assessment visit
Reporting non-conformities: see NA-S23 Summary report
Number of very serious non-conformities; 0
Number of essential non-conformities; 6
Number of minor non-conformities; 3
Summary report: NA-S23
Report from the technical assessor, Anne Grændsen (NA-S2c).

Name of the organisation: Pakistan Standards and Quality Control Authority (PSQCA), Quality Control Centre (QCC), Karachi, Pakistan

Application no.: - **Accreditation no:** Test 212

Type of visit: Surveillance visit

Leader of the organisation: Abdul Ghaffar Soomro
Lead assessor: Inger Cecilie Laake

Number of non-conformity reports attached:

Very serious:	0
Essential:	6

Summary (Including a description of minor non-conformities):

QCC has personnel with satisfactory competence in relation to the accredited activities. The premises are fit for use and properly monitored. The management system covers all relevant topics, and in general the descriptions given are good. However, there are shortcomings in the implementation of some procedures and there are still problems with measurement traceability.

Minor non-conformities:

Time frame for the training carried out is not specified in the CV's.	ISO/IEC 17025 §5.2.1
The lot number reference is missing in the log of sterility checks performed on new lots of filter papers -	ISO/IEC 17025 §4.13
Procedure 01/01 states that documents that have restricted access are marked "CONFIDENTIAL". This is not done in practise	ISO/IEC 17025 §4.3

Recommendation regarding accreditation: It is recommended that the accreditation (Test 212) is maintained under the condition that satisfactory corrective actions to the non-conformities raised are submitted to Norwegian Accreditation within the deadline stated below.

Deadline for presentation of corrective actions: 4 February 2008

15.12.2007 Inger Cecilie Laake Seen by:
date Inger Cecilie Laake, lead assessor Signature of the organisation's representative

Annex:
List of participants during the opening and final meetings

NORWEGIAN ACCREDITATION

07/0216 - Test 212

Participants in introductory and concluding meetings

Name	Position	Introductory meeting	Concluding meeting
A. G. Soomro	D.G. PSQCA		
DR Tahira Zaheer	QMR/DDC QCC		
GUL SANOBER	TM/DD Microbiology		
Amna Khatoon	DTM / Examiner Microbiology		
Muhammad Iqbal	Director QCC		
NAZIR HUSSAIN	Director Laboratories		
Azmat Yar Khan	DQMR/SO		
Sadia Naz	System Analyst		
Dr Tahira Zaheer	QMR.		
GUL SANOBER	TM C Microbiology		
Amna Khatoon	DTM (Microbiology)		
Sadia Naz	System Analyst		
Muhammad Iqbal	Director, QCC		
NAZIR HUSSAIN	Director Laboratories		
Azmat Yar Khan	DQMR/SO		

ACTIVITY:	Surveillance visit	Report no.:	1
ORGANISATION:	PSQCA, Karachi		
Department:	Quality Control Centre (QCC)		
Accreditation no.:	Test 212		
Lead assessor	Inger Cecilie Laake	**Reporting assessor**	Inger Cecilie Laake

DESCRIPTION:

Procedure P-03/01 states that suppliers shall be evaluated against a number of criteria. The form prepared for the evaluations is missing 2 of the criteria (After-sales service and support and price competitiveness), and so far none of the suppliers have been evaluated against these 2 criteria. Not all suppliers have been evaluated.

14.12.2007 Inger Cecilie Laake _____ 14/12/07
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

P-03/01

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

The whole procedure has been change according to the NA guideline (P-03/01 attached) and necessary observations of NA are also noted for future compliance.

Actions are documented in the amendment no: Valvi

☐ It is not necessary to attach documentation

Time limit for correction:

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

[X] The non-conformity is closed based on satisfactory documentation from the organisation
[ ] The non-conformity is closed based on recommendation from the technical assessor
[X] Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 9/5-08 Inger Cecilie Laake
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	2
ORGANISATION:	PSQCA, Karachi		
Department:	Quality Control Centre (QCC)		
Accreditation no.:	Test 212		
Lead assessor	Inger Cecilie Laake	**Reporting assessor**	Inger Cecilie Laake

DESCRIPTION:

A register of complaints has been established, but none of the complaints received have been registered. There is no record available on the handling of the complaints.

14.12.2007 Inger Cecilie Laake _____ 14/12/07
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

P-04/01

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.8
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

The Procedure has been implemented now and will be shown in the next visit.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

The statement above is accepted.

☒ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 8/5-08 Inger Cecilie Laake
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	3
ORGANISATION:	PSQCA, Karachi		
Department:	Quality Control Centre (QCC)		
Accreditation no.:	Test 212		
Lead assessor	Inger Cecilie Laake	**Reporting assessor**	Inger Cecilie Laake

DESCRIPTION:

Internal audits:

- The plan prepared for 2008 is too general. The more specific plan prepared is not a controlled document
- The reports prepared after internal audits are not sufficiently detailed. Information is lacking regarding who was interviewed, what was discussed and positive findings.

15/12-07 Inger Cecilie Laake _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

P-04/01

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.14
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

- The more specific plan for year 2008 is prepared now on form F-08/01 (Form attached).
- The more detailed Audit reports will be prepared for future audits as planed for the year 2008 and will be shown in the next visit.

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 9/5-08 Inger Cecilie Laake
date signature (lead assessor)

ACTIVITY:	Surveillence visit	Report no.:	4
ORGANISATION:	PSQCA, Karachi		
Department:	Microbiology		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Cecilie Laake	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The thermometer in the incubator used for 44,5 ± 0,2 °C is not fit for use with the current calibration data. The measurement uncertainty given in the calibration certificate is not in accordance with the acceptance limit given in the method.

15 Dec 07 — Date — Signature assessor — Signature (Org. representative)

Ref. organisation's doc.
Calibration certificate

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.5
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

Purchase order for calibrated Thermometers for incubator of required range were issued, according to the quotation received from the supplier **5 to 6 week** is required for the supply of desired thermometers from Zeal Company which are traceable to UKAS. The photocopy of purchased order is attached herewith.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

01/03/08 — date — signature (Org. representative)

REASON FOR CLOSING: *(To be filled in by the lead assessor)*

- ☐ The non-conformity is closed based on satisfactory documentation from the organisation
- ☒ The non-conformity is closed based on recommendation from the technical assessor
- ☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 8/5-08 — date — Enger Cecilie Laake — signature (lead assessor)

ACTIVITY:	Surveillence visit	Report no.:	5
ORGANISATION:	PSQCA, Karachi		
Department:	Microbiology		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Cecilie Laake	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Following calibrations are performed by an organization which is not accepted by NA:

- Balance
- Thermometers in incubators, autoclave and water bath

(Reference: Information letter sent to the laboratory 28 Sep 2007.)

15 Dec 07 — Date — Signature assessor — Signature (Org. representative)

Ref. organisation's doc.
Calibration certificates and marks

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Doc 26 a NA Doc 26 b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

For balances we have been informed through UNIDO that you are agreed with NPSL, for that purpose we are requesting to NPSL for recalibration. For the temperature the calibrated thermometer have been purchased from Alla France Company which we are using in lab for INCUBATOR, AUTOCLAVE and WATER BATH photocopy of certificates will be sent through hardcopy.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: ____

01/03/08 — date — signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

- ☐ The non-conformity is closed based on satisfactory documentation from the organisation
- ☒ The non-conformity is closed based on recommendation from the technical assessor
- ☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 8/5-08 — date — Inger Cecilie Laake — signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	6
ORGANISATION:	PSQCA, Karachi		
Department:	Microbiology		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Cecilie Laake	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Point 5.2 and point 5.3 in working instruction for maintenance of glassware is not taken into use.

Neither are tests for heavy metals performed as described in point 6 in work instructions for the use, maintenance & performance check of distillation – deionizer plant.

15 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
TP-01/07
TP-04/13

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Corrective Action:

Both procedures covering these clauses have been revised according to the lab requirements. (TP-Micro-01/07 and TP-Micro-04/13 attached)

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

01/03/08 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 8/5-08 _____
date signature (lead assessor)

Name of the organisation:	**Quality Control Centre, PSQCA**
Assessed locations:	**Karachi**

Accr. no. : TEST 212	Date of assessment: 14 Dec 07
Appl. no.:	15 Dec 07

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Anne Grændsen** Technical area: **Microbiology (P16)**

2. General information

First time visit		Extraordinary visit		Renewal	
Surveillance	X	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	

Technical assessment NS EN ISO/IEC 17025: 2005	X
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Gul Sanober Ghumro	Technical Manager
Amna Khatoon	Examiner microbiology and deputy quality manager

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
Accreditation of the present scope is recommended maintained if the laboratory within the agreed date is submitting NA corrective actions on NCs observed, and the corrective actions taken are considered to be satisfactory.

3.2 Recommendation regarding change of the responsible for validation, when relevant:
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

Shagufta Jabeen has left her position as examiner in the microbiological laboratory. Amna Khtoon has taken over the responsibilities of Shagufta Jabeen.

There are no other essential changes in the laboratories.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The Deputy Director Microbiology is the Technical Manager. She has good competence in microbiology and issues related to quality aspects within the field. Amna Khatoon is appointed as Deputy Quality Manager after the last extraordinary visit. The cooperation between quality manager and the technical management team in microbiology is working well. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: Personnel have access to the documents needed. Availability of quality manual, technical manual and different forms for daily recording in the laboratory is satisfactory. Some working instructions are placed on or nearby the instruments. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: During the assessment it was not observed any document which was not under properly control. *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: See report from lead assessor *Non-conformity no* --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: Currently there is no need for subcontracting analysis. The laboratory is governmental and is performing verification analysis for

	processing plants producing bottled water. If stoppages arise due to technical problems, the laboratory has the possibility to postpone the testing activity. Consequently there is no need for subcontracting.
	Non-conformity no --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has established satisfactory requirements for purchasing. As demonstrated in previous visits to the laboratory: • Chemicals and dehydrated media are of recognised quality. • Chemicals and dehydrated media are satisfactorily marked with recipient date and opening date. • Media and solutions made in the laboratory are satisfactorily labelled. *Non-conformity no* --
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: See report from lead assessor *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: All registrations are satisfactorily recorded in bench records and other forms used in the laboratory. Handling of raw data seems to be taken care of in a good manner. All registrations were easily readable and were properly dated and signed. All files asked for were easily found. A vertical audit was carried out on the Ref. No. QCC/24/Chem/21(1)/2007(709). The sample of bottled water had been analysed for chemical and microbiological parameters. In general the laboratory demonstrated good traceability in connection to all elements included in the analysis. All data asked for were found. The registrations were easily readable and properly dated and signed. *Non-conformity no* --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The laboratory has qualified and experienced personnel. The laboratory has the competence needed to carry out the analysis within the accreditation scope. However the laboratory has a vulnerable situation since the analytical activity is increasing and there are only two authorised analysts. The laboratory has plans for recruiting personnel in near future. *Non-conformity no* --

5.2.1	**Training**
	Description/evaluation: Discussions along with examination of technical registrations and PT-results clarified that proper training/authorisation has been given. The records demonstrate that the laboratory performs the methods according to the methods in the accreditation scope. In 2008 further training in ISO 17025 is planned for the Deputy Director and the Examiner/Deputy Quality Manager. Amongst others, training in internal auditing and handling of complaints will be given a priority. Training in food microbiology is also planned. All personnel have specific, updated CV's. **Minor non-conformity:** Time frame for the training carried out is not specified in the CV's.
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is satisfactory. Parameters listed in the accreditation scope are routinely analysed. In addition analysis of quality control samples (PT samples and ILC-samples) are performed. Both authorised analysts are performing the quality control samples on quarterly basis. The number of routine analysis has increased lately. In the period from July 2006 to July 2007 the laboratory received 60-70 water samples for analysis. The past 5 months the laboratory has received 130 water samples. Real "positive" samples are frequently tested. In the present situation approximately 20% of the samples are from natural contaminated water samples which fail to meet the criteria for bottled water in the national regulations.
5.2.4	**Job descriptions**
	Description/evaluation: Job descriptions are established for all personnel and describe the responsibilities in the laboratory properly. When Shagufta Jabeen left her position in the laboratory, Amna Khatoon took over Shagufta Jabeen's duties. Amna Khatoon's job description is updated and contains her new responsibilities.
5.3	**Accomodation and environmental conditions**
	Description/evaluation: Access to the laboratory is satisfactory restricted. Designated laboratory coats and foot has to be worn in the laboratory. The work flow is well planned and organised. The laboratory has working instructions for general maintenance of equipment and facilities Measures have been taken to avoid contaminating samples and testing. Examination of monitoring records demonstrates that the facilities are fitted for the activity performed.

	The laboratory is monitoring and recording following environmental parameters: • Sterility checks of glassware (routinely) • Bacteriological sterility by air testing; either exposure plates or use of air sampler (monthly) • Sterility testing of equipment and supplies by swab testing (monthly) • Bacteriological and chemical testing of the distilled water used for media production (weekly, monthly or annually depending on the parameter) • Temperature and humidity (daily) Procedures regarding handling of disposals from the testing laboratory were not assessed during this visit.
	Non-conformity no --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See specific clauses below *Non-conformity no* **6**
5.4.1	**General**
	Summary/Conclusion: The laboratory is using recognised, standard methods which are satisfactorily validated. The methods used are appropriate and fit for purpose. The analysis listed in the accreditation scope for test 212 is specified in the national regulations for hygienic testing of bottled water. In general vertical audits and discussions during the assessment demonstrated good compliance between procedures, working instructions and practical routines. The bench records are designed as a memo to the analysts. Collected plates from previous analysis performed last week was examined and discussed. Plates and tubes from positive and negative controls and performance tests were also inspected. The plates demonstrated that the analyst is using a good spreading technique and no contaminated plates were observed. **Essential non-conformity:** Point 5.2 and point 5.3 in working instruction for maintenance of glassware is not taken into use. Neither are tests for heavy metals performed as described in point 6 in work instructions for the use, maintenance & performance check of distillation – deionizer plant.
5.4.2	**Selection of methods**
	Description/evaluation: See clause 5.4.1.

5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: At current stage not relevant. The laboratory is not using methods developed in house or any other non-standard methods. Neither has the laboratory plans to use such methods.
5.4.5	**Validation of methods**
	Description/evaluation: At current stage not relevant. There is no need for validation of methods used in the laboratory. Further information - see point 5.4.3/5.4.4. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Identification of contributions to measurement uncertainty (MU) is not included in the working instructions for the methods in the accreditation scope. The laboratory has started to calculate the measurement uncertainty for "Total Viable Plate Count". A reproducibility study has been performed and the calculation of the MU is performed by the "step by step" method (uncertainty budget). During the discussions the laboratory was warned against using the "step by step" method due to the risk of underestimating the MU. Underestimation can be caused by synergisms etc. The "top down" method is recommended for microbiological analysis. See also ISO 19036. *Non-conformity no* --
5.4.7	**Control of data**
	Description/evaluation: All manually registrations observed in the records were satisfactory. Corrections were not observed during the assessment. The laboratory does not use LIMS. Calculations in connection with the analytical process are manual operations. In the monitoring programmes for equipment, spread sheets are used for drawing trend diagrams. Trend analysis will be followed up in next surveillance visit. *Non-conformity no* --
5.5	**Equipment**
	Description/ valuation: The laboratory has worked out a satisfactory register of equipment. Each item is given a unique identity number. All equipment is satisfactory labelled with the identity number. Working instructions are established for critical instruments. In general the

	maintenance is satisfactory. The instruments are properly monitored. Control results are recorded conscientiously. The following instrument files were reviewed: • Incubators and refrigerators and • Autoclave • Thermometers • Laminar flow hood (air samples) • Balance • pH-meter • Volumetric equipment (Micro pipettes) • In house prepared culture media (Sterility, positive/negative controls)growth promotion and pH-tests) • Deionizer plant (chemical and microbiological control) • Glassware Regarding working instructions for deionizer plant and glassware - see also clause 5.4 NC no 6 included. **Essential NC:** The thermometer in the incubator used for 44,5 ± 0,2 °C is not fit for use. The measurement uncertainty given in the calibration certificate is not in accordance with the acceptance limit given in the method.
	Non-conformity no **4**
5.6	**Measurement traceability**
	Summary/conclusion: Traceability for microbiological methods is established by using reference cultures, participation in PT-schemes and ILCs. The reference cultures are regularly used for approval of in house made culture media or as controls during analyses. The laboratory is using reference cultures (master cultures) provided by Microbiologics. The reference cultures are equipped with quality certificates issued by the producer. Stock cultures are made from the master cultures and are satisfactory stored in the refrigerator in tubes with non selective media. Handling and storage of stock cultures and working cultures is considered to be satisfactory. Onsite calibrations of thermometers, equipment fitted out with digital thermometers and balances are performed by the Pakistan's national metrology laboratory. Calibration certificates are issued. The laboratory has ordered three new reference thermometers which are calibrated by an UKAS accredited organisation. Acknowledgement of the order was presented during the assessment.

	Essential NC: Balances and thermometers have been calibrated by an organization which is not acceptable according to the requirements for measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.)
	Non-conformity no **5**
5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.5 and 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Handling of samples is considered to be satisfactory. Samples are collected from producers of bottled water and sent to the laboratory. Sample information is submitted with the sample. On receipt the sample acquires a unique number. After registration the samples are immediately transferred to the laboratory. Before, under and after analysis the samples are stored in a temperature monitored refrigerator in the microbiological department. The samples are not disposed until the test results are approved. The laboratory has records showing how the samples have been treated from receipt to disposal. *Non-conformity no* --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory is using reference cultures from Microbiologics (positive and negative controls) for control of methods and culture collection. The strains are

	traceable to an international culture collection (ATCC). The laboratory demonstrated proper handling of the reference cultures. The laboratory participates in a PT-scheme for water testing provided by Norwegian Institute for Food and Environmental analysis. The PT-scheme covers the full accreditation scope. The laboratory has participated once after the extraordinary visit. The results are not yet worked out by the supplier. Trend analysis is performed on PT test results. The laboratory has an agreement with PCSIR in Karachi to participate in ILC organised by PCSIR. The laboratory has participated once after the extraordinary visit and the test results PSQCA was in compliance with the test results from PCSIR. In total PT/ILC is performed on quarterly basis.
	Non-conformity no
5.10	**Reporting the results**
	Description/evaluation: Customer reports were reviewed. The technical content of the report is considered to fulfil the requirement in ISO 17025. The accreditation mark is used together with the logo of PSQCA. Regarding placing of the accreditation number, see comments in the paragraph NA dok 14 in the report from lead assessor. Accredited analysis is clearly marked with an asterisk. Reference to methods used is given as a "package", Pakistan Standard (PS): 4639-2004 (R). The laboratory has included limits given in the PS in the reports. Information on measurement uncertainty is given. A statement that the test results relate only to the samples tested is also included. *Non-conformity no* --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant

NA Dok	Other requirement documents
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: See report from lead assessor *Non-conformity no* --
No 25/31	**Accreditation conditions**
	Description/evaluation: See report from lead assessor *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: The balance has been calibrated by an organization which is not acceptable according to the measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) *Non-conformity no* **5**
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: Thermometers have been calibrated by an organization which is not acceptable according to the measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) *Non-conformity no* **5**
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	No specific methods were asked for demonstration. Plates from previous analysis performed last week was examined and discussed. Plates and tubes from positive and negative controls and performance tests were also inspected.	Discussed with: • Amna • Gul Sanober Ghumro
7. Follow up non-conformities from the last visit:	In the report from the extraordinary visit it was given two remarks. The laboratory had not identified sources of measurement uncertainty in the working instruction. The calibration dates for calibration of the pH-meter was not documented. The shortcomings are now satisfactory corrected.	
8. Notes/summary/ conclusion	No further comments	
9. Next visit	• PT-results and trend analysis • Trend analysis (control charts) regarding control of equipment • Balance and temperature calibrations/controls	

16 Dec 2007, *Anne Grændsen*
Technical assessor

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

16 Dec 2007, *Cecilie Laake*
lead assessor

Name of organisation:	MFD, Karachi		
Manager of the organisation:	Javed Ishrat		
Accreditation no/ application no:	Test 213	Date of assessment:	17 12. 07
Sites assessed:	Karachi		

1 The assessment

This report deals with:

Initial ass.		Extraordinary ass.		Renewal	
Surveillance	x	Extension		Full assessment	

Assessment team:

Name	Position
Ismat Gul Khattak	Lead Assessor
Anne Grændsen	Technical Assessor
Inger Cecilie Laake	NA Observer

Personnel interviewed:

Name	**Position**
Javed Ishrat	Director General
Shaukat Hussain	Ex-Quality Manager
Humaira Sultan	Quality Manager
Shazia Naz	Technical Manager

Participants in the concluding meeting:

Name	Position
Javed Ishrat	Director General
Shaukat Hussain	Ex-Quality Manager
Humaira Sultan	Quality Manager
Shazia Naz	Technical Manager
Dr Ali Abbas Qazilbash	UNIDO

Deadline for submission of corrective actions: **04.02.2008**

2 Non-compliances

Categorisation of non-compliances is described in NA Doc 55 and on NA's web-site (www.akkreditert.no).

3 Results from the assessment

Below, the results from the assessment against the accreditation requirements as described in ISO/IEC 17025:2005 (General requirements for calibration and test laboratories) and the requirements defined in the laboratory's own management system, are described.

ISO 17025 – Chapter 4 – Requirements for management

4.1 Organization

Marine Fisheries Department (MFD) was established in 1951 and works under the Ministry of Food, Agriculture & Livestock, Government of Pakistan. The Laboratory holds legal responsibility / authority for testing fish and fishery products, potable water/ice for the purpose of health control and monitoring of production condition, under Pakistan Fish Inspection & Quality Control Act, 1997 and Rules, 1998. Currently the scope of the lab includes microbiology testing only.

All employees have undertaken a written agreement as per Confidentiality Agreement Form *Doc.* # MFD/CML/FF/QM-4.1, the evidence of which was seen by looking into the records of confidentiality for Ms Humaria Sultana who is the new quality manager and Mr Shah Nawaz Thebo, the new Purchase Officer. Both were available.

Mr Shaukat Hussain, the ex-quality manager, had been replaced by Ms Humaira Sultan, who according to him was an under training quality manager. The evidence of being under training could not be seen anywhere in records. It was also noticed that she had been working or signing reports independently, without any evidence of being supervised, despite the fact that she hardly had any know how of either the standard or their own quality system. She had not been exposed to any effective training nor was there any scheduled plan. The lab needs to pay attention to this issue as running the quality system of an accredited lab by untrained quality manager can result in collapse of the system. The quality manager needs immediate training.

The technical manager in the microbiology lab is Ms Shazia Naz, is well trained on the standard.

NC no					
	Compliance	X	Not in compliance		

4.2 Management system

According to the quality manual of the lab, all documents issued to personnel in the laboratory as part of the quality system are reviewed and approved for use by Director General on the recommendations of Management Review Committee/Quality Manager/Technical Managers, prior to issue.

The Quality Manager issues and maintains all documents including a Master Index of all applicable documents which includes, Code number (where applicable), title, revision level (where applicable) or date, review date etc. A total of nine quality manuals have been issued to various concerned officers.

NC no					
	Compliance	X	Not in compliance		

4.3 Document control

A Master Index with identification # MFD/CML/FF/QM-4.3(a) identifying the current revision status in the quality system, is maintained and readily available to preclude the use of obsolete and/or invalid documents. The Quality Manager issues and maintains all documents including a Master Index of all applicable documents. This includes, Code number (where applicable), title, revision level (where applicable) or date, review date etc. Page wise changes are made in the documentation and the next revision number is given. The system is working as per samples selected. These changes in the system are recorded in the document as per Document Amendment Record Sheet in Document # MFD/CML/FF/QM-4.3(c). Quality system documents generated by the laboratory are uniquely identified. Such identification includes the date of issue, revision identification, page numbering, and the total number of pages to signify the end of the document.

The laboratory's documentation control system allows for the amendment of documents by hand. Quality manager is the authority for such amendments. While checking the evidence of the implementation of this system, various quality manuals were checked besides the manual of the quality manager. It was observed that although the hand written change had been typed either on the back of the page or at the end of the page, in these manuals but there was no initial of the quality manager with the changed text.

There are several problems in document control, on which an essential nonconformity is given. See 5.2 for more details.

NC no	02				
	Compliance		Not in compliance	X	

4.4 Review of requests, tenders and contracts

Not covered during this assessment.

NC no	-				
	Compliance		Not in compliance		

4.5 Subcontracting

Not covered during this assessment.

NC no					
	Compliance		Not in compliance		

4.6 Purchase of services and supplies

The laboratory maintains policy and procedures for the selection and purchasing of services and supplies it uses that affect the quality of the tests. According to the procedure, the purchased supplies and services are not used by the laboratory unless they are inspected and approved by the technical personnel regarding their suitability to maintain quality of test results. The Quality Manager, Technical Managers and the Purchasing Manager share responsibility for the qualification and monitoring of suppliers. The suppliers whose performance has proven to be acceptable, and who meet the Government requirements/procedures laid down in "Public Procurement Rules, 2004, Part-II" are approved based on the criteria whether they meet one or more of the requirements, such as ISO 9000 certified, those who were supplying the MFD for last 02 years without any problems. New suppliers based are empanelled after a site visit. The quality assurance certificate is obtained from the supplier for critical consumables. Vendor status is maintained through the use of an Approved Supplier List, which is there. The Quality Manager maintains an Approved Supplier List.

All this documented procedure seems to be ok theoretically, but on interviewing with the newly inducted purchase officer, it was noticed that he did not understand the importance of quality in purchases and he insisted that purchases are made 'as per government rules' of going for the lowest bidder. This level of understanding of the purchase officer of an accredited lab can result in purchasing sub-standard quality critical chemicals and equipment. The purchase officer needs training on his procedure and at least the relevant clause in the standard which is related to purchases.

According to the purchase procedure, quality and delivery performance of all suppliers is continuously monitored via a supplier performance as per "Supplier Quality History Record Doc. # MFD/CML/FF/QM-4.6 (e) during management review meetings, but the record of suppliers quality history could not be seen at all. The lab is not fully following its own procedure. An observation is raised against this clause, as there is room for improvement. This will be checked in the following visit.

The procedure also refers to discontinuation of suppliers if they do not give good service, the evidence of which was seen, as a couple of suppliers have been removed from the short listed suppliers.

NC no					
	Compliance	X	Not in compliance		

4.7 Service to the customer

Not covered during this assessment.

NC no					
	Compliance		Not in compliance		

4.8 Complaints

The laboratory has a system for handling complaints. During the last year, no complaints have been received from any customer. This does not mean that there are no complaints nor could it mean that getting no complaints is an issue. One reason given during the assessment was that the complaint boxes were kept in the laboratories where there was a limited access of the customer. Now during the assessment they were seen in the quality manager's office. The lab may think of other options of getting feedback from clients, giving them the option of both positive and negative. Complaints are first recorded in the form and are logged in Doc. # MFD/CML/FF/QM/4.8. There is need for improving the system of getting feedback.

NC no					
	Compliance	X	Not in compliance		

4.9 Handling non-conforming work

The Laboratories have established and maintain a procedure for Control of nonconforming testing work, and a total of eighteen non-conforming incidents have been recorded on separate forms, but are not logged anywhere. In the reports checked during the assessment, it was observed as if these NC forms were filled without any understanding of the requirements of the questions raised in the form. The root cause was hardly determined and the text in the box for root cause hardly meant anything or was hardly related to root cause. Similarly the corrective action was also just a formality. It was also observed that these forms were not filled in correctly. There shows lack of understanding of the system and its importance for accredited labs. The system needs improvement.

This evidence was sufficient to raise an essential non-conformity. In stead, a remark is made. The implementation of the procedure for handling NCs will be followed up during the coming assessment.

NC no					
	Compliance	X	Not in compliance		

4.10 Improvement

Not covered during this assessment.

NC no					
Compliance		Not in compliance			

4.11 Corrective actions

According to the procedure the quality manager signs the corrective action reports, but during the assessment she could hardly explain the difference between the corrective action and correction. The lab needs to pay attention to this issue and get the quality manager trained on ISO 17025.
See clauses 4.1. and 4.9.

NC no					
Compliance	X	Not in compliance			

4.12 Preventive actions

Not covered during this assessment.

NC no					
Compliance		Not in compliance			

4.13 Technical registrations

See minor non-conformity in the Technical assessor's report.

NC no	Minor NC 3				
Compliance		Not in compliance	X		

4.14 Internal audits

According to the procedure for internal audits, the Quality Manager is responsible for planning the audit and recommending any unscheduled audits to the Director General. The audit schedule reflects that the cycle of internal audits normally be completed in one year. The Quality Manager and Technical Managers are responsible for planning coordinating, and internal quality audits. The audit team comprise minimum of 03 persons, who conducts audits without taking into account the independence of the activity area which is being audited, although the procedure states that internal quality audits are conducted by personnel independent of audited activities/areas. This has resulted in identifying hardly any NCs in their procedure, which undermines the purpose of the audits. All personnel conducting internal quality audits need to undergo effective training to conduct internal audits. The internal audit reports have insufficient details of the audits conducted and are mostly highlighting the problems only.

