

**DEPARTMENT OF COMMERCE****National Institute of Standards and Technology****15 CFR Part 280**

[Docket Number: 970724177-8057-02]

RIN 0693-AB43

**Procedures for Implementation of the Fastener Quality Act**

**AGENCY:** National Institute of Standards and Technology, United States Department of Commerce.

**ACTION:** Final rule and extension of implementation date.

**SUMMARY:** The Director of the National Institute of Standards and Technology (NIST), United States Department of Commerce, and the Under Secretary of the Bureau of Export Administration (BXA), United States Department of Commerce (collectively referred to as the Department), are today issuing a final rule based on comments received in response to the notice of proposed rulemaking published in the **Federal Register** on September 8, 1997 (62 FR 47240-47260) (1997)) amending regulations found at 15 CFR part 280 implementing the Fastener Quality Act (the Act). This final rule establishes the procedures for registration of in-process inspection activities of qualifying manufacturing facilities that use Quality Assurance Systems (QAS), revises definitions and related sections for clarity, and corrects editorial errors. These changes will facilitate the implementation of the Act and will better accommodate modern industry practices by incorporating these practices into the certification process of fasteners covered by the Act. This rule also extends the implementation date of the Fastener Quality Act by sixty days to July 26, 1998.

**DATES:** This rule is effective May 14, 1998. The date of implementation of the Act is July 26, 1998.

**FOR FURTHER INFORMATION CONTACT:** Dr. Subhas G. Malghan, FQA Program Manager, Technology Services, National Institute of Standards and Technology, Building 820, Room 306, Gaithersburg, MD 20899, telephone number (301) 975-5120.

**SUPPLEMENTARY INFORMATION:****Extension of Implementation Date**

The final rule implementing the Fastener Quality Act became effective on November 25, 1996, and was to apply to fasteners manufactured on or after May 27, 1997, the "implementation date". On April 18, 1997, as permitted

by section 15 of the Act, NIST announced a one year delay of the implementation date of the regulations because there were an insufficient number of accredited laboratories to conduct the volume of inspection and testing required by the Act and regulations (62 FR 19041 (1997)). Currently, NVLAP and the NIST-recognized private accreditation bodies have received applications from approximately 430 testing laboratories, a sufficient number for implementation of the Act. Of these, approximately 130 testing laboratories have been accredited and are listed on the NIST Accredited Laboratory List. Although NVLAP and the private accreditation bodies have been working diligently to complete accreditation of these laboratories, it seems unlikely that the necessary 425 laboratories will be accredited by May 26, 1998. Therefore, to ensure that there are a sufficient number of accredited laboratories to conduct the inspection and testing required by the Act, pursuant to section 15 of the Act, NIST is extending the implementation date of the Act by sixty days to July 26, 1998.

**Background—Final Rule**

The Fastener Quality Act (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 and registration of manufacturing facilities engaged in fastener testing; and (3) requiring inspection, testing and certification, in accordance with standardized methods, of fasteners covered by the Act.

The Secretary of Commerce, acting through the Director of NIST, published final regulations implementing the Act on September 26, 1996. Those regulations established procedures under which: (1) Laboratories in compliance with the Act may be listed; (2) laboratories may apply to NIST for accreditation; (3) private laboratory accreditation entities (bodies) may apply to NIST for approval to accredit laboratories; and (4) foreign laboratories accredited by their governments or by organizations recognized by the NIST Director under section 6(a)(1)(C) of the Act can be deemed to satisfy the laboratory accreditation requirements of the Act. The regulation also established, within the Patent and Trademark Office (PTO), a recordation system to identify the manufacturers or distributors of covered fasteners to ensure that the fasteners may be traced to their manufacturers or private label distributors. In addition, the regulations

contained provisions on testing and certification of fasteners, sale of fasteners subsequent to manufacture, recordkeeping, applicability of the Act, enforcement, civil penalties, and hearing and appeal procedures.

Those regulations became effective on November 25, 1996, and were to apply to fasteners manufactured on or after May 27, 1997, the "implementation date". On April 18, 1997, as permitted by section 15 of the Act, NIST announced a one year delay of the implementation date of the regulations because there were an insufficient number of accredited laboratories to conduct the volume of inspection and testing required by the Act and regulations (62 FR 19041 (1997)).

