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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

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FINAL REPORT

UNIDO project XP/ETH/07/004 – "Ethiopia IP II: Food Safety System"- Laboratory Accreditation service

An on site initial assessment of Ethiopia Health and Nutrition Research Institute, Food Microbiology laboratory, Addis Ababa, Ethiopia was performed on the 13th and 14th of February 2008 by an assessor team from Norwegian Accreditation (NA) consisting of Dr. Roald K. Nilsen as lead assessor and Ms. Anne Grændsen as technical assessor. The assessment was performed in accordance with our contact with UNIDO and NA procedures. It consisted of document review of the management system, evaluation of competence and evaluation of implementation of the management system in the laboratory. When doing assessments and granting accreditations internationally NA follow the same procedure as for assessments and granting accreditations in Norway.

The documentation regarding the laboratory management system etc. should according to the contract be sent to NA four weeks before the assessment but it was sent only two weeks before the assessment. Because of this no feedback regarding the documents could be given to the laboratory before the onsite assessment. It was also stated in the UNIDO request for proposal that the laboratory had already participated in proficiency testing (PT) for the parameters in the scope for accreditation. During the assessment it was clear that the laboratory had not participated in any PTs.

The recommendation after the on-site initial assessment was given in the summary report as well as in lead assessor report. The recommendation was as follows: Accreditation is not recommended at present stage. A new initial assessment visit has to be conducted to be able to evaluate if the laboratory later on meets the requirements for accreditation.

Lead assessor report as well as technical assessor report was sent electronically to the laboratory (with copy to UNIDO) on the 25th of February 2008. At the closing meeting at the end of the initial assessment visit the laboratory was asked to correct the NCs raised within the agreed time limit (15th of May 2008) (also stated in the summary report and lead assessor report). Due to problems with the execution of the corrective actions documentation for the actions performed was delayed and sent from the laboratory to NA on the 18th of June 2008. NA gave feedback on the corrective actions on the 4th of July 2008. Only very few of the corrective actions performed were acceptable. A second deadline for further corrective actions was then set. New documentation was received on time (1st of October 2008). Most corrective actions were still not good enough and a feedback on this was given to the laboratory on the 22nd of October 2008. Further feedback regarding corrective actions can not be given by NA at present because we then will act more as consultants than assessors. Our conclusion is that the laboratory still has a lot of work to do before they are ready for a new initial assessment visit. Of special concern is the fact that the laboratory still has not participated in PT.

During the assessors stay in Addis Ababa the lead assessor tried to get in contact with the local UNIDO representative. Finally he got contact with Mr. Yitbarek Fantahun on phone. It was then agreed to meet in the hotel later on during our stay in Addis Ababa but Mr. Fantahun did not turn up as agreed. He did not contact us later on during our stay either. We are a little surprised regarding the lack of involvement of the UNIDO representative during this project.

To be able to meet the requirements for accreditation it seems that the laboratory need further help from consultants that have knowledge in and experience with quality assurance and ISO/IEC 17025 (2005) requirements, particularly for microbiological food testing.
Before a new initial assessment UNIDO should ensure that the laboratory has developed and implemented a system that meets the requirements to a greater extent that they do at present.

Kjeller, 17.11.2008

Roald K. Nilsen

Technical Director

Norwegian Accreditation (NA)

Appendices:
Reports from assessment (LA and TA)
Summary report, NC-forms and list of minor NCs
Final feedback from LA and TA

Name of organisation:	Ethiopia Health and Nutrition Research Institute (EHNRI), Food microbiology laboratory, Addis Ababa		
Manager of the organisation:	Dr. Eshetu Lemma		
Accreditation no/ application no:	SP 697	Date of assessment:	13. and 14.02.2008
Sites assessed:	Food microbiology laboratory		

1 The assessment

This report deals with:

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

Assessment team:

Name	**Position**
Roald K. Nilsen	Lead assessor
Anne Grændsen	Technical assessor (P16 Microbiology)

Personnel interviewed:

Name	**Position**
Eshetu Lemma	Department head
Bisrat Habtemariam	Quality Manager
Samson Girma	Laboratory head/Technical manager

Participants in the final meeting:

Name	**Position**
Eshetu Lemma	Department head
Bisrat Habtemariam	Quality Manager
Endris Mohammed	Team Leader
Samson Girma	Laboratory head/Technical manager
Teklil Biza	Testing officer

Deadline for submission of corrective actions: **15.05.2008.**

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 – 4 – Requirements for management

4.1 Organization

Ethiopia Health and Nutrition Research Institute (EHNRI) is a governmental body under the Ministry of Health.

EHNRI is headed by a Director General. The Food microbiology laboratory belongs to the Bacteriology and Fungal Research Team under the Department of Infectious and Non-infectious Diseases. The department is headed by Dr. Eshetu Lemma.
A technical manager (Head of laboratory) and a quality manager are appointed for the Food Microbiology laboratory. Deputies for key personnel are not appointed (NC9). The names of key personnel and their deputies are not given in the management system (NC9).
The position of Food microbiology laboratory within EHNRI is shown in an organizational chart in the Quality Manual (QM). The organisation within Food microbiology laboratory is also described in the same organizational charts and further explained in the text and job descriptions in QM. The position of the Quality manager (QMR) in the organizational chart is also given and it is also stated in the text that the QMR has direct access to the top management. Quality Managers position is only a temporary position as describe on page 13 in the QM (**minor NC**). In the QM it is described that QMR should be appointed by Director by signature, however this is not implemented (**minor NC**).

SOP 1.8.2 refers to several positions that are not part of the described organization of the laboratory (**minor NC**).
List of all personnel engaged in the Food microbiology lab is not established (NC 9).
The job descriptions for positions/persons are given in the QM but not for supporting staff (NC 9).
See also report from the technical assessor.

How confidentiality for their costumers is achieved is described. Declarations of confidentiality are signed by the personnel of the laboratory. This was checked for two of the personnel on random basis. This declaration of confidentiality covers the whole institute. As discussed during the assessment it might be necessary to establish an additional declaration of confidentiality for the Food microbiology laboratory. This will be followed up at the next assessment visit.
Key costumers are shortly described.
Potential conflicts of interests are discussed and a statement that all activities are conducted independent to any pressure that may influence the work is given.

Information about salary system is not given but all personnel have fixed salaries as employees of a governmental body. The description of this will be further evaluated at the next assessment.
Descriptions on how communication processes are functioning are only partly given in the management system. Different types of meetings are held (among them weekly meetings at the laboratory were all lab personnel are present), but this is not described. The established routine of writing minutes from the meetings is not described either. The description of this will be followed up at the next assessment.

The overall impression is that the laboratory has personnel with satisfying competence and experience, and with enough resources and authorities to carry out their duties.

QM describes activities in temporary mobile facilities. However, it is not described that activities in mobile facilities is not applicable to accredited activities (**minor NC**).

NC no	9				
Compliance			Not in compliance	x	

4.2 Management system

It is described that the management system consists of a QM (SOP 1.1), Standard Operating Procedures (SOPs), Specific procedures, Test methods, Work instructions and records. However, in fact all documents are identified as SOPs, including QM, test methods and forms. No documents are identified as work instructions. These documents exist but are not part of the document control system. The descriptions should be updated accordingly, as discussed during this assessment visit.
The controlled documents seem to cover most of the activities of the laboratories but not all, see appendix to NC 7. A master list of all documents in the system giving the valid editions of each document is established. However, the list contains a lot of incorrect information, see appendix to NC 7 for examples.
The quality documentation is only partly available to all relevant personnel, see appendix to NC 7.
The quality manual has references to SOPs, and the SOPs have references to other SOPs and forms. However, some of these references are incorrect. Examples of this are given in the appendix to NC 7. This is considered as a weakness of the traceability in the system.

Several double descriptions are seen in the management system and some routines are described several places giving different or contradictory descriptions. The laboratory must go through the whole system to ensure that the system is clear and unambiguous.

The Quality policy statement is described but it is not signed by top management (Head of department)(**minor NC**). It is described in 4.2.1 in the QM that the Quality policy statement should be signed by the quality manager (**minor NC**) and not the top management as required in the accreditation standard.
It is not described that the quality objectives shall be reviewed during the management review meeting (**minor NC**).

How the integrity of the management system is ensured when changes in documents and system are introduced is not clearly described. This will be discussed further at the next assessment visit.

See also report from the technical assessor.

NC no	7 (including the appendix)			
Compliance		Not in compliance	x	

4.3 Document control

The description of the document control system is unclear and unsatisfactory, see appendix to NC 7 for details and examples. The system is not properly implemented either, see appendix to NC 7 for details and examples.
The system does not assure that only the latest editions of approved documents are available and in use by the personnel.

The quality documentation is only partly available to all relevant personnel, see appendix to NC 7.
See also report from the technical assessor.

NC no	7 (including the appendix)			
Compliance		Not in compliance	x	

4.4 Review of contracts

Each sample received is registered in a log book at the reception area. Most samples are followed by a sample submission request which is signed by the customer and the laboratory representative and regarded as a contract. The described system is partly implemented as far as checked during this assessment visit (sample no. 014/08 was checked and the contract was ok, sample no. 027/08 was checked but the contract could not be found).The implementation of the system will be further checked during the next assessment visit. See also report from the technical assessor.

The descriptions are partly meeting the requirements:
How simplified contracts for internal costumers are reviewed are not described (**minor NC**).
How oral agreements/contracts are documented and how changes in agreements/contracts is documented is not described (**minor NC**).
The laboratory has also a Custodian but in the description in 4.4 in the QM does not make any references or description of this function. However, there exists a job description of this function in 4.1.5 in the QM. The implementation of the work of the Custodian as well as the description in 4.4 in QM regarding the Custodian will be further evaluated during the next assessment visit.

