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COMMON NONCONFORMITIES DURING PROCEDURE FOR ACCREDITATION OF THE FOOD TESTING LABORATORIES IN THE R.MACEDONIA

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Abstract
During laboratory assessment in the frame of the accreditation procedure, they faced with number of nonconformities which are challenge for receiving the Certificate for accreditation and appropriate corrective measures shall be undertaken. Requirements that should be met by the food testing laboratories in the Republic of Macedonia, in order to gain accreditation certificate, contained in the standard MKC ENISO/IEC 17025:2006, ILAC (International Laboratory Accreditation Cooperation) document, EA (European Cooperation for Accreditation) document, Regulations and Procedures of the Institute for Accreditation of the Republic of Macedonia. In this paper the analysis is made and different proposals are given for the different ways of fulfilling of those requirements. The aim of this study is to emphasis the common nonconformities which are observed during realization of the Procedure of Accreditation of food testing laboratories and corrective measures undertaken. This investigation is of huge meaning for food testing laboratories which are already accredited and those which are planning to be accredited in the Republic of Macedonia. Furthermore, it is a very important for the Institute for accreditation of the Republic of Macedonia to come to conclusions for the weakest sides of the food testing laboratories and the assessment thereof. Such conclusions should initiate undertaking appropriate measures for improvement the Institute's lead and technical assessors work towards nonconformities interpretation, identification and acceptance of the most suitable corrective measures.
Key words: accreditation of food testing laboratories, common nonconformities, ISO/IEC 17025

Introduction

During laboratory assessment in the frame of the accreditation procedure, they faced with number of nonconformities which are challenge for receving the Certificate for accreditation and appropriate corrective measures shall be undertaken. Requirements that should be met by the food testing laboratories in the Republic of Macedonia, in order to gain accreditation certificate, contained in the standard MKC EN ISO/IEC 17025:2006, ILAC (InternationalLaboratoryAccreditationCooperation) document, EA (Europeanco-operationforAccreditation) document, Regulations and Procedures of the Institute for Accreditation of the Republic of Macedonia. In this paper the analysis is made and diferent proposals are given for the diferent ways of fullfiling of those requirements.

If a country's industry could enter on the global market, that country shall establish standards, technical regulations, metrology, testing, conformity assessment, certification and accreditation. All of these elements consists the national quality infrastructure. National quality infrastructure should provide approach to the international standards and technical regulation, to guarantee reliable measures and to establish system for accreditation of the testing bodies and certification on the way that they are international recognize.

The national quality infrastructure in the Republic of Macedonia is consisting of: Institute for Accreditation of the Republic of

Macedonia, Institute for Standardization of the Republic of Macedonia and Biro of Metrology.

Accreditation is third party attestation of the conformity assessment body, which is officially show it's competence for performing the specific tasks from the conformity assessment. Attestation is issue of a statement, based on a decision following review that fulfillment of specified requirement has been demonstrated [1].

National body for accreditation in the Republic of Macedonia is Institute for Accreditation of the Republic of Macedonia (IARM) which is working according the Low of Accreditation [2].

The main fields for performing the procedures of accreditation are: Testing laboratories, Medical laboratories, Calibration laboratories, Inspection bodies and Certification bodies. The accreditation can be mandatory or voluntary.

The laboratories for testing and calibration are accredited according the standard MKC ISO/IEC 17025:2006, ILAC (International Laboratory Accreditation Cooperation), documents, EA (European co-operation for Accreditation) documents and according regulations and procedures of IARM. If IARM intend to grant accreditation for testing laboratory, IARM organize assessment for collecting the dates regarding the fulfillment the requirements of the documents which are mention above.

In the framework of the procedure for accreditation, during assessment the laboratories faced the number of nonconformities which are challenge for taking the appropriate corrective action and receiving the accreditation certificate.

The aim of this investigation is to receive an awareness of the observed nonconformities during performing the procedure of accreditation of food testing laboratories, to make analyze of undertaken corrective measures as well. This investigation has a huge meaning for the food testing laboratories which are already accredited, the food testing laboratories which are in the process of accreditation and for the IARM also to take the conclusion which are the weakest sides of the food testing laboratories from one side and to take some measures for improving the IARM's assessors work and IARM's assessors competence regarding the interpretation of nonconformities and which measures can be accepted as corrective measures.

