



**NISTIR 6261**

## **Program Handbook**

# **Procedures for Obtaining NIST Recognition as an Accreditor of Quality System Registrars Under the Fastener Quality Act**

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Technology Services



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Technology Administration

National Institute of Standards and Technology

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## 1.0 INTRODUCTION

On November 16, 1990, the United States Congress enacted the Fastener Quality Act (FQA), P.L. 101-592 (the Act). The Act was amended in 1996 by Section 11 of P.L. 104-113. The Act protects the public safety by: (1) requiring that certain fasteners which are sold in commerce conform to the specifications to which they are represented to be manufactured; (2) providing for accreditation of laboratories engaged in fastener testing and registration of manufacturing facilities; and (3) requiring inspection, testing, and certification of fasteners covered by the Act.

This handbook describes the NIST requirements that an Accreditor of Quality System Registrars<sup>1</sup> seeking NIST recognition must satisfy to register fastener manufacturers, employing a fastener quality assurance system (QAS). It provides specific guidance on the implementing regulations (the Regulations) published at 15 CFR Part 280 “Procedures for Implementation of the Fastener Quality Act” subparts I through L.<sup>2</sup> **NIST recognition under this program is limited to Accreditation Bodies that accredit quality system Registrars.**

This handbook amplifies subpart K of the Regulations, which is based on ISO/IEC Guide 61, and complements other handbooks in the QAS series. NISTIR 6262 which is based on ISO/IEC Guide 62, provides guidance to Registrars desiring accreditation for meeting the requirements of subpart L of the regulation. NISTIR 6263 provides guidance to Facilities to satisfy the elements of a fastener QAS and contains the audit requirements for Registrars to register facilities.

Selected text from the regulations is presented in italics in some sections of this handbook. For full understanding of all requirements, interested parties are advised to read the regulations in their entirety. In addition to the quality system registration requirements, many other important issues are contained in that document. The Act and Regulations are accessible on the NIST FQA Home Page (<http://www.nist.gov/fqa>).

NIST invites users to provide comments or suggestions for modifications, clarification or improvement of this document. Comments should be addressed to Accreditation Body Evaluation Program (ABEP) Program Manager, NIST, 100 Bureau Drive, Stop 2100, Gaithersburg, MD 20899-2100.

### 1.1 Definitions

For the purposes of this handbook, the following definitions are used. Those definitions taken from the Act or regulations are shown in *italics*.

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<sup>1</sup>Note: In some countries, the bodies which verify conformity of quality systems to specified standards are called “certification bodies,” in others “registration bodies,” in others “assessment and registration bodies” or “certification/registration bodies,” and in still others “registrars.” Reference to such bodies as “Registrars” should not be understood to be limiting.

<sup>2</sup>Section numbers denoted by “Sec.” or “Sec. 280.xxx” in this document reference the regulations at 15 CFR Part 280.

- 1.1.1 **Accreditation:** a procedure by which a body recognized by NIST confirms that a testing laboratory or a quality system registrar of fastener manufacturing facilities that employ a Fastener Quality Assurance System is competent to carry out specific tasks required by the implementing regulations for the Fastener Quality Act.
- 1.1.2 **Accreditation Body Evaluation Program (ABEP):** The program established by NIST to receive applications and to evaluate Accreditors (of testing laboratories or of quality system registrars) to determine if applicants meet applicable requirements of the Act and regulations at 15 CFR Part 280. Based on the evaluation results, ABEP makes recommendations to NIST regarding recognition of Accreditors.
- 1.1.3 **Accredited Laboratory List:** A list compiled and maintained by NIST of all testing laboratories which have been accredited either by NIST or by any NIST-recognized Accreditation Body in accordance with the requirements of The Act and the regulations.
- 1.1.4 **Accredited Registrar:** A quality systems registration body which is accredited by a NIST recognized Accreditor and appears on the Registrars List.
- 1.1.5 **Accreditor:** A Registrar accreditation body or testing laboratory accreditation body that is recognized by NIST, and appears on the Accreditors List.
- 1.1.6 **Accreditors List:** A list of all Accreditors that have been evaluated and recognized by NIST in accordance with the requirements of the Act. Two Accreditors Lists are maintained, one for testing laboratory accreditors and one for Registrar accreditors.
- 1.1.7 **Act:** *The Fastener Quality Act, P.L. 101-592, as amended by P.L. 104-113.*
- 1.1.8 **Approved Signatory:** An individual employed by a facility registered under the Act and these regulations who is recognized by a registrar as competent to sign test reports.
- 1.1.9 **Authorized Representative:** An employee of an organization with the authority to make binding commitments on behalf of the organization. The authorized representative is the person who will be responsible for all communications between the Accreditor and NIST and who will ensure that the Accreditor complies with all NIST program requirements.
- 1.1.10 **Certificate of Registration:** A document issued by a Registrar to a Facility that has met the criteria and conditions of registration. The certificate, together with the assigned code number and scope of registration issued by the Registrar, may be used as proof of registration status.

- 1.1.11 **Facilities List:** A list compiled and maintained by NIST of all Facilities which have been registered by accredited Registrars.
- 1.1.12 **Facility:** A fastener manufacturing facility or a facility performing subcontracted processes for a manufacturing facility, that has been registered by an accredited Registrar and that appears on the Facilities List.
- 1.1.13 **Fastener:** *Fastener means any screw, nut, bolt or stud, washer or other item included within the definition for fastener contained in section 3(5) of the Fastener Quality Act. The term “fastener” does not include a screw, nut, bolt or stud:*
- (1) that is produced and marked as ASTM A307 Grade A,*
  - (2) that is produced in accordance with ASTM F432: or*
  - (3) that is held out as being produced to other than the provisions of standards and specifications published by a consensus standards organization, or a government agency.*

*A screw, nut, bolt, stud or washer held out as being produced according to requirements of a document other than a document published by a consensus standards organization is a fastener within the meaning of the Act and this part if that document incorporates or references (directly or indirectly) standards and specifications published by a consensus standards organization or government agency for purposes of delineating performance or materials characteristics of the fastener.*

- 1.1.14 **Fastener Quality Assurance System (QAS):** *(1) Fastener Quality Assurance System (QAS) means a fastener manufacturing system that has as a stated goal the prevention of defects through continuous improvement, and which seeks to attain that goal by incorporating: (i) Advanced product quality planning; (ii) Monitoring and control of the manufacturing process; (iii) Product verification activities embodied in a comprehensive and written control plan to address critical or significant product/process characteristics, documented process controls (including statistical process control), tests, and measurement systems to be used in production; and (iv) The creation, maintenance, and retention of electronic, photographic, or paper records, available for inspection during the periods required by section 10 of the Act and Sec. 280.809 of the regulations, regarding the inspections, tests, and measurements required by or performed pursuant to the control plan or other quality system documentation, e.g., work instructions. See Section 4.0, Fastener Quality Assurance System Criteria, for amplification of requirements.*
- 1.1.15 **Lot:** *A quantity of fasteners of one part number fabricated by the same production process from the same coil or heat number of metal as provided by the metal manufacturer and submitted for inspection and testing at one time.*