NC no	-

Compliance		Not in compliance	x	

4.5 Subcontracting

The description of use of subcontractors is satisfactory except that it is not clearly stated that accredited test has to be subcontracted only to accredited subcontractors (**minor NC**).
At present no subcontractors have been used so the implementation of the system could not be checked during this assessment.

NC no	-			
Compliance		Not in compliance	x	

4.6 Purchase of services and supplies

EHNRI have a separate office for purchasing which also the Food microbiology laboratory is using but this is not described in the management system (NC 8). This office was not visited during this assessment. The descriptions have to be brought into agreement with present situation as well as in agreement with requirements of the accreditation standard.

No evaluation of the suppliers can be documented (NC 8). No list of approved suppliers are established (including **suppliers** (not producers) of for instance media, reagents, chemicals, glassware, instruments, other consumable, software and hardware and suppliers of service as for examples data support and calibration of equipment (NC 8).

See also technical assessors report and NC 11 given by her.

NC no	8, 11			
Compliance		Not in compliance	x	

4.7 Service to the customer

The service to the costumers (including access to relevant areas for witnessing, advise and guidance and obtaining feedback) is satisfactorily described, but the one responsible for evaluating the results of customer surveys should be named.
In practice feedback forms have been given/sent to a lot of customers lately but only a few have responded. This will be followed up during the next assessment visit.

NC no	-			
Compliance	x	Not in compliance		

4.8 Complaints

The laboratory uses a lot of words and has double descriptions of how to handle complaints. It is described in the QM as well as in SOP 1.8 and also in SOPs 1.8.1 and 1.8.2. The lead

assessor finds SOP 1.8.2 complicated partly because it describes positions in the laboratory which do not exists **(minor NC)**.

In some descriptions the laboratory seems to restrict complaints to test results only, which is not in agreement with the accreditation standard. This will be evaluated further during the next assessment visit.
According to the QMR no complaints are received so far, and implementation of the system was therefore not checked during this visit.

A recording system for complaints is described.

NC no	-				
Compliance		Not in compliance	x		

4.9 Handling non-conforming work

The description and the forms established for registration of NC work is not satisfying. No NCs have been registered during daily work so far using the described system. It is expected that all accredited labs use the system regularly (during daily work). This will be checked at the next assessment visit.
During internal audits NCs have been identified but no NC forms have been filled in.

NC no	13				
Compliance		Not in compliance	x		

4.10 Improvement

Improvements is not specifically described in the management system **(minor NC)**

NC no	-				
Compliance		Not in compliance	x		

4.11 Corrective actions

The description and the forms established for corrective actions are not satisfactory. No NCs have been registered during daily work so far, so the described system for corrective action has not been implemented. It is expected that all accredited labs use the system whenever NC-work have been identified. This will be especially checked at the next assessment visit.
SOPs 1.7/1.7.1 do mix up corrective and preventive actions.

NC no	13				
Compliance		Not in compliance	x		

4.12 Preventive actions

The procedure for preventive action (as described in the QM and the SOPs 1.7/1.7.1) is satisfactory but the laboratory has not started implementing it yet (**minor NC**).
SOPs 1.7/1.7.1. do mix up corrective and preventive actions (see NC 13).

NC no	-				
Compliance			Not in compliance	x	

4.13 Control of records

Retention time of all documents/technical registrations is 5 years as described several places in the management system. Exceptions for the retention time for some records are mention. The laboratory explains that exception mean longer retention time and not shorter retention time. This must be clarified in the descriptions.

There is no system established for the filing of absolute SOPs/work instructions/forms as described in the management system (**minor NC**).
It is not described who has the responsibility for the filing of reports/checklists from internal audits and the location of that file (**minor NC**). Location of different documents is not indicated e.g. on page 2 and 3 of SOP 1.4 (**minor NC**).
The laboratory should go through the whole management system to see if responsibilities and locations of the different records are clearly described. Maybe a table would give a good overview of this.

See also report from the technical assessor and NCs given by her.

NC no	2, 10, 11, 16				
Compliance			Not in compliance	x	

4.14 Internal audits

The last internal audit was performed in November 2007. According to the laboratory this audit should cover all elements of ISO 17025. The report from the audit does not document that all elements were covered. The use of checklist as described in the management system was not followed. The established checklist does not cover all elements of ISO 17025. The work of the Quality manager and observation of test methods should especially be included. See NC 14.

No plan for internal audit is established for 2008 (NC 14).
The audit team defines the scope and time frame of internal audits as described in job description of the audit team (**minor NC**). According to ISO 17025 this is the sole responsibility of the QMR (and is also correctly described in the job description for the QMR, but during discussion with the QMR it became clear that QMR leaves this to the audit team).

The lab has not yet performed vertical audits, only horizontal audit. The use of vertical audits was explained by the lead assessor to the QMR during this assessment. The technical assessor performed a vertical audit together with the Head of the laboratory during this assessment. Vertical audit is a useful tool for both internal auditors and assessors and is expected to be used by all accredited labs as part of internal audit.

Requirements for internal auditors are partly satisfactorily described. It should be more clearly stated that they also need knowledge of ISO 17025. Auditors used in November 07 have attended a course in auditing and ISO 17025 organized by UNIDO. The documentation for this should be kept by the QMR of the Food microbiology laboratory. The laboratory should also establish a list of approved internal auditors (see also 5.2).

NC no	14				
Compliance		Not in compliance	x		

4.15 Management review

The description of management review meetings is satisfactory except that the agenda does not cover review of quality objectives. Recommendations for improvements are also not included in the agenda for the management review (**minor NC**).
Minutes from the last management meeting exists. The minutes are not specific enough when describing evaluations and conclusions that the management drew on each subject of the agenda. In the minutes actions agreed upon were identified but no time limits for follow up was given. The meeting was conducted by the Head of the laboratory and all senior staff members attended the meeting. However, the Head of the Department which is the top management and in charge of resources must be present and chair the meeting. It also seems reasonable that Head of Bacteriology and Fungal Research Team in addition to QMR and Head of laboratory are present. The minutes have to be signed by the top management.

NC no	-				
Compliance		Not in compliance	x		

ISO 17025 – 5 – TECHNICAL REQUIREMENTS

5.2 Personnel

Introduction of new personnel as well as how to document the introduction is not well described (NC 9).
Lists of personnel authorized to do/perform different tasks in the laboratory are not established in the management system, e.g. list of personnel approved to perform each test, to operate equipment, to sign on test certificates (test reports), to be internal auditor (NC 9). Such lists shall also give the dates of authorization.
CVs are established. Job descriptions and work instructions have been established for personnel but not for supporting staff.

See also report from technical assessor.

NC no	9				
Compliance			Not in compliance	x	

5.3 Premises and environment

How access to the laboratory premises is restricted is not described in the management system. No sign is placed on the entrance door to the laboratory saying that access is restricted (**minor NC**).

For laboratory premises and environmental conditions, see technical assessors report and NC 6 given by her.

NC no	6				
Compliance			Not in compliance	x	

5.4 Methods for testing, calibration and validation

See report from the technical assessor and NC 12 raised by her.

NC no	12				
Compliance			Not in compliance	x	

5.5 Equipment

See report from the technical assessor and NC 10 raised by her.

NC no	10				
Compliance			Not in compliance	x	

5.6 Measurement traceability

See report from the technical assessor and NCs raised by her.

NC no	**1, 2, 4, 5, 16**				
Compliance			Not in compliance	x	

5.7 Sampling

Not relevant (not covered by application for accreditation)

NC no					
Compliance			Not in compliance		

5.8 Handling of test and calibration objects

See report from the technical assessor.

NC no					
Compliance			Not in compliance		

5.9 Assuring the quality of results from testing and calibration

See report from the technical assessor and NC 3 and 4 raised by her.

NC no	**3, 4**				
Compliance			Not in compliance	x	

5.10 Reporting results

The description of reporting is generally acceptable.
The test reports (test certificates) issued by the laboratory are satisfactory except that the address of the client is not given and no identification of the method used is given (**minor NC**).
How to make changes in a test certificate (test report) already issued and given/sent to the costumer is satisfactorily described. Practice was not checked during this assessment visit.

The fact that sampling and opinions and interpretation is not included in a possible future accreditation should be clearly described. How to use the accreditation mark and how to identify non-accredited results on an accredited test report must also be described, see NC 15.

NC no	15				
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 use of the accreditation mark is not described in the management system.

NC no	15				
Compliance			Not in compliance	x	

NA-Doc 25/31 Accreditation conditions

This is not described in the management system.

NC no	15				
Compliance			Not in compliance	x	

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

See report from the technical assessor and NC 1 given by her.

NC no	1				
Compliance			Not in compliance	x	

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

See report from the technical assessor and NC 2 given by her.

NC no	2				
Compliance			Not in compliance	x	

NA-Doc. 50 Flexible accreditation (if relevant)

Not relevant.

NC no					
Compliance		Not in compliance			

NA-Doc. 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

Not relevant for initial assessment.

6 Recommendation regarding accreditation

Accreditation is not recommended at present stage.

A new initial assessment visit to the laboratory has to be conducted in order to evaluate if the laboratory meet the requirements. A new assessment can only be performed if the management system is further developed, corrected and implemented, and all NCs raised during this initial assessment is corrected in an acceptable way evaluated by the assessment team.
A new initial conformity assessment visit is not covered by the present UNIDO project.

7 Recommendation regarding suspension

Not relevant.