III. Short history for accreditation

The first world's accreditation body for laboratories is (National Association of Testing Authorities, Australia). NATA is established 1947 and it's a model for many similar world organization. It is formed during Second World War when Australia had a need to provide a ammunition production with high quality. The idea of assessment of the testing standard has been very unusual. The second laboratory accreditation system is form 1972 in New Zeeland. Next year is formed the first accreditation body in Europe – it has been Denmark accreditation body. The first international conference has been held in 1977 in Copenhagen which has leaded to forming a first International Laboratory Accreditation Cooperation - ILAC [3].

IV. Food testing laboratories.

Food testing laboratory is a laboratory which performs food testing on every phase of the process chain (from raw materials to the final products), food contact materials or environmental samples which has influence to the food [4].

Food testing laboratories belong to the next fields [4]:

- Food chemistry,
- Food microbiology,
- Food reology and other physical testing,
- Food toxicology,
- Functional testing,
- Molecular biology (including GMO's testing)
- Sensor testing.

With food testing, the food quality and/or food safety is determinate. The food testing laboratories can be accredited according international standard for accreditation of testing and calibration laboratories MKC EN ISO/IEC 17025:2006 an according GLP, Good Laboratory Practice - OECD (Organization for Economic Co-operation and Development) standard. The international food market often requires accreditation of food testing laboratories according ISO/IEC 17025:2005.

Also, IARM accredit testing laboratories only with this standard.

V. Nonconformity and grading of nonconformity in IARM

When during assessment it has been asserted that some of the requirements of the Standard have not been met, non-conformities in the operation of the CAB shall be identified and appropriate corrective actions prescribed. The CAB's lack of enforcement of its procedures in accordance with prescribed procedures shall be considered as non-conformity. Non-conformity might be also identified in cases when the organization does not abide by the rules of the IARM, EA or ILAC. [5].

1. Grading of non-conformities

Non-conformities are as follows:

- **Critical non-conformity:** If the non-conformity is severe to the extent that it endangers the credibility of the granting or granted accreditation, accreditation is not granted or a suspension or withdrawal of the full scope or part thereof is granted.
- **Non-conformity:** At a particular time a corrective action must be taken on in order to avoid suspension. There might be a need for the corrective actions of such non-conformities to be examined on site in order to confirm successful implementation, especially in cases when the validity of results or integrity of the accreditation body has been compromised. If the Assessment Commission agrees that the organization recognizes the problem at hand, for elimination of non-conformity a written confirmation can be accepted enclosing enforced corrective actions and an objective proof of undertaken measures. The maximum deadline for elimination of a non-conformity is as follows:
  - 3 months for initial assessment;
  - 2 months for surveillance;
  - 3 months in the procedure for extension of scope irrespective of whether the assessment addresses the scope extension only or extension during surveillance.
- **Remarks:** If the non-conformity is a minor one and does not influence the result of the activities, the non-conformity is noted down in the Report of the leading assessor (F05-51, F05-19, F05-48, F05-49, F05-57) and is checked on during the surveillance visit. The CAB should the latest of three months inform the IARM on corrective actions that have been taken on without enclosing proof for enforcement thereof.
- **Observations** are comments by the assessment team on potential improvements of the quality system of the conformity assessment body, though if not applied do not represent a danger to a successful operation of the quality system. [5].

VI. МКС EN ISO/IEC 17025: 2006 – What does it contain?

1. Scope;
2. Normative references;
3. Terms and definitions;
4. Management requirements;
   - ✶ 4.1 Organization,
   - ✶ 4.2 Management system,
   - ✶ 4.3 Document control,
   - ✶ 4.4 Review of request, tenders and contracts
   - ✶ 4.5 Subcontracting of testing and calibration,
   - ✶ 4.6 Purchasing services and supplies,
   - ✶ 4.7 Service to the customer,
   - ✶ 4.8 Complaints,
   - ✶ 4.9 Control of nonconforming testing and/or calibration work,
   - ✶ 4.10 Improvement,
   - ✶ 4.11 Corrective action,
   - ✶ 4.12 Preventive action,
   - ✶ 4.13 Control of records,
   - ✶ 4.14 Internal audits,
   - ✶ 4.15 Management reviews.
5. Technical requirements;
   - ✶ 5.1 General,
   - ✶ 5.2 Personnel,
   - ✶ 5.3 Accommodation and environmental conditions,
   - ✶ 5.4 Test and calibration methods and method validation,
   - ✶ 5.5 Equipment,
   - ✶ 5.6 Measurement traceability,
   - ✶ 5.7 Sampling,
   - ✶ 5.8 Handling of test and calibration items,
   - ✶ 5.9 Assuring the quality of test and calibration results,

✶ 5.10 Reporting the results.

