

**“Instructions for Administration of Accreditation  
Procedures of Conformity Assessment Bodies”  
No. (2) for the Year 2008**

**Issued pursuant to Article (5) of the Law of Standards & Metrology  
No. (22) for the Year 2000**

**Approved by JISM Board of Directors in its session (4/2008), held on  
2008-05-04**

**"Instructions for Administration of Accreditation of Conformity Assessment Bodies"  
No. (2) for the Year 2008**

**Article (1)**

- a. These instructions are called "Instructions for Administration of Accreditation of Conformity Assessment Bodies" No. (2) for the year 2008, which are issued based on article (5) of Standards & Metrology no. (22) for year 2000, and shall be effective from the date of its promulgation in the official gazette.
- b. The following instructions are applicable to all kinds of testing or calibration laboratories, medical laboratories and certification bodies that apply for accreditation and which will be referred to as "conformity assessment bodies".
- c. These instructions were prepared according to the requirements of standards related to Accreditation.

**Article (2): Definitions**

- a- The following terms and phrases, whenever they occur in these instructions, shall have the meanings specified thereunder unless otherwise indicated by the context:
  - **The law:** Law of Standards & Metrology; law no. (22) for the year 2000.
  - **The institution:** the Jordan Institution for Standards & Metrology.
  - **The instructions:** Instructions for Administration of Accreditation of Conformity Assessment Bodies No. (2) for the year 2008
  - **The unit:** The Accreditation Unit in the institution.

**Standards and Guidelines for Accreditation of Conformity Assessment Bodies**

- **Standard 1:** Jordan standard JS 1451:2005 that is the adopted ISO/IEC Standard 17025: 2005 "General requirements for the competence of calibration and testing laboratories", issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), this standard or any amendments that might occur thereon constitute an integral part of the instructions.
- **Standard 2:** ISO 15189: 2007 "Medical laboratories - Particular requirements for quality and competence", issued by the International Organization for Standardization (ISO), this standard or any amendments that might occur thereon constitute an integral part of the instructions.
- **Standard 3:** ISO/IEC 17021: 2006 "Conformity assessment - Requirements for bodies providing audit and certification of management systems", issued by the International Organization for Standardization (ISO) and the International

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Electrotechnical Commission (IEC), this guide or any amendments that might occur thereon constitute an integral part of the instructions.

- **Guide 1:** ISO/IEC Guide 65: 1996 "General Requirements for Bodies Operating Product Certification System", issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), this guide or any amendments that might occur thereon constitute an integral part of the instructions.

### Accreditation Terms

- **Conformity Assessment Body:** Body that performs conformity assessments services including testing, calibration, inspection, product certification, management systems certification (management and environment).
- **Accreditation:** Decision taken by the unit as a formal recognition that a conformity assessment body complies with accreditation requirements according to these instructions.
- **Specified Requirements:** The general accreditation requirements specified in any of the above mentioned standards or guides, the requirements of quality management system of the applicant or accredited body, and any additional technical requirements specified by the unit.
- **Accreditation Bodies Standard:** ISO/ IEC 17011:2004 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies", issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), this guide or any amendments that might occur thereon constitute an integral part of the instructions.
- **The applicant:** The body (Conformity Assessment Body) applying for accreditation.
- **The accredited body (Conformity Assessment Body):** The laboratory or the certification body that is accredited according to the requirements of the instructions.
- **Nonconformity:** a non-compliance made by the applicant or the accredited body to any of the specified requirements.
- **The Corrective Action Period:** The period of time during which the applicant or accredited body shall be committed to close out the non-conformities found by taking the required corrective actions agreed with the unit and as specified in the policy "JAS-P01: Grading of Non-Conformities" issued by the unit, and as specified in this instructions.
- **Assessor or Technical Expert:** is a qualified person with a high technical experience and competence in a specific field, and assigned by Accreditation Unit to conduct an assessment of a laboratory or certification body, or to perform any other technical

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tasks specified by the unit. Qualifications, experience and competence are defined based on the unit's internal procedures and with respect to the assigned tasks.

- **Technical Accreditation Committees:** Committees formed for Accreditation purposes according to these instructions.
- **Surveillance:** Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

b- Definitions included in the Jordanian standard (JS1649:2005) and accreditation unit guideline (JAS-G01: Accreditation & Conformity Assessment - Vocabulary, Definitions & General Abbreviations) are applicable.

### **Article (3): Conditions for Accreditation**

The applicant shall fulfil the following conditions in order to achieve accreditation:

- a- Compliance with the all specified requirements.
- b- Provision of all the necessary arrangements needed by the unit to facilitate the accreditation and surveillance procedures.
- c- Payment of all fees and expenses resulted from accreditation as stated and referred to in the Accreditation Fees Instructions No. (3) for year 2008.
- d- Compliance with all the requirements of the instructions and the internal accreditation policies and procedures of the unit.
- e- Providing valid and correct information to the unit for the aim of Accreditation.