Observation: All these findings were enough to raise an essential non-conformity, but a remark is made. **The lab should seriously improve this system to avoid non-conformity in the future and truly improve their system. This will be followed up in the next assessment.**

NC no					
	Compliance	X	Not in compliance		

4.15 Management review

According to the procedure, the Director General, MFD, periodically and in accordance with a predetermined schedule and procedure, conducts a review of the laboratory's quality system and testing activities to ensure their continuing suitability and effectiveness, and to introduce any necessary changes or improvements. Minutes of the meeting were available. However, the procedure also states that the agenda is circulated two weeks in advance, in support of which no evidence of the implementation was available. **The lab is not fully following its own procedure. This will be followed up on during the next assessment.**

NC no					
	Compliance	X	Not in compliance		

ISO 17025 – CHAPTER 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

The standard requires that the management of the laboratory has to formulate the goals with respect to the education, training and skills of the laboratory personnel, which could not be seen during the assessment. The laboratory is currently not having training needs identification for all personnel such as for quality manager, although some kind of awareness has been arranged, according to one of the documents. This was not sufficient, which was evident during the discussions made during the assessment, and the effectiveness of the training was also not evaluated.

The standard requires that the laboratory shall maintain current job descriptions for managerial, technical and key support personnel, but the job descriptions of the quality manager and purchase managers do not have any date or control number on it. The lab needs to pay attention to the requirements of this clause.

An essential non conformity is given, the details of which is in the NC report.
See §4.3 too.

NC no	02 and Minor NC 3				
	Compliance		Not in compliance	X	

5.3 Accommodation and environmental conditions

Not assessed during this assessment.

NC no					
	Compliance		Not in compliance		

5.4 Test and calibration methods and validation of methods

See Technical assessor report

NC no	07				
	Compliance		Not in compliance	X	

5.5 Equipment

Essential non conformity is given against this clause by the TA.
See Technical assessor's report.

NC no	04				
	Compliance		Not in compliance	X	

5.6 Measurement traceability

One essential and one minor non-conformity is given against this clause by the TA.
See Technical assessor's report.

NC no	04, 05 and Minor NC 1				
	Compliance		Not in compliance	X	

5.7 Sampling

Not applicable.

NC no					
	Compliance		Not in compliance		

5.8 Handling of test and calibration items

See Technical assessor's report..

NC no					
	Compliance	X	Not in compliance		

5.9 Assuring the quality of test and calibration results

See Technical assessor's report. A minor NC is given.

NC no	Minor NC 2				
	Compliance		Not in compliance	X	

5.10 Reporting the results

There are two types of test reports and both do not have the name and address of the client, but according to the lab this was a requirement from the regulatory body, and that they have system in place for traceability of the client. An essential nonconformity is given by the TA.

See Technical assessor's report for details.

NC no	06				
	Compliance		Not in compliance	X	

4 Other requirements

NA-Doc 14 Conditions for the use of NA's logo in accreditation marks and for making reference to accreditation

The lab has a system in place, but the logo has to be according to the specification mentioned in NA-Doc-14, which is currently not as per requirements. The use of the accreditation mark will be followed up on during the next assessment.

NC no	06				
	Compliance		Not in compliance	X	

NA-Doc 25/31 Accreditation conditions

Although the system refers to complying with the accreditation conditions as specified in Doc-25/31, but hardly anybody knew about the NA conditions for accreditation which could be one of the reasons for not informing NA regarding any change in the management.

This is a very serious conformity and if repeated may lead to suspension of the lab. The concerned officers in the organisation must thoroughly go through the document and strictly comply with it. **This will be followed up on during the next assessment visit.**

NC no	01				
	Compliance		Not in compliance	x	

NA-Doc 26 a Requirements for calibration and control of balances for accredited test laboratories

See the Technical assessor's report.

NC no	05				
	Compliance		Not in compliance	X	

NA-Dok 26 b Requirements for calibration and control of thermometers for accredited test laboratories

See the Technical assessor's report.

NC no	Minor NC 1				
	Compliance		Not in compliance	X	

NA-Doc 50 Flexible scope (if relevant)

Not applicable.

NC no					
	Compliance		Not in compliance		

NA-Dok 52 Calculation of measurement uncertainty in calibration

Not relevant.

NC no					
	Compliance		Not in compliance	x	

5 Implementation of corrective actions for non-compliances noted during the previous assessment

The corrective actions from the previous assessment were followed up, the details of which can be seen in the Technical Assessor's report.

6 Recommendation regarding accreditation

When corrective actions have been submitted by MFD, NA should evaluate the need for an extraordinary assessment visit to confirm that the corrective actions reported have been implemented in the laboratory.

7 Recommendation regarding suspension

NA should carefully evaluate the corrective actions submitted for the NCs raised during this assessment and the results of the possible extraordinary visit before a conclusion is made on this issue.

8 Recommendation regarding scope of accreditation

Not Applicable

9 Recommendation regarding administrative/ geographical units

Only the microbiology laboratory in Karachi has the right to perform accredited analysis.

10 Any changes since the previous assessment

The top management, the quality manager and purchase officer have changed. Two new persons have joined in the microbiology labs. NA was not informed regarding the changes in the management.

11 Complaints

The organisation has the right to complain against factual errors in the report. Such complaints shall be forwarded to Norwegian Accreditation within 3 weeks after the assessment report has been sent from Norwegian Accreditation.

12 Other

Not relevant

The undersigned confirms that this report is not violating NA's policies and practices.

Place/ date

Lead Assessor

Place/ date Oslo 28.01.08

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment	
Non-compliances;	07 (separate reporting)
Number of very serious non-compliances	01
Number of essential non-compliances	06
Number of minor non-compliances	03
Summary report	
Accreditation document	
Reports from technical assessors, laboratories	

Name of the organisation: MFD, Karachi

Application no.: - **Accreditation no:** TEST 213

Type of visit: Surveillance visit

Leader of the organisation: Capt. (Retd) Javed Ishrat

Lead assessor: Ismat Gul Khattak

Number of non-conformity reports attached:

Very serious:	1
Essential:	6

Summary:
The laboratory has established a quality system, which covers the elements in ISO 17025:2005 and which is appropriate for the activities within the organisation. The top management has joined in June 2007 and a new Quality Manager is in place, but NA was not informed about this change which is not in conformity with Dok 25/31. The implementation of the quality system generally exists but there are gaps which need to be addressed appropriately. Some shortcomings have been identified regarding:

- Informing about change in key managerial staff
- Document control
- Training need identification
- Goals/objectives for quality staff

On eighteen occasions non conforming work have been raised in the last one year but they are not logged anywhere. No complaints have been received in the last one year, which shows that may be the system needs improvement. Although the personnel are well educated and trained, and they are cooperating well together, and they are demonstrating satisfactory competence according to the scope applied for accreditation on the technical side, the management side needs attention. Although the 'existing Quality Manager' is familiar with the system, but the new Quality Manager needs effective training before she can be handed over the charge to work independently. Purchase Manager also needs training as during interview he stressed on 'government's procedure' of going for the lowest bidder in purchases. There are hardly any goals for the quality personnel, similarly the training need has not been identified even for the new Quality Manager who is very new to the standard and has limited knowledge of accreditation according to ISO 17025.

Recommendation concerning accreditation:
When corrective actions have been submitted by MFD, NA should evaluate the need for an extraordinary assessment visit to confirm that the corrective actions reported have been implemented in the laboratory.

Minor non-conformities

1 Thermometers used for registration of room temperature are not compared with reference thermometers (lack of traceability) (ISO 17025 §5.6, NA Dok. 26b).
2 External (PT/ ILC) and internal inter laboratory control schemes are described, but the minimum frequency of participation is missing (ISO 17025 §5.9).
3 Authorisations of analysts are not signed. Authorisations of personnel for other tasks are not dated and signed (ISO 17025 §4.13/5.2).

Minor nonconformities are followed up on during the next assessment visit. However a confirmation that the minor nonconformities have been corrected within the deadline is required

Time limit for presentation of corrective actions: 04.02.2008

17.12.07 Seen by:

Date Signature lead assessor Signature (organisations repr.)

ANNEXURE-I

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0215

ACTIVITY:	Surveillance visit	Report no.:	01
ORGANISATION:	MFD		
Department:			
Accr./Appl. no.:	TEST 213		
Lead. ass.		**Rep. ass.**	

DESCRIPTION:

The top management has changed in June 2007 and the lab did not inform NA regarding the change in top management. Similarly the quality manager has changed but was not intimated. The lab has to inform NA regarding any change in the key managerial or technical personnel to NA.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	Para 10
Others:	

Non-conformity category:

Very serious	x
Essential	

IMPLEMENTED ACTIONS: As required vide Clause 10 of NA Document 25/31, the NA has been informed regarding changes in key management/ technical personnel i.e. Director General and Purchase Manager vide E.mail letter No. MFD/D(F)/NA2008/5048, dated 16-01-2008 (Annexure 'A'). As regards the Quality Manager, the position has also been explained in the same E mail. Mr. Shaukat Hussain, Director (FT &T) has been assigned, by the top management, to continue his duties as Quality Manager of Microbiology and Chemical Lab-*

Actions are documented in the amendment no: _____

04.02.2008 _____
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☒ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7.5.08 E. F.
date signature (lead assessor)

* oratories vide Office Order No.F.6-72/82-Estt./5040-47, dated 20-12-200 (Annexure 'B'). However, in future, the laboratory shall immediately inform the NA about any changes in key management/technical personnel, if an

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0215

ACTIVITY:	Surveillance visit	Report no.:	02
ORGANISATION:	MFD		
Department:			
Accr./Appl. no.:	TEST 213		
Lead. ass.		**Rep. ass.**	

DESCRIPTION:

The lab has problems with document control such as missing dates, control numbers or signing on hand written changes in other quality manuals.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc:

NA Dok 25/31

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.3
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Necessary corrective actions concerning to missing dates, control numbers and signing on hand written changes in other Quality Manual have been taken (nnexure 'C').

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

04.02.2008 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Lukket etter ekstraordinært besøk

☒ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/5-08 _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	03
ORGANISATION:	MFD		
Department:			
Accr./Appl. no.:	TEST 213		
Lead. ass.		**Rep. ass.**	

DESCRIPTION:

There was no training need identification record for quality manager or the purchase officer. Hardly any training was given to quality manager although in documents she is working as a quality manager and no evidence was shown to prove that she was working under supervision. The job description which doesn't have any date or control number doesn't mention that she is working under supervision of another quality manager for a year. There was no objective/goal set by the management for the quality manager.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Calibration certificate

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.2.2
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

☐ It is not necessary to attach documentation

Time limit for correction:

IMPLEMENTED ACTIONS:

Training needs of Mr. S. M. Zafar Imam (under study / training for Quality Management System) and Mr. Shahnawaz Thebo, Purchase Manager, have been identified (Annexure 'D').

Actions are documented in the amendment no: _____

04.02.2008 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Lukket etter ekstraordinært besøk

☒ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/5-08 _____
date signature (lead assessor)

ACTIVITY:	First time visit	Report no.:	04
ORGANISATION:	Marine Fisheries Department, Karachi		
Department:	Microbiology Laboratory		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The autoclave used for media have no temperature registration.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
QM 5.4-VI

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.5 - 5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	Na doc 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

The laboratory is in process of purchasing temperature logger / temperature strips for recording the temperature of autoclave being used for media preparation. It will take around 06 - 08 weeks for import.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

4.02.2008 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Lukket etter ekstraordinært besøk

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/3-08 _____
date signature (lead assessor)

ACTIVITY:	First time visit	Report no.:	05
ORGANISATION:	Marine Fisheries Department, Karachi		
Department:	Microbiology Laboratory		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Balances have been calibrated by an organization which is not acceptable according to the requirements for measurement traceability.

(Reference: Information letter sent to the laboratory on 28 Sep 2007.)

17 Dec 07 H. Grænd
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Calibration marks and certificates

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Doc 26a

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

The balances are being calibrated by National Physical Standard Laboratory (NPSL). The laboratory also owns UKAS calibrated weights for internal calibration of balances.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

04.02.2008
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Linked

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/5-08 E-F.
date signature (lead assessor)

NA-S22
Non-conformity report

ACTIVITY:	First time visit	Report no.:	06
ORGANISATION:	Marine Fisheries Department, Karachi		
Department:	Microbiology Laboratory		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Following statements are missing in the test reports:

- The test result are only related to the analysed sample
- Information on measurement uncertainty is given on request
- Name and address of the customer

When conclusions are given, reference to the act or national regulation containing specific criteria used for interpretation is missing.

The size of the accreditation logo is not correct.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Test reports

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.10
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

The necessary statements/reference to the national legislation have been incorporated with format of Test Report. The size of NA logo has also been corrected which can be seen on the body of attached test Report (Annexure 'E').

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

04.02.2008 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Lukket etter ekstraordinært besøk.

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/5-08 _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	07
ORGANISATION:	Marine Fisheries Department, Karachi		
Department:	Microbiology Laboratory		
Accr./Appl. no.:	TEST 212		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The quality system does not contain any descriptions of identified contributions to measurement uncertainty.
The Quality Manual point 5.4-VI requires identification and categorisation of sources to measurement uncertainty. This is equivalent with NA's policy on measurement uncertainty.

17 Dec 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
QM 5.4-VI

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Sources contributing to measurement uncertainty have been indentified in Clause vi (b) of Doc. MFD/CML/QM-5.4 (Annexure 'F').

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

04.02.2008 _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

Lukket etter ekstra ordinært besøk

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 7/5-08 E. F.
date signature (lead assessor)

Name of the organisation:	**Marine Fisheries Department**
Assessed locations:	**Karachi**

Accr. no. : TEST 213 Appl. no.:	Date of assessment: 17 Dec 07

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Anne Grændsen** Technical area: **Microbiology (P16)**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	X	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	

Technical assessment NS EN ISO/IEC 17025: 2005	X
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Shazia Naz	Technical Manager-I
Muhammad Miftaul Haq	Deputy Technical Manager-I(a)
Muhammad Azeem Khan	Deputy Technical Manager-I(b)

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant:
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

Personnel:
Mujeeb Rehman (analyst) has left the organisation after last visit.

MFD has employed two new analysts.
- Hina Manzoor
- Amjad Ali

Tariq Hanif (analyst), employed in January 2007, is authorized to perform accredited analysis.

Equipment and facilities:
The laboratory has purchased new calibration thermometers. There are no other major changes.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The technical management system consists of a technical manager (Shazia Naz) and two technical deputy managers (Muhammad Miftaul Haq and Muhammad Azeem Khan). As during the initial visit the management team demonstrated satisfactory competence and experience within microbiology. The management team is well qualified and trained for duties and responsibilities acquired in the present positions. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: In general the quality system is covering all requirements in ISO 17025. **Remark:** The scope in the Quality Manual, clause ii-b, is incorrectly describing histamine analysis on HPLC in fish and fish products as accredited. There are no changes in availability of quality manual, technical manual and different forms for daily recording in the laboratory. All personnel have access to the documents needed. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: See report from lead assessor, **essential non-conformity** included. *Non-conformity no* --

4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Requests and contracts were examined in connection to the vertical audit conducted on a sample with ID No 22/07. The sample drawn was from ribbon fish. The case file contained the documents as described in the quality system. *Non-conformity no* --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory is not subcontracting analysis within the accreditation scope. The laboratory is governmental and is performing verification analysis for the fish industry. If stoppages arise due to technical problems, the laboratory has the possibility to postpone the testing activity. Consequently there is no need for subcontracting. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has established satisfactory requirements for purchasing. As observed during the initial assessment this procedure works is well in the laboratory. Quality requirements are given priority. Chemicals and dehydrated media observed in the laboratory are of recognised quality and are satisfactorily marked with recipient date and opening date. Likewise media and solutions made in the laboratory were satisfactorily labelled. *Non-conformity no* --
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: MFD has described handling of non-conformities and corrective actions in an appropriate way the quality manual. The laboratory has now implemented the NC system in a proper way. *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: Except authorisations of personnel are all registrations satisfactorily recorded in bench records and different forms described in the in the technical manual. As during the initial visit, the laboratory demonstrates that handling of raw data is taken care of in a good manner. In general registrations are easily readable and are properly dated and signed. All files asked for were easily found. A vertical audit was carried out on a sample with ID No 22/07. Ribbon fish samples had been analysed for indicator organisms, Salmonella, Vibro and S. aureus. The laboratory demonstrated good traceability in connection to all elements included in the analysis. The analysis of Salmonella, Vibro and S.

	aureus was correctly marked with "Not included in the accreditation scope" **Minor non-conformity** Authorisations of analysts are not signed. Authorisations of personnel for other tasks are not dated and signed.
	Non-conformity no --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The personnel are qualified and experienced. The laboratory is in the position of competence needed. See also clause 4.13, **minor non-conformity** included *Non-conformity no* --
5.2.1	**Training**
	Description/evaluation: All personnel are properly trained and have specific, updated CV's. Dates of period of training are specifically given. CV's for the Technical Manager-I and her deputies were assessed. Training records for personnel authorised after the initial visit were reviewed: • Tariq Hanif • Hina Manzoor • Amjad Ali Except for the missing dates and signatures (See **minor non-conformity** clause 4.13), were the records satisfactory. Proper training has been given. Authorisations have been given by Technical Manager (I) on basis of the criteria given in the quality system.
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is satisfactorily. Accredited methods are routinely analysed Since the laboratory was granted accreditation in September 2007 approximately 50 samples are analysed. In addition the personnel are performing quality control samples (PT samples or inter laboratory comparisons) quarterly.
5.2.4	**Job descriptions**
	Description/evaluation: Work descriptions for all personnel are included in the technical manual. Satisfactorily work instructions are established for the new analysts: • Hina Manzoor • Amjad Ali

5.3	**Accommodation and environmental conditions**
	Description/evaluation: The laboratory facilities are fitted for the activity performed in the laboratories. The laboratory has proper routines for housekeeping. Procedures for handling of disposals from the testing laboratory are acceptable. Access to the laboratory is restricted to authorized personnel. Designated laboratory coats and foot ware has to be worn in the laboratory. The work flow is well planned and organised. Measures have been taken to avoid contaminating samples and testing. The laboratory monitors and records following parameters: • Daily lab and equipment cleaning • Biological sterility by air testing and swab testing of working benches (monthly) • Bacteriological and chemical testing of the distilled water used for media production (monthly) • Temperature and humidity in the facilities (daily) The records for cleaning, air testing and testing of distilled water were inspected. The described routines are followed in a very good way. The laboratory has improved the following up procedures regarding non-conformity work connected to the monitoring program. A non-conformity has been observed for the air testing. The laboratory's NC-system has been followed thoroughly. **Remark:** Cleaning of ceilings and light tubes is now in the weekly schedule. The records revealed that the laboratory not has followed the weekly program for ceilings and light tubes. The results from the bacteriological air testing demonstrate that the cleaning programme can be reduced to the frequency used in practice.
	Non-conformity no --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: There are no changes since last visit. The laboratory is using standard methods prescribed in regulations given by the national authorities. The methods used are appropriate and fit for purpose. *Non-conformity no*
5.4.1	**General**
	Summary/Conclusion: Se clause 5.4
5.4.2	**Selection of methods**
	Description/evaluation: Se clause 5.4

5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory is not using methods developed in house or any other non-standard methods. Neither has the laboratory plans to use such methods.
5.4.5	**Validation of methods**
	Description/evaluation: The laboratory is solely using standard methods. Consequently there is no need for validation. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Measurement uncertainty is calculated for essential equipment, but not for methods applied for accreditation. **Essential non-conformity:** The Quality Manual point 5.4-VI requires identification and categorisation of sources to measurement uncertainty. This is equivalent with NA's policy on measurement uncertainty. However, no identified contributions to measurement uncertainty are described in the quality system for any of the methods accredited. *Non-conformity no* 7
5.4.7	**Control of data**
	Description/evaluation: The laboratory does not use LIMS. Calculations in connection with the analytical process are manually operations. All manually registrations observed in the records were satisfactorily. *Non-conformity no* --
5.5	**Equipment**
	Description/ valuation: The laboratory has a list of all equipment. Each item is given a unique identity number. The new reference thermometers purchased in May 2007 are implemented in the instrument list. **Remark:** A miss typing was observed in the instrument list for the max temperature given for the thermometer with ID 43(I). Correct temperature should be +50.5 °C not + 5 °C. In general the maintenance is good. The instruments are properly monitored. Control results are recorded. Since the initial visit control charts are established for most of the instruments. The following instrument files were reviewed: • Incubators and autoclaves • Thermometers • RH-metrs • Balances

	• pH-meter
	• Volumetric equipment
	  o Digital pipettes
	  o Glass pipettes
	  o Tubes containing culture media or dilution water
	
	The calibration procedure for the pH-meter has been improved since the initial visit. The pH calibrations and measurements are now considered to be working well.
	
	Likewise procedures for volume control are improved and acceptance limits are clearly defined.
	
	Essential non-conformity
	The autoclave used for media have no temperature registration device.

	Non-conformity no **4**
5.6	**Measurement traceability**
	Summary/conclusion: Since the initial visit the laboratory has purchased reference thermometers calibrated by an UKAS-accredited organization. The calibration certificate was examined and found satisfactorily. Thermometers and equipment fitted out with digital thermometers are in general traceable to the new thermometers. **Remark:** The laboratory describes calibration of thermometers at least on monthly basis. The laboratory has a potential to reduce the workload in this area. See NA Doc 26b for further information. Traceability is established for the microbiological methods by using reference cultures traceable to an international culture collection ATCC. The laboratory is using reference cultures (positive and negative controls) in each run of analysis. The reference cultures are stored and treated in a proper manner. Satisfactory actions are taken to avoid cross contaminations. Purity controls and biochemical tests are performed routinely. **Minor non-conformity:** Thermometers used for registration of room temperature lack traceability to the reference thermometer. **Essential non-conformity:** Balances have been calibrated by an organization which is not acceptable according to the requirements for measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) *Non-conformity no* **5**

5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.5 and 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Samples are mainly collected by MFD inspectors. Sampling procedures are provided by the laboratory. The samples are transported chilled or frozen to the laboratory and sample information is submitted with the sample. On receipt the sample acquires a unique number. Before, under and after analysis the samples are satisfactory stored in freezers or fridges. The samples are not disposed until the test results are approved. The laboratory has good records showing how the samples have been treated from receipt to disposal. A vertical audit of the sample with ID 22/7 demonstrates that the procedures are followed thoroughly. The laboratory had signed for the reception of the sample as described in the quality system. *Non-conformity no* --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory is using reference cultures (positive and negative controls) in each run of analysis. The cultures are traceable to an international culture collection (ATCC). In addition the laboratory participates annually in PT-schemes for water and food testing provided by: • Norwegian Institute for Food and Environmental analysis

	• Board of Lab. Accreditation, Department of Science and Cervices, Thailand The PT-schemes covers the present accreditation scope. Principally the PT-results meet the acceptance criteria. In 2007 MFD has participated in two PT-trials; one for water testing and one for food testing. In 2008 it is planned to participate in three trials for food testing and one trial for water testing. MFD has also established a programme for intra laboratory comparisons. **Remark:** Trend analysis of PT-results is improved since the initial visit, but trend diagrams reflecting a longer time scale should be put into use. Likewise procedures for when to take actions due to observed trends should be established. **Minor non-conformity:** External (PT/ILC) and internal laboratory schemes are described, but the minimum frequency of participation is missing.
	Non-conformity no --
5.10	**Reporting the results**
	Description/evaluation: Test reports were examined during a vertical audit carried out on a sample marked with ID No 22/07. Ribbon fish samples had been analysed for indicator organisms, Salmonella, Vibro and S. aureus. The analysis of Salmonella, Vibro and S. aureus was correctly marked with "Not included in the accreditation scope". Two different templates for test reports are included in the quality system; one for water and ice and another one for fish products. Test reports have still some shortcomings. **Essential non-conformity:** Following statements are missing in the test reports: • The test result are only related to the analysed sample • Information on measurement uncertainty is given on request • Name and address of the customer When conclusions are given, reference to the act or national regulation containing specific criteria used for interpretation is missing. (Opinions and interpretations are not included in the accreditation scope) The shape of the accreditation logo is not correct. *Non-conformity no* **6**

5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: See clause 5.10, **essential non-conformity** included. *Non-conformity no* **6**
No 25/31	**Accreditation conditions**
	Description/evaluation: See report from lead assessor *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: Se clause 5.6, **essential non-conformity** included *Non-conformity no* **5**
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: See clause 5.6 *Non-conformity no* --
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	No specific methods were asked for demonstration. Methods were discussed during vertical audit.	
7. Follow up non-conformities from the last visit:	Non-conformities from last visit is in general satisfactorily implanted.	
8. Notes/summary/ conclusion	No further comments	
9. Next visit	• PT-results and trend analysis • Personnel files; training and authorisation • Excel calculations – locking of essential cells containing equations • Measurement uncertainty • Calibration of balances	

21/12/2007. *Anne Grændsen*
technical assessor

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

date 14.01.08
lead assessor

Name of organisation:	NARC Islamabad		
Manager of the organisation:	Abdul Rashid		
Accreditation no/ application no:	TEST 214	Date of assessment:	21-22 Jan 2008
Sites assessed:	Islamabad		

1 The assessment

This report deals with:

Initial ass. [ ] Extraordinary ass. [ ] Renewal [ ]
Surveillance [x] Extension [ ] Full assessment [ ]

Assessment team:

Name	**Position**
Ms Ismat Gul Khattak	Lead Assessor
Ms Anne Grændsen	Technical Assessor Microbiology
Ms Cecilie Fjeld Nygaard	Technical Assessor Chemical

Personnel interviewed:

Name	**Position**
Amer Mumtaz	Internal auditor
Muhammad Amjad	SSO, Customer Services Incharge

Participants in the concluding meeting:

Name	**Position**
Dr Abdul Rashid	Director General
Dr Samina Khalil	Quality Manager
Mr Nafees Kisana	Director CSO
Ms Khurshid Burney	SSO/TM Micro Labs
Mr Khalid Naseem	SSO/Deputy Customer Services
Ms Saeeda Raza	SSO
Mr Muhammad Amjad	SSO/Incharge Customer Services
Mr Tabassum Hameed	SSO/TM Cereal Labs
Mr Naeem Safdar	SO
Mr Noman Rashid	SO/Internal auditor
Mr Amer Mumtaz	SO/Internal auditor
Ms Ambreen Sadozai	SO

Deadline for submission of corrective actions: **04.03.2008**

2 Non-compliances

Categorisation of non-compliances is described in NA Doc 55 and on NA's web-site (www.akkreditert.no).

3 Results from the assessment

Below, the results from the assessment against the accreditation requirements as described in ISO/IEC 17025:2005 (General requirements for calibration and test laboratories) and the requirements defined in the laboratory's own management system, are described.

ISO 17025 – Chapter 4 – Requirements for management

4.1 Organization

The laboratory has the responsibility to carry out its testing activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer. The laboratory management system covers work carried out in the laboratory's permanent facilities only.

The laboratory is part of NARC which is doing testing of research samples as well as from external clients. External clients include inspection agencies, exporters as well as importers, government organizations needing testing of grains especially wheat. There seem to be no involvement of personnel working on accredited testing activities to avoid any potential conflicts of interest.

The laboratory has a policy for ensuring the protection of its customers' confidential information and proprietary rights, but the lab need to develop policy to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity, as well **(minor nonconformity).**

The laboratory has Quality Manager Dr Samina Khalil, and two technical managers from labs. One of the technical managers is the deputy quality manger whereas the quality manager is a deputy technical manager as well.

NC no	--				
Compliance		Not in compliance		X	

4.2 Management system

The current quality system is complicated and cumbersome and can be simplified. The system's documentation is communicated to, understood by, and implemented by the appropriate personnel by different means such as trainings, meetings and office circulars. The

laboratory has established, implemented and maintained a management system appropriate to the scope of its activities, but it is quite a complicated system and there is room for improvement.

The roles and responsibilities of the quality manager, and technical managers along with their deputies is defined including their responsibility for ensuring compliance with this International Standard, is defined in the quality manual.

The quality objectives can be improved in a way that can be more specific, measurable and time bound. Currently they are very generic.

NC no					
Compliance		X	Not in compliance		

4.3 Document control

The laboratory has established and maintained procedures to control all documents that form part of its management system whether they are internally generated or are from external sources, such as regulations, standards and other normative documents.

Currently the document control procedure is controlled both page wise as well as procedure wise, depending upon the portion that needs changing. In cases where minor changes are made then only pages revision is done. The current practice is that document changes can be made page wise. There are technical procedures which are referred to the technical manuals and are hand written in registers where their records are maintained. There is no step in the document control procedure as to how changes will be made in these handwritten procedures. **(Minor non-conformity).** Further, these hand-written procedures, although are stamped as controlled but have no revision numbers, issue number or date of control. Currently there is no problem but there is a potential for problems in document control. **(Remark)**

Please see TA reports, **minor NC** included.

NC no	--				
Compliance			Not in compliance	X	

4.4 Review of contracts

Although there is a system for signing contract with the customer, and in case of deviation from the contract, there is no system in place. There is no delivery date on the time for testing samples. **(minor non-conformance).**

Please see TA reports.

NC no	--				
Compliance		Not in compliance	X		

4.5 Subcontracting

Not assessed by lead assessor.

Please see TA reports.

NC no	--				
Compliance	X	Not in compliance	-		

4.6 *Purchase of services and supplies*

Not assessed by lead assessor.

Please see TA reports, **minor NC's** included.

NC no	--				
Compliance		Not in compliance	X		

4.7 Service to the customer

Not assessed by lead assessor.

NC no	--				
Compliance	-	Not in compliance	-		

4.8 Complaints

There is a system for complaints. Two complaints have been received in 2007. One is a written complaint and another is a verbal one. The complaints were related to customer section. In one complaint the customer relation officer overlooked typing the ID of the test method provided by the customer, as well as one of the test methods was overlooked. They were properly handled according to the procedure. Complaints are not logged anywhere in a register in the form of a list.

NC no	--				
Compliance	X	Not in compliance			

4.9 Handling non-conforming work

There is a system for handling non-conformances. This system needs improvement. The lab has no system to evaluate significance of the nonconforming work. **(Minor non-conformity)** Reports are not recalled rather a revised report is issued.