8 Recommendation regarding scope of accreditation

See point 6 above and summary report (NA-S23).

9 Recommendation regarding administrative/ geographical units

Not relevant.

10 Any changes since the previous assessment

Not relevant at initial assessment.

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

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

Place/ date: Kjeller, 21.02.2008

Lead Assessor

Place/ date: 25/2-2008

Technical Director, Norwegian Accreditation

13 Enclosures/ references

Agenda for the assessment
Non-compliances;
- Number of very serious non-compliances: 4
- Number of essential non-compliances: 12
- Number of minor non-compliances: 18

Summary report
Reports from technical assessor, laboratories

Name of the organisation:	**EHNRI Food Microbiology**
Assessed locations:	

Accr. no. : SP 697	Date of assessment: 13 Feb 08
Appl. no.:	14 Feb 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

Initial visit	X	Extraordinary visit		Renewal	
Surveillance		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**
Samson Girma	Head Food Microbiology / Technical Manager
Teklil Biza Gizaw	Laboratory analyst / Technical officer / Laboratory technician / Custodian
Tesfoye Keede Sisay	Laboratory analyst / Technical officer / Laboratory technician
Firehiwot Abera	Laboratory analyst / Technical officer / Laboratory technician
Redwan Muzeyin Edicho	Laboratory analyst / Technical officer / Laboratory technician

3. Recommendation

3.1 Recommendation regarding accreditation/renewal:
Accreditation is not recommended at present stage.
See summary report issued on 14 Feb 2008 for further details.

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):

Not relevant

5. Extent of assessment

	Management requirements
4.1	**Organization**
	The organisation is described in Quality Manual. Head of Food Microbiology is also the Technical Manager. He has satisfactory competence and experience within microbiology and has been attending training in ISO 17025 provided by UNIDO. **Remark:** Positions as laboratory analysts, testing officers and laboratory technicians are listed in the organizational chart. Work descriptions are established for the specific positions. Positions held can not be identified in the CV's. The laboratory is requested to clarify this before next visit. The understanding of technical assessor is that all three positions currently can be applied for all researchers employed in the laboratory. In addition one of the researchers takes care of the position as custodian. Regarding identification of key personnel and appointed deputies see also report from lead assessor, **part of essential nonconformity,** included. *Non-conformity no* **9**
4.2	**Quality system**
	Description/evaluation: In general the quality system is covering the requirements in ISO 17025. The implementation is deficient and recording systems are lacking in several areas. See clause 4.13 for further information. The Quality system has three levels; • The quality Manual • SOP's (test methods, specific procedures, culture media receipts) • Work instructions and records Availability of the SOP's, working instructions, and different forms for daily recording in the laboratory are satisfactory. All personnel have access to the documents needed. The personnel demonstrated that they are properly trained,

	but working instructions are not used in daily, analytical work in the laboratory. **Remark:** Technical assessor observed that copies of SOP' were used in connection to the demonstrations in the laboratory. The copies were in compliance with valid versions of the specific SOP.
	Non-conformity no --
4.3	**Document control**
	Description/evaluation: See report from lead assessor, **very serious non-conformity no 7** included. In addition to the examples listed in the Appendix to NC no 7 is following mistakes observed: • The test method for "Coliform count for water" has SOP no. 2.4. The list of test methods identifies the SOP as 2.1.4 and the test method is given as "Coliform test (MPN) for water". • The test method for "Detection of E. coli type 1" in food and water has SOP no. 2.16. The list of test methods identifies the SOP as 2.1.15. • The test method for "Isolation of Salmonella" in food has SOP no. 2.16. The list of test methods identifies the SOP as 2.1.16. • The test method for "Preparation of pure cultures" has SOP no. 2.15. The list of test methods identifies the SOP as 2.1.14. • The test method for "**Streaking** of agar plates" has SOP no. 2.14. The list of test methods identify the SOP as 2.1.14 and the test method is given as "**Inoculation** of agar plates"
	Non-conformity no --
4.4	**Review of requests, tenders and contracts**
	Description/evaluation: The laboratory describes contract reviews ensuring: • Capability • Adequately definition of clients requirements Reviews shall be documented, included contract amendments. Requests and contracts were examined in connection to the vertical audit conducted on water samples with Lab. Reg. No.138/07.The case file contained the requests and reviews as described in the quality system The forms were properly filled in and signed on reception.
	Non-conformity no --
4.5	**Subcontracting of tests and calibrations**
	Description/evaluation: The laboratory is currently not using any subcontractors and has no plans to do so. The capacity is relatively good and the probability for sudden production

	stoppages is low. The present scope does not require sophisticated equipment with long delivery times. Criteria to be applied in future selection and approval of subcontractors are properly described in the management system. The Quality manager is responsible for assessing the competence level and subsequent approval and listing of subcontractors.
	Non-conformity no --
4.6	**Purchasing services and suppliers**
	Description/evaluation: The laboratory has satisfactory requirements for purchasing. Quality requirements are given priority, and brands to be used are described in specific culture media SOP's. In general reagents and dehydrated media observed in the laboratory were of recognised, ISO 9000 approved brands. Most of the dehydrated media are produced by Oxoid, BBL, Lab M, etc. and are in general marked with recipient date and opening date. Dehydrated media and chemicals used in accredited analysis are kept on shelves outside the media preparation area or in the storage room. Except for one bottle, all bottles checked were free flowing powders. Tubes with ready made agars and broth's are kept in room temperature in the laboratory. Reagents and kits as sera for Salmonella typing, API kits from BioMerieux were kept in refrigerators which were properly temperature monitored. **Remark:** In general good laboratory practice is to store ready made plates and tubes in refrigerators. The laboratory should consider changing the storage routines. **Part of essential non-conformity:** *Culture media* • Storage times and storage temperatures are not given in the specific culture media SOP's. However storage conditions for dehydrated powders are properly given. • Tubes containing broth and agar kept at room temperature in the laboratory has no traceability to production date and expiry date • Quite many bottles of dehydrated media stored in the laboratory and storage room have exceeded the expiry date with up to ten years. • There are also observed different kits with exceeded expiry dates, e.g sera for Salmonella typing, API kits from BioMerieux. See also report from lead assessor, **essential non-conformity no 8** included. *Non-conformity no* **11**

4.9-4.11	**Control of non-conformity (NC) testing and/or calibration work/corrective actions**
	Description/evaluation: So far the NC–system has not been put into use. Consequently no assessment was performed within this area. See lead assessors report, essential non-conformity included.
	Non-conformity no --
4.13	**Control of records**
	Description/evaluation: Records are not established within several areas. In general registrations are satisfactorily recorded in instrument records in use. Registrations are principally done by permanent pen, and they are easily readable. A vertical audit was carried out on water samples with Lab. Reg. No.138/07. The samples had been analysed for indicator organisms. The laboratory demonstrated lacks of traceability to timeframes, operators, culture media and reagents t regarding the different working steps included in the analysis. See clause 5.6 for further information. **Parts of essential non-conformities:** *Personnel:* Training records for supporting staff are not established. *Culture media:* A QC record for production is not established (e.g. weighing, heat treatment, pH on end product, physical appearance sterility, suitability etc *pH-meter:* No record is established in connection to the pH- meter. The laboratory has to record calibrations, measurements of control solutions, cleaning and maintenance of electrodes etc. *Traceability raw data:* See clause 5.6.
	Non-conformity no **9, 10, 11 and 16**
5	**Technical requirements**
5.2	**Personnel**
	Summary/Conclusion: The laboratory is in the possession of competence needed. The initial assessment revealed that the personnel have acceptable knowledge of their duties and responsibilities in connection to present positions. Management defines the minimum levels of qualification and experience

	necessary for all posts within the laboratory. Current testing officers have university education on minimum BSc level. The personnel demonstrated that they are properly trained, but working instructions are in general not used in daily, analytical work in the laboratory. It was not observed any non-compliance between procedures and the practical work during the assessment. **Part of essential non-conformity.** • List of all personnel, positions included, is not established in the management system • A list of authorized personnel to perform specific tests is not established. • Personal files containing CV's and certificates for external training are established. The files do not contain any authorisation documents showing the date of authorization, whom has been in charge of authorization and which criteria that are used. • No training records and work descriptions is established for supporting staff. • A description of introduction of new personnel into essential parts of the management system and laboratory routines is not given, including how the introduction as such is going to be documented.
	Non-conformity no **9**
5.2.1	**Training**
	Description/evaluation: See clause 5.2
5.2.2	**Maintenance of competence**
	Description/evaluation: Maintenance of competence is currently satisfactory. Accredited methods are routinely analysed. Annually the laboratory is analysing approximately 350-400 water samples and 200-250 food samples. In addition the personnel are supposed to analyse quality control samples on regular basis (reference materials quarterly and PT samples annually). Training plans for internal and external training was not asked for during this assessment.
5.2.4	**Job descriptions**
	Description/evaluation: Job descriptions are given in the Quality Manual as well as in SOP 6.1 (duplicate!). The testing personnel were well aware of the content in current job descriptions. All staff members contributed well in demonstrations, record reviews and discussions. It is apparent that they have good knowledge of their own duties and responsibilities. Supporting staff was not interviewed during the initial assessment.