### **Article (4) : Application for Accreditation Procedures**

- a- Applicant can obtain the Accreditation application form prepared by the unit attached with "List of Documents Necessary for Accreditation", a copy of these instructions, the questionnaire, checklist and other documents related to Accreditation, the applicant is committed to pay the fees as specified in the Accreditation Fees Instructions No. (3) for year 2008.
- b- The applicant shall submit to the unit two copies of Accreditation application and scope of Accreditation filled with the required information and signed by the legal representative of the applicant.
- c- The applicant shall submit all the following documents required as per the "List of Documents Necessary for Accreditation" along with the Accreditation application:
  - 1- All documents defined in the "List of Documents Necessary for Accreditation".
  - 2- Quality manual, procedures and related forms.
  - 3- A filled copy of the questionnaire prepared by the unit.
  - 4- A filled copy of the checklist prepared by the unit.
  - 5- A report regarding the applicant's participation in proficiency testing schemes and its results.

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- d- The unit checks the completeness of the documents received from the applicant, in case of missing documents or the need for more documents or further information related to the scope of Accreditation, the applicant shall submit them within one month from the day of notification.
- e- The unit studies the ability of Accrediting the Conformity Assessment Body in the applied scope of Accreditation with respect to:
  - 1- Scope of Accreditation included in the unit's scope of work.
  - 2- Availability of assessors/ technical experts in the applied scope of Accreditation.
  - 3- Ability to conduct an on-site assessment within the required time period.
- f- If the unit is capable to accredit the applicant, and the documents received from the applicant are complete, the unit informs the applicant in writing that its application for Accreditation is accepted.
- g- The unit conducts a preliminary meeting with applicant's representatives to clarify Accreditation requirements, the duties and rights of both parties and the cost estimation of Accreditation and the expected time periods for implementation of Accreditation procedures.
- h- In case of the agreement of the two parties, the application will be signed and becomes a contract between the two parties, the applicant is given an identification number and a signed copy of the Accreditation application.

#### **Article (5): Lead Assessor**

- a- The unit decides upon the appointment of an internal or external lead assessor to take over the tasks assigned to him/her according to the unit's internal procedures, and the unit shall inform the applicant with the name of the lead assessor.
- b- The lead assessor shall possess neutrality, impartiality, and necessary expertise according to the unit's internal procedures.
- c- Lead assessors shall take over the tasks assigned to them in the aforementioned procedures and according to the contract signed between the unit and the lead assessor which defines the rights and responsibilities of each party.
- d- If the designated lead assessor is found to have financial or professional interests related to the assessment in a way that may affect his/ her work as a lead assessor and which can be considered as a conflict of interest, or if the lead assessors have been subjected to any influences or pressures that may affect his credibility , in this case the unit is entitled to cancel the contract signed with the him with all its articles and the unit have no responsibilities towards the lead assessor and may choose not to deal with him in future.

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**Article (6): Technical Assessor/ Technical Experts**

- a- The unit decides upon the selection, appointment , and qualifying the technical assessors or technical experts from inside or outside the unit according to its internal procedures in order to assess the technical competence of the applicant to ensure its compliance with the specified requirements.
- b- The technical assessors and technical experts shall possess neutrality, impartiality, and necessary expertise according to the unit's internal procedures.
- c- Assessors shall take over the tasks assigned to them in the aforementioned procedures and according to the contract signed between the unit and the technical assessor/ expert.
- d- If the designated technical assessor/expert is found to have financial or professional interests related to the assessment in a way that may affect his/ her work as a technical assessor/expert and which can be considered as a conflict of interest, or if the he/she have been subjected to any influences or pressure that may affect his credibility , in this case the unit is entitled to cancel the contract signed with him with all its articles and the unit have no responsibilities towards the technical assessor/expert and may choose not to deal with him in future.

**Article (7): Assessment Team**

- a- The unit decides upon the formation of the assessment team consisting from the lead assessor and a number of assessors and/or technical experts that is related to the size of the applicant and the scope of Accreditation.
- b- The unit informs the applicant with the names of the assessment team members, the applicant has the right to object to any of these names in writing - with justification - and request their replacement within one week from date of informing the applicant with the names, otherwise the applicant is considered agreed.
- c- The assessment team shall take over the tasks assigned to them according to the unit's internal procedures.
- d- The unit shall submit the assessment team or any of its members with all the necessary documents related to the applicant or accredited body, needed to conduct any of the assigned assessments effectively, and with respect to Article (20) of these instructions.

