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act in other than an impartial or non-discriminatory manner;

(6) Not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

(b) *Qualification procedures for assessors.* An approved/recognized accreditation body shall have an adequate procedure for:

(1) Qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor, and

(2) Monitoring the performance of assessors.

(c) *Contracting of assessors.* An approved/recognized accreditation body shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior association with laboratories to be assessed.

(d) *Assessor records.* An approved/recognized accreditation body shall possess and maintain up-to-date records on assessors consisting of:

(1) Name and address;

(2) Organization affiliation and position held;

(3) Educational qualification and professional status;

(4) Work experience;

(5) Training in quality assurance, assessment and calibration and testing;

(6) Experience in laboratory assessment, together with field of competence;

(7) Date of most recent updating of record.

(e) *Procedures for assessors.* Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

§ 280.503 Accreditation process.

(a) *Application for accreditation.* (1) A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

(2) Additional relevant information shall be provided to applicant laboratories on request.

(3) A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which

(i) The scope of the desired accreditation is clearly defined;

(ii) The applicant's representative agrees to fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

(iii) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

(4)(i) The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

(A) The general features of the applicant laboratory (corporate entity: Name, address, legal status, human and technical resources);

(B) General information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, If applicable, physical location of laboratories involved;

(C) A definition of the materials or products tested, the methods used and the tests performed;

(D) A copy of the laboratory's quality manual and, where required, the associated documentation.

(ii) The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

(b) *Assessment.* (1) An approved/recognized accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(2) To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

(3) The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

(4) The assessor(s) shall be formally appointed. A lead assessor shall be appointed, if relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

(c) *Sub-contracting of assessment.* (1) If an approved/recognized accreditation body decides to delegate fully or partially the assessment of a laboratory to another body, then the accreditation body shall take full responsibility for such an assessment made on its behalf.

(2) An approved/recognized accreditation body shall ensure that the party to which assessment has been delegated is approved/recognized by NIST.

(d) *Assessment report.* (1) An approved/recognized accreditation body may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

(i) A meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory at which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements;

(ii) The assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

(iii) A report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment.

(2) The final report authorized by an approved/recognized accreditation body and submitted to the laboratory, if it is different, shall include as a minimum:

(i) Date(s) of assessment(s);

(ii) The names of the person(s) responsible for the report;

(iii) The names and addresses of all the laboratory sites assessed;

(iv) The assessed scope of accreditation or reference thereto;

(v) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements.

(3) The reports shall take into consideration:

(i) The technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of test reports or test certificates;

(ii) The adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, the physical facilities, i.e., the environment and the calibration/test equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken;

(iii) Proficiency testing or other interlaboratory comparison performed by the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

(iv) The actions taken to correct any non-compliances identified at previous assessments.

(e) *Decision on accreditation.* (1) The decision whether or not to accredit a laboratory shall be taken by an approved/recognized accreditation body on the basis of the information gathered during the accreditation process.

(2) An approved/recognized accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

(f) *Granting accreditation.* (1) An approved/recognized accreditation body

shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of—

(i) The name and address of the laboratory that has been accredited;

(ii) The scope of the accreditation including:

(A) The tests or types of test for which accreditation has been granted;

(B) For tests, the materials or products tested, the methods used and the tests performed;

(C) For specific tests for which accreditation has been granted the methods used defined by written standards or reference documents that have been accepted by the accreditation body.

(iii) Where appropriate, the persons recognized by the accreditation body as being responsible for the test certificates or the test reports;

(iv) The term of accreditation which shall be valid for a period not to exceed three years;

(v) The accredited laboratory by a unique number.

(2) An approved/recognized accreditation body shall furnish notification to NIST required by Subpart B of this part.

(g) *Surveillance and reassessment of accredited laboratories.* (1) An approved/recognized accreditation body shall have an established documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements.

(2) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this Subpart.

(h) *Proficiency testing.* (1) The approved/recognized accreditation body shall require each fastener testing laboratory it accredits, and each laboratory which has applied to it for accreditation to participate in proficiency testing comparable to that conducted under Subpart C of this part by NVLAP.

(2) Although an accreditation shall not be granted or maintained only on the basis of the results of proficiency testing, accreditation shall not be granted or maintained if required proficiency testing participation is unsatisfactory.

(i) *Certificates or reports issued by accredited laboratories.* (1) An approved/recognized accreditation body shall normally allow an accredited laboratory to refer to its accreditation in test reports and test certificates that contain only the results of tests or types of test for which accreditation is held.

(2) An approved/recognized accreditation body shall have a policy that defines the circumstances in which accredited laboratories are permitted to include in test reports or test certificates, the results of tests for which accreditation is not held and the results of sub-contracted tests.

§ 280.504 Relationship between approved/recognized accreditation body and laboratory.

(a) An approved/recognized accreditation body shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and co-operation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

(b) An approved/recognized accreditation body shall require that an accredited laboratory—

(1) At all times complies with the relevant provisions of these regulations;

(2) Claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

(3) Pays such fees as shall be determined by the accreditation body;

(4) Does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation