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ADAPTATION OF A LABORATORY QUALITY MANUAL BASED ON THE EUROPEAN STANDARD EN 45001:1989 TO ISO/IEC 17025: 1999

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ABSTRACT

The adoption of the International Standard ISO/IEC 17025: 1999 “General requirements for the competence of testing and calibration laboratories”, as the new standard for laboratories and its accreditation has had a global impact. This paper contains an analysis of the sections and clauses that are to be included in a laboratory’s quality manual based on the European Standard EN 45001:1989 “General criteria for the operation of testing laboratories” in order to comply with the requirements of the new ISO Standard.

A “diagnosis audit” to this quality manual was performed using the applicable requirements of ISO/IEC 17025. The content of these two standards was compared for supplementing and drafting the missing sections. The main conclusions from the audit point out that seven clauses from ISO/IEC 17025 need to be included in the quality manual. Thereof, three are new and the rest correspond to activities performed by the organization, which are not fully documented. In this report it will be shown how to introduce the new requirements of the standard into an already-established quality system. Furthermore, the inclusion of some guidelines to those chapters that needed little modification was also performed. The implementation of an ISO/IEC 17025-based quality manual for a laboratory has some advantages. An accredited laboratory by this standard can perform tests in certain areas such as the verification of compliance to regulations on handling, production and placing of food products in market.

TABLE OF CONTENTS

1. INTRODUCTION

The European Technical Committee on Conformity Assessment requested the revision of the International Standard ISO/IEC Guide 25:1990 “General requirements for the competence of calibration and testing laboratories” to the International Organization for Standardization in 1993. As a result of the revision process, the standard ISO/IEC 17025: 1999 “General requirements for the competence of testing and calibration laboratories” was approved. This is the new standard for laboratory operations and it is also considered as the new criteria for laboratory accreditation.

The accredited laboratories by SWEDAC (Swedish Board for Accreditation and Conformity Assessment) have been assessed in accordance with the requirements set out in European standards (the EN 45000 series) and in certain cases, also in accordance with requirements set out in ISO guides and standards (SWEDAC homepage, 2001). One of the on-going activities that these laboratories should carry out is the implementation of ISO/IEC 17025 requirements in their quality manual for further surveillance and re-assessment visits of this accreditation body.

On a global scale, testing and calibration laboratories have used two standards for organizing, planning and documenting their quality systems. The European Standard EN 45001:1989 “General criteria for the operation of testing laboratories” for the European market and ISO/IEC Guide 25 for the non-European market. Now there is only one text. The ISO/IEC 17025 standard provides a more structured and comprehensive approach. It covers testing, sampling and calibration laboratories as well as first, second and third party laboratories, and is brought in line with ISO 9001/2 standard for quality management systems. (van de Leemput 2000).

The basis of this report is a quality manual used in a laboratory that is accredited by SWEDAC. A proposal is made on how to introduce the new requirements of the standard ISO/IEC 17025 in the quality manual. Another subject under review is related to the impact of these requirements in the laboratory quality management system. Some suggestions are given for its implementation in practice.

2. BACKGROUND

2.1 Work done in Europe

In 1993 the European Technical Committee on Conformity Assessment (CEN/CLT TC1) asked the International Organization for Standardization (ISO) to start a revision of the ISO/IEC Guide 25 “General requirements for the competence of calibration and testing laboratories”. The European Standard EN 45001:1989 “General criteria for the operation of testing laboratories” was drawn up in a short period of time and was a mixture of requirements for laboratories and requirements specifically related to accreditation. For this reason, this standard was not considered acceptable, and an inquiry was held to accept ISO/IEC Guide 25 as the successor of EN 45001. The inquiry did not get the necessary majority, which resulted in the letter to ISO. As the question was related to a Guide that was published only three instead of five years after its publication, ISO decided to investigate whether such a revision was useful and necessary. The first step that the Conformity Assessment Committee (CASCO)

took was the organization of a hearing on January 12th 1994 with all the interested parties. A small task force was formed with the aim to come up with a documented recommendation. Based on this recommendation ISO/CASCO decided, in its meeting of June 1994, to start with the revision of ISO/IEC 25. After a six-year period of the revision process, a new standard was approved and adopted, titled ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories". (van de Leemput 2000)

Kohl (1998) and van de Leemput (2000) have summarized the main differences between the content of ISO/IEC 17025 with ISO/IEC Guide 25 as follows.