**Article (8): Technical Assessment Committees**

- a- The Accreditation unit director shall form the following committees for the purpose of accreditation according to the unit's internal procedures subject that their impartiality and integrity are ensured, and based on rules of appointment and operation of accreditation committees, each according to its purpose:

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- 1- The Accreditation Committee.
- 2- The Technical Committee.
- 3- The Appeals Committee.
- b- The unit is entitled to form other technical committees, as necessary, for accreditation purposes.
- c- These committees shall take over the tasks assigned to them by the unit according to the unit's internal procedures.
- d- The unit shall submit the committees with all documents necessary to conduct any of the assigned tasks effectively, and with respect to Article (20) of these instructions.

**Article (9): Preliminary Visit**

- a- At the request of the applicant, the unit conducts a preliminary visit within (2) weeks from the date of signing the Accreditation application.
- b- Accreditation unit director assigns the lead assessor or one of the unit's employees to conduct the preliminary visit to check the following:
  - 1- The preparation and implantation of the applicant's quality system and its compliance with specific requirements.
  - 2- The compliance with technical requirements, such as the availability of technical staff, premises, and equipment, assuring that not to offer any consultation during the visit.
  - 3- Assure the applied scope of Accreditation.
- c- The applicant is committed to pay the fees of preliminary visit as stated and referred to in the Accreditation Fees Instructions No. (3) for year 2008.
- d- The unit prepares a report of the results of the preliminary visit and with the recommendation regarding the situation of the applicant and its readiness for accreditation; the Accreditation director will take the appropriate decision and inform the applicant accordingly.

**Article (10): Review of Quality Manual**

- a- The designated lead assessor shall review the applicant's quality manual according to the specified requirements within one month from the date of signing the accreditation application.
- b- The lead assessor shall prepare a report regarding the compliance of the applicant's quality manual with the specified requirements, and prepare a report of all non-conformities if there are any. The lead assessor recommends based on the documentation assessment findings whether;
  - 1- An on-site assessment can take place; in case there are no non-conformities.

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- 2- Ask the applicant to close the non-conformities within a time period that does not exceed (4) months from the date of issuing the documentation assessment report, to be ready for an on-site assessment, or
  - 3- The applicant submit a new modified quality manual within time period does not exceed (6) months. In this case, the unit re-assess the new quality manual for one more time only.
- c- The unit shall submit the reports to the applicants once the lead assessor finishes the assessment of the quality manual, and proceed with the following procedures:
- 1- The applicant defines the suggested corrective actions and the corrective action period within (7) days from the date of informing the applicant with the non-conformities, corrective action period shall not exceed the time periods mentioned above in clause (b).
  - 2- The lead assessor and at the end of the corrective action period shall evaluate the implemented corrective actions to close the non-conformities, or re-assessment of the new quality manual. If all the non-conformities were closed, the unit informs the applicant with the acceptance of the new quality manual.
  - 3- If the applicant did not close all the non-conformities, the applicant will be given a maximum (2) months to close all the non-conformities.
  - 4- If the applicant submitted a modified quality manual, and 60% or more of the non-conformities raised before are not closed in the modified manual, the application will be rejected and the applicant is informed with that.
- d- When the lead assessor completes the assessment of the quality manual and the applicant closes all the non-conformities (if any), the unit in corporation with the applicant will prepare for an on-site assessment within a maximum period of (6) months from the date of accepting the quality manual according to these instructions.

### **Article (11): The First On-site Assessment of the Competence**

- a- The applicant shall implement the documented quality system for at least (3) months before the on-site assessment for providing evidences on implementation, especially conducting at least one management review meeting and two internal audits.
- b- The assessment team conducts the on-site assessment to confirm the implementation of the quality system and competence in performing testing or calibrations or medical testing or certification activities defined in the scope of accreditation and according to specified requirements. The first on-site assessment shall include the quality system and technical competence of the applicant with witnessing a representative sample from the accreditation scope and applicant's staff.