Please see TA reports.

NC no	--				
Compliance		Not in compliance	X		

4.10 Improvement

Not assessed.

NC no	--				
Compliance	-	Not in compliance	-		

4.11 Corrective actions

There is a good system for identifying a problem within the management system or within the technical operations of the laboratory may be identified through a variety of activities. The laboratory has established procedure and has designated authorities for implementing corrective action whenever nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. The procedure for corrective action starts with an investigation to determine the root cause(s) of the problem. The laboratory monitors the results to ensure that the corrective actions taken have been effective. The significance of non-conformity is not evaluated. Please see clause 4.9.

NC no	--				
Compliance	X	Not in compliance			

4.12 Preventive actions

Not assessed.

NC no	--				
Compliance	-	Not in compliance	-		

4.13 Technical registrations

Generally records were available and were found in order. There is a good traceability in documents and are easily retrievable. All records are held secure and in confidence.

Please see also TA reports.

NC no	--				
Compliance	X	Not in compliance			

4.14 Internal audits

It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. The internal audit is carried out by the two trained and qualified personnel who are, independent of the activity to be audited. Internal audit is conducted annually by trained internal auditors. The internal audit plan and reports reflected that all elements of the system were audited except the testing activities. The work of quality manager is audited by Amer Mumtaz. The micro and cereal labs were audited by an auditor working in cereal lab as an analyst.

NC no	--				
Compliance		X	Not in compliance		

4.15 Management review

The management review was conducted according to a predefined agenda. However instead of assessing the suitability of policies, deficiencies in the quality system documentation was discussed. It is not evident from the minutes of the meeting whether it was really discussed. **(Minor non-conformance).**

NC no	--				
Compliance			Not in compliance	X	

ISO 17025 – CHAPTER 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

The laboratory management has a system which ensures that the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports etc. When using staff that is undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and demonstrated skills, as required for the job.

issue test reports and to operate particular types of equipment. The laboratory has a system that authorizes specific personnel to perform particular types of test, to maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, which is readily available. There are three levels of competence. 1dt level is under supervision, 2nd level stands for working independently and 3rd level means the person is a trainer. Personal file of Mr Noman Rashid Siddiqui and Mr Amer Mumtaz who are internal auditors, were checked. The system seemed to be ok in the files checked.

Please see TA reports, **minor and essential nonconformities,** included.

NC no	1, 6				
Compliance			Not in compliance	X	

5.3 Premises and environment

Please see report of TAs, **minor and essential nonconformity,** included.

NC no	5				
Compliance			Not in compliance	X	

5.4 Test and calibration methods and method validation

Please see TA reports, **minor and essential non-conformities** included.

NC no	2, 7, 8				
Compliance			Not in compliance	X	

5.5 Equipment

Please see TA reports, **minor non-conformity** included.

NC no					
Compliance			Not in compliance	X	

5.6 Measurement traceability

Please see TA reports, **minor and essential non-conformity** included.

NC no	4, 5				
Compliance			Not in compliance	X	

5.7 Sampling

Not relevant

NC no	--				
Compliance		-	Not in compliance	-	

5.8 Handling of test and calibration objects

Please see TA reports.

NC no	--				
Compliance		X	Not in compliance		

5.9 Assuring the quality of results from testing and calibration

Please see TA reports, **minor non-conformity** included.

NC no	--				
Compliance		Not in compliance	X		

5.10 Reporting results

The test reports are generally ok. Description of the sample and testing period is not mentioned in the test report. Logo is used incorrectly. For details plese see Other requirements, NA-Doc 14. **Essential nonconformity** is given.

Please see also see TA reports.

NC no	9				
Compliance		Not in compliance	X		

4 Other requirements

NA-Doc 14 Conditions for the use of NA's logo in accreditation marks and for making reference to accreditation

The lab has a system in place, and the logo is not according to the specification mentioned in NA-Doc-14. There is a box in which the lab ID is written and in another test report the logo seemed to be different. These test reports had ID 390 and 372. In both these test reports the logo was different in shape and size. The lab may use the name of NA in English instead of Norwegian. Please see clause 5.10 for details of **essential NC.**

NC no	9				
Compliance		Not in compliance	X		

NA-Doc 25/31 Accreditation conditions

The laboratory generally complies with the accreditation conditions as specified in Dok 25/31.

NC no	--				
Compliance	x	Not in compliance			

NA-Doc 26 a Requirements for calibration and control of balances for accredited test laboratories

Please see TA reports, **essential non-conformity** included.

NC no	**4, 5**				
Compliance			Not in compliance	X	

NA-Dok 26 b Requirements for calibration and control of thermometers for accredited test laboratories

Please see TA reports, **essential non-conformities** included.

NC no	**3, 4, 5**				
Compliance			Not in compliance	X	

NA-Doc 50 Flexible accreditation (if relevant)

Not applicable

NC no	--				
Compliance		-	Not in compliance	-	

NA-Dok 52 Calculation of measurement uncertainty in calibration

Not applicable

NC no	--				
Compliance		-	Not in compliance	-	

5 Implementation of corrective actions for non-compliances noted during the previous assessment

The corrective actions from the previous assessment were followed up. The implementation was satisfactory. Please see the TA's report.

6 Recommendation regarding accreditation

When satisfactory corrective actions have been submitted by GQTL/NARC, the lab may be recommended for continuation of accreditation

7 Recommendation regarding suspension

Not Applicable

8 Recommendation regarding scope of accreditation

There are no changes in the scope of accreditation. One test is under suspension.

9 Recommendation regarding administrative/ geographical units

Not Applicable

10 Any changes since the previous assessment

Not any significant change except for one person who types the test reports in the customer services section.

11 Complaints

The organisation has the right to complaint against actual errors in the report. Such complaint shall be forwarded to Norwegian Accreditation within 3 weeks after the report has been sent from NA.

12 Other

Not relevant

The undersigned confirms that this report is not violating NA's policies and practices.

Islamabad 22.01.2008

Place/ date 22/1-2008

Ismat Gul Khattak
Lead Assessor

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment
Non-compliances;

Number of very serious non-compliances	00
Number of essential non-compliances	09
Number of minor non-compliances	17

Summary report
Accreditation document
Reports from technical assessors, laboratories 02

Name of the organisation: GQTL, NARC, Islamabad

Application no.: **Accreditation no:** TEST 214

Type of visit: Surveillance visit

Leader of the organisation: Dr. Abdul Rashid

Lead assessor: Ismat Gul Khattak

Number of non-conformity reports attached:

Very serious:	0
Essential:	9
Minor (summary + 2 separate lists)	17

Summary:
The laboratory has established a quality system, which covers the elements in ISO 17025:2005. The laboratory's quality system is appropriate for the activities within the organisation. The top management has a satisfactory commitment to quality assurance. The personnel are well educated, trained, and are working well together. They have demonstrated satisfactory competence according to the scope applied for accreditation. The facilities are fit for purpose and the workflow is well organised. However, some shortcomings have been identified regarding:

- Documentation and document control
- Contract review
- Non conformity
- Management review
- Working procedures
- Environmental condition
- QC programmes to maintain authorisations
- Calibration of equipment and traceability
- Test reports

Minor NC's (management system):

1. Some technical documents in labs are hand written and 'controlled', but with no revision number and control date. There is no procedure for revising these hand written procedures. The system needs improvement. Ref: 4.3.
2. There is no policy on avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. Ref: 4.1.5.d.
3. There is no systematic way of recording deviations from or changes in the contract. Ref: 4.4.
4. The significance of non-conforming work is not evaluated. Ref: 4.9.1.
5. Suitability of policies was not discussed in the Management Review, instead only 'deficiencies in quality system documentation' was discussed. Ref: 4.15.

Note: Please see two separate sheets of minor non-conformities from the two technical assessor reports.

Recommendation concerning accreditation:
If all nonconformities are corrected within the time limit, the recommendation is that accreditation is granted.

Minor non-conformities are followed up during the next assessment visit. However a confirmation that the minor nonconformities have been corrected within the deadline is required

Time limit for presentation of corrective actions: 04.03.2008

22.01.2007 _____ Seen by: _____
date Signature lead assessor Signature (organisations repr.)

Attachment to Summary Report
Minor non-conformities Microbiology (P16)

Name of organization: National Agricultural Research Center (NARC)
Islamabad
Grain Quality Testing Center (GQTL
Food Microb. Lab (FML)

Application no.: -- **Accreditation no:** TEST 214

Type of visit: Surveillance visit

Minor non-conformity	**Reference ISO 17025**
Some lacks are observed in the CV's: • Ambreen Akthar Saddozai – Period of training is not given, just the duration. • Dr Samina Khalil – The positions as Quality Manager and Deputy Technical Manager is not clearly stated.	5.2
Cleaning program for the container of distilled water is not described in the quality system. It is not compliance between practice and procedures in the QA/QC manual. The manual is requiring quarterly checks and the laboratory is performing the checks each second week.	5.3
Performance checks with bio indicators are not used for the autoclaves.	5.5
There are still inconsistency regarding method requirements for incubation/storage temperature and acceptance criteria given in QA/QC Manual for laboratory refrigerators, incubators, water bath and thermometers. Method requirements differ from data given in table 9 in clause 6.1. Not all correction factors are added when the limits are calculated. The laboratory should consider the need for placing liquid in glass thermometers inside equipments that is fitted with digital displays which are calibrated.	5.5/5.6
QC tests on quarterly basis are not performed to maintain approval of analysts. In 2007 PT-sample have been analysed two times. In the QC-programme the laboratory can use supplementary test as:	5.9

Minor non-conformity	Reference ISO 17025
• Intra laboratory tests (ILC) • Reference materials with standardised bacterial content • Etc	

Date: 22.01.2008

Signature:

22/1-08

Attachment to Summary Report
Minor non-conformities Chemistry (P12)

Organization: Grain Quality Testing Laboratory, NARC

Accreditation no: TEST 214

Type of visit: Surveillance visit

Minor NC's chemistry P12	**Reference ISO 17025**
The 2% NaCl solution for determining gluten is not labelled with content or expiry date. This has been improved during the assess ment.	4.6
The control charts for the balances are not traceable to the dates of the measurements.	5.9
The procedure "method validation and verification" in section 5.4 (p.2) in the quality manual does not include uncertainty as a verification/validation parameter.	5.4.5
The laboratory does not have a description of storage conditions (temperature, storage place, time etc.) of samples and CRM's before analysis in the quality system. The CRMs are not labelled with an expiry date; guidelines for determining the expiry date is not given.	5.8
The laboratory is applying a list over chemicals "CC LAB chemicals" which is not a part of the quality system. In this register all the chemicals in use are given an ID and the chemicals are labelled with this ID when stored.	4.6
The laboratory have two different lists of authorized personnel in their laboratory. Both lists are dated 17-12-2007 Issue 3, but the names on the list are not the same.	4.3

Date: 22.01.2008

Signature: Cecilie Fjeld Nygaard Cecilie Fjeld Nygaard

ACTIVITY:	Surveillance	Report no.:	1
ORGANISATION:	Grain Quality Testing Laboratory, NARC		
Department:	Chemistry		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

Objective criteria is given for approval of analyst in procedure section 5.2(p.7) in quality manual for approving analysts, but the criteria are not within the requirements of the measurement uncertainty, e.g for gluten the measurement uncertainty is given as 6%, but the criteria for approval is less than 10% bias. A minor non-conformity regarding lack of objective criteria was given in 2007, but the criteria must meet the requirements of the method.

22 Jan 08 Cecilie F. Nygaard Tabassum Hameed
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.2
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ *It is not necessary to attach* documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: *(To be filled in by the lead assessor)*

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ *Implementation of the corrective actions will be followed up at the next visit*

The non-conformity is closed: _____ _____
date signature (lead assessor)

22/1-08 CFN

ACTIVITY:	Surveillance	Report no.:	2
ORGANISATION:	Grain Quality Testing Laboratory, NARC		
Department:	Chemistry		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

Some methods are not described sufficiently in detail:

- The measurement range (upper and lower) is not given in all of the methods ~~as falling number~~. In NA-S5 the lower measurement range is not described for ash and crude fat. 22/1-08 CFN
- Calculations with the farinograph are done automatically with the instrument software, but this is not described in the method and in which unit the result is given.

Insufficient degree of detailed description was also given as an NC in 2007.

22 Jan 08 Cecilie F. Nygaard Tabassum Hameed
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

☐ It is not necessary to attach documentation

Time limit for correction:

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

ACTIVITY:	Surveillance	Report no.:	3
ORGANISATION:	Grain Quality Testing Laboratory, NARC		
Department:	Chemistry		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The system for temperature control is not satisfactory:

- The Carbolite furnace is being controlled annually and the displayed temperature is calibrated. The deviation in the calibration report is not being used in practice when using the oven and how to apply the correction factor should also be described in the quality system.
- The oven FML-13 is used for drying crude fiber at 120°C. The oven is not controlled regularly by the laboratory but is done by an external organisation annually.

22 Jan 08 Cecilie F. Nygaard Tabassum Hameed
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	No 26b
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0388

ACTIVITY:	Surveillance visit	Report no.:	(4)
ORGANISATION:	NARC, Islamabad		
Department:	All laboratories		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Thermometers, balances and pressure gauges have been calibrated onsite by an organization (NPSL, Islamabad) which is not fulfilling the requirements on measurement traceability:

- The calibration laboratory does not have an unbroken chain of traceability.
- The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed.

However, the laboratories have to a certain extent taken into account the accuracy and measurement uncertainties given in the calibration certificates in a satisfactory way. (See also minor non-conformity raised against the same requirement references)

22 Jan 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Calibration certificates

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA doc 26a NA doc 26b

Non-conformity category:	
Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	5
ORGANISATION:	NARC, Islamabad		
Department:	All laboratories		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:
There are some inconsistencies regarding room temperature in the documentation. Examples on requirement given:

- 25 ± 5 °C (Chemistry methods)
- Target value 24 °C, alarm limits 13 – 27 °C, action limits 10 - 31 C °C (QC/QA Manual microbiology, Clause 4.5)
- 18 ± 2 °C (QC/QA Manual microbiology, Clause 6.1)

The thermometers used are not calibrated.

Chemistry: The room temperature is of no relevance for most of the chemical analysis.

Microbiology: Acceptance limits for room temperature is not established due to method or equipment requirement, but are calculated as standard deviation due to earlier measurements. Just one of the rooms is monitored. In this respect, the room temperature is maybe not so important. The thermometer use is not listed in table 9 in clause 6.1.

All laboratories: The laboratories are advised to carefully evaluate the need for monitoring room temperature and which acceptance criteria to be used

22 Jan 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Calibration certificates

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.3/5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA doc 26a NA doc 26b

Non-conformity category:

Very serious	
Essential	X

☐ It is not necessary to attach documentation

Time limit for correction:

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0388

ACTIVITY:	Surveillance	Report no.:	6
ORGANISATION:	Grain Quality Testing Laboratory, NARC		
Department:	Chemistry		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The competence for all the analysts is not maintained for alle the methods, the e.g. for determination of pH, two analysts are approved, but only one analyst has been doing all the determinations for the past 2-3 years.

22 Jan 08 Cecilie F. Nygaard Tabassum Hameed
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.2.2
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

☐ It is not necessary to attach documentation

Time limit for correction:

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	7
ORGANISATION:	Grain Quality Testing Laboratory, NARC		
Department:	All laboratories		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The buffers used for determining pH are taken from the original vessel and re-used for about a week, which is not acceptable.

The control sample used is a buffer, which is not an appropriate control sample for pH due to the very different ion strength of buffers compared to real samples.

22 Jan 08 Cecilie F. Nygaard Tabassum Hameed
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	8
ORGANISATION:	NARC, Islamabad		
Department:	~~All laboratories~~ Microbiology		
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Culture media preparation/QC:

- Thee preparation receipts on the bottles are used during preparation, but the working procedure is not referring to the receipts.
- There is not compliance between praxis and descriptions. Performance checks are never done for Standard Plate Count Agar by 21 line streaking technique.
- PH measurements of prepared culture media are not properly described. The laboratory is expected to have pH-measurements done on all prepared culture media.

22 Jan 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Procedure for media QC

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	**Surveillance visit**	Report no.:	9
ORGANISATION:	GQTL/NARC		
Department:			
Accr./Appl. no.:	TEST 214		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Ismat Gul Khattak**

DESCRIPTION:

Test report need to be improved. The following shortcomings were identified in the two test reports with ID 390 and 372:

1. Description of the sample and testing period is not mentioned in the test report.
2. Logo is used incorrectly and is not according to the specification mentioned in NA-Doc-14.
3. There is a box in which the lab ID is written and in another test report the logo seemed to be different. In both these test reports the logo was different in shape and size.

22.12.07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.10
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Dok 14

Non-conformity category:	
Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

Name of the organisation: **Grain Quality Testing Laboratory**
Assessed locations: **Islamabad**

Accr. no. : **TEST 214** Appl. no.:	Date of assessment: 21+ 22 Jan 2008

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Cecilie Fjeld Nygaard** Technical area: **P12 Chemistry**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	x	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	

Technical assessment NS EN ISO/IEC 17025:	x
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	***Function / technical area***
Tabassum Hameed	Technical manager cereal chemistry lab
Saeeda Raza	Analyst chemistry lab
Amjid Qureshi	Incharge customer service

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is sending corrective actions to NA within the agreed date, and that the corrective actions are evaluated as acceptable accreditation of the methods applied for is recommended.

3.2 Recommendation regarding change of the responsible for validation, when relevant (valid for flexible scope) :
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

The method for determination of crude fat is currently suspended from the scope by the laboratory. This is due to an instrument breakdown. There are no further changes regarding personnel and instruments.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: Tabassum Hameed is the technical manager for the cereal chemistry lab. The technical management seems to be working satisfactory and the staff is well educated. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: All the methods are available in copies close to the instruments where the analysis is performed. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: The laboratory has two different lists of authorized personnel in their laboratory. Both lists are dated 17-12-2007 Issue 3, but the names on the list are not the same **(minor NC)**. List of chemicals "CC Lab chemicals" (see clause 4.6) is not document controlled. *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Normally the customer provides a letter with the requested measurements. If this is not provided, the laboratory uses a "laboratory contract review record" with the necessary information. *Non-conformity no* --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory has not used sub-contractors yet, but there are plans for using SARC if instrument or capacity problems will arise.

	Non-conformity no --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The 2% NaCl solution for determining gluten is not labelled with content or expiry date. This has been improved during the assessment (**minor NC**). The laboratory is applying a list over chemicals "CC LAB chemicals" which is not a part of the quality system. In this register all the chemicals in use are given an ID and the chemicals are labelled with this ID when stored (**minor NC**). Chemicals (dry and wet) are stored in a separate room before they are opened and taken into use. *Non-conformity no* --
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: NCs are written by all staff members in the laboratory. Chemistry collects all the NCs in a file. The technical manager describes the root cause and corrective actions. The quality manager closes the NC if the corrective actions made are satisfactory. *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: When an analysis is finished, raw data is filled into a data report by the analyst. Vertical audit: Report no. 390 (08-01-2008): Ash, falling number Report no.372 (19-11-2007):% Moisture by moisture meter **Remark:** Test reports with an ✓ indicates tests accredited by Norwegian accreditation. In test report 372 (vertical audit) none of the parameters were marked as accredited, although the accreditation mark is used. This will be looked closer into during the next visit. The use of the NA-logo is not in accordance to NA doc. 14 (see lead assessors report and **NC 9**) The laboratory applies spreadsheets for the QC-charts, but this was not looked further into during the visit. This will be followed up during the next visit. There is traceability to who performs the different measurements, e.g. moisture meter, but this is indirectly through the daily use record. The laboratory could benefit of implementing this information in the same measurement form.
	Non-conformity no --

5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: There are no new employees since the last visit. Imtiaz Hussein has been trained for measuring crude fibre and the training has been done by parallel testing. The training was documented satisfactory. Objective criteria is given for approval of analyst in procedure section 5.2 (p.7) in quality manual for approving analysts, but the criteria are not within the requirements of the measurement uncertainty, e.g for gluten the measurement uncertainty is given as 6%, but the criteria for approval is less than 10% bias. A minor non-conformity regarding lack of objective criteria was given in 2007, but the criteria must meet the requirements of the method. There is a list of authorized operators for the instruments in Annexure E in the technical manual. Most of the methods have 2-4 approved personnel for each of the methods. *Non-conformity no* **1, 6**
5.2.1	**Training**
	Description/evaluation: The personnel are well qualified. The CVs provided were not signed or dated. See clause 5.2.
5.2.2	**Maintenance of competence**
	Description/evaluation: The competence for all the analysts is not maintained for all the methods, the e.g. for determination of pH, two analysts are approved, but only one analyst has been doing all the determinations for the past 2-3 years. Regarding the remaining methods, the maintenance of the competence is regarded as satisfactory based on the number of analysis and participation in PT testing.
5.2.4	**Job descriptions**
	Description/evaluation: Job descriptions are described in 5.2 in the quality manual.
5.3	**Accommodations and environmental conditions**
	Description/evaluation: In some of the methods there are given requirements regarding the temperature conditions during the analysis. However the laboratory is not measuring or meeting these temperature requirements, e.g. gluten room temperature 25°C±5 with wash water 20°C±2. See also **NC no. 5** given by technical assessor P16 regarding all the laboratories. The laboratory was clean, spacious and fit to purpose. The cereal chemistry lab consists of 3 rooms.

	Non-conformity no --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See clauses 5.4.1- 5.4.7. *Non-conformity no* **2, 7**
5.4.1	**General**
	Summary/Conclusion: The laboratory has 2 internal methods (protein and fibre); the remaining methods are reference standards from AOAC or AACC. The laboratory is using the latest edition from 2005. The methods are suitable for the measurements performed. Some methods are not described sufficiently in detail: • The measurement range (upper and lower) is not given in all of the methods. In NA-S5 the lower measurement range is not described for ash and crude fat. • Calculations with the farinograph are done automatically with the instrument software, but this is not described in the method and in which unit the result is given. • Use of amount of water for crude fibre determination and the use of phenophtalein. Insufficient degree of detailed description was also given as an NC in 2007. The buffers used for determining pH are taken from the original vessel and re-used for about a week, which is not acceptable. The control sample used is a buffer, which is not an appropriate control sample for pH due to the very different ion strength of buffers compared to real samples. Reagents are made and recorded in the "reagent preparation record register" with date.
5.4.2	**Selection of methods**
	Description/evaluation: See clause 5.4.1
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: There are plans for expanding the scope within physical measurements.
5.4.5	**Validation of methods**
	Description/evaluation: The procedure "method validation and verification" in section 5.4 (p.2) in the quality manual does not include uncertainty as a verification/validation parameter **(minor NC)**

	The laboratory has not validated any new methods since the last visit. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Measurement uncertainty is calculated and recorded in "uncertainty measurement register". This was recalculated after the last visit from NA. A few of the measurements were checked and they were according to the laboratory's procedure. Regarding the PT tests - this will be revised again after the surveillance visit. *Non-conformity no* --
5.4.7	**Control of data**
	Description/evaluation: All calculations are done manually or calculated automatically by the instrument software. When parallels are measured, the mean value is given as the result. The technical manager approves the results before they are reported to the customer. *Non-conformity no* --
5.5	**Equipment**
	Description/evaluation: The instruments have logbooks established for each of the larger instruments. "Laboratory equipment record" and "maintenance/verification record" all issues regarding the instrument are recorded. These records are being used regularly. A list of all the equipment is listed in "list of equipment" in the QC manual, Annexure 1. The instruments in the list have been given an ID number, e.g CCE-08, which the instruments also are labelled with. Adjustable pipettes are not being used in the chemistry lab. *Non-conformity no* --
5.6	**Measurement traceability**
	Summary/conclusion: The laboratory applies mainly in-house control samples for their analyses, e.g for crude fiber. A control sample is being measured every 10^{th} sample. 2 CRMs are in use: VMA 406 (determination of fat) and HFW 706 (protein, ash, moisture). For pH measurements certifies buffers from Merck are used. Traceability is mainly maintained through PT participation. *Non-conformity no* --
5.6.1	**General**
	Description/evaluation: See clause 5.6

5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Samples received are registered in the sample entry register. The recorded data is transferred to the sample dispatch diary which follows the samples throughout the analysis. When the samples are received in the lab a contract review record is written and given to the technical manager together with the samples. The final results are given back to customer service which sends the test reports to the customer. The laboratory does not have a description of storage conditions (temperature, storage place, time etc.) of samples and CRM's before analysis in the quality system. The CRMs are not labelled with an expiry date; guidelines for determining the expiry date is not given (**minor NC**). In the chemistry lab there ate two cupboards for storing the samples: -samples to be tested -samples tested The laboratory applies permanent marker and for one of the demonstrations, the labelling on the sample measured had been rubbed off. The labelling should insure that this does not happen. *Non-conformity no* --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: A PT program for 2008 is established which covers the scope, except for pH measurements. The laboratory has to participate in a PT-scheme also for pH measurements. Gluten will be covered in 2008 (BIPEA). An ICL has been performed for gluten in 2008, but the results have not yet been returned to the

	laboratory. The laboratory evaluated the PT results based on the PT providers Z-score and bias (<6%) and not their own measurement uncertainty. This has caused problems for the lab for certain measurements, e.g. if the measurement uncertainty is given as 30% it will be difficult to obtain results within a 6% bias. Trend plots of the PT results are established, but these are also plotted with the z-score with no regards to the measurement uncertainty. This will be looked further into during the next visit. The laboratory has established control charts for all the measured control samples and new charts are printed each time a new control sample has been measured. The laboratory may consider a system easier to maintain by plotting the results directly each time a sample is measured without taking new printouts each time. The control charts for the balances are not traceable to the dates of the measurements and they lack unit for the measurements (**minor NC**). *Non-conformity no* --
5.10	**Reporting the results**
	Description/evaluation: The laboratory also issues non-accredited test reports without the NA-logo. These reports are usually a part of a larger research project. There were no NCs regarding the test reports, apart from the use of the logo (see **NC no. 9** from lead assessor). *Non-conformity no* --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: *See clause 4.13* *Non-conformity no* --

No 25/31	**Accreditation conditions**
	Description/evaluation: See report from the lead assessor. *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: There are 3 balances in use for the accredited methods: 6110, CCE-15, CCE-09. The balances are calibrated by the National Physical Standards Lab, which is accredited by PNAC. Regarding traceability on balances-see **NC 4** given by technical assessor P16. The balances are being controlled with weights daily when in use and control charts are also used (see also clause 5.9) *Non-conformity no* **4**
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: The quality control plan pp 4 in the QC manual does not describe how the temperature of the furnace should be corrected and how this will be known for the analysts using the furnace. There was some dissension among the analysts how and if this was done. The system for temperature control is not satisfactory: • The Carbolite furnace is being controlled annually and the displayed temperature is calibrated. The deviation in the calibration report is not being used in practice when using the oven and how to apply the correction factor should also be described in the quality system. • The oven FML-13 is used for drying crude fibre at 120°C. The oven is not controlled regularly by the laboratory but is done by an external organisation annually. Regarding measurement traceability for thermometers -see also **NC 4** given by technical assessor P16. *Non-conformity no* **3 and 4**
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	Crude fiber	Saeeda Raza
	Gluten	Khalid Naseem
7. Follow up non-conformities from the last visit:	NCs: • Description of details in methods • Trend plots PT results, PTs vs scope • PT plans (Gluten 2008) • QC charts Minor NCs: • Expiry dates on prepared solutions • Objective criteria for approval of analyst • validation/verification procedure Corrective actions on all NC's are taken by the laboratory	
8. Notes/summary/ conclusion	The laboratory has a qualified staff and equipment related to the scope that is satisfactory. The staff seems to be very positive to working with the requirements of the quality system. A simplification of the QC charts may be beneficial to the laboratory. Revision of all the methods within the scope may decrease the lack of details in some of the methods.	
9. Next visit (Are there any subjects that need to be strictly evaluated during the next visit, or if specific persons should be present	• Reporting of farinograph results • Use of spreadsheets and protection of formulas • PT testing and scope (pH) • Evaluation of PT results according to the laboratory's own measurement uncertainty • Use of NA logo • Labelling of samples- use of permanent marker sufficient? • Measurement uncertainty. Do the results from the PT test lie within the measurement uncertainty? • Maintenance procedures-controlled documents? • Traceability to who performs all parts of the analysis?	

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

03.02.2008 Cecilie Fjeld Nygaard
technical assessor/expert

date 4/2-08 Ann Grande
lead assessor

Name of the organisation:	**National Agricultural Research Center (NARC), Islamabad**
Assessed locations:	**Grain Quality Testing Lab (GQTL)** **Food microbiology Lab (FML)**

Accr. no. : TEST 214 Appl. no.:	Date of assessment: 21 Jan 08 22 Jan 08

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Anne Grændsen** Technical area: **Microbiology (P16)**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	X	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	
Technical assessment NS EN ISO/IEC 17025: 2005	X
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Ambreen Akthar Saddozai	Scientific Officer
Khurshid Burnei	Technical Manager Microbiology
Muhammad Amjad	In charge Customer Service

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant:
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

There are no other major changes since last visit.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	The technical management team in the Food Microbiology Laboratory consists of a Technical Manager (Khurshid Burney) and a Deputy Technical Manager (Samina Khalil). The management team demonstrated satisfactory competence and experience within microbiology during the assessment They have been working within the NARC, GQTL for many years. Personal interviews combined with information in CV's, demonstrated that the management team is well qualified and trained for responsibilities acquired in the present positions. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: In general the quality system is covering all requirements in ISO 17025. All personnel have access to the documents needed. Working procedures and records connected to the analytical work was placed in the laboratory. Requested documents were easily found. The communication in the laboratory is open minded and friendly. All personnel seem to operate well together. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: During the assessment it was not observed any document which was not under properly control. Document changes are communicated to the personnel in regular meetings.
	Non-conformity no --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Requests and contracts were examined in connection to the vertical audit conducted on samples with ID No 380/2007 and 381/2007. Samples analysed were biscuits from an internal client (research project). The case files contained contract reviews and capability reviews as described in the quality system. The forms were properly filled in on reception and signed respectively by the In charge Customer Service and the Technical Manager.