1. The scope of the standard covers the technical activities of a laboratory and the management and organizational aspects to perform the technical activities in a competent way.
2. The document control clause is brought in line with ISO 9001:1994. More specific requirements for the review, approval, issue and amendment of documents is included.
3. The review of requests, tenders and contracts is a new clause of the International Standard.
4. The clause of "Purchasing services and supplies" is a simplified version of the equivalent clauses in ISO 9001:1994.
5. The clause of "Control of non-conforming testing and/or calibration work" includes the requirement for specific procedures for dealing with non conforming work and results, and is in line with ISO 9001:1994.
6. The "Corrective action" clause includes the requirement of specific procedures for cause analysis, selection and implementation of corrective actions, subsequent monitoring and follow-up audits. This clause is now in line with ISO 9001:1994.
7. "Preventive action" is a clause from ISO 9001:1994 and is new for laboratories. The clause deals with the improvement process and promotes the solution of some problems and non-conforming work.
8. The "Management reviews" clause specifies the aspects that need to be taken into account during a management review.
9. The "Test and calibration methods and method validation" clause includes requirements for the selection of methods, laboratory-developed methods and non-standard methods.
10. The "Measurement traceability" clause is the only section in the standard where a distinction has been made between calibration and testing laboratories.
11. The criteria for the "Sampling" clause are new.
12. The clause "Reporting the results" has an option of including opinions and interpretations in a test report.

The foreword of this International Standard claims that the standard has been produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it now replaces. It contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

The significance of the International Standard ISO/IEC 17025:1999 is mainly due to several factors. First, it is the new standard for laboratories. Secondly, the worldwide

acceptance and recognition by accreditation bodies, such as; The United Kingdom Accreditation Services, Chinese National Laboratory Accreditation, Finnish Accreditation Service, Canadian Association for Environmental Analytical Laboratories, International Accreditation New Zealand and American Association for Laboratory Accreditation. (UKAS, FINAS, CAEAL and IANZ homepages)

2.2 The importance of accreditation

The definition of accreditation and its implications for international trade is as follows. “Accreditation means recognition of the competence of a laboratory. By means of accreditation, testing and calibration laboratories can demonstrate that they meet certain requirements based on international agreements. In an integrating Europe, proof of competence has become an increasingly important factor promoting trade and cooperation. Application for accreditation is voluntary. By means of accreditation, a laboratory can prove the credibility and reliability of its activities and the certificates it grants.” (FINAS 1999).

Laboratory accreditation provides some assurance of the technical proficiency and competence of a laboratory to assess the conformity of a product or service to a set of prescribed standards. Laboratory accreditation is also defined by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) Guide 2 as the formal recognition of the competency of a testing laboratory to carry out specific tests or specific types of tests. A footnote to this ISO/IEC definition indicates that laboratory accreditation may include the recognition of both the technical competence and impartiality of a testing laboratory or only the technical competence. (NIST 1991)

The significance of laboratory accreditation has increased as international recognition and acceptance of test data across national boundaries. It has assumed greater importance in the reduction of technical barriers to trade. The competence of laboratories which perform testing within an evaluation/approval system is vital in securing acceptance of their results by other countries. Mutual acceptance of laboratory test results between countries can reduce the need for unnecessary re-testing and serve as a basis for increased opportunities in international trade.
The contribution of accreditation to international trade is also significant. Accreditation is expected to facilitate international trade, by assisting in the international acceptance of calibration, test and inspection results, as well as certificates. The two mechanisms for this are:

- the mutual recognition agreements between the accreditation bodies themselves, under the auspices of ILAC, EA and other regional accreditation co-operations,
- the reference to accreditation as a means of qualifying services performed for assessing compliance to regulations in bilateral or multilateral treaties and arrangements (e.g. GATT agreements, EU policy or agreements between the EU and third countries). (Eurolab 2000)

2.3 Accreditation in Iceland

In 1990 the Icelandic government and SWEDAC, representing the Swedish government, signed an agreement regarding the development of accreditation and metrology in Iceland. This agreement has been used mainly for the development of an

accreditation scheme. (Fridgeirsson 1996). On the other hand, SWEDAC has signed Multilateral Agreements (MLA) with the European co-operation for Accreditation (EA) in different fields of accreditation and certification (EA 2000).

Iceland has enacted a "Law on weight, measure and accreditation" (Law no. 100 of December 16th 1992) and is still in force. (LS 2001). The relevant points are:

- ✓ LS (Löggildingarstofan, Bureau of legal verifications) shall provide access to accreditation for bodies responsible for testing (including calibration), inspection and certification. LS also has the responsibility for assessing notified bodies and is the recognized authority for GLP (Good Laboratory Practice, rules for chemical testing laboratories).

- ✓ The new metrology law of January 1st 1993 is considered to be general enough to allow the implementation of all the EU directives on measuring instruments as well as directives dealing with accreditation, inspection, certification, and testing.