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- c- If the applicant's scope of work covers more than one conformity assessment activity, the assessment team shall examine a representative number of applicant's activities to assure its competence.
- d- If the applicant's scope of Accreditation is distributed on more than one site, the assessment team shall assess the applicant's headquarter in addition to all sites at which the applicant's main activities take place.
- e- The unit may refer to the assessment team to determine the working days needed to assess the scope of Accreditation. One working day shall not be less than (7) hours and shall not exceed (9) hours not including the breaks.
- f- At the end of the on-site assessment, the lead assessor shall inform the applicant about the extent to which the applicant's quality system and technical competence complies to the specified requirements.
- g- If the assessment team found any non-conformities, the lead assessors shall inform the applicant immediately and in the closing meeting of the assessment, the following actions shall be followed:
  - 1- The lead assessor shall submit a report of the assessment results that clarifies the applicant's compliance to the Accreditation requirements and the non-conformities if founded. Non-conformities are discussed and agreed on.
  - 2- The assessment team agrees with the applicant on the classification of non-conformities according to policy of Grading of Non-Conformities (JAS-P01) issued by the unit, if critical non-conformities are found, the unit shall be informed immediately to arrange for an additional assessment visit.
  - 3- The applicant shall agree with the assessment team on the appropriate corrective actions and the proposed corrective action period immediately or within one week from the date of the on-site assessment. Corrective action period shall not exceed the following periods:
    - (5) Months from the date of first on-site assessment of applicant's competence.
    - (3) Months from the date of the additional visit or surveillance visit or re-accreditation visit, even if it includes expansion of accreditation scope.
  - 4- The assessment team shall agree with the applicant on how to verify the closing of non-conformities, whether through documentation assessment or follow-up visit or additional assessment visit.
  - 5- After the applicant completes the implementation of corrective actions and submitting them to the unit, the unit shall provide them to the designated assessment team to evaluate the appropriateness and effectiveness of the evidences on completing corrective actions to close the non-conformities. If the assessment team finds that corrective actions led to closing out all non-conformities, the applicant is deemed competent and shall be informed thereof.

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- 6- If not all non-conformities were closed completely and effectively, the applicant shall be informed and requested to submit new and appropriate corrective actions, that all non-conformities shall be closed within one month from the date of informing the applicant and the designated assessor shall evaluate that for one more time only.
- 7- After conforming the closing all non-conformities in the second time, the applicant shall be informed. If the applicant did not close all non-conformities appropriately, the applicant shall be informed and all assessment reports and its supplements shall be submitted to Accreditation Committee to take the decision.
- 8- The unit is considered responsible to the applicant for the reports submitted to it regarding the assessment results.
- 9- In case the applicant did not commit with the corrective action periods according to this instructions, assessment reports and its supplements will be submitted to the Accreditation Committee to take the decision.

### **Article (12): Reports of Assessment Team**

- a- Each member of the assessment team submits a report of the on-site assessment results within (2) weeks from the date of the assessment for the technical assessor and/or technical expert, and within (4) weeks for the lead assessor.
- b- The reports shall include the results of the assessment of the applicant's quality system and technical competence, and shall include also the assessment team's recommendation regarding the competence of the applicant to perform the activities defined in the scope of accreditation, and the need to verify that the applicant closed all non-conformities through documents or on-site follow-up visits or additional assessment visit.
- c- After the applicant completes the corrective actions for closing the non-conformities within the agreed corrective action period, the assessment team shall submit to the unit a supplement to the assessment report within maximum (14) days from the date of receiving the corrective actions that clarifies if the applicant closed all non-conformities and includes the recommendation regarding granting the Accreditation.
- d- In case the assessment team did not reach a decision or a recommendation regarding applicant's meeting to the Accreditation requirements, the unit shall be informed in writing and directly to take the proper decision.

### **Article (13): Accreditation Decisions**

- a- After the unit reviews the assessors' reports, assessment reports shall be submitted to the Accreditation committee to take the final decision regarding the Accreditation based on assessors recommendations.

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- b- Any member of the assessment team is not permitted to be a member in the Accreditation committee.
- c- If the assessment reports were not submitted to the Accreditation committee within (6) months from the date of first on-site assessment, an additional re-assessment visit will be conducted, according to the Accreditation Fees Instructions No. (3) for year 2008, and the following cases:
  - 1- Expenses of the additional assessment visit shall be paid by the applicant if it was responsible for the delay.
  - 2- Expenses of the additional assessment visit shall be paid by the Accreditation Unit if it was responsible for the delay.
  - 3- If any of the assessors was responsible for the delay, he/she is committed to conduct the additional visit for free, or his/her fees will be paid to the assessor assigned to replace him/her in conducting the assessment

#### **Article (14): Rejection of Accreditation Application**

- a- The application of Accreditation will be rejected in any of the following cases:
  - 1- Not providing the unit with documents mentioned in clauses (b) and (c) in article (4) within the period defined in clause (d) of the same article.
  - 2- In case of re-assessing the quality manual and more than 60% of the non-conformities raised before are not closed in the modified quality manual.
  - 3- If the applicant did not submit the filled proposed corrective action form within (2) weeks from the date of informing the applicant with results of quality manual assessment or the results of on-site assessment.
  - 4- If the applicant delayed the submission of corrective action for more than (2) weeks from the agreed period with the unit, for closing the non-conformities raised from quality system assessment or on-site assessment.
  - 5- If the non-conformities found during the additional on-site assessment were not closed within the agreed time period mentioned in clause (3) from article (11).
- b- The unit shall inform the applicant of the rejection decision and the reasons thereof. Re-application for accreditation is not accepted before (60) days from the rejection date.