	Non-conformity no --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory is not subcontracting analysis within the accreditation scope. Not specifically assessed during this surveillance visit. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has satisfactory requirements for purchasing. The Pakistani PPR is followed. Quality requirements are given priority. Purchased chemicals and dehydrated media observed in the laboratory are of recognised quality and are satisfactorily marked with recipient date and opening date. Dehydrated media and chemicals used in accredited analysis are kept cupboards in the media preparation area. The shelf life/expiry dates used by the laboratory are now implemented in the QA/QC Manual. Most media are prepared freshly for each analytical commission. Consequently no storage of prepared media was observed in the laboratories. The technical manual is improved since last visit. **Remark:** The refrigerator contained several reagents without any expiry date. However, the laboratory claims that they are not used in accredited analysis. *Non-conformity no* --
4.9-4.11	**Control of non-conformity (NC) testing and/or calibration work/corrective actions**
	Description/evaluation: The laboratory has implemented the NC system properly. NC handling in connection to the PT-results from trial 52 was reviewed. In general corrective actions are taken within a reasonable time after they have been reported. **Remark:** The laboratory is requested to implement a numbering system of NC's before next visit. See also lead assessors report, **minor nonconformity** included.
	Non-conformity no --
4.13	**Control of records**
	Description/evaluation: All registrations is satisfactorily recorded by hand in personal bench records and notebooks described in the in the QA/QC Manual. Handling of raw data is taken care of in a good manner. All registrations are principally done by permanent pen, and they are easily readable, properly dated and signed. Perspicuous trend

	plots connected to the control programme for methods, instruments and environmental conditions are made on monthly basis. All files asked for were easily found. A vertical audit was carried out on samples with ID No 380/2007 and 381/2007. Biscuit samples had been analysed for different microorganisms. The laboratory demonstrated good traceability to timeframes and operators throughout the system regarding all elements included in the analysis. **Remark:** Some of the readings in Ambreen's bench record were not properly dated.
	Non-conformity no --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The personnel are qualified and experienced. The laboratory is in the possession of competence needed.
	Non-conformity no --
5.2.1	**Training**
	Description/evaluation: All personnel, including supporting staff, are listed in the QA/QC Manual. All CV's for scientific and supporting staff were assessed and found to be updated. Demonstrations and discussions verified that the personnel are properly trained. In general period of training is given in the CV for technical trainings. **Minor non-conformity:** Some small lacks are observed in the CV's: • Ambreen Akthar Saddozai – Period of training is not given, just the duration. • Dr Samina Khalil – The positions as Quality Manager and Deputy Technical Manager is not clearly stated.
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is satisfactorily. Accredited methods are routinely analysed. On annually basis approximately 60 samples for each of the parameters in the scope are analysed. In addition the personnel are performing quality control samples (PT samples).
5.2.4	**Job descriptions**
	Description/evaluation: Not specifically assessed during this visit.

5.3	**Accommodation and environmental conditions**

Description/evaluation:
The laboratory facilities are fitted for the activity performed in the laboratories.

The laboratory has proper routines for housekeeping and laboratory safety practices are described. Procedures for handling of disposals from the testing laboratory are acceptable. Access to the laboratory is restricted to authorized personnel. Designated laboratory coats and foot ware has to be worn in the laboratory. Disposable gloves are used when potential pathogen samples/microorganisms are treated. The work flow is well planned and organised. Measures have been taken to avoid contaminating samples and testing. During the assessment the laboratory was tidy and clean.

The laboratory monitors and records following parameters:

- Daily lab and equipment cleaning
- Biological sterility by swab testing of working benches, refrigerator, laminar flow hood and incubators (monthly)
- Bacteriological and chemical testing of the deionised water used for media production (quarterly)
- Temperature and humidity in culture media production area (twice daily)

The records for air testing, surface testing and testing of deionised water were inspected. The described routines are followed in a good way. Nice trend plots are made on monthly basis.

The laboratory has a water tank of distilled water in the culture media production area. The laboratory claims that fresh, distilled water is used if the distillation apparatus is on. Distilled water is kept on the polyethylene container for maximum 2 days.

Minor non-conformity:
Cleaning program for the container of distilled water is not described in the quality system.

It is not compliance between practice and procedures in the QA/QC manual. The manual is requiring quarterly checks and the laboratory is performing the checks each second week.

Essential non-conformity:
There are some inconsistencies regarding room temperature in the documentation. Examples on requirement given:

- 24 ± 3 °C (Microbiology methods)
- Target value 24 °C, alarm limits 13 – 27 °C, action limits 10 - 31 C °C (QC/QA Manual microbiology, Clause 4.5)
- 18 ± 2 °C (QC/QA Manual microbiology, Clause 6.1)

The thermometers used are not calibrated.

	Acceptance limits for room temperature is not established due to method or equipment requirement, but are calculated as standard deviation due to earlier measurements. Just one of the rooms is monitored. In this respect, the room temperature is maybe not so important. The thermometer use is not listed in table 9 in clause 6.1. The laboratories are advised to carefully evaluate the need for monitoring room temperature and which acceptance criteria to be used
	Non-conformity no **5**
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: There are no major changes after accreditation has been granted. The laboratory is using recognised standard methods. Latest valid edition is in use. The accredited methods are appropriate, fit for purpose and satisfactorily listed in the QA/QC Manual. Demonstrations performed during the assessment uncovered conformity between written procedures and the manual operations. **Essential non-conformity:** *Culture media preparation/QC:* • The preparation receipts on the bottles are used for preparation. The controlled working procedure issued by the laboratory is not referring to the receipts on the bottles. • Regarding control routines are there not compliance between praxis and descriptions. Performance checks are never done for Standard Plate Count Agar by 21 line streaking technique. • PH measurements of prepared culture media are not properly described. The laboratory is expected to have pH-measurements done on all prepared culture media. **Remark:** For molten agar the laboratory is using a thermostatically controlled water bath of 45 ± 1 °C. All the methods in the Technical Manual are requiring 48 ± 1 °C which is given in the reference method (FAO). The use of 45 ± 1 °C for molten agar is widely accepted as good laboratory practice. However, the laboratory should bring the method in accordance with established practice. A remark connected to the deviation from the standard method has to be given.
	Non-conformity no **8**
5.4.1	**General**
	Summary/Conclusion: Se clause 5.4

5.4.2	**Selection of methods**
	Description/evaluation: Se clause 5.4
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory is not using methods developed in house or any other non-standard methods. Neither has the laboratory plans to use such methods.
5.4.5	**Validation of methods**
	Description/evaluation: The laboratory is solely using recognised standard methods or internal methods based on standard methods. Currently the laboratory has no need for validation of test methods. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Performance characteristics have been implemented in the method descriptions given in the Technical Manual. Identification/descriptions of different contributions to measurement uncertainty (MU) are not really included. This should be improved before next surveillance visit **(Remark)**. The laboratory has started to calculate the measurement uncertainty for different instruments and working steps. So far the laboratory is using the "step by step" method (uncertainty budget) for calculating the MU. During the discussions the laboratory was warned against using the "step by step" method in microbiology due to the risk of underestimating the MU. Underestimation can be caused by synergisms etc. The "top down" method is recommended for microbiological analysis. The "top down" method is based on internal reproducibility studies. See e.g. ISO/TS 19036 for further information. *Non-conformity no* --
5.4.7	**Control of data**
	Description/evaluation: The laboratory does not use LIMS. Calculations in connection with the analytical process are manually operations. All registrations and calculations observed in the records were satisfactorily done. The procedure of transference of data was checked during the vertical audit of conducted on samples with ID No 380/2007 and 381/2007. No irregularities were observed. Use of Lab code No in personal bench records has improved since the initial visit. The laboratory has worked out trend plots in connection to the monitoring programme for equipment, environmental conditions and PT-results. The trend plots are established in Excel. Proper locking of essential cells containing

	calculations was not investigated during this visit.
	Non-conformity no --
5.5	**Equipment**
	Description/ valuation: The laboratory is well equipped and has listed all equipments. Each item is given a unique identity number. Working instructions are established. In general the maintenance is good. All instruments are properly monitored. Control results are recorded and trend plots are made on monthly basis. The following instrument files were reviewed: • Incubators, refrigerators and autoclaves • Thermometers • Balances • Laminar flow hood • pH-meter • Volumetric equipment (automatic pipettes) **Minor non-conformity:** Performance checks with bio indicators are not used for the autoclaves. See also clause 5.6 regarding traceability (calibrations), **minor and essential non-conformities** included.
	Non-conformity no --
5.6	**Measurement traceability**
	Summary/conclusion: Traceability is established for the microbiological methods by using reference cultures (positive and negative controls) in each run of analysis. The cultures are traceable to an international culture collection (ATCC). The laboratory is purchasing reference cultures from OXOID (Culti Loops) and is in the possession of strains needed. The reference cultures are stored and treated properly. Satisfactory actions are taken to avoid cross contaminations. Purity controls and biochemical tests are performed routinely. All calibrations of equipments are performed onsite by NPLS in Islamabad. Calibration certificates are in place. Correction factors and measurement uncertainty given in the calibration certificates are partly taken into account by the laboratory. **Minor non-conformity.** There are still inconsistency regarding method requirements for incubation/storage temperature and acceptance criteria given in QA/QC Manual for laboratory refrigerators, incubators, water bath and thermometers. Method requirements differ from data given in table 9 in clause 6.1.

	Not all correction factors are added when the limits are calculated. The laboratory should consider the need for placing liquid in glass thermometers inside equipments that is fitted with digital displays which are calibrated. **Essential non-conformity:** Thermometers, balances and pressure gauges have been calibrated onsite by an organization (NPSL, Islamabad) which is not fulfilling the requirements on measurement traceability: • The calibration laboratory does not have an unbroken chain of traceability. • The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed. However, the laboratories have to a certain extent taken into account the accuracy and measurement uncertainties given in the calibration certificates in a satisfactory way. (Reference: Information letter sent to the laboratory on 28 Sep 2007.)
	Non-conformity no **4**
5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.5 and 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: The clients (internal and external) are doing the sampling. Samples are received in the Customer Service Office. On receipt the samples are recorded and acquire a unique number (Lab Code). The samples are also checked

	for damages, proper use of sterile containers and temperature abbreviations. Before, under and after analysis, the samples are stored satisfactorily. The microbiological laboratory is also having a separate record of samples received. A vertical audit was carried out on samples with ID No 380/2007 and 381/2007. Biscuit samples had been analysed for different microorganisms. The audit demonstrates that the procedures are followed thoroughly. The case files contained expected forms, and they were properly filled in on reception and signed respectively by the In charge Customer Service and the Technical Manager.
	Non-conformity no --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory is using reference cultures (positive and negative controls) in each run of analysis. The cultures are traceable to an international culture collection (ATCC). The laboratory is purchasing reference cultures from OXOID (Culti Loops) and is in the possession of strains needed. In addition the laboratory participates at least annually in PT-schemes for foods provided by Norwegian Institute for Food and Environmental Analysis. The PT-scheme covers the present accreditation scope. All analysts participate in every PT-trial. Most test results are satisfactory. PT results outside the laboratory's acceptance limits are properly recorded as NC's. Evaluations of PT results are performed in reasonable time after receiving the test results form the provider. Trend plots are made in excel. Locking of cells containing equations was not assessed during this visit. **Minor non-conformity:** QC tests on quarterly basis are not performed to maintain approval of analysts. In 2007 PT-sample have been analysed two times. In the QC-programme the laboratory can use supplementary test as: • Intra laboratory tests (ILC) • Reference materials with standardised bacterial content • Etc
	Non-conformity no --
5.10	**Reporting the results**
	Description/evaluation: The test report filing system was reviewed. The laboratory has external and internal clients. The test reports are mainly issued to internal clients, and the accreditation mark is not in use on these. The accreditation mark is incorrectly used on external test reports and the testing period is not given. Otherwise the test reports fulfil the technical requirements in ISO17025. See report from lead assessor, **essential non-conformity** included. No amended reports were observed when the report file was checked.

	All approved analysts are also authorised to sign the test reports. **Remark:** In test report with ID No 380/2007 is accredited tests not ticked off as accredited tests. The test report is for internal use and the accreditation mark was not used.
	Non-conformity no --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: The test report file was reviewed. The laboratory has external and internal clients. The test reports are mainly issued to internal clients, and the accreditation mark is not in use on these. The accreditation mark is incorrectly used on external test reports. See report from lead assessor, **essential non-conformity** included. *Non-conformity no* --
No 25/31	**Accreditation conditions**
	Description/evaluation: Not assessed *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: Daily control of balances was performed by standard weights. The control is performed even when the balance is not in use. **Essential non-conformity:** The balance has been calibrated by an organization which is not acceptable according to the measurement traceability. See also clause 5.6.

	Non-conformity no **4**
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: Daily reading of all thermometers placed in laboratory facility and different equipments were performed. The reading is performed even when in equipment is not in use the specific day. **Essential nonconformity:** Thermometers have been calibrated by an organization which is not acceptable according to the measurement traceability. See also clause 5.6. *Non-conformity no* **4**
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* ---

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	FM001, Total Plate count in Foods	Ambreen Akthar Saddozai
	FM 002, Total coliforms in Foods	Ambreen Akthar Saddozai
7. Follow up non-conformities from the last visit:	Non-conformities from last visit are in general satisfactorily implemented.	
8. Notes/summary/ conclusion	No further comments	
9. Next visit	• Excel calculations – locking of essential cells containing equations • Calibration of balances and thermometers • Quarterly competence testing • Identification of contributions to measurement uncertainty • Tolerance limits for micro pipettes • Method descriptions – temperature/practce in water bath for molten agar	

22.01.2008, Anne Grændsen
technical assessor

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

date 04.02.07 Paal R. Nilsen
~~lead assessor~~ process owner Techn. Director

Name of organisation:	PCRWR Islamabad		
Manager of the organisation:	Muhammad Aslam Tahir		
Accreditation no/ application no:	TEST 215	Date of assessment:	17-18 Jan 20087
Sites assessed:	Islamabad		

1 The assessment

This report deals with:

Initial ass. [ ] Extraordinary ass. [ ] Renewal [ ]
Surveillance [x] Extension [ ] Full assessment [ ]

Assessment team:

Name	Position
Ms Ismat Gul Khattak	Lead Assessor
Ms Anne Grændsen	Technical Assessor Microbiology
Ms Cecilie Fjeld Nygaard	Technical Assessor Chemical

Personnel interviewed:

Name	Position
Ms Hifza Rasheed	Quality Manager
Mr Tajammal Hussain	

Participants in the concluding meeting:

Name	Position
Dr Aslam Tahir	Director General
Ms Hifza Rasheed	Quality Manager
Ms Saiqa Imran	Technical Manager
Ms Kiran Anwar	Technical Manager
Ms Farah Naz	Technical Manager
Mr Shafiq-ur-Rehman	Technical Manager
Ms Shazia Ghaffar	Technical Manager
Mr Rizwana Perveen	Deputy Technical Manager
Ms Fauzia Altaf	Deputy Technical Manager
Ms Raheela Naureen	Analyst
Mr Iftikhar	Purchase officer
Mr Akram Aziz	Analyst
Mr Amir Ijaz	Analyst

Deadline for submission of corrective actions: **29.02.2008**

2 Non-compliances

Categorisation of non-compliances is described in NA Doc 55 and on NA's web-site (www.akkreditert.no).

3 Results from the assessment

Below, the results from the assessment against the accreditation requirements as described in ISO/IEC 17025:2005 (General requirements for calibration and test laboratories) and the requirements defined in the laboratory's own management system, are described.

ISO 17025 – Chapter 4 – Requirements for management

4.1 Organization

The laboratory has the responsibility to carry out its testing activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer. The laboratory management system covers work carried out in the laboratory's permanent facilities only.

The laboratory is part of PCRWR, which has currently six regional centers in all the provinces, but will have three more centers by mid 2008. There seem to be no involvement of personnel working on accredited testing activities to avoid any potential conflicts of interest.

The laboratory need to have arrangements to address 4.1.5 of the standard such as arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work. The laboratory need to develop policies for ensuring the protection of its customers' confidential information and proprietary rights, and to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity, as well.

The laboratory need to think about appointing deputy for the Quality Manager, well in time as the trainee DQM will soon be going on transfer to Lahore. Currently the Quality Manager is without a deputy.

NC no	--				
Compliance		x	Not in compliance		

4.2 Management system

The laboratory has established, implemented and maintained a management system appropriate to the scope of its activities. The laboratory has documented its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test results, however there is room for improvement. The current quality system is complicated and cumbersome and can be simplified. The system's documentation is communicated to, understood by, and implemented by the appropriate personnel by different means such as trainings, meetings and office circulars.

The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, is defined in the quality manual.

The quality objectives can be improved in a way that can be more specific, measurable and time bound.

NC no					
Compliance	X	Not in compliance			

4.3 Document control

The laboratory has established and maintained procedures to control all documents that form part of its management system whether they are internally generated or are from external sources, such as regulations, standards and other normative documents.

Currently the document control procedure is controlled both page wise as well as procedure wise, depending upon the portion that needs changing. In cases where minor changes are made then only pages revision is done. The current practice is that document changes can be seen in soft copy as well as in hard copy. The obsolete copy of quality manual is not marked as mentioned in the document control procedure. The system needs implementation **(minor non-conformance).**

The system also allows hand written changes on the one hand and also allows the use of one set of photocopy in the labs which is uncontrolled. There can be problem in the future if a strict control is not maintained.

NC no	--				
Compliance		Not in compliance	X		

4.4 Review of contracts

Although there is a system for signing contract with the customer, and in case of deviation from the contract, there is a form which caters for this need but there is no provision for identifying the sample against which a change is requested **(minor non-conformance).**

Pl see TA reports.

NC no	--				
Compliance		Not in compliance	X		

4.5 Subcontracting

Not assessed by lead assessor.
Please see TA reports.

NC no	--				
Compliance	X	Not in compliance	-		

4.6 Purchase of services and supplies

Not assessed by lead assessor.
Please see TA reports, **minor non-conformities** included. .

NC no	--				
Compliance		Not in compliance	X		

4.7 Service to the customer

Not assessed.

NC no	--				
Compliance	-	Not in compliance	-		

4.8 Complaints

There is a system for complaints. Seven complaints have been received between Feb 2007 and Dec 2007. Most of these complaints were related to delays in giving test reports. They were properly handled according to the procedure. The written complaints are not logged, however verbal complaints are logged in a register.

NC no	--				
Compliance	X	Not in compliance			

4.9 Handling non-conforming work

There is a system for handling non-conformances. According to their procedure, the quality manager identifies root cause and takes follow-up on the corrective action. This system needs improvement. The lab evaluates significance of the nonconforming work by categorizing them into very serious, essential and minor, but its explanation is not available anywhere.
Please see TA reports, **minor non-conformities** included.

NC no				
Compliance		Not in compliance	X	

4.10 Improvement

Not assessed.

NC no	--			
Compliance	-	Not in compliance	-	

4.11 Corrective actions

There is a good system for identifying a problem within the management system or within the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations. The laboratory has established procedure and has designated authorities for implementing corrective action whenever nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. In most of the cases it is the quality manager. Similarly the procedure for corrective action starts with an investigation to determine the root cause(s) of the problem which is also done by the quality manager in most of the cases. The laboratory monitors the results to ensure that the corrective actions taken have been effective which is also done by the quality manager.

Remark:
The lab may look into the possibilities of improving its system.

NC no	--			
Compliance	X	Not in compliance		

4.12 Preventive actions

Not assessed.

NC no	--			
Compliance	-	Not in compliance	-	

4.13 Technical registrations

Generally records were available and were found in order. There is a good traceability in documents and are easily retrievable. All records are held secure and in confidence. The soft copy of the quality documents is only with quality manager and it is in a computer which is password protected.

Please see also TA reports.

NC no	--				
Compliance		X	Not in compliance		

4.14 Internal audits

It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. The internal audit is carried out by trained and qualified personnel who are, independent of the activity to be audited. Internal audit is conducted annually by trained internal auditors. There are five approved internal auditors, which have been approved after qualifying certain laid down criteria. The last audit was conducted in December 2007. Corrective actions have been taken, but the follow-up would be done after 20th Jan 2008. Ms.Kiran conducted the audit of QMR, who was interviewed too. She had a good understanding of the subject. The internal audit plan and reports reflected that all elements of the system were audited except the testing activities. A ***minor non-conformance*** is given.

NC no	--				
Compliance			Not in compliance	X	

4.15 Management review

The management review was conducted according to a predefined agenda, however suitability of policies was not discussed instead only 'displaying of quality policy in all laboratory sections on A3 size frames' was discussed and decided. (**Minor non-conformance**).

NC no	--				
Compliance			Not in compliance	X	

ISO 17025 – CHAPTER 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

The laboratory management has a system which ensures that the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports etc. When using staff that is undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and demonstrated skills, as required for the job.

The management has a system that authorizes specific personnel to perform particular types of test, to issue test reports and to operate particular types of equipment. The laboratory maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, which is readily available but there is hardly any date on which authorization in the personnel files checked, which included personal files of Mr Tajammul Hussain, Mr Akram Aziz, and Ms Kiran Anwar. The system needs improvement. **Minor nonconformance** is given.

Please see TA reports, **minor nonconformity,** included.

NC no	--				
Compliance			Not in compliance	X	

5.3 Premises and environment

Please see report of TAs, **minor nonconformity,** included.

NC no	--				
Compliance			Not in compliance	X	

5.4 Test and calibration methods and method validation

Please see TA reports, **essential and minor non-conformities** included.

NC no	**2, 3, 4 and 5**				
Compliance			Not in compliance	X	

5.5 Equipment

Please see TA reports, **minor non-conformity** included.

NC no					
Compliance			Not in compliance	X	

5.6 Measurement traceability

Please see TA reports, **essential non-conformity** included.

NC no	**6**				
Compliance			Not in compliance	X	

5.7 Sampling

Not relevant

NC no	--				
Compliance		-	Not in compliance	-	

5.8 Handling of test and calibration objects

Please see TA reports.

NC no	--				
Compliance		X	Not in compliance		

5.9 Assuring the quality of results from testing and calibration

Please see TA reports, **essential non-conformity** included.

NC no	**2 and 3**				
Compliance			Not in compliance	X	

5.10 Reporting results

The test reports are generally ok, except where the result is reproduced in the form of not detected. This is ambiguous and needs clarification.

Please see also see TA reports, **essential and minor non-conformity** included..

NC no	**1**				
Compliance			Not in compliance	X	

4 Other requirements

NA-Doc 14 Conditions for the use of NA's logo in accreditation marks and for making reference to accreditation

The lab has a system in place, and the logo is according to the specification mentioned in NA-Doc-14. The lab quality manager has a good understanding of the conditions for the use of logo. The logo is currently used only on test reports only clearly identifying non-accredited tests.

NC no	--				
Compliance		X	Not in compliance		

NA-Doc 25/31 Accreditation conditions

The laboratory generally complies with the accreditation conditions as specified in Dok 25/31.

NC no	--			
Compliance	x	Not in compliance		

NA-Doc 26 a Requirements for calibration and control of balances for accredited test laboratories

Please see TA reports, **essential non-conformity** included.

NC no	6			
Compliance		Not in compliance	X	

NA-Dok 26 b Requirements for calibration and control of thermometers for accredited test laboratories

Please see TA reports, **essential non-conformity** included.

NC no	6			
Compliance		Not in compliance	X	

NA-Doc 50 Flexible accreditation (if relevant)

Not applicable

NC no	--			
Compliance	-	Not in compliance	-	

NA-Dok 52 Calculation of measurement uncertainty in calibration

Not applicable

NC no	--			
Compliance	-	Not in compliance	-	

5 Implementation of corrective actions for non-compliances noted during the previous assessment

The corrective actions from the previous assessment were followed up. The implementation was satisfactory except for document control, where there are minor problems. Please see the TA's report.

6 Recommendation regarding accreditation

When satisfactory corrective actions have been submitted by PCRWR, the lab may be recommended for continuation of accreditation

7 Recommendation regarding suspension

Not Applicable

8 Recommendation regarding scope of accreditation

There are no changes in the scope of accreditation.

9 Recommendation regarding administrative/ geographical units

Not Applicable

10 Any changes since the previous assessment

Some of the labs have been shifted into newly constructed labs such as the lab where tests are performed on Atomic Absorption. Five new research officers have been inducted who have been properly trained and afterwards authorized to do different tasks.

11 Complaints

The organisation has the right to complaint against actual errors in the report. Such complaint shall be forwarded to Norwegian Accreditation within 3 weeks after the report has been sent from NA.

12 Other

Not relevant

The undersigned confirms that this report is not violating NA's policies and practices.

Islamabad 18.01.2008

Lead Assessor

Place/ date Oslo 30.01.08

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment
Non-compliances;

Number of very serious non-compliances	00
Number of essential non-compliances	06
Number of minor non-compliances	18

Summary report
Accreditation document
Reports from technical assessors, laboratories 02

Name of the organisation: PCRWR, Islamabad

Application no.: **Accreditation no:** Test 215

Type of visit: Surveillance visit

Leader of the organisation: Dr. Muhammad Aslam Tahir

Lead assessor: Ismat Gul Khattak

Number of non-conformity reports attached:

Very serious:	0
Essential:	6
Minor:	18

Summary:
The laboratory has established a quality system, which covers the elements in ISO 17025:2005. The laboratory's quality system is appropriate for the activities within the organisation. The top management has a satisfactory commitment to quality assurance. However, some minor shortcomings have been identified regarding:

- Documentation and document control
- Authorisation
- Review of contracts
- Internal audit
- Management Review
- Methods
- Traceability
- Reporting

The personnel are well educated, trained, and are working well together. They have demonstrated satisfactory competence according to the scope applied for accreditation. The facilities are fit for purpose and the workflow is well organised.

Minor NC's connected to the management system:

- The obsolete copy of quality manual is not marked as mentioned in the document control procedure. The system needs implementation. Ref: 4.3
- There is an additional form which caters for revision in contracts, but there is no provision for identifying the sample against which a change is requested. Ref: 4.4
- The internal audit plan and reports reflected that all elements of the system were audited except the testing activities. Ref 4.14
- Suitability of policies was not discussed instead only 'displaying of quality policy in all laboratory sections on A3 size frames' was discussed and decided: Ref: 4.15
- There is hardly any date on which authorization in the personnel files checked. Ref: 5.2

Note: Please see two separate sheets of minor non-conformities attached.

Recommendation concerning accreditation:
If all nonconformities are corrected within the time limit, the recommendation is that accreditation is continued.

Minor non-conformities are followed up during the next assessment visit. However a confirmation that the minor nonconformities have been corrected within the deadline is required

Time limit for presentation of corrective actions: 29.02.2008

18.01.2007 — date

Signature lead assessor

Seen by:

Signature (organisations repr.)

S.Nr. 07/389-6 Vedlegg Nr. 2

Attachment to Summary Report
Minor non-conformities Microbiology (P16)

Name of organization: National Water Quality Laboratory (NWQL), Islamabad

Application no.: -- **Accreditation no:** TEST 215

Type of visit: Surveillance visit

Minor non-conformity	**Reference ISO 17025**
The laboratory has not established temperature tolerance limits for fridges (4°C) and room temperature (25°C) were media and reagents are kept.	5.5
The streaking technique used for control plates in connection to the demonstration could not differentiate the colonies as separate colonies.	5.4
In the present accreditation scope E.coli (ML-MM-05) has a reference to "Standard Methods 9221B/C ". The laboratory has changed one of the culture media in accordance to FAO 1998. The change of culture media is validated, but the working procedure and the test reports have deficiencies due to this. • Reference to FAO is not given in the working procedure • It is not explicit given in the working description were the change in culture media is done • The reference method given in the accreditation scope and the test reports is not correct. The method shall be given as "internal method based on Standard Methods 9221B/C and FAO 1998" The reference for E. coli in the result sheet and the result form is also incorrect.	5.4/5.10
Following reagents were not labelled with the experience date: • Methyl red indicator • Barritt's reagent A and B • Gram stains • pH Buffers For Methyl red indicator and Barritt's reagent A and B was also the production date missing.	4.6/5.4
Air sampling (Ml-MM-08): • The unit (Minutes) is missing in the criteria given for total	5.4

bacterial count, yeast and moulds in the working procedure. However, the criteria could be found on the record sheet. • The period of sampling (Minutes) is also missing in the working procedure. Practise is satisfactory.	
Surface sterility check (Ml-MM-08): The unit (cm^2) is missing in the criteria given for total bacterial count, yeast and moulds in the working procedure. Practise is satisfactory and the criteria could be found on the record sheet.	5.4
Rose Bengal Chloramphenicol Agar Medium is missing in the list "Frequency of media preparations & shelf life" (Ml-MM-08).	5.4
PH measurement in culture media: • Bottles with pH buffers are reused for a week • A control solution or a control buffer is not used after calibration and consequently a control chart is not established	5.4
NC-handling: The laboratory has not been evaluating the NC's impact on test results sent to clients in connection to the root cause analysis. This also applies for the chemistry laboratories.	4.9

Date: 18.01.2008

Signature:

Attachment to Summary Report
Minor non-conformities Chemistry (P12)

Organization: National Water Quality Laboratory, PCRWR

Accreditation no: TEST 215

Type of visit: Surveillance visit

Minor NC's	**Reference ISO 17025**
The test reports do not give the dates for the period of testing	5.10
In the method for determination of Mn in drinking water the preparation of the standards is not described in the method	5.4
Calcium standards used for calibration are not dated	4.6
The time period of previous experience outside PCRWR for the personnel are not given in the CV's or staff qualification and experience record.	5.2

Date: 18.01.2008

Signature: Cecilie Fjeld Nygaard Cecilie F. Nygaard

ACTIVITY:	Surveillance	Report no.:	1
ORGANISATION:	National Water Quality Laboratory, PCRWR		
Department:	Islamabad		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

For some test reports (e.g. MCL-1467-08) there are examples of results given as "nil" or BDL. The laboratory informs that "nil" is zero. The measured concentration shall not be reported below the methods detection limit. BDL is explained in the report as below detection limit without giving the value of the detection limit. The description on this issue is missing in the quality system

18 Jan 08 Cecilie F. Nygaard
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.10
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

To resolve the issue, Detection Limits of analytical parameters are added in the test report.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: 04.