Likewise, the Environmental and Health Agency of Iceland enacted the Regulation No. 522/1994 on "Food control and hygiene in production and distribution of food. Article 21 relates that:
"Testing laboratories that are performing testing according to the Regulations should comply with the rules of EN 45001 and Good Laboratory Practices from OECD and they need to be accredited" (EHA 2001).

3. METHODS

3.1 Diagnostic Audit

A diagnosis audit was performed. It is an in-depth evaluation and comparison of the documentation for the organization, specific elements of the organization, product, services, etc., against the reference standard, predetermined by the client. In this case, the applicable requirements of ISO/IEC 17025: 1999 (ISO 9000 Series)

3.2 Comparison between ISO/IEC 17025 and EN 45000 requirements

A comparison between the requirements of ISO/IEC 17025 and EN 45001 was conducted with the aim of determining the "gaps". The Icelandic Fisheries Laboratories Quality Manual, which has been accredited by SWEDAC, was subjected to the "diagnostic audit" for assessing the compliance with ISO/IEC 17025 requirements (ISO 9000 Series).

3.3 Internal audits

In addition, two scheduled internal quality audits were carried out on December 12th 2000 to the chemical and microbiological laboratories. The procedure and the checklist used are included in the Icelandic Fisheries Laboratories Quality Manual main book and supplements. The purpose of these audits was to verify the effectiveness of the laboratory operations within the quality system to the documented procedures. Traceability, calibration, equipment, samples, proficiency test documents,

control charts, corrective actions applied, written records and the documentation used by the laboratory, were checked in the audits. (Huss 1994, ISO 9000 Series).

3.4 Cross-references from ISO/IEC 17025 to ISO/IEC Guide 25 and EN 45001

Cross-references from ISO/IEC 17025 to ISO/IEC Guide 25 and EN 45001 prepared by Deutshcher Akkreditierrungs Rat, a German accreditation body were also used in the evaluation.

4. RESULTS

The diagnostic audit was used to assess the adequacy of the quality manual content against the specified requirements of ISO/IEC 17025. Through this procedure it was possible to determine the missing clauses of the International Standard (Appendix 1).

The sections that are missing in the laboratory quality manual and their link in the standard are as follows:

- ✓ Review of requests and tenders
- ✓ Preventive actions
- ✓ Method validation
- ✓ Control of non-conforming test work (not fully documented for other related activities)
- ✓ Corrective actions (not fully documented for other related activities)
- ✓ Management reviews (they are performed, but there is no documented procedure)
- ✓ Sampling

These were the “problem areas” identified in the diagnosis audit. They need to be improved according to the ISO/IEC 17025 standard requirements and as a result of the audit itself. The missing clauses are to be included in the quality manual for its further implementation by the laboratory. The wording and content of the missing clauses is in line with the laboratory quality system’s policies and procedures.

A thorough description of each section is given below. Guidelines on how to implement the necessary changes into the quality manual are also provided. Each section also refers to the numeral in the standard.

4.1 Review of requests and tenders

This section corresponds to paragraph 4.4 in the ISO/IEC standard.
It is the laboratory policy to provide analytical services to its clients with promptness, efficiency and quality. For attaining this purpose, the laboratory has prepared different tenders of analytical services to its clients, attending to their specific requirements. In addition to these tenders, the laboratory applies a “Procedure for the review of requests from clients”, before performing tests and analyses to the specified items. In any case, the laboratory assures that the clients’ requirements and the test methods to be used are adequate, defined, communicated and understood by the responsible persons who will perform the analytical work.

The Analytical Services Director and the Head of Department(s) involved will review the customer request and evaluate the actual capability of the laboratory and the necessary resources to accomplish it according to the "Procedure for the review of requests from clients".
Whenever a client's request is received, the responsible person(s) will review it before performing the test(s) with the purpose of checking if:

- ✓ the client requirements are properly defined,
- ✓ the laboratory has the capability to meet the client's requirements

If there are differences between the request and the tender, these shall be solved with the client before the analytical work commences.
At any time a client's request may be reviewed. These events shall be recorded whether significant changes occur or not. Relevant discussion with the client concerning requirements or the results of the analytical work during the period of execution will also be recorded.
Illustrative examples are included in Appendix 2, 3 and 4.

4.2 Preventive actions

This section corresponds to paragraph 4.11 in the ISO/IEC standard
The laboratory will identify the necessity of improvements and potential sources of non-conformities either technical or concerning the quality system. Preventive actions shall be applied in the laboratory daily operations. If the implemented actions are not sufficient to reach the expected results, then an action plan shall be developed, implemented and monitored to reduce the likelihood of occurrence of such non conformities and to take advantage of the opportunities for improvement.

Procedures for preventive action (or action plan) shall include the initiation of such actions and application of controls to ensure that they are effective.