#### **Article (15): Accreditation Certificate/ Accreditation Logo**

- a- The applicant shall be granted an Accreditation certificate demonstrating the scope of accreditation and all sites which have been assessed and where the key activities take place based on the decision of the Accreditation committee and after payment of the fees stated the Accreditation Fees Instructions No. (3) for year 2008.

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- b- The Accreditation certificate is valid for (5) years; date of granting Accreditation and date of expiration shall be defined in the certificate. The accreditation date is set to be from the date of granting accreditation decision taken by the accreditation committee.
- c- The accredited body shall use the logo of Jordan Accreditation System (JAS) on the testing reports or calibration certificates or conformity certificates issued within the Accreditation scope according to the Conditions for the Use of JAS Logo (JAS-S02) which the unit submits to the applicant once they are informed with the Accreditation decision. The accredited body has the right to use the logo in its advertising material and documents according to Conditions for the Use of JAS Logo (JAS-S02).

### **Article (16): Surveillance**

- a- The unit shall make the necessary arrangements to ensure the continuous compliance of the accredited body with the specified requirements. This is done through conducting periodical surveillance visits.
- b- The unit shall prepare at the beginning of each year a program in which the dates of the assessment and surveillance visits are specified. The number of surveillance visits for each accredited body through the Accreditation period shall not be less than (3). Surveillance visits may include a full assessment for the scope of Accreditation and witnessing a representative sample of scope of Accreditation and applicant's staff.
- c- 1- The length of time period between consecutive surveillance visits depends on the scope of accreditation and the competence of the accredited body. In general this period shall not exceed (12) months for the first surveillance visit, and for the consecutive surveillance visits shall not exceed (18) months. The final surveillance visit may be considered to be a re-assessment visit for the aim of re-accreditation if the accredited body applied for re-accreditation within the time period defined in article (18).  
2- If the conformity assessment body is accredited for multi-sites, the period between the surveillance visits shall not exceed (12) months maximum so as all sites will be assessed within the Accreditation period and according to the schedule prepared by the unit for that purpose.
- d- The accredited body shall commit to pay the fees of the surveillance according to the Accreditation Fees Instructions No. (3) for year 2008.

### **Article (17): Expansion of the Scope of Accreditation**

- a- The accredited body is entitled to expand its accreditation scope by adding new test or calibration methods or medical tests or adding new certification activities to the scope of accreditation.
- b- The accredited body shall inform the unit of its intension to expand the scope in writing, and shall pay the fees of expanding the scope before (2) months from the

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surveillance visit, or before (12) months from the re-assessment for the aim of re-accreditation, in this case, the unit shall follow the same previous accreditation procedures, provided that the assessment of the new scope will be carried out in the surveillance visit or in the next re-assessment.

- c- The accredited body is entitled to request the assessment of the new scope before the date of the next surveillance visit, and it shall pay the assessment fees according to the Accreditation Fees Instructions No. (3) for year 2008.
- d- A new accreditation certificate shall be issued reflecting the new accreditation scope, if the accredited body continued to comply with the requirements of the instructions. The expiry date of the Accreditation certificate for the new scope is the same as the expiry date of the Accreditation certificate issued for the scope accredited for the first time.
- e- The accredited body shall commit to pay the fees resulted from expanding the scope according to the Accreditation Fees Instructions No. (3) for year 2008.

#### **Article (18): Accreditation Renewal and Re-assessment**

- a- The accredited body is entitled to re-new its Accreditation every (5) years, it is also entitled to modify its scope of Accreditation by adding or removing any of the test or calibration methods or medical tests or certification activities in the renewal application.
- b- The accredited body shall submit the renewal application (12) months before the expiring date of the Accreditation, and shall define the scope of Accreditation including the scope to be expanded.
- c- If the accredited body did not apply the renewal application before that period, the Accreditation is considered cancelled from the expiring date of Accreditation certificate, until the unit can conduct a reassessment and take the decision regarding the renewal of Accreditation. For this purpose, the unit shall inform the accredited body and the lead assessor before the last surveillance visit that a renewal application shall be submitted within the period stated above in case the accredited body intends to continue the Accreditation.
- d- The period between the decision of renewing the Accreditation and the decision of granting the Accreditation shall not exceed (60) months.
- e- The unit shall re-assess the accredited body by following the same previous accreditation procedures referred to in the instructions to ensure the continuous compliance of the accredited body with the specified requirements, considering the experience gained about the accredited body as a result of the previous assessments and surveillances.
- f- The accredited body shall commit to pay the fees resulted from re-accreditation according to the Accreditation Fees Instructions No. (3) for year 2008.

