CSIR-FOOD RESEARCH INSTITUTE

CSIR-FRI/

REPORT ON THE TRAINING OF STAFF OF FOOD RESEARCH INSTITUTE ACCREDITED LABORATORIES AND SUPPORTING UNITS ON THE NEW ISO/IEC 17025: 2017 STANDARD, THE GENERAL REQUIREMENTS FOR TESTING AND CALIBRATION LABORATORIES.

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Table of Contents

ACRONYMS

CSIR – Council for Scientific and Industrial Research

FRI – Food Research Institute

QMS – Quality Management System

ISO - International Organization of Standardization

IEC - International Electrotechnical Commission

SUMMARY

Following the revision of the ISO/IEC 17025; 2005 standard to the new ISO/IEC 17025; 2017 standard by the International Organization of Standardization (ISO), it became necessary that staff of the accredited laboratories and supporting units of the CSIR-Food Research Institute be trained on the new requirements for the competence of testing and calibration laboratories. In light of this development, the training was aimed at giving participants who were staff of accredited laboratories and supporting staff the necessary information on the major changes in the new standard, training on the requirements of the new standard and suggestions as to how to implement these changes to enable them fully implement these requirements in their various divisions and sections in preparedness for the next SANAS surveillance visit slated for February 2020.

Per the ISO timelines, when a new standard is published, it must be implemented within three years from the date of publication. The training of 30 participants was conducted over a three day period on the 21st, 23rd and 24th of January, 2019. Facilitators for the training were Mr. Ebenezer Tawiah, Mr. Vincent Kyei Baffour and Mrs. Anthonia Andoh-Odoom. The training schedule was presided over by Prof. Charles Tortoe, Deputy Director of the CSIR- Food Research Institute.

1.0 Introduction

Following the revision of the ISO/IEC 17025; 2005 standard to the new ISO/IEC 17025; 2017 standard by the International Organization of Standardization (ISO), it became necessary that staff of the accredited laboratories and supporting units of the Food Research Institute be trained on the new requirements for the competence of testing and calibration laboratories. In light of this development, the training was aimed at giving participants who were staff of accredited laboratories and supporting staff the necessary information on the major changes in the new standard, training on the requirements of the new standard and suggestions as to how to implement these changes to enable them fully implement these requirements in their various divisions and sections in preparedness for the next SANAS surveillance visit slated for February 2020.

Per the ISO timelines, when a new standard is published, it must be implemented within three years from the date of publication. This report therefore details the modules and activities of the 3 day training program facilitated by were Mr. Ebenezer Tawiah, Mr. Vincent Kyei Baffour and Mrs. Anthonia Andoh-Odoom.

1.1 Objective

To enable staff of accredited laboratories and supporting units of the CSIR-Food Research Institute understand the requirements of the new ISO/IEC 17025: 2017 standard, provide them with information on how to implement the requirements and equip then with the technical knowhow on how to implement technical aspects of the standard.

1.2 Welcome Address

In the welcome address, the Deputy Director of the Institute Professor Charles Tortoe, reminded participants on the importance of the training which would equip staff with the requisite knowledge to implement the new requirements within the Quality Management System of the Institute.

1.3 Opening Remarks

In her opening address, the Quality Manager also stressed on the importance of the training to enable implementation of the new standard. She also informed members that a transition team had been constituted to work with the transition plan and the timelines for the Institute was that the

first draft of the quality manual and technical manuals should be ready by the 30th of June, 2019 and the final drafts of the aforementioned documents ready by the 30th of November, 2019 respectively.

1.4 Participants

Thirty staff participated in training workshop. There were 9 staff from the Food Microbiology Division, 8 from the Food Chemistry Division, 3 from Accounts and Stores Section, 7 from the Client Services Section, 2 Internal Auditors and 1 from Food Technology and Research Division.

2.0 Training Modules

The participants were taken through the basics of quality assurance, the history and timelines of the ISO 17025 standard, major changes within the new standard and the requirements of the new standard.

2.1 Basics of Quality assurance

This module served as a refresher for staff, taking them back to the basics of what quality assurance is. Some specifics covered also include who assesses quality? What a management system for quality is and why we need it, how quality is achieved in the laboratory, what constitutes technical competence and what customers of a laboratory want and also on the need to implement the requirements of this standard even if a laboratory is not accredited.