12-2-08 (date) — signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 26.03.08 (date) — signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	2
ORGANISATION:	National Water Quality Laboratory, PCRWR		
Department:	Islamabad		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:
The method for measuring pH in the chemistry lab has insufficiencies:

- The measurement range for pH in water is given as 1-13. The laboratory is not using buffers that cover the whole area. Buffers in the area 4-12 are used. The laboratory can not document the method uncertainty in the range outside the buffer values and the PT's are not in this range. This was also given as a minor NC in 2007.
- The buffers used for calibration are not certified, but the certified buffers are used as control samples. Buffers are not suitable for control samples due to the fact that their ion strength is too high compared to real samples. Remark: This is not the case for P16-microbiology

18 Jan 08 Cecilie Fjeld Nygaard
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4/5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

☐ It is not necessary to attach documentation

Time limit for correction:

IMPLEMENTED ACTIONS: Working range for analysis of water samples in 4-12 on reality basis rather than 1-13. Uncertainity of 4-12 pH is already given in the scope whereas acid/base spiking of real samples is done to be used as control samples.

Actions are documented in the amendment no: 02

12-2-08 Hifza Lakhad.
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ *The non-conformity is closed based on satisfactory documentation from the organisation*
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 26.03.08 Rachel R. Nil
date signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0389

ACTIVITY:	Surveillance	Report no.:	3
ORGANISATION:	National Water Quality Laboratory, PCRWR		
Department:	Islamabad		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The system for approval of PT results and making PT trend plots is not accomplished in accordance with the standard:

- The laboratory does not approve the results and the PT results by comparison with their own measurement uncertainty. The evaluation is done by accepting a bias < 7% compared to the assigned value. This is not in accordance with the uncertainty of the analytical methods.
- Trends of PT results are plotted, but based on the Z-score and not the laboratories own measurement uncertainty.

18 Jan 08 Cecilie F. Nygaard
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4.6./5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Laboratory's acceptance criteria is changed & is now based on Lab's own uncertainity. PT results & next participation will be evaluated on the new criteria & trend charts will be plotted accordingly.

Actions are documented in the amendment no: 04

12-02-08
date

Hija Lovead
signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 26.03.08
date

signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0389

ACTIVITY:	Surveillance	Report no.:	4
ORGANISATION:	National Water Quality Laboratory, PCRWR		
Department:	Islamabad		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

Accuracy is not evaluated in the method validations.

18 Jan 08 Cecilie F. Nygaard
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Description on "Accuracy" is added in the procedure for method validation.

Actions are documented in the amendment no: 04

12-02-08 Hina Farheed
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 23.04.08 Daniel K. Nil
date signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0389

ACTIVITY:	Surveillance	Report no.:	5
ORGANISATION:	National Water Quality Laboratory, PCRWR		
Department:	Islamabad		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismail Gul Khattak	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION

Some of the methods are given with wrong measurement range or no range at all, e.g

- CLAAS-01, 03 has 0 " zero" as lower range
- CLW-01 has zero as lower range and lack unit
- CLAAS-02 lacks measurement range

This was given as a minor NC in 2007.

18 Jan 08 Cecilie F. Nygaard Saiga.
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Measurement ranges for above mentioned procedures are Corrected in the test method manuals & in the Scope.

Actions are documented in the amendment no: 03.

12-02-08 Hijab Rashid
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☒ The non-conformity is closed based on recommendation from the technical assessor
☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 26.03.08 Rashid Ali
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	6
ORGANISATION:	NWQL, Islamabad		
Department:	All laboratories		
Accr./Appl. no.:	TEST 215		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Thermometers, balances and pressure gauges have been calibrated onsite by an organization (NPSL, Islamabad) which is not fulfilling the requirements on measurement traceability:

- The calibration laboratory does not have an unbroken chain of traceability
- The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed.

However, the laboratories have taken into account the accuracy and measurement uncertainties given in the calibration certificates in a satisfactory way.

Temperature recording device in autoclaves used for culture media production are not calibrated.

18 Jan 08 Anne Grændsen — Hilda Rasheed.
Date — Signature assessor — Signature (Org. representative)

Ref. organisation's doc.
Calibration certificate

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA doc 26a NA doc 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

NPSL is participating with SIRIM Malaysia to show traceability for Mass, Temp. & pressure.

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

12-2-08 — Hilda Rasheed.
date — signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

See answer from lab dated 07.05.08. See also letter sent from NA 08.04.08. Will be followed up in December 08.

☐ The non-conformity is closed based on satisfactory documentation from the organisation

☐ The non-conformity is closed based on recommendation from the technical assessor

☒ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: 08.05.08 — Gaute R. Nilsen
date — signature (lead assessor)

Name of the organisation: **National Water Quality Laboratory, PCRWR**
Assessed locations:

Accr. no. : **TEST 215**	Date of assessment: 17.+18.jan, 2008
Appl. no.:	

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Cecilie Fjeld Nygaard** Technical area: **P12 Chemistry**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	x	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	
Technical assessment NS EN ISO/IEC 17025:	x
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Saiqa Imran	Technical manager atomic absorption laboratory
Shfiq-ur-Rehman	Technical manager quality control and client services
Shazia Ghaffar	Technical manager chemistry laboratory

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is sending corrective actions to NA within the agreed date, and that the corrective actions are evaluated as acceptable accreditation of the methods in the accreditation scope is recommended maintained.
3.2 Recommendation regarding change of the responsible for validation, when relevant (valid for flexible scope):
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

There are no changes in personnel.
The laboratories have expanded since the last visit.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The laboratory has one quality manager and three technical managers regarding the accreditation scope in chemistry. The technical management seems to be working very well. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: The work instructions for the methods are hanging on the wall. All the documents found were properly controlled and of the latest version. The quality control manual and methods manual was accessible to everyone working in the laboratory. The quality manual was available at the quality manager's office. It is important that the staff is well acquainted also with the requirements in the quality manual **(remark)**. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: There was neither found any uncontrolled documents during the audit nor old versions of any documents. The CV's applied are written in a template which is not document controlled and a part of the quality system **(remark)**. *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: When the samples are delivered to the laboratory, an order usually follows the samples with a request of which parameters are to be analyzed. If a letter from customer is not given with the samples, the laboratory contacts the customer and fills out an order form (MR07). *Non-conformity no* --

4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory does not apply subcontractors. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: Purchasing has not been assessed. Calcium standards used for calibration are not labelled with date of preparation (**minor NC**). It will therefore not be possible to know the expiry date of the standard. The standards in use could preferable also be labelled with an expiry date even if this is described in the procedure for standard preparation. Reagents are generally labelled with content, date and preparation and expiry date. Dry chemicals are kept in the chemical stock room. **Remark:** The chemicals have not been labelled with an expiry date. Especially for standards (e.g. NaF) this could be critical. The laboratory should also consider the need for drying chemicals (e.g. salts) used for standard solutions, in case they might have absorbed moisture from the environment. *Non-conformity no* --
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: NCs are written by the staff in the laboratory and are given to the technical manager, who identifies the root cause. The quality manager defines the corrective actions together with the technical manager. The laboratory is recording NCs for PT values exceeding the given limits. *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: The measurements are all recorded in personal records and then transferred to a " result record form (chemical lab)" Vertical audit: MCL-1467-08: pH, Alkalinity, Potassium CL-1465-08:Bicarbonate, Hardness All the measurements results, result records customer's orders and test reports are archived together for each samples/batch of samples and stored in the reception. *Non-conformity no* --

5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The time period of previous experience outside PCRWR for personnel is neither given in the CV's nor in the "staff qualification and experience record" (**minor NC**). This also applies for courses and seminars. Approval of the analysts is not dated, e.g. for Shazia (see **minor** NC lead assessors report). The laboratory has prepared a training program for all analysts working in the laboratory. *Non-conformity no* --
5.2.1	**Training**
	Description/evaluation: Approval of personnel is based on training. The training is accomplished in two ways: • Experience and qualifications • Testing & competence record. In this record results of samples measured with a method is recorded. The results are either noted as S=satisfactory and US=Unsatisfactory. The results are satisfactory if they are within the measurement uncertainty. The training checklist is not marked with name, but is kept in specific training file for every analyst.
5.2.2	**Maintenance of competence**
	Description/evaluation: The laboratory performs a large number of analyses within the scope every year and participated in PT testing covering the scope. Maintenance of the competence is assessed as adequate.
5.2.4	**Job descriptions**
	Description/evaluation: Not assessed
5.3	**Accommodations and environmental conditions**
	Description/evaluation: The l chemistry laboratories are placed in the ground floor and 1st floor (AAS-lab). The lab has recently expanded their area and there are currently heavy paint fumes in the laboratory. When the weather is very humid, the laboratory should consider if dry chemicals may be affected by the humidity. Dry chemicals which should be kept dry may be kept in an exsiccator. *Non-conformity no* --

5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See clauses 5.4.1- 5.4.7. *Non-conformity no* **2, 5**
5.4.1	**General**
	Summary/Conclusion: In the method for determination of Mn in drinking water the preparation of the standards is not described in the method. The laboratory has a manual describing the standard preparation, but it is not linked to the method (**Minor NC**). The measurement range for pH in water is given as 1-13, but the laboratory is not using buffers that cover the whole area. Buffers in the area 4-12 are used. The laboratory can not document the method uncertainty in the range outside the buffer values and the PT's are not in this range. This was also given as a minor NC in 2007. The buffers used for calibration are not certified, but the certified buffers are used as control samples. Buffers are not suitable for control samples due to the fact that their ion strength is too high compared to real samples. This is not the case for P16-microbiology **(remark)**. For measurement of pH a description of which buffers are to be used in the analyses is not described in the method. The method mentions 4 buffers, but in practice only 2 buffers are being used, dependant of the pH of the sample. Some of the methods are given with wrong measurement range or no range at all or measurement range is lacking unit, (examples CLAAS-01, 03 has 0 " zero" as lower range; CLW-01 has zero as lower range and lack unit; CLAAS-02 lacks measurement range). This may also apply for the other methods within the scope. This was given as a minor NC in 2007. For titration methods the laboratory is calibrating the titrate solutions.
5.4.2	**Selection of methods**
	Description/evaluation: All of reference standards are from the 1998 issue of "methods for examination of water and wastewater, 20th edition" A later edition of these methods is available and the laboratory has made an order of this edition. Implementation of alterations in the reference methods will be checked during the next visit.
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory has plans of expanding the accreditation scope within chemistry in the nearest future. The laboratory has methods that are suitable for the measurements. All the methods within the scope are based on standard reference methods.

5.4.5	**Validation of methods**
	Description/evaluation: The laboratory has performed validations of the methods within the scope, but accuracy is not a parameter considered in the validation. However, PT tests have been performed. Accuracy need to be established as a part of the procedure for method validation. *Non-conformity no* **4**
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: The laboratory estimates the measurement uncertainty (combined) every time a measurement is done. The laboratory should establish a measurement uncertainty for each method and apply this uncertainty when reporting results in general and evaluating PT results. The laboratory has estimated measurement uncertainty and it is given in NWQL-MR-02. For some method, the measurement uncertainty varies with the measurement range. The estimated measurement uncertainty should also cover the bias from the PT results when evaluating the PT results (see also clause 5.9) The method uncertainty is not given in the methods, but is given in the overview MR-02. *Non-conformity no* --
5.4.7	**Control of data**
	Description/evaluation: All calculations are done manually in laboratory records. Every staff member has a personal record. The measurements are written in the personal records with date, measurement and sample ID is described. Spreadsheets are not in use. *Non-conformity no* --
5.5	**Equipment**
	Description/evaluation: The instruments have an equipment maintenance (TR-08 form), which is kept together with the instrument manuals. Instrumental equipment is labelled with an ID NWQL-no. The spectrophotometer for e.g. measuring sulphate is controlled by NPSL, where % transmission is controlled at a certain wavelength. The instrument is not checked with a filter at certain wavelengths, but this is not so critical since all the measurements are done indirectly with standard calibrations. The laboratory is not accredited for directly measurements of spectrophotometric absorption and transmission. Adjustable pipettes are controlled monthly and recorded. Limit values are given in the form. The laboratory also applies 10mL B-graded pipettes and these are measured monthly and a correction factor is given. It is not necessary to do monthly calibrations of these glass pipettes after a calibration has been done initially. Burettes of B-quality used for titrations are also controlled and calibrated.

	The AAS Vario6 has been moved from another floor the previous day before the surveillance visit. The instrument has not yet been verified after the move that it is in good function, but it has not yet been used for accredited analyses after the move. Verification of new instruments or instruments after being moved should also be described in the quality system.
	Non-conformity no --
5.6	**Measurement traceability**
	Summary/conclusion: The laboratory applies CRMs for many of the analyses where they are available, e.g CRM ICS041-S for measuring sulphates. Certified standard solutions are used for metal analyses (supplier: CPA) and diluted to stock and standard solutions. Expiry date is given on the certified standard solutions. There were not found any non-conformity regarding use, storage and shelf-life of the CRM's. *Non-conformity no* --
5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling** (If relevant)
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: The samples for analysis are delivered in the reception. All received samples are recorded in the "samples storage record" Samples are stored in a refrigeration room before and after analysis. The samples

	are labelled with a lab-code number. In case of metal analyses, the samples are preserved with nitric acid.
	Non-conformity no --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory applies QC charts for all their methods, but the limits may be based on the wrong limits because of the lack of evaluation against PT tests. The control sample for the pH measurements is not suitable (see clause 5.4) The PT testing program covers the whole scope. Approval of PT results is not done by comparison with the laboratory's own measurement uncertainty. The evaluation is done by accepting a bias < 7% compared to the assigned value. This is not in accordance with the uncertainty of the analytical methods. Trends of PT results are plotted, but based on the Z-score and not the laboratories own measurement uncertainty. *Non-conformity no* **3**
5.10	**Reporting the results**
	Description/evaluation: The test reports to the customers do not give the dates for the period of testing (**minor NC**). The laboratory has two methods for determination of fluoride (ISE and Spands method) –only the ISE method is accredited and can be reported as an accredited method. For some test reports (e.g. MCL-1467-08) there are examples of results given as "nil" or BDL. The laboratory informs that "nil" is zero. The measured concentration shall not be reported below the methods detection limit. BDL is explained in the report as below detection limit without giving the value of the detection limit. The description on this issue is missing in the quality system A report from 2007 (974-A: 06.02.07) had given a wrong method uncertainty to the customer. This was given as an NC in 2007. The laboratory has sent a corrected test report to the customer. *Non-conformity no* **1**
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --

	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* –
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: Wrong use of the logo was not revealed under the vertical audit. **Remark:** The laboratory may consider the use of an English version of the logo for Norwegian Accreditation to make it understandable to the customers. *Non-conformity no* –
No 25/31	**Accreditation conditions**
	Description/evaluation: See report from the lead assessor. *Non-conformity no* –
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: Balances are controlled daily when in use, e.g. balance ID 001 is used and controlled with 100g weight and plotted in chart. The laboratory has also purchased a weight in the lower range and documentation of control lower range will be controlled at the next visit. The laboratory does not fulfil the requirements of measurement traceability (**see NC6, P16**). *Non-conformity no* **6**
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: Not relevant for chemistry. *Non-conformity no* –
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* –

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
(Specify method and person. Indicate if method has been examined theoretically/ discussed	CLMC-08 Fluoride in water	Izwana Perveen
	CLAAS-012 Manganese in water	Tajammal Hussain
	CLMC-05 Sulphates in water	Shazia Ghaffar

7. Follow up non-conformities from the last visit:

NCs:

- There are still some details missing in the methods, and given as an NC
- Implementation of QC charts are satisfactory

Minor NCs:

- Trend plots are made, but limits are based on z-score
- Version numbers – all documents examined were updated
- Reporting wrong uncertainty-new report was issued
- Measurement uncertainty is reported for every parameter in every report
- pH range out of calibration range; given as an NC this visit
- Pipettes grade B are controlled and corrective factor applied for correcting the bias

8. Notes/summary/ conclusion

The laboratory has a well qualified staff and equipment related to the scope that is satisfactory. The staff seems to be very positive to working with the requirements of the quality system. The laboratory staff is working well with the quality system, which may in some areas be simplified.

9. Next visit
(Are there any subjects that need to be strictly evaluated during the next visit, or if specific persons should be present

- Evaluation of PT-results and trend plots
- Expiry dates of chemicals, standards and labelling.
- Control of balances, lower and higher range-especially area of weighing samples.
- Verification of the function of the AAS Vario6 after moving the instrument to another floor (jan.08)
- Implementation of alterations of new edition of reference methods (if there are any)
- Description of samples storage and preservation
- Job descriptions

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

20.01.2008 Cecilie Fjeld Nygaard
technical assessor/expert

30.01.08
date

lead assessor

Name of the organisation:	**Pakistan Council of Research in Water Resources**
Assessed locations:	**National Water Quality Laboratory (NWQL), Islamabad**

Accr. no. : TEST 215 Appl. no.:	Date of assessment: 17 Jan 08 18 Jan 08

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Anne Grændsen** Technical area: **Microbiology (P16)**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	X	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	
Technical assessment NS EN ISO/IEC 17025: 2005	X
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Ms Kiran Anwar	Technical Manager
Mr Akram Aziz	Lab Analyst
Mr Rauf Ahmed	Lab assistant
Mr Amir Ijaz	Media Curator

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant:
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

Personnel:

- A research officer, Ms Memona Kahn, is employed in the microbiological laboratory.
- Mr Akram aziz (Lab analyst) is authorized to perform accredited analysis.

Equipment and facilities:

The laboratory has been expanded and refurbished.
Several new incubators have been purchased, but these have not yet been put into use for analyses in the accreditation scope.
There are no other major changes.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The technical manager, Ms Kiran Anwar, has satisfactory education and experience within microbiology. She is well qualified and trained for duties and responsibilities acquired in present position, and she is cooperating with her staff in a very good way. The communication in the laboratory was open and friendly. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: In general the quality system is covering all requirements in ISO 17025. All personnel have access to the documents needed. Working procedures and records connected to the analytical work was placed in one of the incubation rooms. Documents connected to preparation of culture media was placed in the production area. Some working instructions are placed on or nearby the instruments. **Remark:** There is still a potential for reduction of paper in the system. Example: In the working procedures for preparation of culture media many of the clauses are repeated in all the procedures. A general description for media preparation can cover all the clauses that are repeated. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: During the assessment it was not observed any document which was not under properly control. Document changed are communicated to the personnel in

	regular meetings.
	Non-conformity no --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Requests and contracts were examined in connection to the vertical audit conducted on a sample with ID No 1442(A)-07. The sample drawn was bottled water. The case file contained the request form as described in the quality system The form was properly filled in on reception and signed by the customer. The request letter from the customer was also kept in the file. *Non-conformity no* --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory is not subcontracting analysis within the accreditation scope. Not specifically assessed during this surveillance visit. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has satisfactory requirements for purchasing. The Pakistani PPR is followed. Quality requirements are given priority. Purchased chemicals and dehydrated media observed in the laboratory are of recognised quality and are satisfactorily marked with recipient date and opening date. Dehydrated media and chemicals used in accredited analysis are kept separate shelves in the media preparation room. Likewise culture media made in the laboratory were satisfactorily labelled. The technical manual is improved since last visit and the expiry dates used by the laboratory are now described. **Minor non-conformity:** Following reagents were not labelled with the expiry date: • Methyl red indicator • Barritt's reagent A and B • Gram stains • pH Buffers For Methyl red indicator and Barritt's reagent A and B was also the production date missing. *Non-conformity no* --
4.9-4.11	**Control of non-conformity (NC) testing and/or calibration work/corrective actions**
	Description/evaluation: The laboratory has now implemented the NC system properly. All together it is raised 27 NC's in 2007: • 15 NC's are raised on regular basis during daily work • 5 NC's are raised in connection to PT-testing

	• 7 NC's are raised during the internal audits conducted The personnel have been given good training in how to use the NC system. Handling of NC's is mainly done by the Technical Manager in cooperation with the Quality Manager. The Quality Manager is closing the NC's after the corrective action has been performed and verified (if needed). All NC's are closed in a reasonable time after they have been recorded. **Remark:** In the present situation suggestions to corrective actions are given by the Quality Manager. The responsibility can beneficially be transferred to the Technical Manager. The Quality Manager can even then agree to the proposal or request supplementary work to be performed. **Minor non-conformity:** NC-handling: The laboratory has not been evaluating the NC's impact on test results sent to clients in connection to the root cause analysis. (Example: Cross contaminated inoculation loops have been observed in PT-testing. Can this have happened with the customer samples too? Is clearifications with the customers needed or not?) This NC also applies for the chemistry laboratories.
	Non-conformity no --
4.13	**Control of records**
	Description/evaluation: All registrations is satisfactorily recorded in personal bench records and different forms described in the in the technical manual. The laboratory demonstrates that handling of raw data is taken care of in a good manner. All registrations are principally done by permanent pen, and they are easily readable, properly dated and signed. Perspicuous trend plots connected to the control programme for instruments and environmental conditions are made on monthly basis. All files asked for were easily found. A vertical audit was carried out on a sample with ID No 1442(A)-07. Water samples had been analysed for indicator organisms. The laboratory demonstrated good traceability to timeframes and operators throughout the system regarding to all elements included in the analysis. However it was observed NC's in connection to temperature calibration of the autoclaves **(essential NC no 6)** and use/reuse of control solution/trend plots of the pH meter **(minor NC)**. See further information given in clause 5.5 and 5.6 in this report.
	Non-conformity no --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The personnel are qualified and experienced. The laboratory is in the possession of competence needed.

	Non-conformity no --
5.2.1	**Training**
	Description/evaluation: All personnel are properly trained and have specific, updated CV's. Dates of period of training are specifically given in. All CV's were assessed. Period of training is not given in the CV for on job trainings and external trainings. However this can be found in the qualification and experience record Training/approval records for Mr Akram Aziz, authorised after the initial visit, was reviewed and found to be satisfactory. Likewise training record of Ms Memona Kahn who was employed as a training research officer in Dec 2007 was reviewed and found to be satisfactory. In general documentation of training records is done in a very good way. Demonstrations and discussions performed during assessment prove that proper training has been given.
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is satisfactorily. Accredited methods are routinely analysed. On annually basis approximately 500 samples are analysed. However, analyses within the coliform group are mostly performed by MPN-methods. Membrane filtration methods performed are limited. In addition the personnel are performing quality control samples (PT samples or competence samples) quarterly.
5.2.4	**Job descriptions**
	Description/evaluation: Not specifically assessed during this visit. However, current job responsibilities are clearly described in updated CV's. All personnel contributed well in demonstrations, record reviews and discussions. It obvious that they have good knowledge of their own duties and responsibilities.
5.3	**Accommodation and environmental conditions**
	Description/evaluation: The laboratory facilities are fitted for the activity performed in the laboratories. The laboratory has been expanded and refurbished. Testing activities has been performed during refurbishment. In spite some water leakages from the floor above the in monitoring programme for environmental conditions does not show any alarming results. There has been one occasion were the control results were exceeding the action limit. However this has been recorded as a NC and appropriate measures have been taken.

	The laboratory has proper routines for housekeeping. Procedures for handling of disposals from the testing laboratory are acceptable. Access to the laboratory is restricted to authorized personnel. Designated laboratory coats and foot ware has to be worn in the laboratory. The work flow is well planned and organised. Measures have been taken to avoid contaminating samples and testing. During the assessment the laboratory was tidy and clean. The laboratory monitors and records following parameters: • Daily lab and equipment cleaning • Biological sterility by air testing (weekly) • Biological sterility by swab testing of working benches (monthly) • Bacteriological and chemical testing of the deionised water used for media production (monthly) • Temperature and humidity in the facilities (twice daily) The laboratory has removed the water tank from the microbiological laboratory after the initial assessment. Deionised water is now tapped directly from the plant. The records for air testing, surface testing and testing of deionised water were inspected. The described routines are followed in a very good way. Nice trend plots are made on monthly basis. The information is presented to all personnel in the laboratory and the trend plots are placed on the wall in the corridor. **Minor non-conformities** were observed in the working procedures for air quality monitoring and surface testing (sterility) of laboratory rooms. See minor non-conformities in clause 5.4 in for further information.
	Non-conformity no --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: There are no changes after the accreditation has been granted. The laboratory is using recognised standard methods prescribed in regulations given by the national authorities. Latest valid edition is used. The methods used are appropriate and fit for purpose. Choice of analysis is in accordance with the customer request form which is filled in on reception of the samples. Demonstrations performed during the assessment revealed conformity between written procedures and the manual operations in the laboratory. **Minor non-conformities:** 1. The streaking technique used for control plates in connection to the demonstration could not differentiate the colonies as separate colonies.

2. In the present accreditation scope E.coli (ML-MM-05) has a reference to "Standard Methods 9221B/C ". The laboratory has changed one of the culture media in accordance to FAO 1998. The change of culture media is validated, but the working procedure and the test reports have deficiencies due to this.
   - Reference to FAO is not given in the working procedure
   - It is not explicit given in the working description were the change in culture media is done
   - The reference method given in the accreditation scope and the test reports is not correct. The method shall be given as "internal method based on Standard Methods 9221B/C and FAO 1998"

   The reference for E. coli in the result sheet and the result form is also incorrect.

3. Following reagents were not labelled with the expiry date:
   - Methyl red indicator
   - Barritt's reagent A and B
   - Gram stains
   - pH Buffers

   For Methyl red indicator and Barritt's reagent A and B was also the production date missing. Routines for labelling of reagents are not described in the working procedures.

4. Air sampling (MI-MM-08):
   - The unit (Minutes) is missing in the criteria given for total bacterial count, yeast and moulds in the working procedure. However, the criteria could be found on the record sheet.
   - The period of sampling (Minutes) is also missing in the working procedure. Practise is satisfactory.

5. Surface sterility check (MI-MM-08):
   The unit (cm^2) is missing in the criteria given for total bacterial count, yeast and moulds in the working procedure. Practise is satisfactory and the criteria could be found on the record sheet.

6. Rose Bengal Chloramphenicol Agar Medium is missing in the list "Frequency of media preparations & shelf life" (MI-MM-08).