4.3 Method validation

In paragraph 5.4 of the standard 17025 there is a clause 5.4.5 Validation of methods, where some improvements have to be made.

4.3.1 General
Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
The laboratory shall validate:

- ✓ laboratory-designed/developed methods
- ✓ standard methods used outside their intended scope
- ✓ amplifications and modifications of standard methods to confirm that the methods are fit for the intended use

The validation shall be as extensive as is necessary to meet the needs of the field of application. The relevant Department shall record the results obtained, and a statement as to whether the method is fit for the intended use.
The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- ✓ calibration using reference standards or reference materials;
- ✓ comparison of results achieved with other methods;
- ✓ inter-laboratory comparison;

- ✓ systematic assessment of the factors influencing the result;
- ✓ assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience

As a rule, a method validation procedure should contain at least the following:

a) appropriate information;
b) scope;
c) description of the type of item to be tested;
d) parameters or quantities and ranges to be determined;
e) apparatus and equipment, including technical performance requirements;
f) reference standards and reference materials required;
g) environmental conditions required and a stabilisation period needed;
h) description of the procedure, including:
   - ✓ affixing of identification marks, handling, transporting, storing and preparation of items,
   - ✓ checks to be made before the work is started,
   - ✓ checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before use,
   - ✓ the method of recording the observation and results,
   - ✓ any safety measures to be observed;
i) criteria and/or requirements for approval/rejection;
j) data to be recorded and method of analysis and presentation;
k) the uncertainty or the procedure for estimating uncertainty.

4.4 Control of non-conforming test work

This section corresponds to paragraph 4.9 in the ISO/IEC standard.
The laboratory policy is oriented to good professional practices when rendering its analytical services. For attaining this goal, the laboratory has implemented an internal quality control program and applies preventive measures. Quality audits and internal control are carried out for this purpose. Any non conformity that is detected at any stage of the test work or in the result of the test work by the Head of Department, Branch Manager, Quality Manager, Director of Analytical Services or the Director shall be registered in the relevant records.
If a non-conformity is detected or identified during the running of tests, in the results or a departure exists from the laboratory quality system policy the testing work is considered non-conforming. Some examples are included in Appendix 5.
When a non-conforming testing work is registered, the Head of Department/Branch Manager shall review the possible causes that gave rise to this event and shall adopt the corrective actions. Whenever a corrective action is taken, it shall be registered in the relevant record. In Appendix 6 a record is included.
The designated person shall perform follow-up activities to check if the possible causes that lead to the non-conformity have been eliminated. Records of these actions will be maintained and the designated parties informed, according to the relevant procedures.

4.5 Corrective actions

This section corresponds to paragraph 4.10 in the ISO/IEC standard
The laboratory shall establish procedures for the adoption of corrective actions whenever non-conformities in test and internal calibration work, results from tests and

departures from the laboratory quality system policies and procedures are identified/detected. A cause analysis shall be done when starting an investigation to determine the root cause of the non-conformities.
Corrective actions shall be selected and implemented by the responsible/designated person(s) for eliminating the root causes that gave rise to the non-conformities and the prevention of its recurrence. The selection and implementation of corrective actions will be appropriate according to the magnitude and risk of the problem.
If necessary, the laboratory shall document and implement any required changes resulting from any cause analyses in its quality system policies and procedures.
The Head of Department/Branch Manager shall monitor the results from the moment corrective actions were adopted by the responsible person(s). Its main objective is to ensure that the adopted measures have been effective. Under certain circumstances, the laboratory senior management could order the performance of a non-scheduled quality audit to the relevant area(s), where the identification of the above mentioned non-conformities or departures cast doubt on the laboratory compliance with its policies and procedures. The audit will be performed according to the documented procedure in force.

4.6 Management reviews

This section corresponds to paragraph 4.14 in the ISO/IEC standard.
In accordance with a predetermined schedule and procedure, the Quality Manager as the Management representative shall periodically conduct a review of the laboratory quality system, testing and internal calibration activities to ensure their suitability and effectiveness and to assess the need of introducing changes or improvements. The review shall consider:

- ✓ the suitability of the laboratory policies and procedures;
- ✓ reports from managerial and supervisory personnel;
- ✓ the outcome of recent internal audits;
- ✓ corrective and preventive actions;
- ✓ assessments by external bodies;
- ✓ the results of inter-laboratory comparisons of proficiency tests;
- ✓ changes in the volume and type of work;
- ✓ client feedback;
- ✓ complaints;
- ✓ other relevant factors, such as internal controls, resources and staff training.

All the findings from the management reviews and the actions derived from these shall be recorded. The management shall ensure that these actions are carried out in an appropriate manner and agreed time schedule.