Annex A (informative) Nominal cross-references to ISO 9001:2000,
Annex B (informative) Guidelines for establishing applications for specific fields [6].

VII Common nonconformities during procedure for accreditation of the food testing laboratories in the R. Macedonia

For this investigation the reports are review from preliminary, initial assessments, surveillance visits and assessments for reaccreditation from 20 food testing laboratories and their nonconformities reports. There are no observed critical nonconformities in all reviewed reports. The nonconformities are grouped according the ISO/IEC 17025 standard's requirement.

4.1

- Not appropriate organization scheme
- Differences between the company's Organization scheme and its Regulation for working pleases organization and systematization.
- There's no written decision for the management and the quality manager.
- There's no evidence for appointed deputies for key management positions.
- There's no list of sighs.
- There's no evidence of the laboratory legal responsibility.
- There's problem regarding confidentiality, impartiality, and releasing the personal from any kind of internal, external, financial and other kinds of pressure.
- There's no record of the laboratory's staff meetings
- There's no procedure for the introducing the new staff with work.
- There's no record for the personal supervision.

4.2

- ❖ Quality policy doesn't contain the management engagement with the requirements from the standard ISO/IEC 17025 and its continuing improvement.
- ❖ Quality policy it's not issued from the top management.
- ❖ There's differences between Quality policy which is public available and that which is in the Quality manual.
- ❖ There are problems regarding terminology in the laboratories documentation from the quality system and terms and definitions in the standard ISO/IEC 17000
- ❖ Quality Policy is not transfer to the employee.
- ❖ The laboratory staff it's not acquainted with the procedures from the quality system.
- ❖ There's no description of the responsibilities of the laboratory management in the Quality Manuel.

4.3

- ❖ Not respecting the Procedure for document control during changing the old document or creating the new one.
- ❖ Document control procedure doesn't include external document management.
- ❖ Master list of the documentation doesn't contain the Guidelines documents.
- ❖ There's no record for the documents distribution for all or part of them.
- ❖ External documents are not in the master – list of the documentation.
- ❖ Procedures and Guideline are not indexed.
- ❖ Page number from the total pages is not marked.
- ❖ Some of the documents don't contain data as data of making the document, the person which made the document and the person which approved it.
- ❖ Methods for testing and sampling are out of the quality system, they are not on the master-list, they are not uniquely identified and they are not approved.
- ❖ Procedures and guidelines which are connected with the technical requirements from the standard are not updated according to the application of the accreditation for the new methods.
- ❖ The master – list of the documentations is not updated.
- ❖ There's no record of withdrawing of not valid document, withdrawing

documents are not marked and they are not withdraw for use.
- ❖ There's no evidence or there's no records for documentation review.
- ❖ There's no procedure for electronic records control, there approach, responsibilities for their chancheies and their protection.

4.4
- ❖ Laboratory is missing some data regarding date of accepting the sample or methods there's going to be use for testing are not defined and they are not agreed with the costumer.

4.5
- ❖ The laboratory doesn't have clear policy for subcontracting.
- ❖ It's not clear does laboratory inform the costumer for the subcontractor used.
- ❖ The laboratory doesn't maintain the subcontractor register.
- ❖ There's no evidence for subcontracting laboratory that is compliance with the international standard MKC EN ISO/IEC 17025:2006.

4.6
- ❖ There's no procedure for services and supplier evaluation.
- ❖ The laboratory doesn't have a list of approved suppliers.
- ❖ There is no evidence for the characteristic and supplied product quality as technical specification of the supplied equipment, chemicals, reagents and services.
- ❖ There is no procedure and records for chemicals, reagents storage, especially for those which is after validity date.
- ❖ Records for verification for supplied products and services are not complete and they don't give information for verification of the specification required.