- 1.1.16 **Lot Number:** *means a number assigned by a manufacturer to the lot.*
- 1.1.17 **Lot Traceability:** *The recording and maintenance of lot-specific identification information sufficient to trace fasteners from a single lot throughout:*  
(1) *The manufacturer's fabrication or alteration process,*  
(2) *All inspection and testing operations, and*  
(3) *The subsequent chain of distribution in commerce.*
- 1.1.18 **Original Laboratory Testing Reports:** *(1) In general, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test; or (2) For purposes of the alternative procedures for chemical characteristics described in section 5 (d) of the Act and Sec. 280.15 of the regulations only, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test or by the metal manufacturer.*
- 1.1.19 **Recognized Accreditor:** An accreditor that is recognized by NIST and appears on the Accreditors List.
- 1.1.20 **Registered Facility:** A facility that is registered by an accredited registrar and appears on the Facilities List.
- 1.1.21 **Registrars List:** A list compiled and maintained by NIST of all registrars who have been accredited by NIST-recognized Accreditors.
- 1.1.22 **Registration:** procedure by which a body accredited by a NIST recognized Accreditor gives written assurance that a manufacturing facility conforms to the applicable requirements of a Fastener Quality Assurance System.
- 1.1.23 **Tamper-resistant system:** *The use of special paper or embossing stamps or other controls which discourage, prevent or minimize alteration of test reports subsequent to manufacturing, inspection and testing.*
- 1.1.24 **Traceability of Measurements:** *means a documented unbroken chain of comparisons all having stated uncertainties connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and, ultimately, to a primary standard.*

## 2.0 REQUESTING EVALUATION

### 2.1 Who May Apply

Accreditors, foreign or domestic, government or private, that wish to be recognized to

accredit Registrars that, in turn, register Facilities covered under the Act, must submit an application for evaluation to NIST. The application must be completed and signed by the Authorized Representative of the Accreditor.

## **2.2 Application Package**

Application packages may be obtained from NIST on request and include: the **General Application**, the **Program Handbook**, the **Fee Schedule**, and other documents needed for understanding of the program and requirements. Application packages may be obtained from ABEP Program Manager, NIST, 100 Bureau Drive, Stop 2100, Gaithersburg, Maryland, 20899-2100. Requests may be made by mail, or by Fax to: (301) 975-5414.

All forms must be completed in English and must provide sufficient information and detail to fully describe the Accreditor. The applicant may include any enclosures or attachments appropriate to describe applicable capabilities or resources.

An application may be amended at any time prior to a final decision. However, dependent upon the nature of changes, additional time or costs may be incurred by the applicant for NIST to evaluate those changes. An application may be withdrawn at any time prior to a final decision. If an application is withdrawn, the entity may later reapply. See section 3.6 for NIST's refund policy.

## **2.3 NIST Response**

Upon receipt of an application, NIST will: acknowledge receipt of the application; request further information, if necessary; confirm payment of the application fee before proceeding with the evaluation process; and specify to the applicant the next step(s) in the evaluation process. If NIST deems an applicant to be ineligible, all submitted information and fees will be returned with an explanation of the ineligibility.

## **3.0 FEES**

ABEP is operated on a strict cost-reimbursable basis; that is, all costs incurred by NIST in operating the program must be recovered from fees charged to users.

### **3.1 Application Fee**

The application fee is paid by an applicant Accreditor and applied to the cost of conducting the evaluation for recognition. The application fee is an estimate by ABEP of the total cost of performing an evaluation. Once the evaluation has been completed, the applicant will either be billed for, or refunded, the difference between the amount submitted and the actual costs incurred by ABEP.

### **3.2 Listing Fee**

*3.2.1 Registrar Listing Fee:* The Registrar listing fee is paid annually by the Registrars and forwarded to NIST by a recognized Accreditor.

*3.2.2 Facility Listing Fee:* The Facility listing fee is paid annually by the Facility and forwarded to NIST by an appropriately accredited Registrar.

**3.3 Periodic Reassessment Fee** Each recognized Accreditor will be reassessed every two years. Prior to such reassessment the Accreditor will be required to submit a reassessment fee to NIST.

**3.4 Fee Schedule** An ABEP Program Fee Schedule is published by NIST. The fees are subject to change at NIST's discretion. A new fee schedule will be provided to all participants whenever fees are changed.

**3.5 Additional Costs** From time to time NIST must provide evaluation services to applicants or to recognized Accreditors. Since these services are not predictable (e.g., special assessments resulting from major deficiencies, investigation of valid complaints received, changes in management or location of a participant, etc.), these costs will be billed to participants as appropriate.

**3.6 Refund Policy** If an applicant is deemed to be ineligible or withdraws the application prior to any action by ABEP described in section 4, the application fee will be fully refundable. When ABEP has begun an evaluation and has incurred costs, NIST will refund the application fee less any incurred costs.

**3.7 Payment of Fees** An applicant must have paid all amounts due prior to being granted recognition and becoming listed on the Recognized Accreditors List. An applicant must pay all fees and costs due whether or not recognition is granted.

## **4.0 EVALUATION PROCESS**

The process of evaluating an Accreditor consists of a number of activities which must take place prior to granting recognition and continuing thereafter. The sequence begins with initial review of the application, quality system review and evaluation, on-site assessment of Accreditors facilities, witness audits of Registrar and Facility assessments, assessment report, Accreditor response to the assessment report, and final evaluation and decision. After recognition is granted, surveillance activities and periodic on-site assessment visits are conducted.

### **4.1 Quality System Review and Evaluation**

Each applicant must submit copies of its quality documentation for review and evaluation as to whether the quality system promotes an adequate level of performance and quality

management. NIST may need to interact with the Accreditor for clarification of certain items or to request additional information. Quality documentation submitted for review need not be in English, but if an interpreter or translator is required, the applicant will be billed for the expense incurred.

If an applicant cannot submit quality documentation in advance, the review can be performed during the on-site assessment, but extra time may be required and additional cost incurred.

## **4.2 On-site Assessment**

An on-site assessment of an applicant's facilities is conducted prior to initial recognition and every second year thereafter unless the recognition is terminated. The assessment will encompass a physical inspection of technical and administrative facilities and a review of practices, and covers all sites involved in the accreditation process. An assessment team comprised of an ABEP staff member(s) and one or more appropriate technical experts conducts the assessment.

Prior to a regularly scheduled visit, an applicant is informed of the identity of the assessment team and has the right to appeal the selection. Such appeal must be received in writing at least 20 working days prior to the scheduled date of the visit and must provide a substantive reason in order for a change to be made.

If the personnel of the Accreditor being evaluated normally speak (or documentation is written in) a language other than English, the applicant may arrange for an interpreter acceptable to ABEP or ABEP will arrange for an interpreter to accompany the assessment team; the cost will be charged to the applicant.

The normal sequence of an on-site assessment is:

*4.2.1 Entrance Meeting:* Upon arrival at the applicant's facility, the assessment team meets with Management to discuss what is to be accomplished and agree on a plan of action. The meeting allows all parties to become acquainted and gives the assessment team the opportunity to understand the management structure. It is recommended that a staff member be designated as the main contact person to assist the assessment team.