7. PH measurement in culture media:
   - Bottles with pH buffers are reused for a week
   - A control solution or a control buffer is not used after calibration and consequently a control chart (trend plot) is not established

Non-conformity no --

5.4.1	**General**
	Summary/Conclusion: Se clause 5.4
5.4.2	**Selection of methods**
	Description/evaluation: Se clause 5.4
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory is not using methods developed in house or any other non-standard methods. Neither has the laboratory plans to use such methods.
5.4.5	**Validation of methods**
	Description/evaluation: The laboratory is solely using recognised standard methods or internal methods based on standard methods. In the internal method minor changes is done and this is properly validated. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Identification of contributions to measurement uncertainty (MU) is included in the working instructions for methods in the accreditation scope. However, sources of measurement uncertainty should also be weighted due to importance **(Remark).** The laboratory has started to calculate the measurement uncertainty for different instruments and working steps. So far the laboratory is using the "step by step" method (uncertainty budget) for calculating the MU. During the discussions the laboratory was warned against using the "step by step" method in microbiology due to the risk of underestimating the MU. Underestimation can be caused by synergisms etc. The "top down" method is recommended for microbiological analysis. The "top down" method is based on internal reproducibility studies. See also ISO 19036. *Non-conformity no* --
5.4.7	**Control of data**
	Description/evaluation: The laboratory does not use LIMS. Calculations in connection with the analytical process are manually operations. All registrations observed in the records were satisfactorily. The procedure of transference of data was checked during the vertical audit of Since last visit the use of sample serial number has improved in personal Bench

	Records. Bench records belonging to Ms Kiran Anwaar and Mr Akram Aziz were checked. The laboratory has worked out very good trend plots in connection to the monitoring programme for equipment and environmental conditions. The trend plots are established in Excel. Proper locking of essential cells containing calculations was not investigated during this visit.
	Non-conformity no --
5.5	**Equipment**
	Description/ valuation: The laboratory is well equipped and has listed of all equipment. Each item is given unique identity numbers. Since the initial visit several new incubators have been purchased, but these have not yet been put into use for analyses in the accreditation scope. In general the maintenance is good. All instruments are properly monitored. Control results are recorded and trend plots are made on monthly basis. Since the initial visit use of correction factors given in calibration certificates have been improved. Acceptance limits have also been established for volumetric devices. The following instrument files were reviewed: • Incubators, fridges and autoclaves • Thermometers • Balances • Laminar flow hood • pH-meter • Volumetric equipment (automatic pipettes) **Minor non-conformity:** The laboratory has not established temperature tolerance limits for fridges (4°C) and room temperature (25°C) were media and reagents are kept. See clause 5.6 regarding traceability (calibrations)
	Non-conformity no --
5.6	**Measurement traceability**
	Summary/conclusion: Traceability is established for the microbiological methods by using reference cultures traceable to an international culture collection ATCC. The laboratory is using reference cultures (positive and negative controls) in each run of analysis. The reference cultures are stored and treated in a proper manner. Satisfactory actions are taken to avoid cross contaminations. Purity controls and biochemical tests are performed routinely. However, the streaking technique demonstrated during the assessment could not differentiate the colonies as separate colonies. This is of importance regarding purity checks. See **minor non-conformity**

	described in clause 5.4. All calibrations of equipments are performed onsite by NPLS in Islamabad. Calibration certificates are in place. Correction factors and measurement uncertainty given in the calibration certificates are taken into account by the laboratory. **Essential non-conformity:** Thermometers and balances and pressure gauges have been calibrated by an organization which is not acceptable according to the requirements for measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) Temperature recorder on the autoclave is not calibrated *Non-conformity no* **6**
5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.5 and 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: The customers are doing the sampling. However, sampling procedures are provided by the laboratory. Samples are received at the reception desk. On receipt the samples are recorded and acquire a unique number. The samples are also checked for damages, proper use of sterile containers and temperature abbreviations. Samples not meeting the laboratory's requirement are refused. In some very few cases the customer wants

	to have refused samples analysed. Then the request is stamped and approved by the customer as such. Before, under and after analysis the samples are stored satisfactorily. The microbiological laboratory is also having a separate record of samples received in the laboratory. The quality system is improved since last visit. Working procedure ML/MM01 is now describing that samples which are going to be tested in the microbiology lab and the chemistry lab is treated by the microbiology lab first. A vertical audit of the sample with ID No 1442(A)-07 demonstrates that the procedures are followed thoroughly. The laboratory had signed for the reception of the sample as described in the quality system.
	Non-conformity no --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory is using reference cultures (positive and negative controls) in each run of analysis. The cultures are traceable to an international culture collection (ATCC). In addition the laboratory participates at least annually in PT-schemes for water provided by Norwegian Institute for Food and Environmental analysis. Competence testing is also performed on quarterly basis for approved personnel. Results from the competence testing were not investigated in detail during this surveillance visit. The PT-schemes covers the present accreditation scope. In 2007 the laboratory has participated in two PT trials. PT results outside the laboratory's acceptance limits are properly recorded as NC's. In 2008 the laboratory has also planned to participate in a FAPAS trial in UK in February.
	Non-conformity no --
5.10	**Reporting the results**
	Description/evaluation: Test reports were examined during a vertical audit carried out on a sample labelled with ID No 1442(A)-07. Except for the method reference described in the minor non-conformity below, the test reports fulfil the requirements in ISO17025. No amended reports were observed when the report file was checked. **Minor non-conformity:** In the present accreditation scope E.coli (ML-MM-05) has a reference to "Standard Methods 9221B/C ". The laboratory has changed one of the culture media in accordance to FAO 1998. The change of culture media is validated, but the working procedure and the test reports have deficiencies due to this. • Reference to FAO is not given in the working procedure

	• It is not explicit given in the working description were the change in culture media is done • The reference method given in the accreditation scope and the test reports is not correct. The method shall be given as "internal method based on Standard Methods 9221B/C and FAO 1998" The reference for E. coli in the result sheet and the result form is also incorrect.
	Non-conformity no --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: Use of accreditation mark was checked during the vertical audit conducted on the sample labelled with ID No 1442(A)-07 . The accreditation mark is used in test reports according to the requirements described in NA Doc 14. *Non-conformity no* --
No 25/31	**Accreditation conditions**
	Description/evaluation: Not assessed *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: **Essential non-conformity:** The balance has been calibrated by an organization which is not acceptable according to the measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) *Non-conformity no* **6**

No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: **Essential nonconformity:** Thermometers have been calibrated by an organization which is not acceptable according to the measurement traceability. (Reference: Information letter sent to the laboratory on 28 Sep 2007.) *Non-conformity no* **6**
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	Total Coliforms and E. coli (MPN methods) ML/MM-06	Mr Akram Aziz
7. Follow up non-conformities from the last visit:	Non-conformities from last visit are in general satisfactorily implemented.	
8. Notes/summary/ conclusion	No further comments	
9. Next visit	• Excel calculations – locking of essential cells containing equations • Calibration of balances and thermometers • Membrane filtration methods for total Coliforms and E. coli, ML/MM-05 • Quarterly competence testing • Validation of new incubators before they are put into use • Training an approvals for Training research officer (newly employed)	

20.01.2008, Anne Grændsen
technical assessor

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

date 30.01.08
lead assessor

Name of organisation:	Southernzone Agricultural Research Centre (SARC) Karachi		
Manager of the organisation:			
Accreditation no/ application no:	TEST 217	Date of assessment:	14 Jan and 15 Jan 2008
Sites assessed:			

1 The assessment

This report deals with:

Initial ass.	☐	Extraordinary ass.	☐	Renewal	☐
Surveillance	X	Extension	☐	Full assessment	☐

Assessment team:

Name	**Position**
Anne Grændsen	Lead assessor
Cecilie Fjell Nygaard	Technical Assessor P12
Dr Tahira Zaheer	Observer

Personnel interviewed:

Name	**Position**
Mumbarik Ahmed	Project Director (Quality Manager)

Participants in the concluding meeting:

Name	**Position**
Mumbarik Ahmed	Project Director (Quality Manager)
Dr U.N. Kahn	Director General
Saquib Arif	Deputy Quality Manager
Dr Zahida Parveen	Technical Manager

Deadline for submission of corrective actions: **03.03.2008**

2 Non-compliances

Categorisation of non-compliances is described in NA Doc 55 and on NA's web-site (www.akkreditert.no).

3 Results from the assessment

Below, the results from the assessment against the accreditation requirements as described in ISO/IEC 17025:2005 (General requirements for calibration and test laboratories) and the requirements defined in the laboratory's own management system, are described.

ISO 17025 – Chapter 4 – Requirements for management

4.1 Organization

Southernzone Agricultural Research Centre is a part of Pakistan Agricultural Research Council (SARC) under Federal Ministry of Food Agricultural and Livestock. SARC is responsible for research and development in Agricultural sector in the province of Sindh.

Since last visit there is no change in key personnel, including dedicated duties and responsibilities. SARC quality management system consists of Director General, Quality manager, technical manager of Proximate Analysis, technical manager of microbiology/Plant pathology laboratory and technical manager of the Chemistry laboratory.

The quality manual describes other activities the laboratory is involved in besides accredited testing.

A deputy quality manager is appointed after the initial assessment. **Remark:** The positions as Quality Manager and Deputy Quality Manager can beneficially be stated in Qualification and Experience Record (SARC/FF/QM-5.2(c)).

In the initial assessment it was concluded that information on the wage system for laboratory personnel contra independency of total number of samples and their results was not properly described in the quality system. The quality Manual, clause 4.1, now describes that recruited personnel have monthly salary based on Government regulations.

NC no	--				
Compliance	X	Not in compliance			

4.2 Management system

A fully revised Quality Management System was issued on March 15th 2007. There is no change in the quality policy or the management commitment to provide testing services in compliance with ISO 17025. The structure of the Quality system is divided in 3 levels:

- Quality Manual (QM)
- Technical Manual (TM)
- Forms and formats

SARC is currently still a small organization with few employees. Meetings conducted are a mixture of formalized and in formalized meetings. The revised QM is a result of good teamwork in informal meetings. Consequently there was no need for extra

information/summaries when the revised document was issued. Summaries are made from formalized monthly meetings and from Management Reviews.
The list showing the documents included in the Quality manual is improved since the initial visit and is now under proper document control.

Likewise descriptions of how the management ensures that the integrity in the management system is maintained by changes of the system and the management commitment to work according to the requirements in the standard and continuously improve the management system is now included.

See also report from technical assessor regarding access to QM and TM.

NC no	--			
Compliance	X	Not in compliance		

4.3 Document control

Major improvements are seen since the initial visit. The laboratory has a Master Index identifying the current revision status of all documents. No uncontrolled documents were observed during the surveillance visit.

NC no	–			
Compliance	X	Not in compliance		

4.4 Review of contracts

The clauses concerning requests, tenders and contracts are adequately described. The customer request is considered to be the client contract. The requests are reviewed and accepted by DG, Quality manager and the Technical Managers. The testing capabilities are ensured by the Technical Managers.

Lab code 051107200 and 310707198 were checked. Satisfactory client requests were found in the files, and the requests were properly dated and signed by personnel mentioned above.

NC no	--			
Compliance	X	Not in compliance		

4.5 Subcontracting

There is no change since last visit. Currently the laboratory is not using any subcontractor's and. and has no plans to do so. There is consequently no list of potential subcontractors. The procedure for future use of subcontractors for accredited services with the scope of the laboratory's accreditation is adequately.

The quality manual describes how customers will be informed on use of subcontractors and how the results from such analysis are reported.

NC no	--				
Compliance		X	Not in compliance		

4.6 Purchase of services and supplies

Governmental requirements for purchasing laid down in PPR are followed.

SARC has a technical committee that approves all purchasing. Either the Quality Manager or the Technical Managers are present in the committee meetings and can influence on the quality to be selected. Quality is given a priority. ISO 9000 suppliers are preferred.

Minor non-conformity:
The procedure for purchasing services and supplies is not in compliance with established practice (description of technical committee and maintenance/placing of suppliers list). The approved suppliers list was not inspected during this surveillance visit.

NC no	--				
Compliance			Not in compliance	X	

4.7 Service to the customer

The laboratory has a description of how the laboratory is willing to cooperate with its customers to clarify their needs, and how the laboratory ensures confidential handling regarding other customers. The procedure is not yet been fully implemented. A filing system for customer feedback is established. The filing system contains a limited number of feedback formats submitted to the laboratory in April 2007.

Essential non-conformity:
How to conduct the seeking of customer feedback (positive and negative) is insufficient described in the quality manual.

The recording and filing of customer feedback given by phone, e-mail etc is not descried the quality manual. Currently such feedback is lacking in the customer feedback file.

NC no	3				
Compliance			Not in compliance	X	

4.8 Complaints

The laboratory has established a policy and procedure for registration, handling complaints. All complaints are handled by the Quality Manager. Corrective actions are communicated to the customer in writing.

No complaints have been recorded in 2007

NC no	--				
Compliance	X	Not in compliance			

4.9 Handling non-conforming work

The laboratory has a satisfactory description of the procedure and policy concerning non-conformities.

The NC system was put into use in July 2007. However NC's are exclusively reported in connection with internal audits. In 2007 are in total 18 NC's risen. Root cause analyses and corrective actions are performed within reasonable time. **Remark:** 4 different forms are used in connection to the handling of NC system. This seems to unnecessary complicated and time consuming.

Essential non-conformity:
The non-conformity system is not fully implemented. NC's are not yet recorded "on daily basis". NC's are so far only recorded in connection with internal and external audit. This is not in compliance with the description given in the Quality Manual, clause 4.9 i) a).

NC no	4				
Compliance		Not in compliance	X		

4.10 Improvement

The laboratory has established a satisfactory description of the tools that are going to be used in the process of improving the quality system.

Improvements are going to be discussed in internal meetings and during the Management Reviews. So far improvement has not been discussed during the Management reviews. See clause 4.15, **essential non-conformity** included.

NC no	2				
Compliance		Not in compliance	X		

4.11 Corrective actions

See clause 4.9 in this report.

NC no	--				
Compliance	X	Not in compliance			

4.12 Preventive actions

The procedure for how potential source for non-conformities shall be identified and rules for issuing, implementation and monitoring of action plans have been improved since last visit and is now fulfilling the requirement in ISO 17025.

Preventive actions shall be discussed during the Management Reviews. So far preventive actions have not been discussed during the Management reviews. See clause 4.15, **essential non-conformity** included.

NC no	--				
Compliance		Not in compliance	X		

4.13 Technical registrations

The laboratory demonstrates that handling of raw data is taken care of in a good manner. All registrations are principally done by permanent pen, and they properly dated and signed. All records reviewed were tidy and easily readable. Very few corrections were observed. When corrections are done it is according to the descriptions in the Quality Manual. The described routines fulfil the requirement in ISO 17025.

A vertical audit was carried out on a sample with Lab Sample Code 051107200. A flour sample had been analysed for different chemical parameters. The laboratory demonstrated good traceability to timeframes and operators throughout the system regarding to all elements included in the analysis. **Remark:** However it was observed some very few registrations performed with pencil. This should be avoided in the future.

See also report from the technical assessor P12.

NC no	-				
Compliance	X	Not in compliance			

4.14 Internal audits

The quality system states that a predetermined procedure and schedule for auditing are prepared by the Quality manager on annual basis. Internal quality audit schedules for 2007 and 2008 were reviewed. The schedules cover all elements in ISO 17025.

The laboratory started using the system of internal audits in July 2007. Consequently have not all elements in ISO 17025 been audited in 2007. However, technical elements belonging to clause 5.3-5.10 have been audited for both proximate and mycotoxin analyses. PCSIR Karachi was asked to perform a part of the internal audit. Reports from the audits contain both positive and negative findings. In 2007 a total 18 NC's have been raised during internal audits. Root cause analyses and corrective actions are performed within reasonable time.

The internal audits are conducted by the Quality Manager or the Technical Managers. No one has been auditing their own work areas.

NC no	–				
Compliance	X	Not in compliance			

4.15 Management review

The description of how the management review will be conducted is satisfactory. The laboratory has been conducting two Management reviews in 2007. A third review was planned in December, but this is rescheduled and will be conducted after the surveillance visit.

Essential nonconformity:
Management reviews conducted in 2007 are not in compliance with the descriptions in the quality manual. Only progress on removal NC's of have been discussed. Deficiencies in conducting the Management Reviews will also have an impact on other clauses in the standard (4.10, 4.12 and 5.2)

NC no	2				
Compliance		Not in compliance	X		

ISO 17025 – CHAPTER 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

Since last visit, Mr Muhammad Shakeel (Lab Keeper) had been transferred from a non accredited work area of SARC to the accredited laboratories. The confidentiality declaration was signed Feb 23rd 2007 and a CV was established. The lab keeper was not yet approved to use equipment on his own. The lead assessor discussed with the Quality Manager the minimum level of information expected to be given for different elements in the Quality Manual.

The laboratory has established plans for training. The plan for 2007 was reviewed. The plan for 2008 was not yet prepared. The plan for 2008 was scheduled to be worked out in advance of next Management Review meeting.

Essential non-conformity:
The CVs are incomplete:

- Previous working experience acquired outside SARC is missing
- Dates or period of relevant training are frequently missing
- Name of organisation providing the training is frequently missing

The quality manual does not describe a minimum frequency for updating CV's. Mr Kadir Kamran's CV was not updated regarding training acquired in august 2007.

See also technical assessor's report, **essential non-conformities** included.

NC no	**1 and 6**				
Compliance			Not in compliance	X	

5.3 Premises and environment

See technical assessor's report.

NC no	--				
Compliance		X	Not in compliance		

5.4 Methods for testing, calibration and validation

See technical assessor's report, **minor and essential non-conformity** included.

NC no	**8**				
Compliance			Not in compliance	X	

5.5 Equipment

See technical assessor's report **minor non-conformity** included.

NC no	--				
Compliance			Not in compliance	X	

5.6 Measurement traceability

See "Other requirements", NA-Doc 26a and NA-Doc 26b in this report, **essential non-conformity** included.

See also technical assessor's report, **essential non-conformities** included.

NC no	**7, 9 and 12**				
Compliance			Not in compliance	X	

5.7 Sampling

Not relevant

NC no	--				
Compliance		-	Not in compliance	-	

5.8 Handling of test and calibration objects

See technical assessor's report.

NC no	--				
Compliance	X	Not in compliance			

5.9 Assuring the quality of results from testing and calibration

See technical assessor's report, **essential non-conformities** included.

NC no	**5, 10 and 11**				
Compliance		Not in compliance	X		

5.10 Reporting results

Since last visit the laboratory has improved the description on information which is mandatory to be included in test reports. The description principally complies with the requirements in ISO 17025.

The file of test reports from 2007 was reviewed. The laboratory has not yet started issuing test reports which includes the accreditation mark. Consequently non-accredited analyses are so far not marked as such. All other requirements are included and are found to be satisfactory. Test reports containing opinions and interpretations were not observed. Neither were amendments to test reports found. All test reports checked were properly signed by authorized personnel (QM or TM). Electronic transmission of test results is not in use.

The laboratory is planning to put the accreditation mark into use shortly. The laboratory presented a proposal where the accreditation mark was included in the test report. The accreditation number has to be filled in under the accreditation mark. Otherwise the test report seems to be satisfactory.

Reporting and use of logo has to be followed up during next surveillance visit.

Remark:
The Quality Manual, clause 5.9 iii) does not state that the laboratory is not accredited for giving opinions and interpretations. Neither is it specified that opinions and interpretations have to be marked with "Not accredited" if they are included in the test reports.

NC no	--				
Compliance	X	Not in compliance			

4 Other requirements

NA-Doc 14 Conditions for the use of NA's logo in accreditation marks and for making reference to accreditation

SARC has stated in the Quality Manual, clause 4.17, that instruction for use of the accreditation mark given in NA doc 14 shall be followed. However the laboratory has not started using the accreditation mark yet, but is planning to put it into use shortly.

Reporting and use of logo has to be followed up during next surveillance visit.

Remark:
In clause 4.17 in the Quality Manual NA Doc 14 is referred to as a guideline. However the document is a requirement document.

NC no	--				
Compliance		X	Not in compliance		

NA-Doc 25/31 Accreditation conditions

SARC has cooperated well with the accreditation body in the period between the initial visit and the surveillance visit. The organization has forwarded all documents asked for within agreed time limits.

Remark:
In clause 4.16 and 4.17 in the Quality Manual NA Doc 25/31 is referred to as a guideline. However the document is a requirement document.

NC no	--				
Compliance		X	Not in compliance		

NA-Doc 26 a Requirements for calibration and control of balances for accredited test laboratories

Essential non-conformity:
Balances have been calibrated onsite by an organization (PCSIR, Karachi) which is not fulfilling the requirements on measurement traceability:

- The calibration laboratory does not have an unbroken chain of traceability
- The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed

(However the technical content of the calibration certificate is acceptable.)

NC no	**12**				
Compliance			Not in compliance	X	

NA-Dok 26 b Requirements for calibration and control of thermometers for accredited test laboratories

Essential non-conformity:
Max-min thermometers used for recording temperatures in fridges are not calibrated.

See also technical assessor's report, **essential non-conformities** included.

NC no	**9 and 12**			
Compliance		Not in compliance	X	

NA-Doc 50 Flexible accreditation (if relevant)

Not relevant

NC no	--			
Compliance	-	Not in compliance	-	

NA-Dok 52 Calculation of measurement uncertainty in calibration

Not relevant

NC no	--			
Compliance	-	Not in compliance	-	

5 Implementation of corrective actions for non-compliances noted during the previous assessment

The corrective actions from the previous assessment are properly followed up. Details can also be seen in the TA's report.

6 Recommendation regarding accreditation

If the laboratory within the agreed time limit is submitting satisfactory corrective actions to NA on all non-conformities recorded, accreditation of the present scope is recommended maintained.

Minor non-conformities are described in this report will followed up during the next assessment visit. However a confirmation that the minor nonconformities have been corrected within the deadline is required.

7 Recommendation regarding suspension

Not relevant

8 Recommendation regarding scope of accreditation

There are no changes in the scope of accreditation.

9 Recommendation regarding administrative/ geographical units

Not relevant

10 Any changes since the previous assessment

There are no relevant changes since last visit.

11 Complaints

The organisation has the right to complaint against actual errors in the report. Such complaint shall be forwarded to Norwegian Accreditation within 3 weeks after the report has been sent from NA.

12 Other

No further comments.

The undersigned confirms that this report is not violating NA's policies and practices.

Islamabad, 19.01.2008

Lead Assessor

Place/ date: Oslo 30.01.08

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment
Non-compliances;

Number of very serious non-compliances	0
Number of essential non-compliances	12
Number of minor non-compliances	05

Summary report
Accreditation document
Report from technical assessor P12

Name of the organisation: Southernzone Agricultural Research Centre (SARC) Karachi

Application no.: **Accreditation no:** TEST 217

Type of visit: Surveillance visit

Leader of the organisation: Dr. U.N. Kahn

Lead assessor: Anne Grændsen

Number of non-conformity reports attached:

Very serious:	0
Essential:	12
Minor: (separate list)	5

Summary:
The laboratory has established a quality system, which covers the elements in ISO 17025:2005. The documentation is fully revised and is improved since last visit. The quality system is appropriate for the activities within the organisation. The top management has a satisfactory commitment to quality assurance. The quality system is improved since the initial visit. However, some shortcomings have still been identified regarding implementation on:

- Use of the non-conformity system
- Customer feedback system
- Training and authorisations
- Handling of chemicals and solutions
- Methods; descriptions, external controls, internal controls
- Calibrations of thermometers and balances

The key personnel are well educated and trained, and they are cooperating well together. They are demonstrating satisfactory competence according to the accreditation scope.

The laboratories are well equipped, the facilities are fit for purpose and the workflow is well organised.

Recommendation concerning accreditation:
If the laboratory within the agreed time limit is submitting satisfactory corrective actions to NA on all non-conformities recorded, accreditation of the present scope is recommended maintained.

Minor non-conformities are followed up during the next assessment visit. However a confirmation that the minor nonconformities have been corrected within the deadline is required

Time limit for presentation of corrective actions: 03.03.2008

15.01.2008
date

Signature lead assessor

Seen by:

Signature (organisations repr.)

Norwegian Accreditation

Name of the organisation	SARC, Karachi
Accreditation No. - Case No.	TEST 217 - 07/0217
Dato of assessment:	14 Jan + 15 Jan 2008
General information:	Surveillelance visit

Name	Title	Participant Opening meeting	Participant Final meeting
DR. UN Khan	DG SARC/PARC Karachi.		
Mubarik Ahmed	Director/ Quality Manager GATL		
SAQIB ARIF	DQM/TM-II		
DR ZAHIDA PARVEEN	TM, / SSD SARC		
Dr. Ali Abbas Qazilbash	UNIDO/TATA National Expert Lab. Accreditation		
DR. Tahira Zaheer	QMR PSQCA / Observer		
Cecilie F. Nygaard	Techn. accessor PT2	X	X
Anne Grande	Lead assessor	X	X
Seema Ismail	Observer	-	
SAQIB ARIF	DQM/TM-II		

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Organization: Southernzone Agricultural Research Centre (SARC) Karachi

Accreditation no: TEST 217

Type of visit: Surveillance visit

Minor NC's	**Reference ISO 17025**
The detection limits are not determined in the method verifications where this is necessary, e.g. Aflatoxins	5.4
The laboratory has not established routines for assuring use of the latest reference standards	5.4.2
There is not compliance with the temperature used specified for sample type between reference standard and method description.	5.4
The 1 L standardized bucket used for determining the bulk density weight has no documentation of correct volume of the bucket.	5.5
The procedure for purchasing services and supplies is not in compliance with established practice (description of technical committee and placing of suppliers list).	4.6

Date: 15.01.2008

Signature: Cecilie Fjeld Nygaard/ Anne Grændsen

ACTIVITY:	Surveillence visit	Report no.:	1
ORGANISATION:	SARC, Karachi		
Department:	Management system		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The CVs are incomplete:

- Previous working experience acquired outside SARC is missing
- Dates or period of relevant training are frequently missing
- Name of organisation providing the training is frequently missing

Mr Kadir Kamran's CV was not updated regarding training acquired in august 2007. The quality manual does not describe a minimum frequency for updating CVs.

15 Jan 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
CVs

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.2
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillence visit	Report no.:	2
ORGANISATION:	SARC, Karachi		
Department:	Management system		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The management reviews conducted in 2007 is not in compliance with the descriptions in the quality manual. Only progress on removal NC's of have been discussed.

Deficiencies in conducting the Management Reviews will also have an impact on other clauses in the standard (4.10, 4.12 and 5.2)

15 Jan 07 Anne Grændsen
Date Signature assessor

Signature (Org. representative)

Ref. organisation's doc.
Quality manual 4.15

Minutes of meetings from the Management Review Committee

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.15 (4.10-4.12-5.2)
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	3
ORGANISATION:	SARC, Karachi		
Department:	Management system		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

How to conduct the seeking of customer feedback is insufficient described in the quality manual.

The recording and filing of customer feedback given by phone, e-mail etc is not descried the quality manual. Currently such feedback is lacking in the customer feedback file.

15 Jan 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Quality manual 4.7

File for feedback from clients

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.7
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	4
ORGANISATION:	SARC, Karachi		
Department:	Management system		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

The non-conformity system is not fully implemented. NC,s are not yet recorded "on daily basis". NC's are so far only recorded in connection with internal and external audit. This not in compliance with the description given in the Quality Manual, clause 4.9 i) a)

15 Jan 07 Anne Grænd
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
Quality manual 4.9
NC reports

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	5
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The system for quality control charts is not satisfactory, e.g

- The measurement uncertainty in e.g. control chart for falling number is much greater than the methods measurement uncertainty,
- Some of the QC charts lack unit and numbering, and the limits are not explained/given in the charts
- The quality system does not describe how to establish the control charts, limit values, how they shall be used and which actions that are going to be taken when values are exceeding the defined limits.

15/1-08 Cecilie F. Nygaard _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	6
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

There is no defined criteria for approval of an analyst in an analytical method or procedure –on which basis is an analyst approved. Examples:

- Comparisons with other authorized personnel parallel testing)
- Analysis of RM's or CRM's
- Analysis of PT-samples
- Demonstrations under observation of tutor

There is no specified listing of approved personnel.

15/1-08 Cecilie F. Nygaard
Date Signature assessor

Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.2
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

15/1-08 CFN

ACTIVITY:	Surveillance	Report no.:	7
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The system for handling reagents solutions and reference materials is not sufficient, e.g.

- solutions on the laboratory bench are not labelled with content nor expiry date
- referance materials used are not labelled with an expiry date

15/1-08 Cecilie F. Nygaard
Date Signature assessor

Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.6/4.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	8
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The analytical methods do not include important information such as:

- measurement range –both upper and lower. Both upper and lower limits should also be given in the overview of methods, and can beneficially be mentioned in the method description
- unit of measurement uncertainty
- information of which quality control sample to be used and when. In the quality manual in 5.9.i)a) is only defined regularly without defining how often regularly is.
- number of parallels to be measured. In practice this varies between the methods and this is not described in the methods.
- How solutions are made (e.g. 2% NaCl) and shelf life

15/1-08 Cecilie F. Nygaard Sai
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
07/0217

ACTIVITY:	Surveillance	Report no.:	9
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The oven used for ashing the samples at 550°C had no documented traceability on the temperature. The oven har been calibrated by the We Brothers Scientific Ltd., but this calibrations report is not accreditated. The laboratory also needs to establish routines for how they correct the deviation from the true value of the temperature in the oven (this can e.g. be described in the QM and oven labelled with correction value)

15/1-08 Cecilie F. Nygaard
Date Signature assessor

Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	No. 26a
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	10
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The quality control samples are measured monthly, and all the samples measured in the time period between two quality controls lack traceability.

15/1-08 Cecilie F. Nygaard Signature assessor — Signature (Org. representative)
Date

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance	Report no.:	11
ORGANISATION:	Southern zone Agricultural Research Centre (SARC)		
Department:	Karachi		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Cecilie Fjeld Nygaard

DESCRIPTION:

The laboratorys system for evaluating PT tests/CRM/ILC is insufficient.
The laboratory does not evaluate the results from the PT test/ILC/CRM against their own measurement uncertainty.
Trend plots of PT tests are not established. A plan for PT tests has been made for 2008(TM.5.4), but does not include gluten in wheat, which is available on the market.
For the parameters that are not covered by the PT testing, an ILC har been accomplished but the participating laboratories are not all on the same quality level.

15/1-08 Cecilie F. Nygaard Sign
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	12
ORGANISATION:	SARC, Karachi		
Department:	Management system		
Accr./Appl. no.:	TEST 217		
Lead. ass.	Anne Grændsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Max-min thermometers used for recording temperatures in fridges are not calibrated.

Balances have been calibrated onsite by an organization (PCSIR, Karachi) which is not fulfilling the requirements on measurement traceability:

- The calibration laboratory does not have an unbroken chain of traceability
- The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed

(However the technical content of the calibration certificate is acceptable.)

15 Jan 07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA doc 26a NA doc 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

I hereby declare that I will not disclose any confidential information I should access during my involvement as a technical assessor or observer for Norwegian Accreditation (NA) to other persons than relevant NA personnel.

I fully realise that this declaration of confidentiality also applies when my engagement is completed (ref. Public Administration Act §13).

With the term confidential information means technical, financial or personal, and/or other information of competitive or ethical causes which might be sensitive.

I understand that my work for NA cannot be used in a commercial way without NA approval.

I oblige myself to inform NA if I or my employer has performed services for a client the last three years, or are free of any interest that might cause either of us to act in a non-discriminatory manner.

14/01/08
date

signature, assessor/observer

DR. TAHIRA ZAHEER
name in block letters

As the assessors employer we accept this declaration, and we realise that we cannot use any influence that can cause impartial conflicts with respect to this declaration.

date

signature employer

Extract from Public Administration Act §13:

It is the duty of anyone rendering services to, or working for, an administrative agency, to prevent others from gaining access to, or obtaining knowledge of, such matters as may be disclosed to him in the course of his duties and which relate to the following

1. an individual's personal affairs, or
2. technical devises, production methods, business analyses and calculations and industrial and trade secrets otherwise, if these are of such a nature that others may exploit them in their own business activities.