	Remark: The laboratory should be aware of the potential risks connected to duplicate information given in the Quality System. In future it might lead to non compliances when updating similar information in different documents at the same time.
5.3	**Accommodation and environmental conditions**
	Description/evaluation: The laboratory facilities are in general suitable for the activities performed. The laboratory has proper routines for housekeeping. Procedures for handling of disposals from the testing activities are acceptable. During the assessment the laboratories were tidy and clean. The Quality Manual states that access to the laboratory is restricted to authorized personnel. See **minor NC** raised by lead assessor regarding this issue. Designated laboratory coats and protecting glows have to be worn in the laboratory. The work flow is well planned and organised. Measures have been taken to avoid contaminating samples and testing. All testing activities are performed in a laminar flow hood. Cleaning and disinfection of the working surface before starting testing activities was properly done. The laboratory has described a monitoring programme which include following parameters: • Regular lab and equipment cleaning • Biological sterility by air testing • Surface testing by swab testing • Surface testing of pathogens where pertinent to scope • Bacteriological and chemical testing of the distilled water used for media production • Room temperature and humidity. Except the record for testing of distilled water, were all other asked for inspected if excising. **Essential non-conformity:** • The quality system has requirements regarding humidity (45-50) and temperature (20-25°C). No measurements of RH and temperature are performed. • The quality system is describing that bacteriological air testing, surface screening by swab tests and a monitoring programme for pathogens where pertinent to scope is required. o No further details are given regarding the parameters of choice, testing frequencies, acceptance limits and actions to be taken when exceeding the limits.

	o Currently the monitoring programme is not performed for all parameters listed above. **Remarks:** During the two days of assessment all windows and doors were open in laboratory rooms. Insects (flies) were observed inside the rooms. In spite of using a laminar flow hood for all testing activities, the laboratory should consider changing this routine to avoid potential cross contaminations. The Management System describes floors, walls and ceilings to be smooth and easily cleaned. However it was observed missing tiles on floors and walls were plastering/mortar had been filled in. It shall be emphasised that plastering/mortar has a potential risk for bacterial growth.
	Non-conformity no **6**
5.4	**Test and calibration methods and method validation**
	Summary/Conclusion: The laboratory is using recognised standard methods or official methods. Demonstrations performed during the assessment revealed conformity between written procedures and the manual operations in the laboratory. **Very serious non-conformity:** The Quality manual SOP 1.1 states that latest edition of methods is going to be used. However the laboratory has no system in place to follow up which methods that is currently valid. Most of the official and standard methods applied for are outdated and regarded as obsolete documents. Currently the laboratory has no access to the valid, official and standard method needed. See attachment for further information.
	Non-conformity no **12 (attachment included)**
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 official methods. Currently the laboratory has no need for full validations of test methods. However the laboratory has in the Quality Manual described in a satisfactorily way parameters which is considered to be applicable in validation plans/studies. *Non-conformity no* --
5.4.6	**Estimation of uncertainty of measurement**
	Description/evaluation: Identification of contributions to measurement uncertainty (MU) is described in the Quality Manual. How to calculate the MU is not described. **Remarks:** In clause 5.4.6.3 in the Quality Manual the laboratory has given a limited number of sources contributing to the MU. Sources of MU are not identified for each method or a group of methods specifically. This should be improved before the next assessment. Regarding estimation of MU, a reference to ISO 5725 and the GUM-report is given. The laboratory should preferably not use 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. The laboratory should be aware of that requirement connected to calculating MU will shortly be applied by the accreditation body.
	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. The procedure of transference of data was checked during a vertical audit conducted on water samples with Lab. Reg. No.138/07. All transferences of data were done properly. No use of trend plots in Excel was observed during the assessment.
	Non-conformity no --
5.5	**Equipment**
	Description/ valuation: The laboratory is well equipped and has lists containing all equipment. Each item can be traced to the equipment SOP number. The SOP's describes calibrations, maintenance, recording and actions to be taken if control results are exceeding action limits. The laboratory has established a system for labelling broken

	instruments out of use or instruments which are not properly calibrated. In general the maintenance is good. All instruments are properly monitored but calibrations are not satisfactorily for temperature devices and balances. See clause 5.6, NA Doc 26a and NA Doc 26b, **essential non-conformities** included, for further information. Control results are recorded. The following instrument files were reviewed: • Incubators, refrigerators and autoclaves • Thermometers and data loggers • Balances • Laminar flow hood • pH-meter • Volumetric equipment (pipettes and cylinders) **Remark:** Volumetric glassware (pipettes and cylinders) is not included in the list of equipment or in the list of parameters to be monitored. This should be implemented before next assessment. Volumetric glassware of Class B is in use. The EBRO data logger listed in the equipment list is not in use any more due to break down of the computer containing the soft ware. **Part of essential non-conformity:** *pH-meter:* A two point calibration is in use, but the SOP is not describing the use a control solution after calibration. (A third buffer is accepted for culture media QC).
	Non-conformity no **10**
5.6	**Measurement traceability**
	Summary/conclusion: Traceability is established for the microbiological methods by using reference cultures (positive controls) in each run of analysis. The cultures are traceable to an international culture collection (NTCC) and are procured from CCUG in Gothenburg, Sweden. In addition the quality of test results are assured by using reference materials provided from SLV, Sweden. The reference stock cultures and the reference materials are stored in a freezer. Working cultures of reference strains are kept in a refrigerator. The temperature is monitored on daily basis in the freezer and the refrigerator. Working cultures are kept on blood agar Regarding sub culturing of the reference cultures the laboratory has been restricted the maximum five passages. **Remark:** Plates were not protected against drying and/or cross contaminations during storage. Inspected plates seemed to be too dry. The agar on the plates was broken on several working cultures. However no contamination was observed on the

	plates inspected. The laboratory is requested to consider storage in separate boxes or plastic bags in the future. **Essential non-conformities:** *Reference strains:* • The descriptions in the quality system regarding maintenance and use of reference strains are insufficient. • Neither has the laboratory established any recording system regarding maintenance and use of reference strains. *Balances and thermometers:* • See information in clause NA Doc 26 a and NA Doc 26 b *Raw data:* When conducting the vertical audit on Lab. Reg. No.138/07 following observations were done: • Traceability to individual working steps in the method is partly lacking (dates and signatures) • Traceability to batches of culture media, kits and solutions used are missing **Very serious non-conformity:** *Reference materials:* • The reference materials in use have expiry dates in May 2006. • So far the materials are mot used on quarterly basis as described in the quality system. • The reports issued have o not included references to personnel performing the specific tests o occasionally wrong acceptance limits o no information on non-conformity handling when the results are exceeding the acceptance limits o no trend analysis (trend plots) • The reference material which is in use does not cover the parameters "Anaerobic colony count" and "Moulds". • The laboratory has not used the reference materials for following parameters: o Enterobacteriaceae o Enumeration of E. coli (P/A tests is satisfactory performed) • For coliforms the reference material is insufficiently diluted to meet the tolerance limits given from the provider.
	Non-conformity no **1, 2, 4, 5 and 16**
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 No sampling methods are applied for. *Non-conformity no* --
5.8	**Handling of test and calibration items**
	Description/evaluation: Sanitarians are doing the sampling. However the laboratory is providing guidance on sampling. Sampling equipment can also be collected from the laboratory. Sterile bottles with or without Na-thiosulphate are prepared for water sampling. On receipt the samples are recorded and acquire a unique number by the custodian. Before, under and after analysis the samples are stored satisfactorily. Measures to avoid cross contaminations are taken. Temperatures are recorded in refrigerators. A vertical audit conducted on water samples with Lab. Reg. No.138/07 demonstrates that the procedures are followed thoroughly. The laboratory had recorded and signed for the reception of the sample as described in the Management System. During demonstrations laboratory coats and protecting disposable gloves was used as described in the quality system. All samples were prepared in the laminar flow hood and bench surfaces were properly cleaned and disinfected with ethanol to avoid cross contaminations.
	Non-conformity no --
5.9	**Assuring the quality of test and calibration results**
	Description/evaluation: The quality manual is correctly requiring use of traceable reference strains, reference materials (CRM's and/or RM's) and PT-participation.

	The laboratory is using reference cultures (positive controls) in each run of analysis. The cultures are traceable to an international culture collection (NTCC) and are procured from CCUG in Gothenburg, Sweden. In addition the quality of test results are assured by using reference materials provided from SLV, Sweden. See clause 5.6 for further information. **Very serious non-conformities:** *PT-partipation:* The laboratory has not yet participated in any PT-schemes for water and food testing. *Reference materials:* See clause 5.6
	Non-conformity no **3 and 4**
5.10	**Reporting the results**
	Description/evaluation: The Quality Manual has a satisfactory description of the content of test reports and of reporting test results. Test results shall be signed by the testing officer and the Head of Food Microbiology Laboratory. Electronic transmission of test results is currently not in use. Test reports were examined in connection to a vertical audit carried out on water samples with Lab. Reg. No.138/07. The test report was signed as described in the Quality Manual. **Minor NC's** according to test reports were observed. See report from lead assessor for further information. No amended test reports were observed in the report file reviewed. **Remark:** The Quality Manual states that EHNRI Food Microbiology Laboratory is not involved in the provisions of opinions and interpretations. However opinions and interpretations were given in the test report reviewed. After the laboratory has been granted an accreditation, such statements have to be marked with "Opinions and interpretations are not included in the accreditation scope".
	Non-conformity no --
5.10.5	**Opinions and interpretations**
	Description/evaluation: Not relevant Opinions and interpretations are not included in the scope applied for accreditation. *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: Not assessed See lead assessors report *Non-conformity no*
No 25/31	**Accreditation conditions**
	Description/evaluation: Not assessed See lead assessors report *Non-conformity no* --
No. 26a	**Requirements for calibration and control of weighing machines in accredited testing laboratories**
	Description/evaluation: **Essential non-conformity:** • Balances have been not been calibrated onsite by an accredited calibration laboratory or a laboratory which is a signatory to BIPM. • The laboratory is not checking the balances with standard weights on daily basis as described in the Quality system.
	Non-conformity no 1
No. 26b	**Calibration of thermometers in connection with accreditation of test laboratories**
	Description/evaluation: **Essential nonconformity:** • The laboratory has two reference thermometers, but the calibration certificates are missing. However, the thermometers are labelled with marks from a calibration laboratory accredited by DANAC. • The correction factors and the measurement uncertainties are not taken into account when thermometers for daily use are compared against the reference thermometer. • The temperature recording device on the autoclaves is not compared against a