4.7 Sampling

This section corresponds to paragraph 5.7 in the ISO/IEC standard.
If the laboratory should perform sampling of food products, water, seawater and surfaces upon request from clients and accreditation bodies for subsequent testing in its facilities; sampling plans and sampling procedures will be applied.
These documents will be available at the location where sampling is to be performed.
The sampling plans for products shall be based upon Military Standards 105 Series, ISO Standards and Codex Standard for Pre Packaged Foods (Duncan 1974, Kramer and Twigg 1979). Other sampling procedures should be applied according to the type and presentation of products and places where products are assessed. For

microbiological analysis, specific-sampling procedures must be used (Messer et al. 1992). Attention should be paid to the sampling process itself to obtain valid test results and to preserve samples from deterioration and contamination.
When a client requests the laboratory to take samples using procedures other than are described in the quality manual, this shall be recorded in the relevant sampling data and related records, and communicated in advance to the designated personnel.
The laboratory has procedures for recording relevant data and operations relating to sampling that form part of its analytical service. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant), the sampling location and other relevant data.
The laboratory has a list of approved personnel to take samples for further testing in its facilities.

5. DISCUSSION

The missing clauses have been drafted for its inclusion in the laboratory quality manual. The writing and content of these clauses is in line with the laboratory quality system's policies and procedures. In this way, the quality manual conforms to ISO/IEC 17025 requirements. Three clauses are new in the laboratory quality management system: review of requests and tenders, preventive actions and method validation. The first one is linked to the quality of analytical services. The second and third clauses bear a direct relationship with the quality of analytical results provided by the laboratory to its clients.

The clause 4.4 "Review of requests and tenders" is brought in line with ISO/DIS 9001 "Quality Management Systems. Requirements". Its inclusion in the laboratory quality management system stands for a change in the criteria of analytical services rendered to its clients. Being a new requirement of ISO/IEC 17025, it is at the same time a criterion for assessing the laboratory competence (Folke 1988). Its utilization in practice involves some advantages for the interested parties, primarily the set-up of conditions for analytical services and a significant improvement of its quality.

Preventive actions in clause 4.11 is also a new approach in the quality management system of the laboratory. It is considered to be a pro-active process to identify opportunities for improvements, rather than a reaction to the identification of problems and complaints. Some examples of these actions could be the regular review of the laboratory working operational procedures, the analysis of test results of products including trends and proficiency test results. Its practical contribution in the laboratory operations must be reflected in the quality of its analytical results.

Method validation is an explicit requirement included in ISO/IEC 17025, but was utterly absent in EN 45001. It is defined as the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. The ISO/IEC 17025 standard recommends that it must be applied when the laboratory runs non-standard methods, laboratory-developed methods and standard methods used outside their intended scope, and amplifications and modifications of standard methods. Not being a big issue for an accredited laboratory that uses standard methods and internationally accepted methods, the validation of methods may also be applied for determining the performance of a method.

All of these clauses that are to be included in the quality manual of an accredited laboratory generate additional working procedures, records and demand a change in attitude from the laboratory managerial and technical personnel. Additional training in some techniques of quality improvement could be necessary when implementing preventive actions. The study of method validation recommended by the Association of Official Analytical Chemists (AOAC) should be considered for the laboratory's future activities. The last but not least important activity for the implementation of the changes in the laboratory quality system is its dissemination. The laboratory senior management should undertake seminars and lectures and other initiatives. The time frame to implement the ISO/IEC standard requirements will depend on the laboratory specific conditions and the way utilized to overcome the resistance to change.

6. CONCLUSIONS

1. The laboratory quality manual contains all the relevant clauses of ISO/IEC 17025.

2. The content of each clause is in compliance with the applicable requirements of this International Standard and in line with the laboratory quality system policies and procedures.

3. The laboratory quality system is in line with ISO/DIS 9001 Quality Management Systems. Requirements, following the inclusion of the ISO/IEC 17025 new clauses.

4. The changes to be introduced in the laboratory quality manual are not numerous, as a result of its continuous revision carried out regularly.

7. RECOMMENDATIONS

1. A clause needs to be completed by drafting the missing items. In this way, the laboratory quality manual meets all the applicable requirements of ISO/IEC 17025 in the laboratory operations.

2. The laboratory is encouraged to implement the clause “Review of requests and tenders” from ISO/IEC 17025. This stands for an improvement in the quality of its analytical services.

3. The laboratory senior management must disseminate the changes in the quality management system. Some ideas and initiatives for implementing the changes are provided, including the direct participation of staff.

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APPENDIX 1. RESULTS OBTAINED IN THE DIAGNOSIS AUDIT.