4.7
- ❖ There is no evidence for possessing of feedback from the clients.
- ❖ Luck of the procedure for other client's data protection when some client participate on the testing of its sample or protect the data from the other visitors in the laboratory, or if the laboratory has that kind of procedure there are no records.
- ❖ Luck of procedure for returning the sample to its owner after testing performed.
- ❖ There are no records from the contact and the meetings with the costumer.
- ❖ The analyzes of the questionnaires is not made, and the frequency of the contact with the clients is not defined.
- ❖ There is no record from the questionnaires analysis from the clients regarding the quality of the services they offer.

4.8
- ❖ There is no record from the complies which are receive verbal.

4.9
- ❖ The laboratory doesn't inform the clients for appearing of nonconformity during testing activities and there is no evidence for undertaken corrective measure immediately together with the decision for accepting the nonconformity.
- ❖ There is no prescribing evidence when the client is informed for the nonconformity appearing during the testing.
- ❖ There are no records for identified nonconformities during performing the everyday activities of testing.
- ❖ There is no evidence for appointing the personal who is responsible for informing the client concerning the appeared nonconformity.
- ❖ The procedure for nonconformity management doesn't assumed nonconformity from the PT participation.

4.10
- ❖ The laboratory doesn't have records for improving during analyzes of the quality goals, results from the data analyzes, corrective measures and management review.
- ❖ The analyze of the given goals from the previous year is not performed.
- ❖ The laboratory doesn't assign value measurable goals.
- ❖ From some nonconformity from the IARM assessment the corrective measures are not undertaken.

4.11

- There is no record for cause analyzes for appearing nonconformity, for which the corrective measure is undertaken or documentation from the management system doesn't assumed that kind of procedure.
- Measures which arise from the nonconformities during the testing, complies or management review are not recognize as corrective measures.
- There are corrective measures only from internal audit.
- The laboratory doesn't fulfill corrective measure form from the IARM assessment remarks.
- There is no evidence for measuring the corrective measure efficiency.

4.12

- Not recognizing of some activities as preventive measures.
- There is no record and there is no initiative of the employee for undertaking the preventive measures.
- Records from the undertaken preventive measures are not clear, some dates are missing or they existing but they are not logic, so the date of undertaken preventive measure is not comply with the date of measuring the efficiency of the preventive measure or the dates are not record.
- Some of the activities for improving the working conditions are not recorded as preventive measure.
- There is misunderstanding regarding the meaning of the "preventive measure" and there is no difference between corrective and preventive measure.

4.13

- The most common nonconformity from this part of the standard is wrong dates in the records or they are not written.
- The page number and the total page number is not marked in the technical records and the records mistakes are not treated according standard requirement.
- Part of the records is not marked and they are not part of the system.
- The records are not kept on secure and safety place.
- There is no procedure for electronic records control, their protection, determination of responsibilities for records back-up and its frequency.
- The record's keeping time is not defined.
- The records list is not updated.

4.14

- Internal audit plan is not respected and internal audit are not perform with the require frequency.
- There is no program for internal audit.
- There is no evidence that director of the laboratory organization is informed for the date for internal audit.
- Not undertaking the corrective measures for the nonconformities from the internal audit.
- There is no evidence for the internal auditor's competence.
- Not respecting the internal audit procedure and not respecting the plan of internal audit.
- There is no internal auditors list.
- The internal audit team member is a quality manager who is not independent.
- There is no record from the meeting when the decision is made for the internal audit dates and its team member.
- From the internal audit program is not clear which part of the laboratory activity is covered from whom of the audit team.
- There is no evidence that during internal audit the test method and other technical requirements from the standard are checked.
- There is no evidence for the internal audit team member's competence.

4.15

- The laboratory's procedure doesn't contain or management review doesn't cover all inputs elements from the standard.
- Records from the management review don't contain proposed measures, due dates and assign responsibilities.

5.2

- The defined responsibilities are not complete for each of the personal.
- Not updates personal files.