*4.2.2 Walk Through and Staff Introductions:* The assessment team briefly tours the facilities to familiarize its members with the layout and to get acquainted with staff members who are responsible for the areas of interest.

*4.2.3 Assessment:* All phases of the operation pertaining to the scope of the request for evaluation are reviewed. A checklist developed from the criteria contained in Section 7 of this Handbook is used to guide the review and ensure uniformity of assessment from one Accreditor to another. The assessors review



relevant documents and files, observe specific operations, and interview staff members.

The assessment focuses on ascertaining that the actual operation of the Accreditor is the same as described in the quality documentation. All procedures involved in the accreditation process are reviewed.

Personnel representing the following must be available for interview by the assessment team:

- management personnel;
- persons who make accreditation decisions;
- accreditor auditors;
- clerical and support personnel;
- technical project managers; and
- quality assurance staff.

The assessment team also observes and evaluates:

- information and reporting systems, database systems;
- all files, records, documents relating to accreditation procedures, policies, and activities;
- assessment reports of selected Registrars;
- selected final evaluation reports on which accreditation was based;
- appeals and complaints regarding the Accreditor, Registrars, and Facilities; and
- auditor qualification, training, and competency records.

The assessment team must have freedom of movement and access to all persons and information relating to the request for evaluation. The assessment team treats all information and conversations as confidential. Information is only disclosed as may be required by law.

The assessment team may need to review information considered proprietary; all such information is treated accordingly. Refusal to allow review of such materials may result in denial of recognition.

*4.2.4 Development of On-Site Assessment Report:* The assessment team develops a draft report containing a comprehensive review of the team's impressions on both the strengths and weaknesses of the applicant. Any deficiencies requiring resolution are clearly identified.

*4.2.5 Exit Meeting:* Once the assessment team is satisfied that it has completed its task at the site and has developed a draft report, a meeting is scheduled to discuss the findings with management. At the conclusion of this meeting the Authorized Representative of the Accreditor must sign the draft report, acknowledging the



discussions and the responsibility to respond, in the allotted time, to any deficiencies identified.

### **4.3 Witness of Registrar and Facility Assessments**

As part of the evaluation process, the Accreditor will be requested to allow members of the ABEP assessment team to witness the Accreditor's evaluation of Registrars and the Registrars' evaluations of Facilities.

ABEP will discuss with the Accreditor the number and identity of the Registrars and Facilities to be visited. The Accreditor must pay all associated costs.

### **4.4 Final Report**

ABEP staff prepares a final report from the draft report and forwards it to the applicant after the assessment. In most cases, the final report will be essentially the same as the draft report unless additional information has been uncovered during witness audits of Registrar assessments, or there were issues that required clarification.

The final report is normally the vehicle that presents the definitive assessment findings. However, in some cases additional information may surface with significant bearing on the evaluation, and a supplementary report may be necessary. Any supplementary report that includes required actions will be promptly forwarded to the applicant.

### **4.5 Applicant Response to Deficiency Findings**

The applicant must respond to all identified deficiencies, in writing, to ABEP. Specific corrective actions taken, or the proposed plans to resolve each deficiency, must be described. Plans must include specific actions, time frames, dates, etc. In some cases, an additional on-site visit, at additional cost, may be necessary to observe stated resolutions.

New applicants are generally expected to resolve deficiencies within 90 days of receipt of final report; ABEP must be informed if additional time is required. If the applicant's actions cause the evaluation process to take longer than one year, additional administrative costs may be incurred.

Accreditors holding a current valid NIST recognition must resolve all deficiencies within 30 days of receipt of the final report or other written notifications or recognition may be suspended until full conformance is demonstrated.

### **4.6 Final Evaluation Decision**

Upon completion of all assessment activities, NIST convenes an evaluation panel to conduct a final evaluation of all information collected regarding an applicant, then makes a decision on the appropriate action. (See 5.0 Program Actions.)

The decision is based on the review and evaluation of all materials submitted by the accreditation body, reports covering the quality system review, on-site assessment(s), witness audits, and deficiency resolution.

#### **4.7 Surveillance**

NIST may, at its discretion, whether or not for cause, conduct a full or partial on-site visit or other forms of surveillance of a recognized Accreditor, or any Registrar accredited, or any Facility registered by an Accredited Registrar, to observe or verify conformance with program requirements. A written report of NIST findings will be provided to the Accreditor and any response required shall be forwarded to ABEP in accordance with paragraph 4.5.

### **5.0 PROGRAM ACTIONS**

NIST may grant, deny, suspend, or terminate recognition of an Accreditor under the Program.

#### **5.1 Granting Recognition**

An Accreditor that demonstrates conformance with all Program requirements will be granted recognition as having demonstrated the ability to evaluate and accredit Registrars that register fastener Facilities and publicly attest to their conformance with NIST QAS requirements through registration.

The Accreditor is provided with documentation stating the terms and conditions of the recognition and the specific Scope of Activities for which recognition is granted.

#### **5.2 Denial**

Recognition will be denied if an applicant fails to demonstrate conformance with all Program requirements. NIST will notify the applicant in writing of its intention to deny and the reason(s) therefore. An applicant is given 90 days to resolve any deficiencies which form the basis of the proposed denial. Unless resolution is achieved in that time, the applicant is denied recognition.

An applicant may appeal a denial by submitting to the NIST Director a statement of reasons why recognition should not be denied (See 5.6 Appeal.)

#### **5.3 Suspension**

If it is determined that a Recognized Accreditor temporarily cannot demonstrate conformance, e.g., a deficiency is uncovered during surveillance or if the Accreditor has changed ownership, recognition may be suspended until full conformance has been demonstrated.

If recognition is suspended by NIST, the Accreditor may neither grant additional accreditations under the Act after the date of the suspension, nor conduct any evaluation activities covered by the recognition. The Accreditor must, within 5 days of receipt of notification of suspension, inform all of its Accredited Registrars that it has been suspended, and ask each Registrar to inform all FQA registered Facilities, including applicants, of the suspension.

The Accreditor's written notice shall state the effective date of NIST's suspension and shall inform the Registrars and Facilities that NIST will not delist them unless they contributed to the conditions which led to the suspension, or removal is otherwise justified in NIST's judgement.

## **5.4 Termination**

Termination of participation in the Program by a recognized Accreditor may be voluntary or involuntary.

*5.4.1 Voluntary Termination:* A Recognized Accreditor may at any time voluntarily terminate its participation in the Program by giving written notice to NIST and to all accredited Registrars and associated Facilities.

*5.4.2 Involuntary Termination:* NIST may terminate, fully or partially, the recognition of an Accreditor whenever it deems such action to be in the public interest. Such an action may result if the Recognized Accreditor engages in fraud or other illegal activity, is unable to meet NIST requirements, or exhibits other factors detrimental to producing an acceptable accreditation program.