Following issuance of the final regulations on September 26, 1996, the automobile industry approached the Department and expressed its concern that the Act and the implementing regulations did not recognize the use of modern manufacturing methods using prevention-based quality assurance systems employing statistical process controls (SPC). On February 4, 1997, a Public Workshop was held at NIST to solicit information from all interested parties, including the automobile, aerospace, construction, and fastener industries on the use of prevention-based quality assurance systems employing SPC in the manufacture of fasteners. The Department published a notice of proposed rule making in the **Federal Register** on September 8, 1997, seeking public comments on proposed amendments to the regulations that recognize the use of prevention-based quality assurance systems under the Act.

To incorporate Quality Assurance Systems/Statistical Process Control (QAS/SPC) into the regulations, the Department proposed adding § 280.104, Accreditation of Certain Manufacturing Facilities as Laboratories; subpart I, Special Rule for the Accreditation of Certain Fastener Manufacturing Facilities, Whose Implemented Fastener Quality Assurance Systems Meet Defined Requirements, as Laboratories; subpart J, Recognition of Foreign Registrar Accreditation Bodies; subpart K, Requirements for Registrar Accreditation Bodies (Accreditors); and subpart L, Requirements for Registrars. In addition, the Department proposed adding a definition of Fastener Quality Assurance System (FQAS) and defining the terms Accreditor, Registrar, and Facility. The Department also proposed amendments to section 280.6, Laboratory Test Reports and § 280.10, Sampling, to specify requirements for facilities.

### Summary of Public Comments Received by the Department in Response to the September 8, 1997 Request for Public Comments, and the Department's Response to the Comments

As noted above, on September 8, 1997, the Department published in the **Federal Register** (62 FR 47240-47260) (1997) (Sept. 8, 1997) a proposed rule to amend 15 CFR part 280. The Department received 125 responses to the request for comments. Twenty-five comments were received from fastener manufacturers, twenty domestic and five foreign; twenty-five were from associations, twenty domestic and five foreign; thirteen were from consultants; ten were from fastener distributors; eight were from entities involved in laboratory accreditation/facility registration, three laboratory assessors, two fastener testing laboratories, one laboratory accreditor, one foreign QAS registrar, and one foreign registration accreditation body; eight were manufacturers of products that incorporate fasteners, five from the aerospace industry, two from the automobile industry (one domestic and one foreign), and one foreign equipment manufacturer; eight were from government agencies; six were from importers of fasteners; one was from a foreign exporter of fasteners; one was from a raw material manufacturer; and twenty were from other interested parties, fifteen domestic and five foreign. Of the some 125 commenters, 69 commented on the issue of incorporating SPC/QAS into the FQA regulations. A detailed analysis of the comments follow.

As explained in detail below, based on the comments received, the Department has included all the proposed changes, with some editorial corrections and clarifications, in the final rule. For further clarification, the Department also has included definitions for recognized accreditor, accredited registrar, registered facility, and authorized representative, and has amended the definition of consensus standards organization to clarify that it is NIST that will identify such organizations.

### Comments on the Overall Effectiveness of the Proposed QAS Regulation

Of the 125 commenters, 69 commented on the issue of incorporating SPC/QAS into the FQA regulations; 44 favored the incorporation of SPC/QAS into the FQA regulations, and 25 were opposed.

Of the 44 commenters who favored the incorporation of SPC/QAS into the FQA regulations, thirteen were fastener

manufacturers, ten domestic and three foreign; thirteen were trade associations, ten domestic and three foreign; six were manufacturers of products that incorporate fasteners, three aerospace manufacturers, two automobile manufacturers (one domestic and one foreign), and one foreign equipment manufacturer; three were fastener distributors; three were consultants; one was a government agency; one was a foreign QAS registrar; and four were other interested parties, two domestic and two foreign.

Of the 25 commenters opposed to the incorporation of SPC/QAS into the FQA regulations, four were consultants; four were laboratory accreditors/accessors; three were domestic fastener manufacturers; two were fastener distributors; three were government agencies; one was a raw material manufacturer; and seven were other interested parties.