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**Article (19): Extension of Accreditation Certificate Validity**

- a- In contrary to what was mentioned in the above article (18-d), the Accreditation committee is entitled to extend the validity of the Accreditation certificate for a period that does not exceed (2) months for an accredited body which its Accreditation has expired before taking the decision of renewing the Accreditation, provided that:
- 1- The accredited body has submitted a renewal application for Accreditation within the period stated in clause (b) from article (18).
  - 2- The re-assessment visit aimed for the renewal was conducted before the expiring date of Accreditation, and the assessment results were good and do not include any critical non-conformities.
- b- In case the applied Accreditation scope for renewal is different from the previous accredited scope, and in addition to what is mentioned in clause (a), the Accreditation shall be extended only for the Accreditation scope accredited previously and which the applicant intends to renew its Accreditation and was assessed in the re-assessment visit.

**Article (20): Protecting Confidentiality**

- 1- All information, data and documents related to granting or rejecting or suspending or withdrawing the Accreditation, or any reports or official documents related to the unit are considered confidential, any of board of directors members or unit's employees or technical committees members or assessors or experts, are not allowed to reveal any of them.
- 2- The unit shall take all necessary arrangements and precautions to ensure protecting the confidentiality according to its internal procedures.

**Article (21): Changes to the Accreditation Requirements**

- a- The unit shall publish about the basic changes to the accreditation requirements specified in the standards and guidelines in the official gazette, and also shall inform the applicants and accredited bodies with the procedures need to be followed to implement the new changes. The unit shall define the period needed for implementing the changes according to the requirements specified in any of the modified standards or guidelines.
- b- The unit shall inform in writing all applicants and accredited bodies about additional requirements or the basic changes to the accreditation requirements in addition to the technical polices and guidelines issued by the unit with defining the period needed for implementation.

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- c- The applicant and accredited bodies shall implement the new changes and shall inform the unit with procedures taken to achieve that within the time period specified for that.
- d- At the end of the period needed to implement the changes mentioned in the above clauses (a) and (b), the unit shall assess the implementation of changes by the accredited bodies during the surveillance visits or re-assessments or additional assessment visits what ever is appropriate.

### **Article (22): Changes in the Accredited Body**

- a- The accredited body shall notify the unit of any intended major changes that may affect the following:
  - 1- The organization structure; if changes include personnel whose work affects the quality of the accredited test or calibration results or certification activities.
  - 2- The quality management system, including the quality manual and related procedures.
  - 3- The announcement method regarding Accreditation and the use of logo are to be agreed upon with the unit.
  - 4- The equipment and tools used for the accredited test or calibration methods and which Accreditation was granted upon.
  - 5- The premises, or facilities or the environmental conditions affecting the accredited test or calibration methods or certification activities which Accreditation was granted upon.
  - 6- The legal or commercial status of the accredited body or applicant.
  - 7- Any other changes which might affect the accreditation scope.
- b- The unit shall check the compliance of the accredited body with the requirements of the instructions, in view of any of the aforementioned changes, through the surveillance visits or re-assessments or additional assessment visits whatever appropriate.
- c- The unit is entitled to suspend the Accreditation immediately if it was found that the accredited body has done any major changes that affect the Accreditation scope without informing the Accreditation unit according to article (23) in the instructions.

### **Article (23): Withdrawal or Suspension of the Accreditation**

- a- The Accreditation committee is entitled to suspend accreditation temporarily –either for the whole or part of the accreditation scope – for a period that does not exceed (90) days in one of the following cases:
  - 1- If the assessment team found major non-conformities in the accredited body during the surveillance visits or re-assessments that might cast doubt on its

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- competence to perform the tests or calibrations or certification activities specified in the scope of accreditation.
- 2- If the accredited body does not implement the changes on its system to comply with the modified Accreditation requirements within the periods specified in clause (a) and (b) in article (21).
  - 3- If the accredited body does not comply with any other procedures relevant to accreditation set by the unit.
  - 4- If the accredited body does not submit the form of proposed corrective actions within (2) weeks from the date of being informed of the on-site assessment results.
  - 5- If the accredited body delays the submission of the corrective actions for a period that exceeds (2) weeks after the date agreed with the unit.
- b- The accredited body shall be informed of the suspension decision, whether it was total or partial, and the reasons thereof as soon as it is taken.
- c- 1- In the case of total suspension; if the suspension period was over and the accredited body did not make the necessary correction, the accreditation will be withdrawn.
- 2- In the case of partial suspension; if the suspension period was over and the accredited body did not make necessary correction, this part from the previous accreditation scope is canceled, and a new accreditation certificate shall be issued clarifying the current accreditation scope.