*5.4.3 Termination Procedures:* NIST will notify the Recognized Accreditor in writing of the intent to terminate the recognition and the reason(s) therefore. The notice will state, as a minimum, that recognition is suspended as of the date of the notice, and that the Accreditor may not grant additional accreditations under the Act, nor conduct any evaluation activities covered by the recognition.

A Recognized Accreditor is given the opportunity to respond to, rebut or correct any deficiencies which form the basis of proposed termination. If the basis for the termination is not reconciled within 30 days, or such longer time as NIST may allow, the termination becomes effective.

A Recognized Accreditor may appeal to the NIST Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, delay implementing the termination action pending a final decision by the Director. If recognition is terminated, the Accreditor may neither state nor imply that it has NIST recognition, nor may it grant any accreditation under the former NIST recognition.

NIST shall send a written notice to all the terminated Accreditor's Registrars and associated Facilities informing them of the termination and the effective date. The notice shall inform Registrars and Facilities that NIST will not delist them unless they contributed to the conditions which led to the suspension, or in NIST's judgement removal is otherwise justified. They will be advised that, if they want to continue operating under the Act, Registrars should expeditiously seek accreditation from an Accreditor currently recognized by NIST. Registrars will be advised as to the date by which they must acquire another accreditation to avoid removal from the Registrars List.

An Accreditor whose recognition has been terminated may submit a request for re-evaluation if and when it believes that it can demonstrate conformance with the requirements.

### **5.5 Options in Response to an Adverse Action**

If NIST proposes to deny, suspend, or terminate recognition of an Accreditor, and the applicant or recognized Accreditor has been so notified in writing, citing the specific reasons or elements of nonconformance with the requirements, the Accreditor may choose to:

- (A) Appeal the decision and request that recognition be granted or continued by providing appropriate justification, or
- (B) Submit additional information for further evaluation. If additional on-site visits, etc., are required, additional costs may be incurred by the Accreditor, or
- (C) Accept the decision.

### **5.6 Appeal**

An applicant or a Recognized Accreditor under the Program may appeal to the NIST Director any action taken against it. All appeals must be in writing and must include complete documentation setting forth the appellant's position. The appeal of an action must be filed with NIST within 30 days of that action.

Appeals should be addressed to: The Director, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2100, Gaithersburg, Maryland 20899-2100.

The applicant or Recognized Accreditor will be informed of the Director's decision within 60 days following receipt of an appeal.



## **6.0 OBLIGATIONS OF A RECOGNIZED ACCREDITOR**

### **6.1 Continuous Conformance**

It shall be incumbent upon a Recognized Accreditor to conform to all requirements throughout the period of participation. Failure to maintain conformance is cause for suspension or termination of recognition.

NIST will conduct a complete on-site assessment of each Recognized Accreditor every two years. Other types of surveillance are conducted at least annually to ensure continued conformance.

Upon request, a Recognized Accreditor shall make available to NIST any document, information, or material related to the recognized accreditation activities.

### **6.2 Proper Use of Accredited Status and Claims**

Neither a Recognized Accreditor, nor any Registrar accredited under The Act, nor any Registered Facility shall take any action which:

constitutes or implies certification, approval, or endorsement by NIST or any other agency of the U.S. Government, of fasteners entered into commerce in the United States; or

constitutes or implies that the Accreditor, or the Registrar, or Facility is recognized by NIST for any activities beyond those specified in the NIST recognition documents.

### **6.3 Keeping NIST Informed**

*6.3.1 Organizational Changes:* A Recognized Accreditor must inform NIST within 30 days of any major change in any factors which might affect its ability to operate, as specified, such as replacement of personnel (e.g., the Executive, key supervisors, quality manager, and accreditation decision makers); any major change in procedure, policy making or direction; or change in location, ownership, or business affiliations. Failure to provide timely and accurate information may result in termination of recognition.

*6.3.2 Accredited Registrar Status:* NIST will maintain a list of all Registrars who have been accredited by all Accreditors recognized by NIST. Only those Registrars on the Registrars List are eligible to register Facilities which are subject to the Act and implementing regulations.

Each recognized Accreditor must keep NIST informed of all FQA Registrar accreditation actions. This information is vital for maintaining a current Registrars List. All new accreditations, renewals, terminations, revocations, suspensions, changes in scope (additions or deletions), must be reported to NIST within seven days, in English, by the

Recognized Accreditor. Accreditors are also responsible for collecting and forwarding to NIST the annual Registrar listing fee.

Recognized Accreditors should be mindful that even though they may have issued accreditation certificates to Registrars, such Accredited Registrars may not register Facilities as meeting the requirements of the Fastener Quality Act regulations before the date their names appear on the Registrars List. Further, only a Recognized Accreditor may notify NIST of the accreditation action.

The notification of accreditation status by the Recognized Accreditor must include the following elements of information:

1. Name of Recognized Accreditor
2. Name of Accredited Registrar
3. Address of Registrar (Country, state, city, postal code)
4. Copy of accreditation Certificate
5. Name of Registrar's Authorized Representative and telephone/Fax numbers
6. Nature of the accreditation action (e.g., initial, renewal, change in scope, etc.)
7. Scope of accreditation/change and effective dates

*6.3.3 Accreditors List:* NIST will maintain a list of the names and pertinent information on all Recognized Accreditors which comply with the requirements of the Program. Only listed Accreditors are eligible to accredit Registrars to register Facilities under the Act and implementing regulations. A Recognized Accreditor must remain in conformance with all conditions and requirements to retain its listing.

*6.3.4 Facilities List:* NIST will prepare and maintain a list of Facilities registered by Registrars on the Registrar List. Names and information regarding Registered Facilities will be included on the list based on information submitted to NIST only by accredited Registrars who submit the Facility listing fee established by NIST along with the information specified by NIST.

The Accreditors List, the Registrars List, and the Facilities List will be maintained on an electronic database and entries will be updated as information becomes available on the NIST FQA Home Page (<http://www.nist.gov/fqa>).

## **6.4 Subcontracting**

If a Recognized Accreditor, an Accredited Registrar, or Registered Facility subcontracts any work, the subcontractor shall conform to Sec. 280.807 of the regulations. In addition, quality documentation shall include procedures for subcontracting even if subcontracting is not a normal practice.

***Sec. 280.807 Subcontracting.***

*If a Recognized Accreditor, an Accredited Registrar, or a Registered Facility subcontracts any of its functions to another entity it must place the work with another recognized Accreditor, accredited Registrar, or registered Facility; inform the client, before the fact, that subcontracting will be necessary, and clearly indicate in all appropriate records and reports to the client specifically what functions were subcontracted.*

**6.5 Reports**

Recognized Accreditors, accredited Registrars and registered Facilities shall conform with the requirements of Sec. 280.808 of the regulations.

***Sec. 280.808 Reports.***

*Reports and records shall be maintained in such a manner to preserve original data, and be collected as required into a final form, sufficient to satisfy customer and legal requirements. Such reports shall be provided upon request to the Bureau of Export Administration, to the National Institute of Standards and Technology, or to any other agency of the federal government authorized to obtain such records under this part<sup>1</sup>*

**6.6 Recordkeeping Requirements**

Recognized Accreditors, Accredited Registrars and Registered Facilities shall conform with the requirements of Sec. 280.809 and Sec. 280.7 of the regulations.