- The laboratory doesn't have procedure and plan for training and there is no record for evaluation of the training efficiency.
- There is no procedure and record for surveillance of the new employee.
- There is not assigned personnel for performing the specific testing, handling with the equipment and sign the test reports.
- Luck of records for the personal competence for specific activities.
- During test methods witnessing the laboratory staff shows insufficient knowledge for testing activities or equipment handling.
- The realization plan analysis for the training plan and analysis of the training needs are not made.
- The competence matrix is not clear and complete.

5.3

- There is no procedure for hygiene maintaining and glass cleaning.
- There is no evidence for performed cleaning of the premises.
- There is no evidence for temperature control and other environmental condition which influence of the test results in the laboratory premises for testing, chemicals, reagents and samples storage, refrigerators and other devices or warehouses.
- Inappropriate placement of analytical scales, inappropriate bases of the scale which has vibration influence, scale which is placed in the premises with evaporating of chemicals and presents of humidity.
- Risk of cross contamination between sterilization and decontamination in the microbiological laboratories and storage of the reference strains in the reception unit.
- The laboratory doesn't have limits for environmental control as temperature, humidity, biological sterility.
- There is no record for air pollution and working surfaces pollution.
- There is no procedure for undertaking the activities when environmental condition are not according method requirement and the staff doesn't know how to react and which are their responsibility.

5.4

- There is no records for standard method verification, validation of nonstandard method and records for calculation of measurement uncertainty.
- Luck of records for validation of nonstandard methods or validation is not complete and some parameters are missing as limit of detection, reproductyvity, robustness, sensitivity.
- The method is not performing according to the standard method requirements which laboratory apply for accreditation.
- The records of calculation of measurement uncertainty don't contain all components which influence of the test result.
- There is no records and data for the testing activities.
- There is no statement that method is appropriate for intending use.
- Method guidelines are not according with the standard method.

5.5

- Laboratory equipment for methods performing is not calibrated; the calibration certificates are from not accredited laboratory and don't contain explanation, measurement uncertainty and data for deviation.
- There is no guidelines and records for equipment intermediate checks.
- The equipment which is not in use or defective it's not clearly marked.
- There is no appropriate equipment for the specific testing method or there is no appropriate chemicals, reagents, dissolvers, distillated water with appropriate purity, indicators which are declare with certificate or made according appropriate procedure.
- Water bath, driers, incubators, thermostats, refrigerators, stoves ignition are not calibrated.
- There is no record for the temperature in the water bath, incubators (this kind of nonconformity can apply on 5.3 from the standard also).
- The equipment is calibrated only in one point from the working range or is calibrated in the interval of values which its not use or calibrated outside working range.

- ❖ Equipment list is not complete and doesn't contain all laboratory equipment.
- ❖ The glass from "A" class is mixed together with the glass of lower classes.
- ❖ There is no records of regularly maintains of the equipment.
- ❖ There is no calibration plan.
- ❖ There is no evidence for quality.
- ❖ The calculations in the laboratory are performing with the calculator.
- ❖ The calibration label contains due date of calibration.
- ❖ There is no matrix of competence for the equipment.

5.6

- ❖ The equipment is not calibrated or the plan of calibration is not respect.
- ❖ The laboratory doesn't use certified reference materials.
- ❖ The equipment is calibrated in the accredited laboratory, but accreditation is issued from the accreditation body which is not EA MLA signature.
- ❖ The Certified reference material which is use for equipment calibration doesn't contain all parameters which influence of the equipment performance.
- ❖ Guidelines for internal calibration don't contain the assign responsibilities for internal calibration, responsibilities for data calculation and the competence of the personnel.
- ❖ Calibration of the water bath, drier or similar equipment is made in one space point, which is not evidence of then deviation from other space points.
- ❖ There is no calibration plan or some data is missing for the frequency of the calibration or the plan of calibration doesn't contain the calibration frequency for all equipment.

5.7

- ❖ There is no statement that laboratory doesn't perform sampling activities.
- ❖ There is luck of data for pH and conductivity of water, the amount of tacking food sample.

5.8

- ❖ There is no time limit for storage the sample, when additional testing is needed.
- ❖ There is no procedure for receipt, handling, storage and disposal of the samples and their not appropriate storage in uncontrolled conditions together with chemicals and dissolvers which can lead to cross contamination.
- ❖ The laboratory doesn't respect the procedure for record, marking and identification of the testing samples.
- ❖ There is no procedure, record and define responsibilities for treating the sample which is not appropriate for testing.
- ❖ During receipting the sample, critical parameters for sample conditions are not defined .
- ❖ There is no procedure for treating the sample after testing.