	reference thermometer. Records are not established for the autoclaves. • Thermometers for daily use placed in the incubators have not an accuracy that is fit for purpose. • Requirements for maximum temperature deviations regarding daily readings of incubators (SOP no 3.1.1 and. 3.1.2) are not in agreement with the method requirements. • Temperature requirements for the incubator shaker (SOP no 3.1.3) are missing. • Thermometers which are calibrated by an accredited calibration laboratory are not used in equipment which require < ± 0,3 °C • All comparison studies against reference thermometers are performed solely at 44°C and don't really cover the temperature range used.
	Non-conformity no **2**
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:
	SOP 2.1.11 Enumeration of *S. aureus* in Foods	Teklil Biza Gizaw
	SOP 2.1.16 Isolation of *Salmonella* spp in Foods	Tesfoye Keede Sisay
	SOP 2.1.27 Enumeration of fecal coliforms in Water (same SOP is also used for food)	Firehiwot Abera / Redwan Muzeyin Edicho
	SOP 2.1.15 Detection of *E.coli* Type I in Water	Firehiwot Abera / Redwan Muzeyin Edicho
7. Follow up non-conformities from the last visit:	Not relevant	
8. Notes/summary/ conclusion	No further comments	

9. Next visit	A new initial assessment is recommended after corrective actions have been taken regarding NC's risen during this assessment. Further development of the Quality System is needed.

20.02.2008, *Anne Grændsen*
Technical assessor

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

date 21.02.08
lead assessor

S.Nr. 08/9-4 Vedlegg Nr. 2

NORSK AKKREDITERING

NA-S23
Summary report

Case no:
08/0009

Name of the organisation: Ethiopia Health and Nutrition Research Institute, Food microbiology laboratory, Addis Ababa, Ethiopia

Application no.: SP 697 **Accreditation no:**

Type of visit: **Initial assessment**

Leader of the organisation: Eshetu Lemma

Lead assessor: Roald K. Nilsen

Number of non-conformity reports attached:

Very serious:	4
Essential:	12
Minor:	18

Summary:
An initial assessment of the Food microbiology laboratory at EHNRI has been performed. The general impression is that there are major deficiencies regarding implementation of the management system. It is also found that the laboratory does not document their work sufficiently leading to lack of traceability in the documentation.
The competence of the laboratory personnel is satisfactory, the work flow is well planed, and they are well equipped with new instruments. Media preparation, analytical work, cleaning and autoclaving are well separated.

Minor NCs are listed separately.

Recommendation concerning accreditation:
Accreditation is not recommended at present stage.
A new initial conformity assessment visit to the laboratory has to be conducted in order to evaluate if the laboratory meet the requirements. A new assessment can only be performed if the management system is further developed, corrected and implemented; and all NCs raised during this initial assessment is corrected in an acceptable way evaluated by the assessment team.
A new initial conformity assessment visit is unfortunately not covered by the present UNIDO project.

Time limit for presentation of corrective actions: **15.05.2008**

14.02.2008 Roald K. Nilsen Seen by:
date Signature lead ass./techn. ass. Signature (organisations repr.)

Annex:
Participations or list of participations at the opening and final meeting.
List of minor NC given by lead assessor.

Participants at opening and final meetings during the assessment of SP697
Dates: 13th and 14th of February 2008

Name	Position	Function/responsebility	Opening meeting (cross out)	Final meeting (cross out)
Eshetu Lemma	Dept. Head		✓	✓
Endris Mohammed	Bacteriology & mycology [illegible] team leader		✓	✓
Tekill Bira	Testing officer		✓	✓
Samson Girma	Head, Food mic[illegible]		✓	✓
Bisrat Ahmed	Quality manag.		✓	✓

NORSK AKKREDITERING

SP 697

Minor Non-conformances registered by lead assessor

Case no:
08/0009

Description of minor NCs	Ref. to ISO 17025
Quality Manager position is only a temporary position as describe on page 13 in the QM	4.1
Page 20 of the quality manual describe that quality manager should be appointed by Director by signature. A signature is not given.	4.1
It is described in 4.2.1 in quality manual that the Quality policy statement should be signed by the quality manager. Quality policy statement is not signed by top management.	4.2.2
It is not described that the quality objectives shall be reviewed during the management review meeting.	4.2.2/4.15
How simplified contracts for internal costumers are reviewed is not described.	4.4
How oral agreements/contracts are documented is not described? How to document changes in agreements/contracts is not described.	4.4
It is not clearly stated that accredited test has to be subcontracted only to accredited subcontractors.	4.5
The procedure for preventive action is not implemented as described in the quality manual and the SOP.	4.12
SOP 1.8.2 refers to a lot of positions that is not part of the described organization of the laboratory. SOP 1.8.2 is complicated.	4.1 and 4.8
Improvements is not specifically described in the management system	4.10
There is no systematic system established for the filing of absolute SOPs/work instructions/forms as described in the management system.	4.13
It is not described who has the responsibility for the filing of reports/checklists from internal audits and the location of that file.	4.13
Location of different documents is not indicated e.g. on page 2 and 3 of SOP 1.4	4.13
The audit team defines the scope and time frame of internal audits as described in job description of the audit team. This shall be the responsibility of the quality manager.	4.14
Recommendations for improvements are not included in the agenda for the management review.	4.15
A description of how access to the laboratory is restricted is missing. No sign is placed on the entrance door to the laboratory saying that access is restricted.	5.3
The test reports issued by the laboratory is satisfactory except that the address of the client is not given and no identification of the method used is given	5.10
QM 4.1.3 describes activities in temporary mobile facilities but it is not described that this is not applicable to accredited tests.	

Addis Ababa, 14.02.08.

Roald K. Nilsen

Norsk Akkreditering
Fetveien 99, 2007 Kjeller
Telefon +47 64 84 86 00 / Telefaks +47 64 84 86 01

S.Nr. 08/9 - 4 Vedlegg Nr. 4

NORSK AKKREDITERING

NA-S22
Non-conformity report

Case no.:
08/0009

ACTIVITY:	Initial visit	Report no.:	1
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

- Balances have been not been calibrated onsite by an accredited calibration laboratory or a laboratory which is a signatory to BIPM.
- The laboratory is not checking the balances with standard weights on daily basis as described in the Quality system.

14 Feb 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

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:	Initial visit	Report no.:	2
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Thermometers/temperature:

- The laboratory has two reference thermometers, but the calibration certificates are missing. However, the thermometers are labelled with marks from a calibration laboratory accredited by DANAC.
- The correction factors and the measurement uncertainties are not taken into account when thermometers for daily use are compared against the reference thermometer.
- The temperature recording device on the autoclaves is not compared against a reference thermometer. Records are not established for the autoclaves.
- Thermometers for daily use placed in the incubators have not an accuracy that is fit for purpose.
- Requirements for maximum temperature deviations regarding daily readings of incubators (SOP no 3.1.1 and. 3.1.2) are not in agreement with the method requirements.
- Temperature requirements for the incubator shaker (SOP no 3.1.3) are missing.
- Thermometers which are calibrated by an accredited calibration laboratory are not used in equipment which require < ± 0,3 °C
- All comparison studies against reference thermometers are performed solely at 44°C and don't really cover the temperature range used.

14 Feb 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 / 4.13
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	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)

ACTIVITY:	Initial visit	Report no.:	3
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

PT-participation:
The laboratory has not yet participated in any PT-schemes for water and food testing.

14 Feb 08 _____ _____
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: _____

_____ _____
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:	Initial visit	Report no.:	4
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Reference materials:

- The reference materials in use have expiry dates in May 2006.
- So far the materials are mot used on quarterly basis as described in the quality system.
- The reports issued have
  - not included references to personnel performing the specific tests
  - occasionally wrong acceptance limits
  - no information on non-conformity handling when the results are exceeding the acceptance limits
  - no trend analysis (trend plots)
- The reference material which is in use does not cover the parameters "Anaerobic colony count" and "Moulds".
- The laboratory has not used the reference materials for following parameters:
  - Enterobacteriaceae
  - Enumeration of E. coli (P/A tests is satisfactory performed))
- For coliforms the reference material is insufficiently diluted to meet the tolerance limits given from the provider.

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.9/5.6
NS-EN 45	
ISO Guide 66	
EMAS	
NA Dok 25/31	
Others:	

Non-conformity category:

Very serious	X
Essential	

☐ 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)

ACTIVITY:	Initial visit	Report no.:	5
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Reference strains:

- The descriptions in the quality system regarding maintenance and use of reference strains are insufficient.
- Neither has the laboratory established any recording system regarding maintenance and use of reference strains.

14 Feb 08 _____ _____
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:	

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:	Initial visit	Report no.:	6
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Environmental monitoring programme:

- The quality system has requirements regarding humidity (45-50) and temperature (20-25°C). No measurements of RH and temperature are performed.
- The quality system is describing that bacteriological air testing, surface screening by swab tests and a monitoring programme for pathogens where pertinent to scope is required.
  - No further details are given regarding the parameters of choice, testing frequencies, acceptance limits and actions to be taken when exceeding the limits.
  - Currently the monitoring programme is not performed for all parameters listed above.