***Sec. 280.809 Recordkeeping.***

*Each recognized Accreditor, accredited Registrar, or fastener manufacturer whose Facility has been registered shall retain all applicable records required under the Act and this part for 5 years. All records are subject to the requirements in Sec. 280.7 of this part.*

***Sec. 280.7 Recordkeeping Requirement.***

*(a) Each laboratory accredited under Subparts C, D, or E or Sec. 280.104 of this part shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations. The final test report or the test records maintained by the laboratory shall contain sufficient information to permit the test to be repeated at a later time if a retest is necessary. The laboratory shall maintain the test report and a record of all original observations, calculations, and derived data. The records shall include the identity of*

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<sup>1</sup> Use of the term “part” in the regulations refers to 15 CFR Part 280, “Procedures for Implementation of the Fastener Quality Act.”

*personnel involved in sample preparation and testing. Procedures for storage and retrieval of records must be documented and maintained in the laboratory's quality manual.*

*(b) Manufacturers, importers, private label distributors, and persons<sup>1</sup> who significantly alter fasteners shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations.*

*(c) Original records required. Persons required to keep records under this part must maintain the original records in the form in which that person receives or creates them unless that person meets all of the conditions of paragraph (d) of this section relating to reproduction of records. Original laboratory test reports described in sections 280.5, 280.6, 280.13, and 280.15(b) of this part must be kept.*

*(d) Reproduction of original records. A person required to keep records under this part may maintain reproductions of documents other than laboratory test reports instead of the original records using any photographic, photostatic, miniature photographic, micrographic, automated archival storage, or other process that completely, accurately, legibly and durably reproduces the original records (whether on paper, microfilm, or through electronic digital storage techniques). The process must meet all of the requirements of paragraphs (d)(1) through (d)(9) of this section.*

*(1) The system must be capable of reproducing all records on paper.*

*(2) The system must record and be able to reproduce all marks, information, and other characteristics of the original record, including both obverse and reverse sides of paper documents in legible form.*

*(3) When displayed on a viewer, monitor, or reproduced on paper, the records must exhibit a high degree of legibility and readability. (For purposes of this section, legible and legibility mean the quality of a letter or numeral that enable the observer to identify it positively and quickly to the exclusion of all other letters or numerals. Readable and readability mean the quality of a group of letters or numerals being recognized as complete words or numbers.)*

*(4) The system must preserve the initial image (including both obverse and reverse sides of paper documents) and record all changes, who made them and when they were made. This information must be stored in such a manner that none of it may be altered once it is initially recorded.*

*(5) The regulated person must establish written procedures to identify the individuals who are responsible for the operation, use and maintenance of the system.*

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<sup>1</sup>The Regulations define Persons as any individual, partnership, limited partnership or corporate entity and/or a representative, agent or designee.



*(6) The regulated person must establish written procedures for inspection and quality assurance of records in the system and document the implementation of those procedures.*

*(7) The system must be complete and contain all records required to be kept by this part or the regulated person must provide a method for correlating, identifying and locating records relating to the same transaction(s) that are kept in other record keeping systems.*

*(8) The regulated person must keep a record of where, when, by whom, and on what equipment the records and other information were entered into the system.*

*(9) Upon request by the Bureau of Export Administration or NIST, the regulated person must furnish, at the examination site, the records, the equipment and, if necessary, knowledgeable personnel for locating, reading, and reproducing any record in the system.*

*(e) Destruction or disposal of records. If the Bureau of Export Administration, NIST or any other government agency makes a formal or informal request for any record or records, such record or records may not be destroyed or disposed of without the written authorization of the agency concerned. This prohibition applies even if such records have been retained for a period of time exceeding that required by paragraph (a) or (b) of this section.*

*(f) All persons required to keep records by this part must furnish those records when requested to do so by an employee of the Bureau of Export Administration or NIST.*

## **7.0 ACCREDITOR REQUIREMENTS**

### **7.1 Introduction**

This section sets out organizational, operational and other requirements that must be met by an Accreditor in order to be recognized by NIST under Subparts J or K of the regulations. It also sets out the requirements against which an Accreditor assesses the competence of an applicant Registrar. These requirements include conditions with respect to Subpart I of the regulations.

These requirements are based on ISO/IEC Guide 61 - *General requirements for assessment and accreditation of certification/registration bodies*, and are provided below, with specific NIST guidance as indicated in **bold print**.

## 7.2 Requirements for Accreditors (From Subpart K of the Regulations)

### *Sec. 280.1010 Accreditors.*

#### *(a) General provisions.*

*(1) The policies and procedures under which the Accreditor operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this part.*

*(2) The Accreditor shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the applicant body or membership of any association or group, nor shall accreditation be conditional upon the number of bodies already accredited.*

*(3) The accreditation criteria against which the competence of a registrar is assessed shall be those outlined in subpart L of this part. If an explanation is required as to the application of these documents to a specific accreditation program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the Accreditor.*

**Accreditors shall audit registrars using the criteria contained in 15 CFR Part 280 Subparts I and L (See NISTIR 6262 *Accreditation Requirements for Quality System Registrars Under the Fastener Quality Act.*)**

**Accreditors shall assure that registrars register Facilities using the criteria contained in 15 CFR Part 280 Sec. 280.104 and Subpart I (See NISTIR 6263 *Quality Assurance System Registration Requirements for Facilities Under the Fastener Quality Act.*)**

*(4) The Accreditor shall confine its requirements, assessment and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.*

*(b) Organization of a recognized Accreditor. The structure of the Accreditor shall be such as to give confidence in its accreditations. In particular, the Accreditor shall:*

*(1) Be impartial;*

*(2) Be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation;*

*(3) Identify the management (committee, group or person) which will have overall responsibility for all of the following:*

*(i) Performance of assessment and accreditation as defined in this part;*

*(ii) Formulation of policy matters relating to the operation of the Accreditor;*

*(iii) Decisions on accreditation;*

*(iv) Supervision of the implementation of its policies;*

*(v) Supervision of the finance of the Accreditor; and*

*(vi) Delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf.*

*(4) Have documents which demonstrate that it is a legal entity;*

*(5) Have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the Accreditor; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;*

*(6) Ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;*

*(7) Have rights and responsibilities relevant to its accreditation activities;*

*(8) Have adequate arrangements to cover liabilities arising from its operations and/or activities;*

*(9) Have financial stability and resources required for the operation of an accreditation system;*

*(10) Employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing accreditation functions relating to the type, range and volume of work performed, under a responsible senior executive;*

**The senior executive shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale.**

**The executive shall have appropriate experience/education in management principles/application, technical knowledge, and personnel management.**

*(11) Have a quality system, as outlined in Sec. 280.1010(d), giving confidence in its ability to operate an accreditation system for registration bodies;*

*(12) Have policies and procedures that distinguish between accreditation and any other activities in which the Accreditor is engaged;*

*(13) Together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;*

*(14) Have formal rules and structure for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions;*