ISO/IEC 17025 items	applicable clauses	clauses included in the Quality Manual	Comments
4. Management requirements			
4.1 Organization	14	14	
4.2 Quality system	9	9	
4.3 Document control	10	10	
4.4 Review of requests, tenders and contracts	8	-	A new requirement of the ISO standard
4.5 Subcontracting of test and calibrations	4	4	
4.6 Purchasing services and supplies	4	4	
4.7 Service to the client	1	1	
4.8 Complaints	1	1	
4.9 Control of non-conforming work	7	-	A new requirement of the ISO standard
4.10 Corrective actions	5	-	A new requirement
4.11Preventive actions	2	-	A new requirement
4.12 Control of records	7	7	
4.13 Internal audits	4	4	
4.14 Management review	2	2	They are performed without a documented procedure.
5. Technical requirements			
5.1 General	2	2	
5.2 Personnel	5	5	
5.3 Accommodation and environ-mental conditions	5	5	
5.4 Test and calibration methods and method validation	14	10	Clause 5.4.5 for method validation is missing
5.5 Equipment	19	19	
5.6 Measurement traceability	7	7	Clause 5.6.3.4 is partially documented
5.7 Sampling	3	3	Sampling criteria are missing
5.8 Handling of test and calibration items	4	4	
5.9 Assuring the quality of test and calibration results	6	6	
5.10 Reporting of results	14	14	
Total	157	131	

APPENDIX 2. PROCEDURE FOR REVIEW OF REQUESTS AND TENDERS.

1. Objective

To establish a standard procedure for the review of requests from clients, at the time they ask for the laboratory analytical services.

2. Scope

This procedure covers the laboratory analytical services and it is mainly intended for the accredited test methods.

3. Responsibilities

The Director of Analytical Services Division and the Head(s) of Department involved.

4. References

The Laboratory Quality Manual Main Book and supplements, and Quality handbooks for the departments. The Laboratory tender in an analytical service-format.

5. Development

5.1 A client asks for the laboratory analytical services for one or various products with his requirements.

5.2 The laboratory reviews the client's request.

The necessary information for this review encompass:

- ✓ Type of product to be tested.
- ✓ Purpose of the test (HACCP verification; regulatory HACCP verification; compliance with regulatory requirements in inspection and surveillance by inspection bodies, official agencies, etc.; legal requirements for export; other purposes).
- ✓ Test(s) to be performed.
- ✓ Test method to be used in each analysis.
- ✓ Sample size (quantity and number).
- ✓ Sampling procedure applied by the client or to be applied by the laboratory.
- ✓ Conditions of handling, packaging, storage, preservation and transport of samples.
- ✓ Identification to be included in the package, bag, bottle, etc.
- ✓ Samples are sent to the lab, or
- ✓ The laboratory takes samples at the client's facility.
- ✓ Time frame the test result/certificate is ready, from the time the sample is received in the laboratory or taken from the plant.
- ✓ Test report or certificate.
- ✓ Inclusion of opinion and professional judgement upon the client's request. It may also depend on the market requirements and under special situations.
- ✓ Communication means that shall be used by the laboratory to send the test report or certificate (fax, e-mail, post office, a carrier from the client, other means).

- ✓ Other requirements to be agreed between the parties

For this review, the laboratory takes into account its capability and resources to meet the client request.

5.3 The laboratory answers the client proposing him a tender of analytical services.

5.4 The client goes over the laboratory tender.

5.5 The client accepts the laboratory tender.

5.6 The client and the laboratory reach to an agreement concerning the tender of analytical services.

5.7 The Director of Analytical Services Division informs the Head (s) of Department about the agreement with the client.

5.8 The Head of Department involved is acquainted about the agreement with the client. This information is kept for planning purposes. He/she must bear in mind that the purpose of the test should never be informed to the analyst.

In the event that the client rejects the laboratory tender.

5.5.1 The client rejects the laboratory tender.

5.6.1 The client and the laboratory negotiate new terms and conditions of the analytical service.

5.7.1 The client and the laboratory reach to an agreement.

5.7.2 The Director of Analytical Services Division informs the Head (s) of Department about the agreement with the client

5.8 The Head of Department involved is acquainted about the agreement with the client. This information is kept for planning purposes. He/she must bear in mind that the purpose of the test should not be informed to the analyst.