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.3
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:	Initial assessment	Report no.:	7
ORGANISATION:	Ethiopia Health and Nutrition Research Institute, Addis Ababa		
Department:	Food microbiology laboratory		
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald K. Nilsen	**Rep. ass.**	Roald K. Nilsen

DESCRIPTION:

The description of the document control system is not satisfactory.

The document control system is not properly implemented.

Se appendix to this NC (NC 7) for details.

14.02.08 Roald K. Nil
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	x
Essential	

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)

Description

- How documents are approved in practice is not described. The laboratory can not document that each document (except the quality manual) is approved by the person given the authority to approve.
- According to the description in quality manual and in SOP 1.4 the Director shall evaluate and approve all documents in the management system, but this is not implemented (Department head has approved all documents).
- A lot of cross-references in not correct. Examples:
  - Reference to 4.4 in 4.2.4 in the quality manual.
  - Reference to SOP 2 in QM 4.3.3.1
  - Reference to SOP 9 in QM 4.14.1
- Description of numbering of documents in the management system is actually a description of how to give ID to samples.
- How the staff is informed about changes/new editions of procedures etc. is not described – However practice is acceptable (information on weekly lab meetings).
- Master list (SOP 1.0 named Contents) edition 2 does not contain all information that is requested in the description in the quality manual.
- Several of the references in Master list (SOP 1.0 named Contents) edition 2 are incorrect (or the SOPs are incorrectly marked). Examples:
  - SOP 3.7.1 is marked as SOP 3.8.7 in the Master list.
  - SOP 4.9 is marked as SOP 4.1.9 in the Master list.
  - Two documents are marked as SOP 7.1. One of them are probably SOP 6.1 as indicated in Master List.
  -The following SOPs have been given wrong names in the master list: 5.1, 5.5 5.6 and 5.7.
- Rules for identification of changes in documents are not implemented.
- Work instructions are not part of the document control system
- The document history in SOP 1.4 is not correct.
- The document history record form (SOP 1.4.1) is not in use.
- Computerized system: Rules for revising documents and any limitation of excess to documents in the management system are not described.
- Not all SOPs (eg. SOP 7.1-7.4) are available to the personnel in hard copy
- No rules for outprint and copying of documents in the management system are described.
- Sample collection format and Water sample collection format in not a part of the document control system.
- SOP 3.13 edition 1 and 3.19 edition 1 is displaced on the wall of the laboratory. The valid edition of these documents is no.2.
- The latest edition of the forms used to record cleaning is not in use. An old version is in use.

Addis Ababa, 14.02.08.

Roald K. Nilsen

ACTIVITY:	Initial assessment	Report no.:	8
ORGANISATION:	Ethiopia Health and Nutrition Research Institute, Addis Ababa		
Department:	Food microbiology laboratory		
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald K. Nilsen	**Rep. ass.**	Roald K. Nilsen

DESCRIPTION:

The use of the purchasing office is not described and their role in evaluating suppliers is not clarified.

No evaluation of suppliers can be documented.

For each media/reagent the producer is identified in the media SOP, however no list of approved suppliers is established.

14.02.08 Roald K. Nilsen _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.6
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:	Initial visit	Report no.:	09
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Roald Kåre Nilsen/ Anne Grændsen

DESCRIPTION:

- No deputy for key personnel has been appointed (e.g quality manager, technical manager)
- The names of key personnel and their deputies are not given in the management system.
- List of all personnel, positions included, is not established in the management system
- A list of authorized personnel to performing specific tests is not established.
- Personal files containing CV's and certificates for external training are established. The files do not contain any authorisation documents showing the date of authorization, whom has been in charge of authorization and which criteria that are used.
- No training records and work descriptions is established for supporting staff.
- A description of introduction of new personnel is into essential parts of the management system and laboratory routines is not given, including how the introduction as such is going to be documented.

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.1 and 5.2
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:

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:	Initial visit	Report no.:	10
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

pH-meter:

- A two point calibration is in use, but the SOP is not describing the use a control solution after calibration. (A third buffer is accepted for culture media QC).
- No record is established in connection to the pH- meter. The laboratory has to record calibrations, measurements of control solutions, cleaning and maintenance of electrodes etc.

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
SOP No 3.8.3

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	5.5/4.13
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:	Initial visit	Report no.:	11
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Culture media

- A QC record for production is not established (e.g. weighing, heat treatment, pH on end product, physical appearance sterility, suitability etc
- Storage times and storage temperatures are not given in the specific culture media SOP's. However storage conditions for dehydrated powders are properly given.
- Tubes containing broth and agar kept at room temperature in the laboratory has no traceability to production date and expiry date
- Quite many bottles of dehydrated media stored in the laboratory and storage room have exceeded the expiry date with up to ten years.
- There are also observed different kits with exceeded expiry dates, e.g sera for Salmonella, API kits from BioMerieux.

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.
SOP No 3.8.3

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.6, 4.13
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

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

NORSK AKKREDITERING

NA-S22
Non-conformity report

ACTIVITY:	Initial visit	Report no.:	12
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Methods:
The Quality manual SOP 1.1 states that latest edition of methods is going to be used. However the laboratory has no system in place to follow up which methods that is currently valid. Most of the official and standard methods applied for are outdated and regarded as obsolete documents.

Currently the laboratory has no access to the valid official and standard method needed.

See attachment for further information.

14 Feb 08 _____ _____
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	X
Essential	

☐ 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)

Method deviations
SOP 2.1.1- Aerobic Plate count • Reference is given to the latest addition of APHA 2001 and all earlier versions. Only the latest edition is regarded as valid. • Reference is also given to the Standard Method for Examination of Dairy Products. However SOP 2.1.1 is not in compliance with this standard which is describing 1 % skimmed milk supplement in PCA. • Acceptance limits for incubation is not given in SOP 2.1.1 • Temperatures given on page 3 are not in compliance with equipment temperatures on page 1.
SOP 2.1.20-Determination of Anaerobic colony count • A reference to NMKL is given but NMKL has no method for this parameter. However the method is described in APHA 2001. The assessor has not checked if there are compliance between the APHA method and the SOP issued by the laboratory.
SOP 2.1.2- Enumeration of coliforms (MPN) • Reference to an obsolete document is given and has to be updated. • Temperature given on page 3 and in paragraph "method principle" is not in compliance with equipment temperatures on page 1.
SOP 2.1.27- Fecal coliform count (MPN) • Reference to an obsolete document is given and has to be updated. • A reference to 2.1.2 has to be added. Otherwise is the first part of the method lacking. 2.1.1 is also giving information on positive and negative controls and equipment to be calibrated.
SOP 2.1.21- Enumeration of enterobacteriaceae • A reference to NMKL is given. The method number is missing and the edition is incorrectly given. The application NA-S5 is giving reference to APHA 1992 which is obsolete. The laboratory has to decide which reference that is going to be used before updating the method. • APHA 2001 doesn't require use of confirmatory tests. Identification with biochemical kits can be used if desired. • NMKL doesn't describe use of MacConkey Agar. • Some temperature confusions are observed. In page 2, 1. Inoculation and incubation is incubation for 22-26 hours described. On next page incubation is described for 48 hours.
SOP 2.1.21- Determination of aerobic colony count for moulds and yeasts in food • Reference to an obsolete document (APHA 1976) is given and has to be updated

Method deviations
(APHA 2001) • In the valid edition pour plate is not in use any more. • Neither is PDF in use. Choice of preference is DRBC. Alternatively shall DG 18 or PCA supplemented with chloramphenicol be used for some foods. The new media is suppressing competing micro flora better and is taking better care of stressed yeast cells. • The incubation time is shortened from 5-7 days to 5 days.
SOP 2.1.11- Enumeration of S. aureus • A reference to NMKL is given. The method number is missing and the edition is incorrectly given. • Use of Mannitol Salt Agar is no option in the NMKL standard method. BPA and/or Blood Agar shall be used. • Reference to biochemical tests has to be included (coagulase etc) • The Coagulase test given in SOP 2.2.11 has reference to APHA 1992 which is obsolete. If this method is updated to the latest version the laboratory has to assure the compliance between APHA method and the NMKL standard method.
SOP 2.1.16- Isolation of Salmonella • A reference to NMKL is given. The method number is missing (71) and the edition is incorrectly given. The application NA-S5 is giving reference to BS 5763: part 4 but the edition is missing. The laboratory has to decide which reference that is going to be used before updating the method. • The currently SOP is not in compliance with NMKL 71. • Temperature given on page 1in "equipment to calibrate" is not in compliance with temperatures given later on in the SOP.
SOP 2.1.8- Aerobic Plate count for water • Reference to an obsolete document (Standard methods for water and wastewater APHA 19th Ed) is given and has to be updated (Standard methods for water and wastewater APHA 21th Ed)
SOP 2.1.1- Coliform count for water • The assessor has not checked if WHO 1971 is still valid • The SOP has been given a incorrect number (2.4) compared to the list of test methods (2.1.4)

Date: 14.02.2008

Signature:

ACTIVITY:	Initial assessment	Report no.:	13
ORGANISATION:	Ethiopia Health and Nutrition Research Institute, Addis Ababa		
Department:	Food microbiology laboratory		
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald K. Nilsen	**Rep. ass.**	Roald K. Nilsen

DESCRIPTION:

The laboratory has not started using the system for registration of non-conforming work and for corrective action as described in the quality manual and SOP 1.6 and 1.7.
SOP 1.7 is mixing corrective and preventive actions.

The form established to register NCs and corrective actions (SOP 1.7.1) is not satisfactory.
How each NC is identified with a running number is not described, neither that all NC forms should be kept in a binder.