*(15) Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and shall not offer or provide, directly or indirectly, those services that accredit others to perform, consulting services to obtain or maintain accreditation, or services to design, implement or maintain a certification scheme;*

*(16) Have policies and procedures for the resolution of complaints, appeals and disputes received from bodies or other parties about the handling of accreditation of any related matters;*

*(17) Have a structure where members are chosen to provide a balance of interest, where no single interest predominates; and*

**The Accreditor shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance.**

*(18) Assure that other products, processes or services that may be offered, directly or indirectly, do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.*

*(c) Subcontracting.*

*(1) When an Accreditor decides to subcontract work related to accreditation (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The Accreditor shall **include procedures for subcontracting in its quality documentation, shall only subcontract work to another NIST recognized Accreditor and shall:***

*(i) Take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;*



*(ii) Ensure that the subcontracted body or person is competent and complied with the applicable provisions of this part, including Sec. 280.807, and is not involved, either directly or through its employer, with the design, implementation or maintenance of a registration scheme in such a way that impartiality could be compromised;*

**The Accreditor must: place work with another NIST recognized Accreditor; inform the client, before the fact, that subcontracting will be necessary; and clearly indicate in all appropriate records and reports to the client specifically what functions were subcontracted, and**

*(iii) obtain the consent of the applicant or accredited body.*

*(2) Requirements in paragraphs (c)(1)(i) and (ii) of this section are also relevant, by extension, when an Accreditor uses, for granting its own accreditation, work provided by another Accreditor with which it has signed an agreement.*

*(d) Quality system.*

*(1) The management of the Accreditor with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.*

*(2) The Accreditor shall operate a quality system in accordance with the relevant elements of this part and appropriate to the type, range and volume of work performed. This quality system shall be documented, and the documentation shall be available for use by the staff of the Accreditor.*

*(3) The Accreditor shall ensure effective implementation of the documented quality system procedures and instructions.*

*(4) The Accreditor shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to ensure that a quality system is established, implemented and maintained in accordance with this part, and report on the performance of the quality system to the management of the Accreditor for review and as a basis for improvement of the quality system.*

*(5) The quality system shall be documented in a quality manual and associated quality procedures,*

**NIST reviews the quality documentation to evaluate whether it contains current, complete, and detailed information describing the Accreditor and the internal organizational structure and quality system used to control the quality of all accreditation activities. The documentation should contain policies, procedures and methods to cover all aspects of the operation to ensure that the managerial,**

**technical, administrative and human factors elements which might affect the quality of services are under control. Guidance in developing or operating a quality system can be found in the References and the quality manual shall contain or refer to at least the following:**

*(i) A quality policy statement;*

**including quality objectives**

*(ii) A brief description of the legal status of the Accreditor, including the names of its owners, if applicable, and, if different, the names of the persons who control it;*

*(iii) The names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation function;*

*(iv) An organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those making decisions regarding accreditation;*

*(v) A description of the organization of the Accreditor, including details of the management (committee, group or person), its constitution, terms of reference and rules of procedure;*

**The following shall be included:**

**primary functions of key personnel;**

**technical resources, including facilities, equipment;**

**the function and location of each unit which is involved in Registrar accreditation activities for Fastener Facilities; and**

**scope of operation of the Accreditor.**

*(vi) The policy and procedures for conducting management reviews;*

*(vii) Administrative procedures including document control;*

*(viii) The operational and functional duties and service pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;*

*(ix) The policy and procedures for the recruitment and training of Accreditor personnel (including auditors) and monitoring their performance;*

*(x) A list of its subcontractors and details of the procedures for assessing, recording and monitoring their competence;*

*(xi) Its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;*

*(xii) The policy and procedures for implementing the accreditation process, including:*

*(A) The conditions for issue, retention and withdrawal of accreditation documents*

*(B) Checks of the use and application of documents used in the accreditation*

*(C) The procedures for assessing and accrediting applicants; and*

*(D) The procedures for surveillance and reassessment of accredited bodies.*

**Policies and procedures shall be included to describe how the Accreditor:**

**adjudicates all matters relating to its operation;**

**reviews policies;**

**reviews finances;**

**conducts staff training;**

**creates committees as required;**

**provides for and responds to comment by affected entities;**

**controls the ownership, use and display of the accreditation documents, and the manner in which a Registrar may refer to its accreditation status;**

**maintains control over information collection and handling, e.g., Registrar status, scheduling of renewals, on-site audits, auditor assignments, etc.;**

**determines applicant eligibility;**

**conducts the on-site assessment, including criteria for assessment, checklists, report forms and requirements;**

**makes decisions on accreditation actions, e.g., accreditation, renewal, revocation, suspension, denial, termination;**

**allows Accredited Registrars to refer to their accredited status on documents;**

**handles complaints, e.g., from Registrars, Registrar clients, regulatory agencies, etc.;**

**controls Accredited Registrar subcontracting services;**

**provides surveillance of Accredited Registrars;**

**controls information dissemination, including confidentiality requirements, e.g., directory, electronic media, publicity, phone calls;**

**permits the prompt notification to NIST and other interested parties of any change in the status of an Accredited Registrar;**

**maintains and retains records, and**

**reviews and updates the quality system.**

*(xiii) The policy and procedures for dealing with appeals, complaints and disputes; and*

*(xiv) The procedures for conducting internal audits based on appropriate international documentation.*

**(e) Conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation.**

*(1) The Accreditor shall specify the conditions for granting, maintaining, extending and reducing accreditation, and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the accredited body's scope of accreditation. In particular, the Accreditor shall require the accredited body to notify it promptly of any intended changes to the quality system or other changes which may affect conformity.*

*(2) The Accreditor shall have procedures to grant, maintain, withdraw and suspend accreditation; to extend or reduce the scope of accreditation; and to conduct reassessment in the event of changes significantly affecting the activity and operation of the accredited body (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the Accreditor.*



*(f) Internal audits and management reviews.*

*(1) The Accreditor shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. The Accreditor shall ensure that personnel responsible for the area audited are informed of the outcome of the audit; corrective action is taken in a timely and appropriate manner; and the results of the audit are documented.*

**NIST requires that the entire quality system be audited at least annually.**

*(2) The top management of the Accreditor shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this part and the stated quality policy and objectives. Records of such reviews shall be maintained.*

*(g) Documentation.*

*(1) The Accreditor shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request:*

*(i) Information about the authority under which the Accreditor operates;*

*(ii) A documented statement of its accreditation system, including its rules and procedures for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;*

*(iii) Information about the assessment and accreditation process;*

*(iv) A description of the means by which the Accreditor obtains financial support, and general information on the fees charged to applicants and accredited bodies;*

*(v) A description of the rights and duties of applicants and accredited bodies, as specified, including requirements, restrictions or limitations on the use of the Accreditor's logo and on the ways of referring to the accreditation granted, in conformance with Sec. 280.804(d); and*

**The Accreditor shall make available to NIST:**

**the accreditation criteria (requirements) that Registrars must satisfy in order to be granted accreditation;**

**copies of program handbooks, or other explanatory documents; and**

**examples of all forms used, e.g., applications for accreditation, control forms, and data sheets, audit checklists, report forms, etc.; and**

(vi) *Information on procedures for handling complaints, appeals and disputes;*

(vii) *A directory of accredited bodies including their locations, describing the scope of accreditation granted to each.*

(2) *The Accreditor shall establish and maintain procedures to control all documents and data that relate to its accreditation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the Accreditor, or applicants and accredited bodies, when required to perform any function relating to the activities of applicants and accredited bodies.*

(h) Records.

(1) *The Accreditor shall maintain a record system to suit its particular circumstances and to comply with this part. The records shall demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending or withdrawing accreditation. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of five years.*

(2) *The Accreditor shall have a policy and procedures for retaining records for a period of five years. The Accreditor shall have a policy and procedures concerning access to these records consistent with paragraph (h)(1) of this section.*

(i) Confidentiality.

(1) *The Accreditor shall have adequate arrangements, consistent with applicable laws, to safeguard confidentiality of the information obtained in the course of its accreditation activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf.*

(2) *Except as required in this part, information about a particular body shall not be disclosed to a third party without the written consent of the body.*

**Sec. 280.1011 Accreditor personnel.**

*(a) General provisions.*

*(1) The personnel of the Accreditor involved in accreditation shall be competent for the functions they perform.*

*(2) Information on the relevant qualifications, training and experience of each member of the personnel involved in the accreditation process shall be maintained by the Accreditor. Records of training and experience shall be kept up to date.*

*(3) Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.*

*(b) Qualification criteria for auditors and technical experts.*

*(1) In order to ensure that assessments are carried out effectively and uniformly, the minimum relevant criteria for competence shall be defined by the Accreditor.*

*(2) Auditors shall meet the requirements of the appropriate international documentation.*

*(3) Technical experts are not required to comply with the requirements for auditors, and guidance on their personal attributes may be obtained from appropriate international documentation.*

*(c) Selection procedure.*

*(1) The Accreditor shall have a **documented** procedure for selecting auditors and, if applicable, technical experts on the basis of their competence, training, qualifications and experience, and for initially assessing the conduct of auditors and technical experts during assessments, and subsequently monitoring the performance of auditors and technical experts.*

**The Accreditor shall have documented selection criteria that each potential auditor must meet.**

**The criteria shall contain requirements for education, technical, quality systems, management, and communication skills, with a specified minimum number of years of applicable experience for each category.**

*(2) When selecting the audit team to be appointed for a specific assessment, the Accreditor shall ensure that the skills brought to each assignment are appropriate. The team shall:*

(i) *Be familiar with the Fastener Quality Act and its implementing regulations, accreditation procedures and accreditation requirements;*

(ii) *Have a thorough knowledge of the relevant assessment method and assessment documents;*

(iii) *Have appropriate technical knowledge of the fastener technology for which accreditation is sought and, where relevant with associated procedures and their potential for failure (technical experts who are not auditors may fulfil this function);*

(iv) *Have a degree of understanding sufficient to make a reliable assessment of the competence of the accredited body to operate within its scope;*

(v) *Be able to communicate effectively, both in writing and orally, in the required languages;*

(vi) *Be free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example,*

*(A) Audit team members or their organization shall not have provided consulting services to the applicant or accredited body which compromise the accreditation process and decision; and*

*(B) In accordance with the directives of the Accreditor, the audit team members shall inform the Accreditor, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the body to be assessed.*

(d) *Contracting of assessment personnel.*

*The Accreditor shall require the personnel involved in the assessment to sign a contract or other document by which they commit themselves to comply with the rules defined by the Accreditor, including those relating to confidentiality and those relating to independence from commercial and other interest, and any prior and/or present link with the bodies to be assessed. The Accreditor shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for personnel outlined in this subpart.*

(e) *Assessment personnel records.*

*(1) The Accreditor shall possess and maintain up-to-date records on personnel conducting assessments, consisting of:*

*(i) Name and address;*



- (ii) *Affiliation and position held in the organization;*
- (iii) *Educational qualifications and professional status;*
- (iv) *Experience and training in each field of competence of the Accreditor;*
- (v) *Date of most recent updating of record; and*
- (vi) *Performance appraisal.*

(2) *The Accreditor shall ensure, and verify, that any subcontracted body maintains records, which satisfy the requirements of this part, of assessment personnel who are subcontracted to the Accreditor.*

*(f) Procedures for assessment teams.*

*Assessment teams shall be provided with up-to-date assessment instructions and all relevant information on accreditation arrangements and procedures.*

**Sec. 280.1012 Decision on accreditation.**

*(a) The decision whether or not to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Those who make the accreditation decision shall not have participated in the audit.*

*(b) The Accreditor shall not delegate authority for granting, maintaining, extending, reducing, suspending or withdrawing accreditation to an outside person or body.*

*(c) The Accreditor shall provide to each of its accredited bodies accreditation documents such as a letter outlining the scope of accreditation and a certificate signed by an officer who has been assigned such responsibility. These accreditation documents shall identify, for the body and each of its sites covered by the accreditation:*

*(1) The name and address;*

*(2) The scope of the accreditation granted, including as appropriate:*

*(i) The type of registration scheme;*

*(ii) The standards and/or other normative documents and regulatory requirements against which products, services or systems are registered; and*

*(iii) Product categories.*

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*(3) The effective date of accreditation and, as applicable, the term for which the accreditation is valid.*

*(d) In response to an application for an amendment to the scope of an accreditation already granted, the Accreditor shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.*

***Sec. 280.1013 References to accredited status.***

*(a) An Accreditor which is proprietor or licensee of a symbol or logo, intended for use under its accreditation program, shall have a policy governing its use. It shall normally allow and accredited body to refer to its accreditation in certificates, reports, and stationery and publicity material relating to accredited activities.*

*(b) The Accreditor shall not allow use of its mark or logo in any way which implies that the Accreditor itself approved a product, service or system registered by an accredited body. Where a Facility is registered only with respect to its quality assurance system, the symbol or logo shall not be used on a product or in any other way that may be interpreted as denoting product conformance, as required by Sec. 280.804(d).*

*(c) The Accreditor shall take suitable action to deal with incorrect reference to the accreditation system, or misleading use of accreditation logos found in advertisements, catalogues, etc. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.*

***Sec. 280.1014 Change in the accreditation.***

*The Accreditor shall give due notice of any changes it intends to make in its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited Registrar carries out any necessary adjustments to its procedures within such time as, in the opinion of the Accreditor, is reasonable.*

***Sec. 280.1015 Appeals, complaints, and disputes.***

*The Accreditor shall keep a record of all appeals, complaints and disputes, and remedial actions relative to accreditation; take appropriate corrective and preventive action; and document the actions taken and assess their effectiveness.*

***Sec. 280.1016 Access to records of appeals, complaints, and disputes.***

*The Accreditor shall require each applicant and accredited Registrar to make available to it, when requested, the records of all complaints, appeals and disputes, and subsequent actions.*

## ***Requirements for Assessment***

### ***Sec. 280.1020 Application for accreditation.***

*(a)(1) The Accreditor shall maintain up-to-date, as specified in Sec. 280.1010(g)(1), detailed descriptions of the assessment and accreditation procedure, the documents containing the requirements for accreditation, and documents describing the rights and duties of accredited Registrars, and shall provide them to applicants and accredited Registrars. The Accreditor shall require that an accredited Registrar:*

*(i) Always complies with the relevant provisions of this part;*

*(ii) Makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, records (including internal audit reports) and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;*

*(iii) Only claims that it is accredited with respect to those activities for which it has been granted accreditation;*

*(iv) Does not use its accreditation in such a manner as to bring the Accreditor into disrepute, and does not make any statement regarding its accreditation which the Accreditor may consider misleading or unauthorized;*

*(v) Upon suspension or withdrawal of its accreditation, discontinues use of all advertising matter that contains any reference thereto and returns any accreditation documents as required by the Accreditor;*

*(vi) Does not allow the fact of its accreditation to be used to imply that a product, process, system, or person is approved by the Accreditor, as required by Sec. 280.804(d);*

*(vii) Ensures that no accreditation document, mark or report, or any part thereof, is used in a misleading manner; and*

*(viii) In making reference to its accreditation status in communication media such as documents, brochures or advertising, complies with the requirements of the Accreditor.*

*(2) When the desired scope of accreditation is related to a specific program any necessary explanation shall be provided to the applicant. If requested, additional application information shall be provided to the body.*

*(b) The Accreditor shall require an official application form, duly completed and signed by a duly authorized representative of the applicant, in which or attached to which:*

*(1) The scope of the desired accreditation is defined; and*

*(2) The applicant agrees to comply with the requirements for accreditation and to supply any information needed for its evaluation,*

**including the requirements of the Act and regulations.**

*(c) At least the following shall be provided by the applicant prior to the on-site assessment:*

*(1) The general features of the applicant body, such as corporate entity, name, address, legal status and, where relevant, human and technical resources;*

*(2) General information concerning the body covered by the application, such as its functions, and its relationship in a larger corporate entity, and its physical locations;*

*(3) A description of the systems or products it registers and the standards or other normative documents applicable to each; and*

*(4) A copy of its quality manual and, where required, the associated documentation.*

***Sec. 280.1021 Preparation for assessment.***

*(a) Before proceeding with the assessment, the Accreditor shall conduct, and maintain records of, a review of the request for accreditation to ensure that:*

*(1) The requirements for accreditation are clearly defined and documented;*

*(2) Any difference in understanding between the Accreditor and the applicant is resolved; and*

*(3) The Accreditor has the capability to perform the accreditation service with respect to the scope of the accreditation sought, the location of the applicant's operations, and any special requirements such as the language used by the applicant.*

*(b) The Accreditor shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.*

*(c) The Accreditor shall nominate a qualified audit team to evaluate all material collected from the applicant and to conduct the audit on its behalf. Experts in the areas to be assessed may be attached to the Accreditor's team as advisers.*

*(d) The applicant shall be informed of the names of the members of the audit team who will carry out the assessment, with sufficient notice to appeal against the appointment of any particular auditors or experts.*



*(e) The audit team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the audit shall be agreed upon with the applicant. The mandate given to the audit team shall be clearly defined and made known to the applicant, and shall require the audit team to examine the structure, policies and procedures of the applicant, and confirm that these meet all the requirements relevant to the scope of accreditation, and that the procedures are implemented and are such as to give confidence in the registrations of the applicant.*

**Sec. 280.1022 Assessment.**

*(a) The audit team shall assess all services of the applicant covered by the defined scope against all applicable accreditation requirements.*

*(b) The Accreditor shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant before an initial accreditation is granted for any function requiring on-site activity by the applicant.*

**Sec. 280.1023 Assessment report.**

*(a) The Accreditor may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that:*

*(1) A meeting takes place between the audit team and the applicant's management prior to leaving the premises, at which the audit team provides a written or oral indication on the conformity of the applicant with the particular accreditation requirements and provides an opportunity for the applicant to ask questions about the findings and their basis;*

*(2) The audit team provides the Accreditor with a report of its findings as to the applicant's conformity to all of the accreditation requirements;*

*(3) A report on the outcome of the assessment is promptly brought to the applicant's attention by the Accreditor, identifying any nonconformity to be discharged in order to comply with all of the accreditation requirements;*

*(4) The Accreditor shall invite the applicant to comment on the report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the accreditation requirements identified during the assessment, and shall inform the applicant of the need for full or partial reassessment or whether a written declaration to be confirmed during surveillance will be considered adequate;*

*(5) The report shall contain as a minimum:*

*(i) The date(s) of the audit(s);*

- (ii) The name(s) of the person(s) responsible for the report;*
- (iii) The names and addresses of all sites audited;*
- (iv) The assessed scope of accreditation or reference thereto;*
- (v) Comments on the conformity of the applicant with the accreditation requirements and, where applicable, any useful comparisons with the results of previous assessment of the applicant; and*
- (vi) An explanation of any differences from the information presented to the applicant at the closing meeting.*

*(b) If the final report authorized by the Accreditor differs from the report referred to in paragraphs (b) (3) and (5) of this section, it shall be submitted to the applicant with an explanation of any differences from the previous report. The report shall take into consideration:*

- (1) The qualification, experience and authority of the staff encountered;*
- (2) The adequacy of the internal organization and procedures adopted by the applicant to give confidence in the quality of its services; and*
- (3) The actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.*

***Sec. 280.1024 Surveillance and reassessment procedures.***

*(a) The Accreditor shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited Registrar continues to comply with the accreditation requirements.*

**Accreditors shall conduct Registrar office surveillance assessments at least once each year and witness audits commensurate with the number of registered fastener QAS facilities with a frequency not less than the following schedule: 1-30, 1 audit; 31-100, 2 audits; 101-250, 3 audits and over 251, 4 audits.**

*(b) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of the applicant as described in this part.*

*(c)(1) The Accreditor shall have arrangements to ensure that an accredited Registrar informs it without delay of changes in any aspects of its status or operation that affect its:*

*(i) Legal, commercial or organizational status;*

*(ii) Organization and management, for example key managerial staff;*

*(iii) Policies or procedures, where appropriate;*

*(iv) Premises; and*

*(v) Personnel, equipment, facilities, working environment or other resources, where significant.*

*(2) The accredited Registrar shall also inform the Accreditor of other such matters that may affect activities, or conformance with the requirements, or any other relevant criteria of competence specified by the Accreditor.*

## **8.0 REGISTRAR REQUIREMENTS**

Registrar requirements are contained in 15 CFR Part 280 subparts I and L and NISTIR 6262 *Accreditation Requirements for Quality System Registrars Under the Fastener Quality Act.*

## **9.0 FACILITY REQUIREMENTS**

Facility requirements are contained in 15 CFR Part 280 Sec. 280.104, subpart I and NISTIR 6263 *Quality Assurance System Registration Requirements for Facilities Under the Fastener Quality Act.*

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