The term "personal affairs" shall not include place of birth, national registration number, nationality, civil status, occupation, residence and place of employment, unless such information discloses a client relationship or the like which must be considered personal. Moreover, the King may issue specific regulations on what kind of information is to be considered personal, on which agencies may give private individuals information as stated in the preceding sentence and on such other information concerning an individual's personal status, as well as prescribing the terms and conditions for providing such information.

The pledge of secrecy shall also continue to apply after that the person concerned has terminated his service or work. Nor may he exploit such information as mentioned in this Section is his own business activities or in service or work for others.

Name of the organisation: **Southern zone Agricultural Research Centre (SARC)**	
Assessed locations:	
Accr. no. : **TEST 217** Appl. no.:	Date of assessment: 14.+15. April 2008

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Cecilie Fjeld Nygaard** Technical area: **P12 Chemistry**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	x	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	
Technical assessment NS EN ISO/IEC 17025:	x
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Saquir Arif	Technical manager, grain quality lab
Mubarik Ahmed	Quality manager
Zahida Parveen	Technical manager, analytical lab
Nagmus Sahar	Analyst, analytical laboratory

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is sending corrective actions to NA within the agreed date, and that the corrective actions are evaluated as acceptable accreditation of the methods r is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant (valid for flexible scope) :
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

There are no changes in personnel since last visit. A new technician has been working in the laboratory, but not with accredited analysis. No other changes with instruments or the laboratory facilities.

The laboratory has plans to extend the scope (PCB, metals) during the next visit from NA.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The technical management seems to overall be working satisfactory, but in some areas the implementation of measurement traceability is not satisfactory. There are 2 technical managers covering the scope of the accredited methods; Dr. Zahida Parveen and Saquir Arif. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: The technical manual is available in the grain quality lab for all the analysts, but there was no copy in the analytical lab of neither the quality manual nor the technical manual. However, the manuals are available at both the technical managers' offices. In order to implement the quality system in an efficient way, it would probably be favourable to give all the analysts easier access to copies of these manuals in such a way that they are used in the daily work. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: No non-controlled documents in the quality system were found during the audit. The laboratory has quite a few papers hanging on the wall and they are parts of the analytical methods. All of these papers were copies from the valid versions of the methods. *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Orders from the customers are placed by an accompanying letter with a pre-paid check from the customer together with the samples to be analyzed. The customer order has in connection with the vertical audit a description of the samples,

	parameters to be analyzed with reference to the reference standard.
	Non-conformity no --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory does not apply subcontractors within the method scope. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The system for handling reagent solutions and reference materials is insufficient. The laboratory does not have a list of approved suppliers of chemicals, reference materials and consumables. Reference materials and solutions made for accredited methods are not labelled with content or expiry date. (See also **minor NC** raised by lead assessor) *Non-conformity no* 7
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: NC's were only written in connection with the internal audits and not on a daily basis by the staff (see lead assessor's report). There were not found any NC's from the QC charts during the surveillance visit. It should be clear also to the technical managers how customer complaints and feedback are treated (see also NC 3, lead assessor). *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: When recording the results, they are either attached (from printer) or written directly in the form, e.g. for grain quality laboratory "quality analysis of wheat". In this form the parameters which are to be analyzed are marked. All the results are properly signed (of analyst) and dated. Vertical audit: Report 10.08.2007: sample 261207202, Dry gluten, ash content. Report 26.10.2007: sample 222007199, falling number, Moisture content The raw data from the measurements are kept filed in the laboratory. *Non-conformity no* --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: A laboratory technician has been employed since the last visit, but the training is not completed and documentation is not yet in place. Up to now the technician has not been working with accredited methods.

	There are no defined criteria for approval of an analyst in an analytical method or procedure. Approval is described only generally in the quality manual. In practice, training is given and approval is based on analysis of reference material or pre-analyzed samples, but this is neither documented nor described in the quality system. The laboratory has no documentation on who are authorised for each specific method. This is neither given in the CV's nor in an overview (listing). This will be followed up during the next surveillance visit.
	Non-conformity no **6**
5.2.1	**Training**
	Description/evaluation: CV's are not all updated, e.g Dr. Zahida Parveen 2002-2008? The description of experience and qualification is not documented sufficiently. The laboratory describes a training programme in QM 5.2. (Further information, see lead assessors report)
5.2.2	**Maintenance of competence**
	Description/evaluation: The maintenance of the competence is regarded as satisfactory by analyzing a sufficient number of samples every year. The number of analyses is influenced by seasonal variations of wheat production.
5.2.4	**Job descriptions**
	Description/evaluation: Each employee has a job description. This is given in the quality manual chapter 4.1.
5.3	**Accommodations and environmental conditions**
	Description/evaluation: The laboratory consists of several rooms in the same end of the building. There are separate rooms for e.g. grain quality testing, sample preparation and analytical measurements. The laboratory appears to be clean, tidy and suitable for its purpose. *Non-conformity no* --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See clauses 5.4.1- 5.4.7. *Non-conformity no* **8**
5.4.1	**General**
	Summary/Conclusion: Some of the analytical methods lack important details such as measurement range and limit of detection. The measurement range should include both lower and upper limits. E.g. for falling number, the upper measurement limit is not

	given in the overview of the methods (only lower limit 62 seconds). All the methods give the method uncertainty, but the units of the uncertainty are left out. The laboratory does not mention in the methods how many parallels are to be measured. In practice, e.g for measurement of gluten the number of parallels is normally 2, but if these two parallels deviate a lot, the laboratory measures another 2 parallels. The criteria for measuring more than 2 parallels is not described and also there is no description of how the results are to be reported (mean value, all parallels?). The use of the precision divider is not described in any of the methods, but is used in practice as a part of the sample preparation for several of the methods within the scope. The use of quality control samples is described in the QM in 5.9.i) a) in a general matter, but does not identify specifically how often the control samples are to be analyzed and which quality control samples are used for each specific method. Solutions made by the laboratory and used in accredited methods are not described how they are made and shelf-life, e.g. 2% NaCl (see also clause 4.6) For determination of ash in wheat flour, the laboratory's method gives a temperature range for all flour/grain matrices, while in the reference standard this is not given as a range, but as different given temperatures (**minor NC**)
5.4.2	**Selection of methods**
	Description/evaluation: **Remark:** There are not established any routines for assuring that the latest version of the reference method is applied. There was a reference method from 1977, but the laboratory could not assure that this was the latest edition. This will be followed up during next surveillance visit.
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory has plans for expanding the scope of methods including PCB and heavy metals, but the work is not ready until the next ordinary visit. Except one method, all the methods within the accreditation scope are based on reference standards.
5.4.5	**Validation of methods**
	Description/evaluation: The detection limits have not been determined in the method verifications. This should be determined in the methods where this is relevant, e.g. for Aflatoxins but may also apply to other methods (**minor NC**).
	Non-conformity no –
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Estimation of the method uncertainty has been performed and is documented in

	connection with the method verifications. The raw data for the measurement uncertainty is documented in SARC/MU/GQ-03.
	Non-conformity no --
5.4.7	**Control of data**
	Description/evaluation: All data are calculated manually. There is no use of a LIMS system. The data are always transferred manually. *Non-conformity no* --
5.5	**Equipment**
	Description/evaluation: For determination of the bulk density weight of wheat grains, a 1L standardized bucket is used, but a correct volume of the bucket could not be documented **(minor NC).** The laboratory does not apply spreadsheets for any of the calculations in the scope of accredited methods. All calculations are done by hand or given directly by the instrument software (e.g. with ELISA; aflatoxins). The instruments have been given an ID and are labelled according to this ID in the list of equipment (QM, 5.5). The analytical laboratory applies two adjustable pipettes that are used for extracting standards and samples. Volumetric output of these pipettes has not been checked during this visit. This will be followed up during next surveillance visit **(Remark).** Records for the instruments are now in use, but there should be enough space in the record to write some more detailed information. The laboratory applies the form "equipment maintenance/service/calibration record". *Non-conformity no* --
5.6	**Measurement traceability**
	Summary/conclusion: See clause 5.6.1-5.6.3 and clause 4.6. *Non-conformity no* --
5.6.1	**General**
	Description/evaluation: If available CRM's or RM's have been found, the laboratory applies reference materials for the methods within the scope. Control samples are kept in a refrigerator in the analytical laboratory, but the expiry date is lacking (see also clause 4.6). For the measurement of Aflatoxins, the expiry date was written on all of the standard solutions and reagents.

5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6. The laboratory applies reference materials when this is available. Reference material from FAPAS (certified) and AACC (not certified) are in use. For falling number the reference material HPW760 from AACC is in use. An "in-house" QC sample is also in use.
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: The samples are received by the "grain and storage research institute", 2nd floor. The samples are recorded. All relevant information is filed. The samples are given an ID based on day-month-year-serial number. The samples are labelled with this sample ID. Samples are kept for 3 months after analysis before they are discarded. *Non-conformity no* --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The system for quality control charts is not satisfactory described and implemented. The appearance and content of the QC charts need to be well defined with specification of the limits given in the charts, the units and the system has to describe which actions are to be taken when limits are exceeded. However control charts for all the methods have been established and are placed on the wall in the laboratory. The quality control samples are measured monthly. All the samples measured in the time period between two quality controls lack traceability. This also applies for the control weights of the balances (ref. Clause 26 a.) Trend plots of PT tests are not established. A plan for PT tests has been made for 2008 (TM.5.4), but does not include gluten in wheat, which is available on the

	market. For the parameters that are not covered by the PT testing, an ILC has been accomplished but the participating laboratories are not all accredited. However the results from the different laboratories do not deviate very much. Evaluations on the PT/ILC/CRM results are performed according to the z- score of the PT provider. The laboratory's own measurement uncertainty is not included. E.g. for PT test of Aflatoxins in maize the deviation from the "true value" (2.25ppb) exceeds the method uncertainty (0.8 ppb). Trend plots of PT tests are not established. A plan for PT tests has been made for 2008(TM.5.4), but does not include gluten in wheat, which is available on the market.
	Non-conformity no **5, 10, 11**
5.10	**Reporting the results**
	Description/evaluation: All the test reports are filed in "test reports" in the laboratory. The laboratory has not implemented the use of the NA-logo with TEST-number in their reports since the accreditation was granted. *Non-conformity no* --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: The laboratory has not implemented the use of the logo since the accreditation was granted. The laboratory has to include TEST 217 in connection to the accreditation mark. *Non-conformity no* --
No 25/31	**Accreditation conditions**
	Description/evaluation: See report from the lead assessor.

	Non-conformity no
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: In the grain quality lab there are 2 balances in use: • Fine balance IM-18 • Gross weight IM-10 (up to 2000 kg) The balances are controlled monthly, and it is informed that they are controlled in the same time period as the samples are weighed. If the laboratory performs weightings of real samples in addition to the monthly weight controls, a weight control should be made. The QC chart for e.g. the Sartorius balance does not have units or numbering on the vertical axis. The balances in the analytical laboratory will be controlled at the next visit. See also report from lead assessor, **essential** NC included *Non-conformity no* --
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: An annealing furnace is used for determining the ash content in wheat and flour. It is for the time being not in use, but has been up to jan .08. The furnace has been calibrated by an external supplier (We Brothers limited) which is probably not accredited for calibrations. The report has no accreditation mark. The laboratory needs to evaluate the intervals and the temperature control of the furnace. See also report from lead assessor, **essential** NC included *Non-conformity no* **9**
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
	Falling number in wheat flour GQ-05	Amin Ahmed (no discussion). Discussion with Saquir Arif
	Gluten in wheat flour GQ-04	Amir Khan (no discussion). Discussion with Saquir Arif
	Ash content in wheat flour GQ-06	Saquir Arif (only discussion due to furnace out of order at time of surveillance visit)
7. Follow up non-conformities from the last visit:	• Control of balances and documentation of control. Control and documentation is done, but an NC is given on the QC charts. • Not sufficient documentation of registration analyst, date of analysis. This is now sufficient • Log journal for instruments is in place and in use • Validation of the methods has been performed and contain conclusion, but LOD has not been determined (see clause 5.4.5) • PT programme and traceability	
8. Notes/summary/ conclusion	The laboratory has a qualified staff and equipment related to the scope that is satisfactory. The staff seems to be very positive to working with the requirements of the quality system.	
9. Next visit	• QC charts- necessary information, frequency • Balances including QC charts- and sufficient frequency of control. • Specification of analysts qualified to perform the specific methods within the scope. Remark for clause 5.2. • Documentation of training in CV's • Sample identification under analysis-could not be checked because all samples were cleared away before the visit. • Control and documentation of adjustable pipettes. • NC's from QC charts and PT tests	

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

17.01.2008 Cecilie Fjeld Nygaard
technical assessor/expert

date ..... *lead assessor*

Name of organisation:	PCSIR Karachi		
Manager of the organisation:	Mrs Askari Begum		
Accreditation no/ application no:	TEST 218	Date of assessment:	18-19 Dec 2007
Sites assessed:	Karachi		

1 The assessment

This report deals with:

Initial ass.		Extraordinary ass.		Renewal	
Surveillance	X	Extension		Full assessment	

Assessment team:

Name	**Position**
Ms Ismat Gul Khattak	Lead Assessor
Ms Anne Grandsen	Technical Assessor Microbiology (P16)
Mr Erik Figensdon	Technical Assessor Chemistry (P12)

Personnel interviewed:

Name	**Position**
Mr Mohsin Ali	Incharge IL section
Ms Ameera Zahid	S.O
Ms Hina Asghar	S.O

Participants in the concluding meeting:

Name	**Position**
Mrs Askari Begum	Acting DG
Mr Syed Zainul Inad	QM
Ms Khaula Shirn	AQM
Dr Aisha Nelofar	DTM
Dr Alia B. Munshi	PSO/TM
Dr Razia Sultana	PSO/DQMR
Mr Ishatullah Siddiqui	SSO/DTM/DQMR
Dr Khalid Jamil	DTM
Mr Muhammad Arif	DQMR
Ms Seema Ismat	TM, Microbiology
Mr Kaisar Sabir	DTM, Microbiology

Deadline for submission of corrective actions:
07.02.2008

2 Non-compliances

Categorisation of non-compliances is described in NA Doc 55 and on NA's web-site (www.akkreditert.no).

3 Results from the assessment

Below, the results from the assessment against the accreditation requirements as described in ISO/IEC 17025:2005 (General requirements for calibration and test laboratories) and the requirements defined in the laboratory's own management system, are described.

ISO 17025 – Chapter 4 – Requirements for management

4.1 Organization

PCSIR Laboratories Complex, Karachi works under the Ministry of Science & Technology. It holds legal responsibility for its operation and is organized to operate according to the requirements of ISO/IEC 17025, with in its permanent facility or on location, at customers' site.

The laboratory has arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work and maintains confidentially of the work; the evidence of which was seen for many staff members including Mr Rehmatullah purchase officer.

In the initial assessment, the issue of who would be the quality manger out of the three deputy quality mangers, in case he is on long leave, has now been resolved. Ms Khaula Shireen has been deputy as the Associate Quality Manager.

NC no	--				
Compliance	X	Not in compliance			

4.2 Management system

The laboratory has established, implemented and maintained a quality system appropriate to the scope of its activities. The laboratory has documented its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test. The current control version of Quality manual is Revision # 01; Issue # 02. Documents are revised page wise, and issue will be changed when the whole document has been changed for more than 50%. The previous document review was conducted in October 2006, and according to the management review meeting the next document review will be conducted after Eid and before 28th Feb 2008.

Quality manager is authorized to change quality documents, whereas technical managers are authorized to do the document change for technical documents.

The laboratory has set general objectives for its employees such as besides others 'ensure the confidence, impartiality, judgment and operational integrity', which is very general and 'plan and review goals periodically, which include aspects related to servicing' but there are no goals available within the lab. The objectives should be realistic and preferably measurable within time limit, if possible.

Observation is raised to improve objectives.

NC no	--				
Compliance		X	Not in compliance		

4.3 Document control

Quality system documents generated by the laboratory are uniquely identified. Such identification includes the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority. The procedure states that authorized editions of appropriate documents should be available at all relevant locations and therefore approximately 15 sets of quality manuals are distributed.

There is a system in place which states that documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements. Document distribution list KL/QMR/FF/403/02 refers to the copies of manuals distributed. Each document has its own distribution sheet and has its own document change history.

On the other hand, there is a documented system for removal of invalid or obsolete documents are promptly removed from all points of issue or use, but during assessments same documents with different controlled dates were seen such as in the case of key personnel record form # KL/QMR/FF/502/06 REV # 05, Issue # 03 and with two different issue dates 30/10/2007 & 08/11/2007.

There was essential NC in the initial assessment.

NC no	2				
Compliance			Not in compliance	X	

4.4 Review of contracts

According to the procedure for contracts all enquiries processed by the ILO. The ILO obtains a properly signed application/request letter from the customers and ensures that the application/request letter clearly describes his requirements. TM/DTM in consultation with respective HRD/OIC compiles a list of test capabilities along with methods and communicates it to ILO. (KL/Centre/Division/FF/404/05) and a copy is also sent to QMR for record. The procedure further states that ILO accepts the test jobs. For some clarification ILO may consult with respective TM/DTM. Mr Mohsin Ali is the new incharge of IL section, who has been

recently transferred in July 2007. He has other trained officers working under him, who according to him have been guiding him in his work. Case # ILD/ATR-1648/07 and ILD/ATR-3877/07 were checked from the month of June and Dec 2007. For the first one all the record could be seen, for the second case the report was still in the preparation stage.

Test reports are prepared by the technical managers, who would identify both accredited and non-accredited tests on the report.

NC no	--				
Compliance		X	Not in compliance		

4.5 Subcontracting

Not covered during this assessment.

NC no	--				
Compliance		-	Not in compliance	-	

4.6 Purchase of services and supplies

Not covered during this assessment.

NC no	--				
Compliance		-	Not in compliance	-	

4.7 Service to the customer

The laboratory has a procedure for seeking feedback, both positive and negative, from its customers. The feedback is analyzed and is represented statistically. In the past one year 52 feed backs have received but they were mostly positive.

According to the procedure, ILO keep record of customers feed back and surveys on KL/ILO/FF/407/02. The ILO logs the feed back form and send it to QMR. QMR presents the feed back report in MRC Meeting.

NC no	--				
Compliance		X	Not in compliance		

4.8 Complaints

The laboratory has a policy and procedure for the resolution of complaints received from clients or other parties. A total of five complaints have been received from customers and all are related to late delivery of test reports. All corrective actions had a root cause of insufficient human resource. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

regular weekly checks/controls were made on the micropipette. The intermediate checks were made only in one range and did not cover the whole under use. Control charts were available for Atomic Absorption. The test report was having an incorrect NA's logo. No statement was given on uncertainty measurement. The report was not delivered on time but on 03-12-07. Observation: The staff needs to understand the requirements of ISO 17025.

See also clause 5.10, NA Doc 14 and Technical assessor reports, **minor non-conformities** included.

NC no	--				
Compliance			Not in compliance	X	

4.14 Internal audits

According to the quality manager the laboratories have 21 internal auditors, out of which three have participated in the assessor course in ISO 17025. The quality manager has attended a one-day internal auditor training in September 2003. In reality most of the internal auditors did not conduct satisfactory internal audits as per their reports.

The standard requires that the internal audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited, whereas in these laboratories the quality manager has been auditing parts of his own work such as quality system, document control, document change, internal audits and management review etc.

An essential non conformity is given against this clause. The lab needs to train its internal auditors and conduct audit by auditors which are independent of the activity which is being audited. This was an essential in the initial assessment.

NC no	1				
Compliance			Not in compliance	X	

4.15 Management review

Two management review meetings have been conducted on 24th April and 17th Nov 2007. The meetings were generally ok. Agenda were circulated and minutes had satisfactory details, but the management shall ensure that where possible, the actions are carried out within an appropriate and agreed timescale.

NC no	--				
Compliance		X	Not in compliance		

regular weekly checks/controls were made on the micropipette. The intermediate checks were made only in one range and did not cover the whole under use. Control charts were available for Atomic Absorption. The test report was having an incorrect NA's logo. No statement was given on uncertainty measurement. The report was not delivered on time but on 03-12-07. Observation: The staff needs to understand the requirements of ISO 17025.

See also Technical assessor reports, **minor non-conformities** included.

NC no	--				
Compliance		Not in compliance	X		

4.14 Internal audits

According to the quality manager the laboratories have 21 internal auditors, out of which three have participated in the assessor course in ISO 17025. The quality manager has attended a one-day internal auditor training in September 2003. In reality most of the internal auditors did not conduct satisfactory internal audits as per their reports.

The standard requires that the internal audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited, whereas in these laboratories the quality manager has been auditing parts of his own work such as quality system, document control, document change, internal audits and management review etc.

An essential non conformity is given against this clause. The lab needs to train its internal auditors and conduct audit by auditors which are independent of the activity which is being audited. This was an essential in the initial assessment.

NC no	1				
Compliance		Not in compliance	X		

4.15 Management review

Two management review meetings have been conducted on 24th April and 17th Nov 2007. The meetings were generally ok. Agenda were circulated and minutes had satisfactory details, but the management shall ensure that where possible, the actions are carried out within an appropriate and agreed timescale.

NC no	--				
Compliance	X	Not in compliance			

ISO 17025 – CHAPTER 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

The standard requires that the management of the laboratory has to formulate the goals with respect to the education, training and skills of the laboratory personnel, which could not be seen during the assessment. .

The standard requires that the laboratory shall maintain current job descriptions for managerial, technical and key support personnel, whereas during the assessment it was observed that there was no job description for deputy quality manager, Dr Razia Sultana. Training record on form number KL/QMR/FF/502/01 and job description on form KL/QMR/FF/502/03 both with rev. # 01, issue # 03 and with issue date 31. 01.07 was checked for Ameera Zahid and Hina Asghar.

Please see Technical assessor reports, **essential non-conformities** included..

NC no	**02 & 03**				
Compliance			Not in compliance	X	

5.3 Premises and environment

Not assessed by lead assessor during this assessment.
Please see Technical assessor reports.

NC no	--				
Compliance		X	Not in compliance		

5.4 Methods for testing, calibration and validation

There was a non-conformity in the initial assessment too.
See Technical assessor reports, **essential and minor non-conformities** included.

NC no	**3 & 6**				
Compliance			Not in compliance	X	

5.5 Equipment

Essential non conformity is given against this clause by the TA.
There was a non-conformity in this area in the initial assessment.
See Technical assessor reports, **essential and minor non-conformities** included.

NC no	**7**				
Compliance			Not in compliance	X	

5.6 Measurement traceability

Essential non conformity is given against this clause by the TA.
There was a non-conformity in this area in the initial assessment too.
See Technical assessor reports **essential non-conformities** included.

NC no	**7 & 10**				
Compliance			Not in compliance	X	

5.7 Sampling

Not applicable.

NC no	--				
Compliance		-	Not in compliance	-	

5.8 Handling of test and calibration objects

See Technical assessor reports

NC no	--				
Compliance		X	Not in compliance	-	

5.9 Assuring the quality of results from testing and calibration

See Technical assessor reports, **essential and minor non-conformities** included.

NC no	**4, 5 & 9**				
Compliance			Not in compliance	X	

5.10 Reporting results

There are four types of test reports, according to the quality manager: one with PNAC's logo, another with NA's logo, third carrying both logos and the fourth types with the logo of accreditation body.

NA's logo on the test report is used in an incorrect manner. An essential non-conformity is given. Please see under NA Dok 14.

See also Technical assessor reports for details.

NC no	**8**				
Compliance			Not in compliance	X	

4 Other requirements

NA-Doc 14 Conditions for the use of NA's logo in accreditation marks and for making reference to accreditation

The lab has a system in place, but the logo has to be according to the specification mentioned in NA-Doc-14, which is currently not as per requirements.
See also Technical assessor reports for details.

NC no	8				
Compliance		Not in compliance	X		

NA-Doc 25/31 Accreditation conditions

The laboratory generally complies with the accreditation conditions as specified in Dok 25/31.

NC no	--				
Compliance	X	Not in compliance			

NA-Doc 26 a Requirements for calibration and control of balances for accredited test laboratories

Please see the TA's reports, **essential non-conformities** included..

NC no	**7 & 10**				
Compliance		Not in compliance	X		

NA-Dok 26 b Requirements for calibration and control of thermometers for accredited test laboratories

Please see the TA's reports, **essential non-conformities** included.

NC no	**7 & 10**				
Compliance		Not in compliance	X		

NA-Doc 50 Flexible accreditation (if relevant)

Not applicable

NC no	--				
Compliance	-	Not in compliance	-		

NA-Dok 52 **Calculation of measurement uncertainty in calibration**
Not applicable

NC no	--				
Compliance	-	Not in compliance	-		

5 Implementation of corrective actions for non-compliances noted during the previous assessment

The corrective actions from the previous assessment were followed up, the details of which can be seen in the TA's report.

6 Recommendation regarding accreditation

If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

When corrective actions have been submitted by PCSIR, NA should evaluate the need for an extraordinary assessment visit to confirm that the corrective actions reported have been implemented in the chemistry laboratory.

7 Recommendation regarding suspension

Not Applicable

8 Recommendation regarding scope of accreditation

There are no changes in the scope of accreditation.

The requested extension of the scope with reference to the methods listed in NA-S5 submitted to NA before the initial visit will not be recommended, until the existing system is working smoothly. Chemistry test methods that have not been included in the Accreditation document have to be applied for, in the next assessment and have to be assessed again.

9 Recommendation regarding administrative/ geographical units

Not Applicable

10 Any changes since the previous assessment

Please see from TA's reports.

11 Complaints

The organisation has the right to complaint against actual errors in the report. Such complaint shall be forwarded to Norwegian Accreditation within 3 weeks after the report has been sent from NA.

The undersigned confirms that this report is not violating NA's policies and practices.

Karachi, 19.12.2007

Ismat Gul Khattak
Lead Assessor

Place/ date: 09.01.08

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment
Non-compliances;

Number of very serious non-compliances	01
Number of essential non-compliances	09
Number of minor non-compliances	12

Summary report
Accreditation document
Reports from technical assessors, laboratories

Name of the organisation: PCSIR, Karachi

Application no.: **Accreditation no:** TEST 212 218

Type of visit: Surveillance visit

Leader of the organisation: Mrs Askari Begum (Acting DG)

Lead assessor: Ismat Gul Khattak

Number of non-conformity reports attached:

Very serious:	1
Essential:	9

Summary:
The surveillance visit was conducted for the chemistry and the microbiology labs. Mrs Askari Begum was the Acting DG since the DG has gone abroad. The current scope of accreditation is within microbiology, chemical, leather and textile testing.

The laboratory has established a quality system, which covers the elements in ISO 17025:2005. The quality system is quite complicated and has a potential to be simplified. The quality system has been in place since 2004, as the laboratory is also accredited by PNAC. During assessment the following shortcomings were identified:

- Document control
- Internal audits and training of internal auditors
- Uncertainty measurement
- Proficiency testing
- Control charts
- Test reports and use of NA's logo
- Calibration and traceability

The laboratory has competent, well-educated and trained personnel, and they are cooperating well together. The technical staff demonstrated satisfactory competence in the scope the laboratory is accredited for. The facilities are fit for purpose and the workflow is well organised.

Minor non-conformities:

1. Job description of DQMR Ms Razia Sultana was not available in the system.
2. Microbiology: The working steps recorded in the bench record were not properly dated and signed.
3. Microbiology: The monthly use of positive and negative reference strains is not documented in the media control programme.
4. Microbiology: The laboratory claims to have a tolerance limit of ±5% for weighing samples. The description was not found in the laboratory's quality system.

5. Microbiology: Calibration certificate for Pipette No 371demonstrated that the pipette did not meet the tolerance limit given by the laboratory, 100 µl ± 2 µl. Information in the calibration certificate was 98 µl ± 2 µl (U_e, k=2).
6. Microbiology: the working instruction for mould and yeasts (KL/FMRRC/WI/003) is inconsistent regarding plating and calculation.
7. Chemistry: The methods do not give any information of internal quality control or control material.
8. Chemistry: Method 014 Fat in cereal food does not state the quality of the solvents.
9. Chemistry: Cross references between procedures are often lacking; Example - method 095 Sorbic acid do not refer to the UV operating procedure.
10. Chemistry: Date of analyses was not recorded for Ochratoxin and Aflatoxin, and there was no documentation of batch number of the ochratoxin and aflatoxin standards. Same was observed during vertical audits in environmental chemistry.
11. Chemistry Pharma: Technical registration (records) in connection to the Sudan red method was insufficient.
12. Chemistry Environmental: The thermometer on the fridge was not calibrated.

Methods accepted during this visit

The requested extension of the scope with reference to the methods listed in NA-S5 submitted to NA before the initial visit will not be recommended, until the existing system is working smoothly. Chemistry test methods that have not been included in the Accreditation document have to be applied for, in the next assessment and have to be assessed again.

Recommendation concerning accreditation:

When corrective actions for all NCs, including minor NCs, have been submitted by PCSIR, NA should evaluate the need for an extraordinary assessment visit to confirm that the corrective actions reported have been implemented in the laboratory.

Time limit for presentation of corrective actions: 07.02.2008

19.12.07		Seen by:	
Date	Signature lead assessor		Signature (organisations repr.)

ACTIVITY:	Surveillance visit	Report no.:	1
ORGANISATION:	PCSIR Karachi		
Department:			
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Ismat Gul Khattak**

DESCRIPTION:

The internal audit is not in compliance with the requirements of the standard. The internal auditors are not independent of the activity area such as QMR auditing document control, quality system, internal audit and management reviews. The internal auditors needs appropriate training to improve the auditing system.

Essential NC # 6 from the previous assessment.