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

Ref. organisation's doc.

Requirement ref.:	
ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.9, 4.11
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:	Initial assessment	Report no.:	14
ORGANISATION:	Ethiopia Health and Nutrition Research Institute, Addis Ababa		
Department:	Food microbiology laboratory		
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald K. Nilsen	**Rep. ass.**	Roald K. Nilsen

DESCRIPTION:

An internal audit was performed in November 2007 which should cover all elements of ISO 17025. The report from the audit does not document that all elements were covered.
The use of checklist as described in the management system was not followed.
The established checklist does not cover all elements of ISO 17025. The work of the Quality manager and observation of test methods should especially be included.

No plan for internal audit is established for 2008.

The lab has not perform vertical audits, only horizontal audit.

14.02.08 Roald K. Nilsen
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.14
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: _____

☐ 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:	Initial assessment	Report no.:	15
ORGANISATION:	Ethiopia Health and Nutrition Research Institute, Addis Ababa		
Department:	Food microbiology laboratory		
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald K. Nilsen	**Rep. ass.**	Roald K. Nilsen

DESCRIPTION:

The use of the accreditation mark is not described in the management system.

A description of how the laboratory intends to comply with the conditions stated in NA Doc. 25/31 is not included in the management system.

14.02.08 _____ _____
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	x
Others:	NA Doc. 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:	Initial visit	Report no.:	16
ORGANISATION:	EHNRI Food Microbiology		
Department:			
Accr./Appl. no.:	SP 697		
Lead. ass.	Roald Kåre Nilsen	**Rep. ass.**	Anne Grændsen

DESCRIPTION:

Traceability raw data:
When conducting the vertical audit on Lab. Reg. No.138/07 following observations were done:

- Traceability to individual working steps in the method is partly lacking (dates and signatures)
- Traceability to batches of culture media, kits and solutions used are missing

14 Feb 08 _____ _____
Date Signature assessor Signature (Org. representative)

Ref. organisation's doc.

Requirement ref.:

ISO/IEC 15189	
ISO/IEC 17020	
ISO/IEC 17024	
ISO/IEC 17025	4.13/5.6
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)

NC no	Reason for closing	Conclusion
1	• Balances have been not been calibrated onsite by an accredited calibration laboratory or a laboratory which is a signatory to BIPM. • The laboratory is not checking the balances with standard weights on daily basis as described in the Quality system. The laboratory has ordered a calibration of balances from the National Metrology Institute which is accredited by DKD. Further more the laboratory has established a record for daily checks of the balances with standard weights. No evidence of implementation is provided	Not closed **Supplementary documentation is needed. Will be followed up during next visit.**
	New evaluation 20.10.2008: The calibration certificates submitted is not bearing the accreditation marks from DKD. (Accredited calibration??) It has to be clarified if on site calibration of balances is included in the accreditation scope of QSAE. Copy of the record for daily checks of the balance is still not submitted to NA	
2	*Thermometers/temperature:* • The laboratory has two reference thermometers, but the calibration certificates are missing. However, the thermometers are labelled with marks from a calibration laboratory accredited by DANAC. • The correction factors and the measurement uncertainties are not taken into account when thermometers for daily use are compared against the reference thermometer. • The temperature recording device on the autoclaves is not compared against a reference thermometer. Records are not established for the autoclaves. • Thermometers for daily use placed in the incubators have not an accuracy that is fit for purpose. • Requirements for maximum temperature deviations regarding daily readings of incubators (SOP no 3.1.1 and. 3.1.2) are not in agreement with the method requirements. • Temperature requirements for the incubator shaker (SOP no 3.1.3) are missing. • Thermometers which are calibrated by an accredited calibration laboratory are not used in equipment which require < ± 0,3 °C • All comparison studies against reference thermometers are performed solely at 44°C and don't really cover the temperature range used. The quick silver reference thermometer has now a satisfactory calibration certificate. However the TESTO temperature device has not satisfactory traceability. The TESTO certificate is not from an accredited calibration laboratory, but is issued by an ISO 9001 approved supplier. The laboratory is describing that: • Correction factors in calibration certificates are implemented. • The Min-Max thermometer has been calibrated against	**Closed, however see comment** **Will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	the reference thermometers. • They have started to use the reading of digital thermometer to record the temperature of the incubators and for those which require high accuracy. The SOPs for incubators are correctly updated. • They have started to compare the reference thermometer with the working thermometer at 44^{0}C and 5 ^{0}C. • No evidence on implementation is given for the listed changes	
	New evaluation 20.10.2008: The laboratory now exhibit satisfactory calibration certificates (QSAE which is DKD accredited) for the TESTO temperature device and the device is also compared against the liquid in glass reference thermometer. Evidence on implementation of temperature comparisons is given (SOP 3.11.8). The temperature deviation is established. The raw data do not give any information on measurement uncertainties and how the laboratory takes this into account. *Comment:* The laboratory has given information about new control routines for the autoclave. The max-min thermometer is broken and the laboratory has decided to only use control by a bio indicator. This is not acceptable. Temperature measurements and bio indicators shall be used for control of autoclaves.	
3	*PT-participation*: The laboratory has not yet participated in any PT-schemes for water and food testing. Still not in place.	Not closed **Supplementary documentation is needed. Will be followed up during next visit.**
	New evaluation 20.10.2008: Still not in place.	
4	*Reference materials:* • The reference materials in use have expiry dates in May 2006. • So far the materials are mot used on quarterly basis as described in the quality system. • The reports issued have o not included references to personnel performing the specific tests o occasionally wrong acceptance limits o no information on non-conformity handling when the results are exceeding the acceptance limits o no trend analysis (trend plots) • The reference material which is in use does not cover the parameters "Anaerobic colony count" and "Moulds". • The laboratory has not used the reference materials for following parameters: o Enterobacteriaceae o Enumeration of E. coli (P/A tests is satisfactory performed) • For coliforms the reference material is insufficiently diluted to meet the tolerance	Partly closed **Supplementary documentation is needed. Will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	limits given from the provider. The laboratory has purchased new reference materials. Invoice from the supplier is enclosed as evidence. Due to a delay in delivery of dehydrated media and supplements needed after updating the methods, the laboratory has not yet started using the new materials. ***New evaluation 20.10.2008:*** No new information given.	
5	*Reference strains:* • The descriptions in the quality system regarding maintenance and use of reference strains are insufficient. • Neither has the laboratory established any recording system regarding maintenance and use of reference strains. SOP 5.2 is still not satisfactory. The SOP is not describing how the laboratory is keeping stock cultures, for how long they are kept, testing performed on purity and biochemical reactions etc. This also applies for the working cultures. The "Food Microbiology Analysis Data Sheet" is not a satisfactory record for maintenance of reference strains. However the record gives satisfactory traceability to reference strains used during analysis. ***New evaluation 20.10.2008:*** SOP 5.2 is improved and is principally fulfilling the requirements. However, the laboratory allows sub culturing (refreshing) the working culture. The maximum numbers of sub cultures has to be established. Likewise record for maintenance of reference strains has to be described and implemented.	Not closed **Improved documentation is needed. Will be followed up during next visit.**
6	*Environmental monitoring programme:* • The quality system has requirements regarding humidity (45-50) and temperature (20-25°C). No measurements of RH and temperature are performed. • The quality system is describing that bacteriological air testing, surface screening by swab tests and a monitoring programme for pathogens where pertinent to scope is required. o *No further details are given regarding the parameters of choice, testing* frequencies, acceptance limits and actions to be taken when exceeding the limits. o Currently the monitoring programme is not performed for all parameters listed above. The Quality Manual is revised. The monitoring program now describes use of air sterility testing and surface testing of pathogens according to the scope of application. Testing frequencies are not given. Evidence on use of the revised procedure is not given. Supplementary documentation is needed.	**Closed** **Implementation will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	New evaluation 20.10.2008: The laboratory is now describing monthly environmental testing.	
9	• No deputy for key personnel has been appointed (e.g quality manager, technical manager) • The names of key personnel and their deputies are not given in the management system. • List of all personnel, positions included, is not established in the management system • A list of authorized personnel to performing specific tests is not established. • Personal files containing CV's and certificates for external training are established. The files do not contain any authorisation documents showing the date of authorization, whom has been in charge of authorization and which criteria that are used. • No training records and work descriptions is established for supporting staff. • A description of introduction of new personnel is into essential parts of the management system and laboratory routines is not given, including how the introduction as such is going to be documented. A list of personnel is established. Key positions and deputy key positions are given in the list. Supporting staff is still not included on the list. A satisfactory training record is established. A copy of recent updates shows that supporting staff is included. No evidence regarding specific authorisations for the different tests in the scope of application (Na-S5) is provided (lists of approved personnel, authorized documents from personnel files etc.) No new information of introduction of newly recruited personnel into essential parts of the quality system is given.	Partly closed **Improved documentation is needed. Will be followed up during next visit.**
	New evaluation 20.10.2008: Supporting staff is now satisfactory included in the list of personnel. Evidence regarding authorisations for the specific tests in the scope of application (Na-S5) is still lacking. Likewise is information of introduction of newly recruited personnel into essential parts of the quality system lacking.	
10	*pH-meter:* • A two point calibration is in use, but the SOP is not describing the use a control solution after calibration. (A third buffer is accepted for culture media QC). • No record is established in connection to the pH- meter. The laboratory has to record calibrations, measurements of control solutions, cleaning and maintenance of electrodes etc. The laboratory describes that they have implemented use of a third buffer as a control solution. The evidence to support this is not satisfactory. No record for the control and maintenance of the pH-meter is enclosed. Supplementary documentation is needed.	**Closed** **Implementation will be followed up during next visit**