#### **Article (24): Voluntary Suspension of the Accreditation Scope**

- a- The accredited body shall inform AU before (1) month from the intended date to suspend the accreditation voluntarily by canceling part of the test or calibrations or methods or the activities related to certification specified in the Accreditation scope, new accreditation certificate shall be issued clarifying the current accreditation scope.
- b- The Accredited body shall inform the unit before (2) months from the intended date to suspend the accreditation for the total scope of Accreditation, and the accreditation is considered canceled from that date.

#### **Article (25): Foreign Accreditation**

- a- If a conformity assessment body, which has applied or been granted accreditation by a foreign Accreditation body for a certain scope of accreditation, applied to the unit for Accreditation for the same scope, the following actions are taken:
  - 1- Assure that the foreign Accreditation body complies with the general requirements for accreditation bodies and internationally recognised by the related international organisations.

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- 2- Check the specified criteria which the foreign accreditation was granted upon.
  - 3- If such criteria are similar to the specified requirements described in the instructions, the unit in cooperation with the foreign accreditation body conducts a joint assessment or surveillance according to the unit's internal procedures. After the joint assessment the joint assessment reports are submitted to the Accreditation committee to take the Accreditation decision.
  - 4- If the requirements are different from the specified requirements described in the instructions, the unit follows the complete accreditation procedures taking into consideration that this body is accredited.
  - 5- In case the joint assessment or surveillance can not be conducted, the unit shall follow its internal procedures to select, assign and form the assessment team to conduct the on-site assessment according to these instructions.
- b- If a conformity assessment body applies for Accreditation for a scope of Accreditation different from the scope accredited by a foreign accreditation body, the unit follows the complete accreditation procedures according to these instructions.

### **Article (26): Appeal**

- a- The accredited body is entitled to lodge an appeal to the unit within (30) days from the date in which the accredited body was informed of any decision taken by the unit and which the applicant or the accredited body considers not appropriate, this includes the following cases:
- 1- Reject the Accreditation application.
  - 2- Refuse to conduct the on-site assessment.
  - 3- Requests related to cretin corrective actions.
  - 4- Changes in scope of accreditation.
  - 5- Decisions related to refuse granting Accreditation or suspend it or cancel it or withdrew it totally or partially.
  - 6- Any decision that may lead to not granting Accreditation.
- b- The Accreditation director shall form an Appeal Committee to study the appeal, and to take the right decision in this regard according to the internal procedures prepared by the unit for this purpose.
- c- The members of the assessment team for the appellant whose reports were the basis for the appealed decision or any of AU staff shall neither take part in discussing nor in making any decision in its concern.
- d- The unit is entitled to use persons, other than its staff to participate in the Appeal Committee work, provided that they have the necessary experience, competence and impartiality. The appealing body shall be charged all the expenses resulted from any arrangements taken to solve its appeal if the committee's decision agrees with the

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unit's decision. The unit shall inform the appealing body with the estimated cost in advance according to the Accreditation Fees Instructions No. (3) for year 2008.

- e- The unit shall inform the appealing body of the decision taken by the Appeal Committee concerning its appeal and the reasons thereof within (1) month from the date of submitting the appeal in writing, and the decision is deemed final and the consequent actions needed are taken.

### **Article (27): Promulgation in the Official Gazette**

- a- The unit promulgates about the following in the official gazette:
- 1- Granting, expanding and renewal of the Accreditation.
  - 2- Withdrawal of the Accreditation –either partially or totally-and the reasons thereof. These shall be promulgated after (30) days from the date of taking the decision of withdrawal.
  - 3- Amendments to the Accreditation standards or guides.
  - 4- Amendments to the instructions.
- b- In case of withdrawal of the Accreditation, if the accredited body lodged an appeal to the institution, the decision of withdrawal of the Accreditation shall not be promulgated in the official gazette until the Accreditation director decides regarding this appeal based on the appeal committee recommendation, and the (CAB) is informed with the decision.

### **Article (28): Additional Provisions**

- a- In case a customer submits to the unit a complaint against an accredited body, the unit is entitled to conduct a sudden visit to the accredited body without informing them.
- b- The conformity assessment body shall maintain all records related to the Accreditation scope for at least (5) years.

### **Article (29) : Support Services**

The unit performs the following support services:

- a- Conducting specialized training courses in Accreditation and its management and technical requirements for assessors, experts, and conformity assessment bodies. The unit may contract external specialized experts to conduct specialized technical courses, according to the Accreditation Fees Instructions No. (3) for year 2008.
- b- Organizing proficiency testing programs according to the unit's internal procedures, which define the terms, requirements, and the nature of the programme intended to be held. To organize any PT program, the unit shall contract an accredited reference lab for the preparation, distribution, and analysis of the reference samples used in the

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program and perform any tasks requested by the unit according to the unit's internal procedure. The unit may contract external specialized experts for the Advisory Committee of the program to be organized, according to the Accreditation Fees Instructions No. (3) for year 2008.