19 Dec 07 _____ _____

Date | Signature assessor | Signature (Org. representative)

Ref. organisation's doc:

NA Dok 25/31

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.14
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	x

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____

date | signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date | signature (lead assessor)

ACTIVITY:	**Surveillance visit**	Report no.:	2
ORGANISATION:	PCSIR Laboratories complex, Karachi		
Department:			
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Ismat Gul Khattak**

DESCRIPTION:
Copies of different documents found in the food lab were not under document control. There were documents in Quality Managers office too with problems in issue dates. One document had two different dates but the same issue, revision number such as KL/QMR/FF/502/06 Rev 05, Issue 03.

See also NC 3 from January 2007

.

19.12.07 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.3
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

☐ It is not necessary to attach documentation

Time limit for correction:

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	**Surveillance visit**	Report no.:	3
ORGANISATION:	PCSIR Laboratories complex, Karachi		
Department:	All assessed chem. labs		
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Erik Figenschou**

DESCRIPTION:
PCSIR has no documentation that confirms that the estimated uncertainty is correct.

See also NC 11 from January 2007

19.12.07 E. Figenschou Ishrat Begum
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.4.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:	
Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	**Surveillance visit**	Report no.:	4
ORGANISATION:	PCSIR Laboratories complex, Karachi		
Department:	All assessed chem. labs		
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Erik Figenschou**

DESCRIPTION:

PCSIR's PT system in chemistry is not fully implemented. For instance:

- There is no comparison with own uncertainty
- No results (only Z-score) are reported on the summary form
- No statistical analyses is documented
- For the pH analysis another matrix than cereal was used in the PT

See also NC 14 from January 2007

19.12.07 E. Figenschou Asrari Begum
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	**Surveillance visit**	Report no.:	5
ORGANISATION:	PCSIR Laboratories complex, Karachi		
Department:	Food Chemistry lab + Pharma Chem Lab + Environment Chem		
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Erik Figenschou**

DESCRIPTION:
PCSIRs Control chart's system in food chemistry lab is not fully implemented. The templates are prepared, but not in use. On the templates the action is based on fixt number not on statistical calculations.

See also NC No 14 from January 2007

19.12.07 E. Figenschou Askari Begum
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	X
Essential	

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

☐ It is not necessary to attach documentation

Time limit for correction:

_____ _____
date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____
date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	6
ORGANISATION:	PCSIR Karachi		
Department:	Microbiology		
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Anne Grændsen**

DESCRIPTION:

The laboratory has not identified and weighted sources of measurement uncertainty for any of the methods in microbiology.

19 Dec 07 _____ _____

Date Signature assessor Signature (Org. representative)

Ref. organisation's doc:

–

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.5 and 5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Dok 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____

date signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	7
ORGANISATION:	PCSIR Karachi		
Department:	Microbiology		
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Anne Grændsen**

DESCRIPTION:

The laboratory has shortcomings in the temperature area:

- The temperature registration device in the autoclave used for media production is not calibrated.
- The temperature registration device in the incubator used or yeasts and moulds is not fit for purpose. Accuracy in reading is not satisfactory.
- In general the error given in the calibration certificates are taken into account when reading "thermometers". However the information on expanded measurement uncertainty is not used.

19 Dec 07 _____ _____

Date | Signature assessor | Signature (Org. representative)

Ref. organisation's doc:

–

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.5 and 5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Dok 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____

date | signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date | signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	8
ORGANISATION:	PCSIR Karachi		
Department:			
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Anne Grændsen**

DESCRIPTION:

The test reports has shortcomings:

- The accreditation mark is not correctly used:
  - "TEST shall be given in capital letters
  - Accreditation number shall be placed directly below the logo (mid position)
  - ISO 17025 shall not be written together with the accreditation mark
- A statement like "Information on measurement uncertainty will be given on request" or "Measurement uncertainty is not calculated for microbiological analysis is missing".

19 Dec 07 _____ _____

Date | Signature assessor | Signature (Org. representative)

Ref. organisation's doc:

–

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.10
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Dok 14

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____

date | signature (org. representative)

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation

☐ The non-conformity is closed based on recommendation from the technical assessor

☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date | signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	9
ORGANISATION:	PCSIR Karachi		
Department:			
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Anne Grændsen**

DESCRIPTION:

The procedure for handling and following up PT-results is deficient.

- Description of how to perform of trend analyses is missing.
- Trend diagrams for water analysis have been established. However the diagrams have not been properly updated.

19 Dec 07 _____ _____

Date | Signature assessor | Signature (Org. representative)

Ref. organisation's doc:

Technical manual microbiology paragraph 5.9

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Dok 14

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

Actions are documented in the amendment no: _____

_____ _____

date | signature (org. representative)

☐ It is not necessary to attach documentation

Time limit for correction:

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date | signature (lead assessor)

ACTIVITY:	Surveillance visit	Report no.:	10
ORGANISATION:	PCSIR Karachi		
Department:			
Accr./Appl. no.:	TEST 218		
Lead. ass.	Ismat Gul Khattak	**Rep. ass.**	**Anne Grændsen**

DESCRIPTION

Balances are not calibrated by an organization which is fulfilling the requirements on measurement traceability:

- The calibration laboratory does not have an unbroken chain of traceability
- The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed.

For the temperature area the traceability is acceptable, but bullet point no 2 above also applies for the temperature area.

(Reference: Information letter sent to the laboratory 28 Sep 2007.)

19 Dec 07 _____ _____

Date | Signature assessor | Signature (Org. representative)

Ref. organisation's doc:

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	*5.6*
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	NA Doc 26a NA Doc 26b

Non-conformity category:

Very serious	
Essential	X

IMPLEMENTED ACTIONS:

☐ It is not necessary to attach documentation

Time limit for correction:

Actions are documented in the amendment no: _____

_____ _____

date | *signature (org. representative)*

REASON FOR CLOSING: (To be filled in by the lead assessor)

☐ The non-conformity is closed based on satisfactory documentation from the organisation
☐ The non-conformity is closed based on recommendation from the technical assessor
☐ Implementation of the corrective actions will be followed up at the next visit

The non-conformity is closed: _____ _____

date | signature (lead assessor)

Name of the organisation:	**PCSIR Laboratories complex, Karachi**
Assessed locations:	**All chemical laboratories**

Accr. no. : TEST 218 Appl. no.:	Date of assessment: 18. – 19. December 2007

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Erik Figenschou** Technical area: **P12 Chemistry**

2. General information

1. time visit [ ]	Extraordinary visit [ ]	Renewal [ ]
Surveillance [X]	Extension of scope [ ]	Complete assessment [ ]

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	[ ]
Document review	[ ]

Technical assessment NS EN ISO/IEC 17025:	[X]
Technical expert NS-EN ISO/IEC 17025:	[ ]
Technical assessment NS EN ISO/IEC 15189:	[ ]
Technical expert NS-EN ISO/IEC 15189:	[ ]

Interviews

Name	**Function / technical area**
Ms. Askari Begum	Technical manager Chemical FOOD
Zuzzer Ali Shamsuddin	Technical deputy - Chemical FOOD; Mycotoxins Lab
Dr. Khalid Jamil	Technical deputy – Chemical FOOD ;Food technology
Dr. Arfa Yasmin	Technical manager - Chemical Pharma
Dr. Alia Bano Mnushi	Technical manager - Chemical-Environment

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant (valid for flexible scope) :
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
The requested extension of the scope with reference to the methods listed in NA-S5 submitted to NA before the initial visit will not be recommended, until the existing system is working smoothly. *Chemistry test methods that have not been included in* the Accreditation document have to be applied for, in the next assessment and have to be assessed again.

4. Changes since the last visit (if any):

No essential changes

5. Extent of assessment

4	**Management requirements**
4.1	**Organization**
	Description/evaluation: There are three chemical laboratories: Chemical Food is divided in three different sections: Food technology, Mycotoxine and Microbiologi. Ms. Askari Begum is the technical manager (TM) of the laboratory. A technical deputy (TD) is the head of each section. Chemical –Environment with Dr. Alia Bano Mnushi as technical manager. Chemical Pharma with Dr. Arfa Yasmin as technical manager. The scientific staff reports to TD or TM and the supporting staff reports to the scientific staff. Responsibility and authority is described in the job descriptions. The technical management works satisfactorily practice. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: The quality system consists of a quality manual, one technical manual for each of the laboratories in addition to method descriptions and procedures. Method descriptions and other documents are available for the staff. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: The documents studied in all the laboratories were all valid (correct version) Copies of the working instructions were found on the walls in food technology laboratory. The documents were valid, but there was **still no traceability** to the original document. **Se also NC No 2 (and NC No 3 from January 2007).** *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: Not assessed during this surveillance visit. *Non-conformity no* --

4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: Not assessed during this surveillance visit. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: Not assessed during this surveillance visit. *Non-conformity no* --
4.9/4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: Not specifically assessed during this surveillance visit. However, during the assessment there was not found any NC's which should been recorded, *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: Raw data are registered in different records. The registrations were satisfactorily performed for the assessed methods in the food laboratory. A vertical audit was performed in the Chemical-Pharma Lab of Sudan Red in spices. All recorded information was found, but technical registrations in connection to the Sudan red method was insufficient (**Minor NC**) A vertical audit was also performed in the Chemical food Lab of ochratoxin and Aflatoin. The registrations of raw, date, calculations were satisfactory. Lead assessor performed a vertical audit in the Chemical-Environment lab and observed a **minor NC:** The thermometer on the fridge was not calibrated. **Remark:** The different laboratories have different ways of recording technical data. *Non-conformity no* --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: Practical demonstrations and discussions with the staff and management showed the personal were competent perform their different tasks. In general the technical staff has long experience and has been working at PCSIR for many years. The interviews demonstrated that they were well qualified to perform analysis within the scope of accreditation. **Remark:** With a very few exceptions, the competence in understanding uncertainty is lacking. The situation is similar regarding evaluations of results from external and internal quality controls. The laboratory is vulnerable in this area.

	Non-conformity no
5.2.1	**Training**
	Description/evaluation: Not assessed during this surveillance visit.
5.2.2	**Maintenance of competence**
	Description/evaluation: In general the personnel have sufficient testing experience to maintain their competence in testing. **Remark:** The analyses of Sudan Red performed in Chemical Pharma and of Ochratoxin in Chmical Food have only given negative test results (no Sudan red or Ocretoxin found in the samples). Regarding maintenance of the competence in evaluating the test results from samples where the compounds are present in a sample this might create a problem in a longer time frame. The lab does not use a control sample. **See also NC 5.**
5.2.4	**Job descriptions**
	Description/evaluation: The personal have updated CVs. The CVs examined during the visit have sufficient information of formal education, training and employment history.
5.3	**Accommodation and environmental conditions**
	Description/evaluation: The accommodations are suitable for the activities in the laboratories. The laboratories were orderly and clean. *Non-conformity no*
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See the specific clauses below *Non-conformity no* --
5.4.1	**General**
	Summary/Conclusion: The work instructions for the methods are better than in January, but there are still lacks in the instructions. For instance this **minor NCs**: • All labs: The methods do not give any information of internal quality control or control material. • Food: Method KL/FMRRC/WI/014 Fat in cereal food does not state the quality of the solvents. • Food: Cross references between procedures are often lacking; Example - method KL/FMRRC/WI/095 Sorbic acid do not refer to the UV operating procedure • Food: Date of analyses was not recorded for Ochratoxin and Aflatoxin, and

	there was no documentation of batch number of the ochratoxin and aflatoxin. Method demonstration where performed in the Chemical food lab and the Chemical Pharma lab. During the demonstrations the staff showed that they are competent to perform the procedure. In the Chemical-Environment the practical activities was not assessed this time. The methods were discussed with the management.
5.4.2	**Selection of methods**
	Description/evaluation: Not assessed during this surveillance visit
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: The laboratory does only use standard methods.
5.4.5	**Validation of methods**
	Description/evaluation: Since last assessment the laboratory had revised the procedures for validation and verification. The description is now sufficient, and a discussion with the technical management (for all the laboratories) confirmed that they understand validation. Since there are no new methods, the practice of validation is not assessed. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: The laboratory has a procedure for estimation of uncertainty. The technical assessor did not receive detailed results from the PTs prior to the assessment. Consequently it was no possibility to assess the estimation of the uncertainty. In connection to the corrective actions, the laboratory will evaluate the uncertainty of the different parameters (and if correct them if needed) before the results are submitted to NA. *Non-conformity no* **3**
5.4.7	**Control of data**
	Description/evaluation: Not assessed during this surveillance visit. *Non-conformity no* --

5.5	**Equipment**
	Description/evaluation: All instruments and equipments examined in all three labs have now log books (records). They where updated and periodically maintains was recorded. The UV/VIS instruments in Chemical food and Chemical Pharma were satisfactory maintained and "calibrated". **Remark:** Date and signature was missing in Chemical Pharma when the UV/VIS instrument was "calibrated". *Non-conformity no* --
5.6	**Measurement traceability**
	Summary/conclusion: Chemical traceability is established by using CRM or by participation in PT programs. This was not studied in practise during this assessment. For traceability of temperature and weight see the reports from the technical assessor in microbiology and the lead assessor. *Non-conformity no* --
5.6.1	**General**
	Description/evaluation: Se 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: Se 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: Se 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Samples and standards used in connection with the demonstrations were labelled satisfactorily. The chemicals and reagent were properly labelled. *Non-conformity no* --

5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: During the assessment in 2007 a NC was identified: *The methods in Chemical Pharma and Chemical Food, are not evaluated by using control charts. The control charts used in the Environmental department does not include the work up procedure.* The chemical food laboratory sent NA templates for plotting the control chart and the NC was closed. An inspection of the control charts showed that they still were empty and not in use. In Chemical Pharma no control chart system existed. Chemical-Environment could not show the technical assessor any control chart that included the work up procedure. **See NC No 5 which was classified as Very serious.** The test results from PT's which was submitted to NA prior to the assessment was lacing information about the assigned value, the laboratory result and comparison with the uncertainty of the laboratory. During the assessment the laboratory could not show that they had performed any trend analyses. **Se NC No 4.** *Non-conformity no* **4, 5**
5.10	**Reporting the results**
	Description/evaluation: Not assessed in detail. See the report from the technical assessor in microbiology. *Non-conformity no* --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope (if relevant)
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: See report from the technical assessor in microbiology. The logo was used in the same way in all laboratories. *Non-conformity no* --

No 25/31	**Accreditation conditions**
	Description/evaluation: Not assessed *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: Some of the balances in Chemical food and Chemical Pharma were assessed. These balances were controlled with control weight daily. The measurement was recorded and they made a graphic control chart. *Non-conformity no* --
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: Some of the fridges in Chemical food were evaluated. These were controlled daily, and the results were recorded. *Non-conformity no* --
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant. *Non-conformity no* --

6. Demonstrations	Method identity/parameter/ object:	Demonstrated by/discussed with:
(Specify method and person. Indicate if method has been examined theoretically/ discussed	KL/FMRRC/WI/095 Sorbic acid	Dr. Khalid Jamil
	KL/FMRRC/WI//014 Fat	Misbah Klodum
	KL/FMRRC/WI/022 Ochratoxins "A"	Aftab Ahemfd
	KL/PRC/WI/022 Sudan I, II, III and IV	Dr Amir
7. Follow up non-conformities from the last visit:	NC No. 1 and 14 were not implemented. New NC's was given the lab.	
8. Notes/summary/ conclusion	No further comments	

9. Next visit (Are there any subjects that need to be strictly evaluated during the next visit, or if specific persons should be present	• Method description • PT evaluation • Evaluation and us of control chard • Uncertainty • Technical records

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

date 9/1-08 E Fjelsrschen.
technical assessor/expert

09.01.08
date Roald R. Nil
~~lead assessor~~ Technical Director

Name of the organisation:	**PCSIR, Karachi**
Assessed locations:	**Microbiology (P16)**

Accr. no. : **TEST 218** Appl. no.:	Date of assessment: 18 Dec 07

(The complete report may be repeated. Extract from the report can only be repeated when this is accepted in writing by Norwegian Accreditation)

1. Reporting assessor/expert

Name: **Anne Grændsen** Technical area: **Microbiology (P16)**

2. General information

1. time visit		Extraordinary visit		Renewal	
Surveillance	X	Extension of scope		Complete assessment	

Specification of surveillance activities not mentioned above:

Surveillance with assessment of selected elements	
Document review	
Technical assessment NS EN ISO/IEC 17025:2005	X
Technical expert NS-EN ISO/IEC 17025:	
Technical assessment NS EN ISO/IEC 15189:	
Technical expert NS-EN ISO/IEC 15189:	

Interviews

Name	**Function / technical area**
Mrs Seema Ismat	Technical manager
Mr Korish Husnain Saher	Deputy technical manager
Mrs Anila Siddique	Scientific officer
Miss Sabeen Survary	Research assistant
Mr Mohammad Nasim Khan	Scientific officer

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
If the laboratory is submitting satisfactory corrective actions to NA within the agreed date, accreditation scope is recommended maintained.

3.2 Recommendation regarding change of the responsible for validation, when relevant:
Not relevant

3.3 Recommendation regarding changes/extension of accreditation scope:
Not relevant

4. Changes since the last visit (if any):

Personnel:

- Miss Nadia Gul has been employed for approximately half a year. She left the PCSIR to continue her education.
- Mrs Anila Siddique has resumed her position after three month of maternity leave.

There are no major changes in equipment and facilities.

5. Extent of assessment

	Management requirements
4.1	**Organization**
	Description/evaluation: The technical management team consists of a technical manager and a deputy technical manager. During the assessment the management team demonstrated satisfactory competence and experience within microbiology. The management team is well qualified and trained for duties and responsibilities acquired in the present positions. All personnel in the laboratory are now listed properly in the quality system. *Non-conformity no* --
4.2	**Quality system**
	Description/evaluation: There are no changes in availability of quality manual, technical manual and different forms for daily recording in the laboratory. All personnel have access to the documents needed. *Non-conformity no* --
4.3	**Document control**
	Description/evaluation: In general the document control is well implemented in the microbiology laboratory. Traceability from working instructions to supplementary instructions is improved after the initial visit. *Non-conformity no* --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: All enquiries are handled by the IL section. The ILO obtains a properly signed

	request letter from the customers and ensures that the request letter clearly describes his requirements. Requests, tenders and contracts were examined in connection to a vertical audit conducted on case file no 3751/07. The case file in the IL section contained the case sheet and the request letter from the customer. See also report from lead assessor.
	Non-conformity no --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory is not subcontracting analysis within the accreditation scope. *Non-conformity no* --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has established satisfactory requirements for purchasing. As observed during the initial assessment this procedure works is well in the laboratory. Quality requirements are given priority. Chemicals and dehydrated media observed in the laboratory are of recognised quality and are satisfactorily marked with recipient date and opening date. Likewise media and solutions made in the laboratory were satisfactorily labelled. *Non-conformity no* --
4.9-4.11	**Control of nonconforming testing and/or calibration work/corrective actions**
	Description/evaluation: PCSIR has described handling of non-conformities and corrective actions in an appropriate way the quality manual. The laboratory has implemented the NC system. From April 2007 to December 2007 the laboratory has raised 12 non-conformity reports. After the initial assessment handling of non-conformity work observed in connection to PT-participation has improved and is now properly recorded. *Non-conformity no* --
4.13	**Control of records**
	Description/evaluation: As during the initial assessment all registrations are satisfactorily recorded in bench records and different forms. Except for the minor non-conformities described below, handling of raw data is taken care of in a good manner. All files asked for were easily found. All registrations are principally done by permanent pens and are easily readable. However, see **remark** given in clause 5.2.1. During the method demonstrations it was observed that the individual working steps recorded in the bench record were not properly dated and signed (**minor**

	non-conformity). *Only the starting date and the date of the final reading were recorded.* A vertical audit was carried out on samples labelled with case number 3751/07. In addition to the minor nonconformity described above it was revealed that the use of monthly use of positive and negative reference strains is not documented in the media control programme **(minor non-cionformity).** The autoclave used for media preparation is not equipped with calibrated thermometer or thermocouples (See **essential NC No 7** described in clause 5.6 and NA Doc 26b).
	Non-conformity no --
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The laboratory has qualified and experienced personnel. Regarding the accreditation scope, the laboratory is in the position of necessary competence. *Non-conformity no* --
5.2.1	**Training**
	Description/evaluation: CV's of the management team were reviewed and found updated. The deputy technical manager has in 2007 been provided external training on international standards and regulations for the food industry based on HACCP. The training record for Miss Nadia Gul was reviewed. All documents described in the quality system were found in her personal file. The documents were properly dated and signed. Authorisation for water testing was given by the technical manager in late winter 2007. Pencil writing was observed in the record for inter laboratory testing. However, original raw data was properly written with permanent pens. **(Remark).** The training record for Mrs Anila Siddique was also reviewed. Her maternity leave lasted for three month in 2007. The requirement in the quality system is obligatory retraining for personnel that goes on leave for more than four month. Retraining and inter laboratory testing has been provided Mrs Siddique even if this is not required. Demonstrations of two of the methods in accreditation scope by two different analysts proved that proper training has been given. Principally the laboratory performs the methods according to working instructions and the standard methods.
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is considered to be satisfactory. Methods in the accreditation scope are routinely analysed in the laboratory. In addition the personnel are performing quality control samples (PT samples etc.)

	and intra laboratory tests on regularly basis.
5.2.4	**Job descriptions**
	Description/evaluation: Job descriptions for Miss Nadia Gul and Mrs Anila Siddique were reviewed. The descriptions were stored in their personal files and they were properly dated and signed.
5.3	**Accommodation and environmental conditions**
	Description/evaluation: The facilities are fitted for the activity performed in the laboratories. The laboratory has proper routines for housekeeping. Procedures for handling of disposals from the testing laboratory are acceptable. Access to the laboratory is restricted to authorized personnel. Designated laboratory coats and foot ware has to be worn in the laboratory. The work flow is well planned and organised. Measures have been taken to avoid contaminating samples and testing. Cracks in the floor observed during the initial visit in the testing room used for cultivation of class 2 microbes in food are repaired. The laboratory monitors and records following parameters. • Bacteriological sterility by air testing (exposure plates) on monthly basis • Room temperature and humidity on daily basis • Bacteriological and chemical testing of the distilled water used for media production The records for air testing were inspected. The described routines are followed. *Non-conformity no* --
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: See specific clauses below *Non-conformity no* --
5.4.1	**General**
	Summary/Conclusion: The laboratory is using recognised standard methods (BAM and APHA) which are satisfactorily validated. The methods used are appropriate and fit for purpose. Detailed and well arranged work instructions for all methods are established. The working instruction for mould and yeasts (KL/FMRRC/WI/003) is inconsistent regarding the description of plating (number of plates) and calculation **(Minor non-conformity).** The practical demonstrations revealed that the laboratory claims to have a tolerance limit of ±5% for weighing samples. The description was neither found in any work instruction nor elsewhere in the quality system **(Minor non-**

	conformity).
5.4.2	**Selection of methods**
	Description/evaluation: See clause 5.4.1.
5.4.3/ 5.4.4	**Laboratory-developed methods/ Non-standard methods**
	Description/evaluation: Not relevant. The laboratory is not using methods developed in house or any other non-standard methods. Neither has the laboratory plans to use such methods.
5.4.5	**Validation of methods**
	Description/evaluation: Currently there is no need for validation of in-house methods or non-standard methods in the laboratory. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: **Essential non-conformity:** The laboratory has not identified and weighted sources of measurement uncertainty for any of the methods in microbiology. (*Wrong reference to paragraphs in ISO 17025 is given in the NC form No 6*) *Non-conformity no* **6**
5.4.7	**Control of data**
	Description/evaluation: The laboratory does not use LIMS. Calculations in connection with the analytical process are manually operations. After the initial assessment, spreadsheets are established for trend diagrams in water analysis. Proper locking of cells was not investigated since the spreadsheets were not properly implemented yet. Locking of cells containing essential formula will be followed up during next visit. *Non-conformity no* --
5.5	**Equipment**
	Description/ valuation: The laboratory has no new instruments received after the initial assessment. All equipments are satisfactorily labelled with unique identity number. Working instructions are established for critical instruments. In general the maintenance is satisfactorily. The instruments are appropriate monitored. Control results are recorded. The following instrument files were reviewed: • Incubators

	• Thermometers • Balances • pH-meter • Autoclaves • Micro pipettes and glass pipettes **Minor non-conformity:** Calibration certificate for Pipette No 371demonstrated that the pipette did not meet the tolerance limit given by the laboratory, 100 µl ± 2 µl. Information in the calibration certificate was 98 µl ± 2 µl (U_e, k=2). See **essential non-conformity** for temperature devices described in clause 5.6.
	Non-conformity no **7**
5.6	**Measurement traceability**
	Summary/conclusion: Traceability for microbiological methods is established by using reference cultures traceable to international culture collections (ATCC). The cultures are purchased from Oxoid as 3rd generation cultures. The stock cultures are kept in a freezer outside the microbiology facilities. To get access to the freezer personnel must have permission/key from the technical manager. Calibrations of thermometers, equipment fitted out with digital thermometers, balances, ph-meter etc. are performed by the PCSIR's calibration laboratory which is accredited by PNAC. **Essential non-conformities:** The laboratory has still shortcomings in the temperature area: • The temperature registration device in the autoclave used for media production is not calibrated. • The temperature registration device in the incubator used or yeasts and moulds is not fit for purpose. Accuracy in reading is not satisfactorily. In general the error given in the calibration certificates are taken into account when reading "thermometers". However the information on expanded measurement uncertainty is not used. Balances are not calibrated by an organization which is fulfilling the requirements on measurement traceability: • The calibration laboratory does not have an unbroken chain of traceability • The calibration laboratory is not accredited by a MLA signatory accreditation body. Neither has the BIPM MRA been signed For the temperature area the traceability is acceptable, but bullet point no 2 above also applies for the temperature area. (Reference: Information letter sent to the laboratory 28 Sep 2007.) *Non-conformity no* **7 and 10**

5.6.1	**General**
	Description/evaluation: See clause 5.6
5.6.2	**Specific requirements**
5.6.2.1	**Calibration**
	Description/evaluation: Not relevant
5.6.2.2	**Testing**
	Description/evaluation: See clause 5.5 and 5.6
5.6.3	**Reference standards and reference materials**
	Description/evaluation: See clause 5.6
5.7	**Sampling**
	Description/evaluation: Not relevant *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Sample information is submitted to the laboratory with the sample (case sheet and letter from client). On receipt the sample acquires a unique number. Before, under and after analysis the samples are stored in a refrigerator/freezer in the laboratory. The temperature during storage is monitored. The samples are disposed after approval the test results. The laboratory is recording in a proper manner how the samples are treated from receipt to disposal. *Non-conformity no* --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The laboratory is using reference cultures (positive and negative controls) in the monitoring program of culture media produced in-house. However, monthly use of the control cultures is not documented in the media control programme **(minor non-cionformity)**.The cultures are satisfactory traceable to international culture collections (ATCC) and are purchased from Oxoid as 3rd generation cultures. In addition the laboratory participates in PT-schemes for water and food testing provided by Norwegian Institute for Food and Environmental Analysis and FAPAS in UK. The PT-schemes cover the accreditation scope. All authorized personnel participate each time there is a trial. In total the authorized personnel are analysing external quality control samples 3-4 times a year. In general most of the PT- results meet the acceptance criteria given. For non-

	conformity work, NC's are raised. Two NC's are dealt with since the initial assessment. **Essential non-conformity:** The procedure for handling and following up PT-results is deficient. • Description of how to perform of trend analyses is missing. • Trend diagrams for water analysis have been established. However the diagrams have not been properly updated.
	Non-conformity no **9**
5.10	**Reporting the results**
	Description/evaluation: Test reports were examined during a visit in the IL section. The test reports still have shortcomings. **Essential non-conformity:** The accreditation mark is not correctly used: o "TEST shall be given in capital letters o Accreditation number shall be placed directly below the logo (mid position) o ISO 17025 shall not be written together with the accreditation mark A statement like "Information on measurement uncertainty will be given on request" or "Measurement uncertainty is not calculated for microbiological analysis is missing". *Non-conformity no* **8**
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant *Non-conformity no* --
	Flexible scope
	Description/evaluation: Not relevant
NA Dok	**Other requirement documents**
No. 51	**Flexible accreditation**
	Description/evaluation: Not relevant *Non-conformity no* --
No 14	**Rule for use of Norwegian Accreditation's (NA) logo and for references to NA's accreditation**
	Description/evaluation: See essential non-conformity described in clause 5.10 *Non-conformity no* **8**

No 25/31	**Accreditation conditions**
	Description/evaluation: Not assessed *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: Se clause 5.6 *Non-conformity no* --
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: See clause 5.6 *Non-conformity no* --
No 52	**Expression of the uncertainty of measurement in calibration (EA-4/02)**
	Description/evaluation: Not relevant *Non-conformity no* --

6. Demonstrations	**Method identity/parameter/ object:**	**Demonstrated by/discussed with:**
	KL/FMRRC/WI/003: Enumeration of moulds and yeasts	Miss Sabeen Survary
	KL/FMRRC/WI/004: Total coliforms, fecal coliforms and E. coli	Mrs Anila Siddique
7. Follow up non-conformities from the last visit:	Corrective actions for all non-conformities raised during the initial assessment are properly implemented.	
8. Notes/summary/ conclusion	No further comments	
9. Next visit	• PT-results and trend analysis • Locking of cells in spreadsheets • Identification of contributions to measurement uncertainty	

date 21/12 - 07 *Tone Grøntvedt*
Technical Assessor/expert

The undersigned states that the content in the report is not in conflict with NA's policy and practice.

date 09.01.08 *Roald R N L*
Technical Director