NC no	Reason for closing	Conclusion
	New evaluation 20.10.2008: A copy of the log book is now presented. The log book contains control data from July to October.	
11	*Culture media* • A QC record for production is not established (e.g. weighing, heat treatment, pH on end product, physical appearance sterility, suitability etc • Storage times and storage temperatures are not given in the specific culture media SOP' • Tubes containing broth and agar kept at room temperature in the laboratory has no traceability to production date and expiry date • Quite many bottles of dehydrated media stored in the laboratory and storage room have exceeded the expiry date with up to ten years. • There are also observed different kits with exceeded expiry dates, e.g sera for Salmonella, API kits from BioMerieux. A satisfactory QC record for culture media is established. A copy of the record shows that the laboratory has implemented the new procedure. All culture media SOPs are revised. Information of labelling of prepared culture media is now included in the SOPs. Storage temperature for prepared media is also included. However, storage times are still missing. Final pH is given in some SOPs but are missing in others (Examples PCA, LIA, BA, +++). Supplementary documentation is needed. When final pH is given the laboratory is using the word "should" in stead of "shall". The laboratory describes that expired media and kits are isolated and new consumables are put into order. ***New evaluation 20.10.2008:*** The culture media SOPs are improved and are now containing satisfactory shelf lives.	**Closed** **Practical use of the SOPs will be followed up during next visit**
12	*Methods:* The Quality manual SOP 1.1 states that latest edition of methods is going to be used. However the laboratory has no system in place to follow up which methods that is currently valid. Most of the official and standard methods applied for are outdated and regarded as obsolete documents. Currently the laboratory has no access to the valid official and standard method needed. See attachment for further information. All methods are now revised in a proper way. Only valid versions are currently in use.	**Closed**
16	*Traceability raw data:* When conducting the vertical audit on Lab. Reg. No.138/07 following observations were done: • Traceability to individual working steps in the method is partly lacking (dates and signatures)	**Closed** **Implementation has**

NC no	Reason for closing	Conclusion
	• Traceability to batches of culture media, kits and solutions used are missing A "Food Microbiology Analysis Data Sheet" is established. The data sheet seems to take care of the proper traceability. No evidence on implementation is given.	**to be followed up during next visit**

Date: 21.10.2008

Anne Grændsen
Technical assessor

NC no	Reason for closing	Conclusion
7	*The description of the document control system is not satisfactory.* *The document control system is not properly implemented.* *Se appendix to this NC (NC 7) for details.* The description of the document control system has improved but is still not satisfactory. For instance: • It is not clearly described who (which position) can approve each (type of) documents. • Document control of forms • Mistakes in cross-references still exists e.g. ref. to section 4.1.4 in OM section 4.2.4. • Is it now described how info on changes in documents are given to staff? • Computerized systems still not described. Document history is a part of SOP 1.4 and the List of documents is part of the QM. This seems to de very unpractical since these documents then have to be changes whenever documents in those lists are changed. If is recommended that these lists are established as separate documents. Master list has not been sent to lead assessor for verification. Implementation: This has to be checked on-site but from the documentation we can see that role for identification of changes in documents (as described in 4.3.3.2 in QM) is not implemented. ***New evaluation 22.10.2008:*** It is still unclear who can approve all types of documents. Responsibilities are given for procedures and policies but what about all other types of documents which is part of the management system? A new master list is established but it is not a controlled document. The master list only includes some of the SOP's. What about the rest of the SOPs and all other documents in the management system? A master list should give an overview of all the documents in the	**Partly closed** **Supplementary documentation/descriptions have to be developed.** **The document control system will be evaluated again and followed up during next visit.**

NC no	Reason for closing	Conclusion
	management system and the valid edition of each document. No new information found regarding other issues raised during the first feedback. The quality manual will be evaluated in connection with a new assessment visit. The enclosed quality manual is dated (on page 1) 2007/07/15 (date of issue) but the in headings on each page no date is given (effective date). The edition no. is still the same (3. edition) although changes have been done. The document control of the QM is not good enough.	
8	*The use of the purchasing office is not described and their role in evaluating suppliers is not clarified.* *No evaluation of suppliers can be documented.* *For each media/reagent the producer is identified in the media SOP, however no list of approved suppliers is established.* The description in the QM has now been updated. No documentation for implementation has been received so this has to be checked during next visit.	**Partly closed** **Will be followed up during next visit.**
13	*The laboratory has not started using the system for registration of non-conforming work and for corrective action as described in the quality manual and SOP 1.6 and 1.7.* *SOP 1.7 is mixing corrective and preventive actions.* *The form established to register NCs and corrective actions (SOP 1.7.1) is not satisfactory.* *How each NC is identified with a running number is not described, neither that all NC forms should be kept in a binder.* Numbering of filled in NC-forms is now described. For the rest of the NC no documentation have bee sent in for verification (revised SOP 1.7 and SOP 1.7.1) have not been sent in). No documentation that show that NCs are registered on NC form and handled/corrected according to SOP 1.7 is not revived either. ***New evaluation 22.10.2008:*** SOP 1.1 is revised but still it is a mixture of corrective and preventive action. ISO 17025 says: If a non-conformity is registered corrective action(s) shall be performed. If a potential corrective action is identified a preventive action	**Not closed** **Supplementary documentation is needed. Will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	shall be performed. The SOP does not clearly state what an NC is (this is described in ISO 17025). The laboratory has to describe more clearly and in accordance with ISO 17025 what their policy regarding registration of NCs is. SOP 1.7.1 is sent in electronically but we are not able to download it. However, filled in forms have also been sent in. They show that there are no headings in the form indication where to put the proposed corrective actions. The forms filled in are all concerning NCs given by the NA team during the assessment visit. The lab has therefore not documented that they register NCs during their daily work. Several parts of the forms are not filled in. All parts of the form should be filled in so that we can see that has been considered.	
14	*An internal audit was performed in November 2007 which should cover all elements of ISO 17025. The report from the audit does not document that all elements were covered.* *The use of checklist as described in the management system was not followed.* *The established checklist does not cover all elements of ISO 17025. The work of the Quality manager and observation of test methods should especially be included.* *No plan for internal audit is established for 2008.* *The lab has not performed vertical audits, only horizontal audit.* No documentation for corrective actions has been sent to the lead assessor. ***New evaluation 22.10.2008:*** No revised checklists have been sent in for evaluation. No plan for internal audits for 2009 has been sent in. A new internal audit has been performed. In the report it is claimed that a vertical audit is performed. However, no indication of a vertical audit can be found in the audit report. When doing a vertical audit you start with a copy of a test report sent to a costumer and you then trace back all registrations done in connection to the test results reported in that report. The report does not give enough information on what was checked during the audit. In NA Dok 9 the following guidance regarding internal audits are given:	**Not closed** **Supplementary documentation is needed. Will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	The main purpose of internal audits is to ensure that the quality system has been implemented. During internal audits it is checked that the requirements of the quality manual (and related documentation) has been implemented at all levels in the organisation, and that the management system complied with the accreditation requirements. The audits shall cover all parts of the laboratory's management system covered by the accreditation standard and additional requirements given by the accreditation authority. **The audit plan should cover all activities related to the general management system and testing/ calibration activities but also site testing, sampling, flexible scope and opinions and interpretations if covered by the laboratory's accreditation. Personnel employed on contract and subcontractors should also be included in the audit plan. The work of the quality manager should be audited periodically corresponding to the other elements of the quality system.** **The cycle for internal audits shall be completed in one year.** **Care should be taken to control the value of internal audits that are performed by personnel not completely independent of the audited activity.** **The audit plan should include both horizontal and vertical audits.** **<u>Horizontal audits</u> comprises a detailed control of the elements of the management system, e.g. training of personnel, maintenance of competence, equipment, reference standards, validation, internal quality control, handling of PT/ILC results, test methods, document control, preventive actions, handling of non-conformities, corrective actions, archiving, internal audits and handling of complaints.**	

NC no	Reason for closing	Conclusion
	In vertical audits a representative number of test reports are chosen at random. All activities connected to these tests are checked. The tests are repeated if possible. **The format of reports from internal audits should be formalised as far as possible to ease the performance of the audit itself. For example, it can be useful to prepare a form where the elements to be audited are listed and non-conformities and corrective actions are registered.** **It may also be appropriate to prepare a standard format for the reports from internal audits to ensure that a summary and conclusions are included in the report.** **Reports from internal audits should not only refer to the non-compliances noted, but also include positive statements and the auditor's summary and /or conclusions.** **Quality audits performed by customers, the accreditation authority or other external parties do not reduce the laboratory's own need to perform internal audits.**	
15	*The use of the accreditation mark is not described in the management system.* *A description of how the laboratory intends to comply with the conditions stated in NA Doc. 25/31 is not included in the management system.* The laboratory claims that this is now described on page 11 of the Quality Manual. No evidences of such descriptions are found there (SOP 1.1 Edition 3 effective from 1.5.08). ***New evaluation 22.10.2008:*** The use of the accreditation mark is now described. However, the description is making reference to NA Dok. 25/31 but it is **NA Dok. 14** that describe the rules for use of the accreditation mark. The descriptions are too short and for instance a	Not closed **Supplementary documentation is needed. Will be followed up during next visit.**

NC no	Reason for closing	Conclusion
	description of where the laboratory plan to use the accreditation mark must be given. A description of how the laboratory intends to comply with the conditions stated in NA Doc. 25/31 is still not included in the management system.	

22.10.2008

Roald K. Nilsen
Lead assessor