### **Article (30) : General Provisions**

- a- If any case arises and was not tackled in the instructions or if any conflict regarding the implementation of the instructions comes up, it shall be referred to the Accreditation Committee which is entitled to make the appropriate decision thereof.
- b- All formerly accredited bodies by the unit -prior to the issuance of the instructions- which intend to sustain their Accreditation according to the new criteria set up herein shall adjust their current situation to comply with requirements of the instructions, within one month from the promulgation of this instruction in the official gazette.
- c- These instructions cancel and replace the “Instructions for Administration and Implementation of Accreditation of Testing and Calibration Laboratories” no. 1 for the year 2002.
- d- The annexes or any future amendments on them are considered as a part of this instructions and the concerned bodies shall implement them.

### **Article (31) : Legal Violations of the Instructions**

If the accredited body committed any violations to the instructions, the Accreditation committee is entitled take the necessary and needed actions and procedures, which it deemed appropriate.

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## **Annex (1)**

### **The Laboratories**

#### **Amendments on the test or calibration standard which Accreditation was granted upon.**

- a- The accredited laboratories are committed to have and implement the updated version of the test or calibration standards which Accreditation was granted upon; if applicable, and if not; the laboratory shall provide a clear justification to the unit.
- b- The accredited laboratories shall implement the basic amendments on the test or calibration standard within the period defined by the body which issued it or by the unit for this purpose.
- c- The unit and through the appropriate assessment team will evaluate the implementation of such amendments by the accredited laboratories.

#### **Withdrawal of the test or calibration standard which Accreditation was granted upon.**

If the test or calibration standard which Accreditation was granted upon was withdrawn by the body which issued it, the Accreditation certificate shall be amended as follows:

- a- If the accredited laboratory decides to stop using the withdrawn test or calibration standard, then it will be withdrawn from the Accreditation scope and a new Accreditation certificate is issued to clarify the new status.
- b- If the accredited laboratory decides to keep working according to the withdrawn test or calibration standard, the unit shall be informed to check the validity of this standard and its compliance to the technical requirements, and accordingly the Accreditation committee decides to continue with the Accreditation or suspend it based on the recommendations of the assessment team. And in case the committee decides to continue with the Accreditation, the Accreditation certificate shall be amended to refer to this standard as withdrawn.

#### **Quality System in Laboratories**

- a- The unit issues a group of technical polices, which can be mandatory or as a guidance or general information to clarify Accreditation procedures or to explain Accreditation requirements or others. The laboratory shall study those polices and work on:
  - 1- Including them in documents which are within its procedures of quality document control.
  - 2- Implementation of the mandatory polices according to what is mentioned in their introduction.

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- 3- Providing the unit with documents which proves the implementation upon the unit's request and within the period defined for this purpose.
- b- The laboratory shall include the following documents within its implemented quality system in addition to the requirements mentioned in standard (1) and (2):
- 1- A list that includes all test and calibration methods mentioned in the scope of Accreditation and the authorized personnel to perform them, the laboratory shall keep the documents which define the criteria for that.
  - 2- Clear definition for the part of organization which will be accredited or is accredited by the unit.
  - 3- Appoint quality and technical managers with defining their qualification, job descriptions and their deputies.
  - 4- If the laboratory is classified as a first party lab, then it shall include a clear organizational structure within its quality manual that shows the technical and administrative interrelations between the lab and other departments in the organization which the lab belongs to.
  - 5- Procedures that are implemented by the laboratory to communicate internally with its staff and customers, and define their frequency of use.
- c- In case of subcontracting, the laboratory shall:
- 1- Subcontract in necessary and urgent situations only.
  - 2- Define the criteria that are the foundation for selecting the subcontractor, which shall be either an accredited lab by internationally recognised Accreditation body or a lab that implements standard (1) or (2). And in the last case the lab shall define the procedures followed to evaluate the competence of the subcontractor.
  - 3- The applicant or the accredited body is responsible before the unit for the tests or calibration methods performed by the subcontractor, and the legal obligations of granting the Accreditation certificate to the accredited body.
  - 4- The accredited lab in its issued test reports or calibration certificates that include subcontracted tests or calibrations shall mention that those tests or calibrations were performed by a competent or accredited subcontractor.
- d- The lab shall have a clear procedure for participating in proficiency testing schemes, and shall have a specific procedure for measurement uncertainty; the lab shall keep evidences that prove the implementation of these procedures.

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