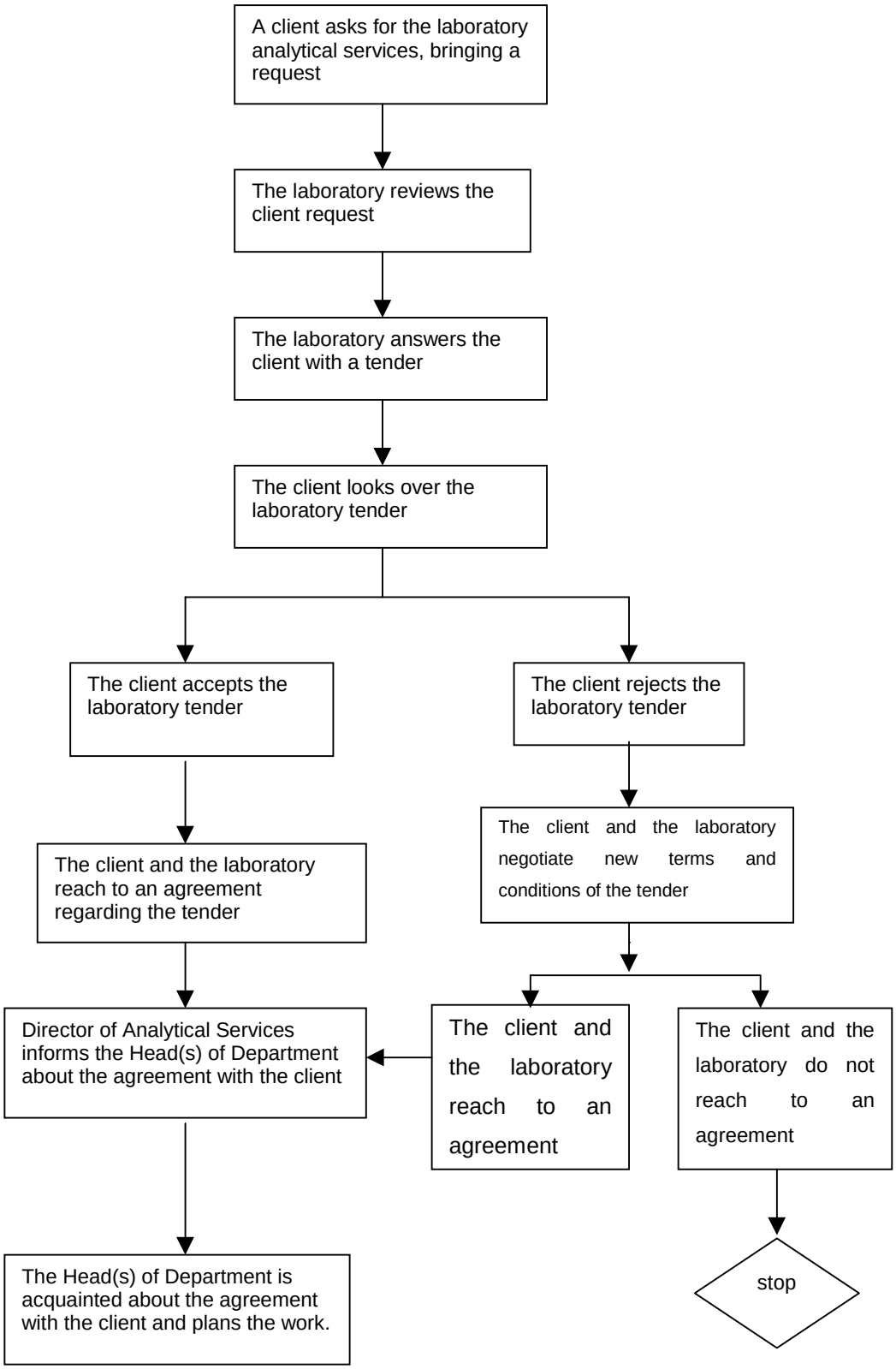
6. Records

The records that shall be used in this procedure will be:

a) Record of agreement(s) with the client request for analytical services.

b) Record of amendment(s) for client agreement(s) with the laboratory, either requested orally or on writing to the laboratory.

APPENDIX 3. GRAPHIC OF "REVIEW OF REQUESTS AND TENDERS"



APPENDIX 4. ANALYTICAL SERVICE TENDER FOR LABORATORY XXX

PRODUCT: FROZEN FISH FILLET AND FISH PRODUCTS

MICROBIOLOGICAL ANALYSES TO BE PERFORMED

- PLATE COUNT
- COLIFORM (TOTAL AND FAECAL)

Name of the method: Total plate count: Pour-plate method
Reference: American Public Health Association (APHA): Compendium of Methods for the Microbiological Examination f Foods, 3. ed. 1992
Detection limit: 10 colony forming unit in 10 g or 1 ml
Responsible person: Head of Microbiological Department

Name of the method: Total plate count: Pour-plate method
Reference: American Public Health Association (APHA): Compendium of Methods for the Microbiological Examination f Foods, 3. ed. 1992
Detection limit: 200 colony forming unit in 1 g
Responsible person: Head of Microbiological Department

SAMPLE SIZE: 250 g

NUMBER OF SAMPLES TO BE SENT: One sample (for company HACCP verification)
Five samples (for regulatory HACCP verification)

SAMPLING PROCEDURE TO BE APPLIED: According to the laboratory guidelines for microbiological sampling of products.