2.2 History and revision timelines of the standard

Under this component of the course, the facilitator gave a brief overview of the various changes the standard had evolved from, starting as a guide document (Guide 25:1999). A review of this guide begun in 1993 and was completed and published in 1999. Subsequently, the ISO partially reviewed the document and published it in 2005 as the ISO/IEC 17025:2005 standard, a document that spells out the general requirements for the competence of testing and calibration laboratories. Usually, standards are reviewed every 5 years however in 2010, the ISO felt it was too soon to review the document. A full review was therefore undertaken in 2014 and the revised standard was published in November 2017.

2.3 Major Changes

The major/main changes in the new standard are that, with the new ISO/IEC 17025: 2017 standard there is a process approach and risk based thinking is applied. A definition of laboratory has also been included. The structure of the clauses has been changed to align with the ISO 9001 and there is more emphasis on impartiality, information technology, data integrity, and validity of software and the application of decision rules for statements of conformity. There is also emphasis on metrological traceability and the scope of the standard has been redefined.

2.4 Terms and Definitions

The new standard defines certain terminology used in the document. Some of these are impartiality, laboratory, decision rule, verification and validation. The definition for laboratory has been included and defined as a body performing testing, calibration and sampling associated with subsequent testing or calibration.

2.5 General Requirements

The general requirements are covered in Clause 4 of the new standard. Two major items are addressed under general requirements and these are Confidentiality and Impartiality where the laboratory is to act in fairness, without bias and be neutral.

2.6 Structural Requirements

The structural requirements are covered in Clause 5 of the new standard and indicates that laboratories should be legal entities with management who have overall responsibility for the laboratory. Other requirements include the need to define and document our range of activities and ensure that their activities meet the requirements of the standard, customers, regulatory authorities and organizations providing recognition. It is mandatory that there is a defined organization and management structure and personnel shall be given authority and resources to perform their duties as well as ensuring effective communication.

2.7 Resource Requirements

The resource requirements covered under clause 6 of the new standard has 6 main sub-clauses covering general, personnel, facilities and environmental conditions, equipment, metrological

traceability and Externally provided products and services. This clause specifies the need for availability of personnel, facilities, equipment, system and support services necessary to manage and perform laboratory activities.

2.8 Process Requirements

The process requirements in Clause 7 of the standard was covered under 11 sub-clauses which are:- review of requests, tenders and contracts, selection, verification and validation of methods, sampling, handling of test /calibration items, requirements for technical records, evaluating measurement uncertainty, assuring the validity of results, reporting results, complaints, nonconforming work as well as control of data and information management. The method validation and decision rule concepts were explained in detail with worked examples to enable staff fully grasp the concepts.

2.9 Management Requirements

The new standard's management requirements are now covered under Clause 8 of the new standard. Although the new standard offers two options, A and B with the management requirements, the CSIR-FRI focus was on the option A since the Option B was for Laboratories whose management system conforms to the ISO 9001. Under this requirement, staff were trained on the minimum requirements of a laboratory management system, the types of documentation required and control of documents. The new concept of risk per the standard was introduced to participants where the laboratory has to plan and implement actions to address risks and opportunities in order to increase the effectiveness of the management system. Other requirements covered during the training workshop were on the need for identification of opportunities for improvement, seeking feedback from customers, corrective actions, internal audits and management reviews.

3.0 Group Activities

The training was interspersed with group activities focused on identifying risks to impartiality, identifying risks and opportunities, and doing group work on how to apply the decision rule.



Participants in a group discussion

One of the facilitators

4.0 Observations and general remarks

The training was successful and participants had gained an understanding of the requirements of the new standard. Working in groups, they also identified risks to impartiality and risks and opportunities pertaining to their various sections.

5.0 Conclusions and recommendations

The training was very successful and very interactive with participants being taken through the new requirements, suggestions on implementation and how to calculate measurement uncertainty and conduct method validation and importantly how to determine which decision rule to apply when a customer requests a statement of conformity. Participants also practiced some worked examples on calculating measurement uncertainty and decision rules. Examples were drawn from practical examples of laboratory situations to deepen understanding of issues. Questions from staff

were also geared towards understanding the new requirements. In the course of discussions, it also came to light strongly that provision of adequate resources in the form of personnel, equipment and laboratory consumables were key in achieving a smooth implementation and maintenance of the Quality Management System. In his closing remarks, the Chair for the training urged staff to work hard at implementing the requirements in their various divisions and sections to meet timelines and be successful at the next SANAS surveillance visit.