5.9

- ❖ The laboratories don't use referent materials or certified referent materials, or there is no record for PT participation.
- ❖ There is no evidence for participation on PT or ILC for the new methods applied or there is no 4 year plan for PT participation and the sub discipline are not determinate for PT or ILC participation.
- ❖ The laboratory doesn't take any measures when the negative result from PT participation has arrived.
- ❖ There is no stated frequency or there is no plan for controlling the testing results with control material and there is no procedure for undertaken measures after the diagrams analyzes.
- ❖ There is no use of statistical methods of Shewhart diagrams data review or if they use it there is no stated frequency for that activity.
- ❖ The results from ILC participation are not analyzed and there is no defined criteria for accepting the results.
- ❖ The causes from the deviation from the mean value are not analyzed.

5.10

- ❖ The data from the test reports doesn't contain requirements from the article 5.10.2 and 5.10.3 from the standard.

- The test report is not clear and precise, doesn't possessed appropriate title, and clear identification, the method used are not stated, the amount of the tested sample, and the measurable unit which related to the test result are not stated.
- There is no explanation for the marks used, name, surname and function of the person who sigh the test result.
- The non accredited methods are not clearly marked.
- Opinion and interpretation of the test result is not marked according IARM Regulation on Requirements for use of the accreditation mark, text reference to accreditation and reference to IARM's EA MLA Signatory status.
- There is no statement that test results refer to the delivered sample.
- The test report doesn't contain information that sampling is accredited activity.
- There is no logo or reference to the accreditation status on the test report.
- The end of the test report is not clearly marked.

VII.1 Improving the work of a assessment team

The team of regular and extraordinary assessments, which IARM form for conformity assessment bodies, consists of the lead assessor and technical assessors or experts from the assessed field. Improving the assessors work from the food testing field has aim to increase the awareness and understanding of the assessors for ISO/IEC 17025's requirements from one side and harmonization of the assessment process which lead to equivalent treatment to all food testing laboratories, to all laboratories also and to other conformity assessment bodies. One of the measures for improving is the way of expressing the nonconformity. The assessors shouldn't formulate the nonconformity as suggestion or consultation how laboratory could act, but to state what is missing or for what has a lack of evidence. For example, it noted the following: "The test report should contain the information from the 5.10.2 from the standard" or "The sterilization activity and decontamination should be divided" or "The laboratory must issue a procedure for acting in the case when the temperature is above requested value". Sometimes the nonconformities are related with requirements which don't exist in the standard or appropriate mandatory documents, as: "The equipment is not calibrated from the competent calibration laboratory, only internal calibration is performed", "The personal files don't contain the statements of confidentiality and impartiality", "There is no list of obsolete documents", "Microbiological control of the working surfaces is not performed according EA document EA 4/10" [1, 7]. There are nonconformity reports which contain more than one nonconformity. For example: "There is no calibration certificate, calibration plan doesn't contain all laboratory equipment and the calibration frequency is not defined". Sometimes the assessors connect the nonconformity with one part of the standard, but actually it is related with another part. The nonconformity for lucking the referent material the assessor connects it with 5.6 (Measurement traceability), actually it is related with 5.5 from the standard (Equipment). The same nonconformity is grading different with different assessors.

Conclusion

The most frequent nonconformity from preliminary visits or from initial assessment, surveillance visit or reassessment is not calibrated equipment or Calibration Certificate doesn't fulfilled standard's requirements. This nonconformity is connected with technical requirements from the standard ISO/IEC 17025 (clausal 5) [6]. From the technical requirements the most frequent remark is related with "Opinion and interpretation of the test result". They are located on the same side with the test result and they are not marked according Regulation on Requirements for use of the accreditation mark, text reference to accreditation and reference to IARM's EA MLA Signatory status– P 05 [43]. The most frequent remark from the management requirements is related with treating the mistakes in the technical records, thus they are not corrected according standard's requirements. From the preliminary visits the most frequent nonconformities are follow: In the the Quality Policy is luck a commitment of the management to comply to the standard and lack of a written appointment of members of the top management and quality manager [8].

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