THE LABORATORY MAY TAKE SAMPLES AT THE COMPANY FACILITIES.

CONDITIONS FOR HANDLING, PACKAGING, STORAGE, PRESERVATION AND TRANSPORTATION OF SAMPLES: According to the laboratory guidelines for microbiological sampling of products. Utilization of insulated containers, plastic bags, quick transport, usage of dry ice, preservation and package of samples in sanitary conditions.

PURPOSE OF THE TEST: company HACCP verification; regulatory HACCP verification; compliance with regulatory requirements in inspection and surveillance by inspection bodies, official agencies, etc.; legal requirements for export; other purposes).

INFORMATION TO BE INCLUDED WITH THE SAMPLE:

- ✓ sender of the specimen
- ✓ date and time when the specimen was taken
- ✓ type of specimen
- ✓ processing of the specimen
- ✓ size of the lot
- ✓ producer
- ✓ exporter (if applicable)
- ✓ reason for test
- ✓ type of analysis requested
- ✓ payer for service
- ✓ parties to receive the certificate/test report
- ✓ disposal of remainder
- ✓ signature and telephone number of person who took the specimen
- ✓ other information

SAMPLE REMAINDER TO BE RETAINED AT THE LABORATORY OR THE CLIENT WISHES
SAMPLE REMAINDER TO BE SENT BACK TO HIS FACILITY

TIME LIMIT FOR RETAINING SAMPLES:

TIME LIMIT THE RESULT REPORT/CERTIFICATE IS READY: minimum 3 days after the sample is received in the laboratory.

TEST RESULT/CERTIFICATE (are sent to the client by e-mail, fax, post-office, with a carrier)
OTHER REQUIREMENTS TO BE AGREED WITH THE CLIENT

STANDARD PRICES FOR EACH TEST

APPENDIX 5. SOME EXAMPLES OF NON-CONFORMITIES IN TEST WORK

1. Use of non-calibrated instruments/equipment in test work.
2. Use of instruments/equipment whose calibration period is expired.
3. Use of instruments/equipment beyond its limits of measurement in a specified method.
4. Use of instruments/equipment with the label of "out of order".
5. The internal calibration of instruments/equipment is not performed according to the documented procedures.
6. Failure to accomplish with the indicated frequency for the calibration of instruments/equipment.
7. Improper storage conditions of weighing standards and other reference instruments.
8. Weighing standards and other reference instruments are used in the laboratory daily work.
9. Use of reagents and media beyond its shelf life.
10. Use of reagents and media in physical conditions unfit for use in test work.
11. Use of chemical solutions and media beyond its shelf life, according to the information marked in the label.
12. Use of de-ionized water/distilled water whose physical/chemical properties do not conform to International Standards/Guidelines of Water for Analysis.
13. Non-trained personnel working in accredited test methods.
14. Incomplete application of analytical procedure in the performance of tests.
15. Bias in the application of analytical procedures in the performance of tests
16. Signature of result report/certificates by non-authorized personnel.
17. Issuance of result report/certificates without being checked by the designated persons.
18. Improper storage of chemicals and media (temperature, humidity, stowage rate, etc.)
19. Handling of strong alkali, acids and other related chemicals out of the hoods.
20. Digestion of samples in the hoods which are turned off.
21. The performance of test works with the ventilation system not operating properly.
22. The disposal of wastes is not carried out according to the safety regulations in force.
23. Receipt, handling, storing and transporting of chemicals and other hazardous substances without using the established individual protective items.
24. Failure to observe the safety regulations in force at the laboratory when performing test work.
25. Eye wash stations and safety showers do not operate properly.
26. The fire extinguisher is expired and has not been replaced.
27. Incomplete supply of first aids dressing materials.
28. Access of alien people to the laboratory, who are not duly authorized.
29. Alien people going around the laboratory without being accompanied by the authorized/designated person(s).
30. Documents are not filed in the right folder.
31. Some documents are missing according to a consecutive numbering, or according to a cross-reference check.
32. Internal control activities are not performed according to the documented procedures and with the indicated frequency.
33. Failure to document corrective actions arising from internal controls and audits.
34. Corrective actions are properly documented, but there is no enough evidence of the results obtained from its implementation.

APPENDIX 6. RECORD FOR NON-CONFORMING TEST WORK IN THE LABORATORY.

XXX Laboratories Dept. of _____

Date	Test/calibra-	Test	Non-conformity	Analyst	Responsible

	tion work	report/certif icate	detected/identified		person