*Comment:* Support for the proposed incorporation of QAS/SPC into the regulation was widespread, although many raised questions on details of the regulation, as is explained more fully elsewhere in this document. However, a substantial minority of the commenters, twenty-five, expressed the concern that without final testing, the QAS/SPC scheme proposed by NIST would not ensure the quality of fasteners covered by the regulations, and would fail to protect the public safety.

*Response:* The decision by the Department to include QAS/SPC into the regulations as an alternative to end-of-line sampling and testing is based upon strong evidence that QAS/SPC reduces the defect rate in the fastener manufacturing process. A lower defect rate means that fewer fasteners are manufactured that fail to comply with relevant standards and specifications, and thus that fewer defective fasteners will enter into commerce. Public safety is preserved and enhanced. Furthermore, the Department has structured the regulation to provide checks and balances to ensure that this is the case.

The administrative record for this rule-making contains strong evidence that QAS/SPC systems utilizing continuous monitoring and control in the manufacturing process yields a substantially lower defect rate than do traditional manufacturing techniques that rely solely upon end-of-line sampling and testing. Testimony at the Public Workshop of February 7, 1997 indicates that the use of QAS/SPC may reduce the defect rate from the range of thousands or tens of thousands parts-per-million experienced by traditional manufacturing techniques to

approximately 100 parts-per-million. The improved manufacturing techniques embedded in QAS/SPC thus improve the quality of fasteners by reducing the portion of each lot that fails to meet standards and specifications. The regulations being issued today offer the benefits of QAS/SPC manufacturing to consumers in this country. But consistent with the FQA, these regulations also mandate in-process inspection and testing of fasteners manufactured under QAS/SPC systems, to verify that the promise of QAS/SPC is the reality.

As a means of providing checks and balances to the process controls that underlie the QAS/SPC methodology, the regulations mandate in-process inspection and testing of fasteners to assure the quality of fasteners, and thus the protection of public safety. Process controls in QAS/SPC facilities are required by the regulation to be augmented by all testing required by the standards and specifications that the manufacturer holds out that a given lot meets. The general rule is set out in § 280.104(a), which states that registration of a fastener manufacturing facility employing a fastener quality assurance system (FQAS) shall be deemed to meet the requirements of accreditation of a laboratory under the FQA. This general rule is amplified in § 280.2, which defines the term FQAS, and § 280.10, which sets out requirements for sampling methods to be followed by QAS/SPC facilities.

These sections of the regulation address three issues in the regime required of QAS/SPC facilities:

- What is the sampling methodology required of QAS/SPC facilities as part of their responsibility to conduct in-process testing and inspection?
- What specific tests and testing techniques must QAS/SPC facilities apply to the samples that are to be tested?
- Where must these tests be performed?

*Sampling* is a concept that will not always be relevant in the QAS/SPC environment. The definition of FQAS speaks about "process inspection embodied in a comprehensive and written control plan for product/process characteristics, process controls (including statistical process control), tests, and measurement systems that will occur during mass production." The Department recognizes that under QAS/SPC, some tests and inspections will be conducted on every fastener in the lot. That is, the test sample will be one hundred percent of the fastener lot. Section 280.10(c), as it has been revised as a result of the public comment

process, makes this point clear by stating, as one alternative, that "a manufacturer operating a Registered Facility may elect to conduct inspections and tests upon all of the fasteners within a specified lot, provided that this election is documented in the control plan of its Fastener Quality Assurance System." Otherwise, the sample size is governed by the general rule in § 280.10(a), which states that "[f]or tests conducted either in a laboratory on the Accredited Laboratory List or in a Registered Facility, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which provides for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with that standard or specification"; or the first alternative in § 280.10(c) "For tests conducted in a Registered Facility, and not in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample for inspections and tests by the Facility shall be determined by the sampling plan provided by its Fastener Quality Assurance System or by standards and specifications intended for use with a Fastener Quality Assurance System, as appropriate."

Tests are as required in the relevant standards and guidelines.

Where testing occurs in the QAS/SPC regime is governed by § 280.104(b) of the regulations, which requires that all in-process laboratory inspection and testing must be performed in laboratories accredited under the FQA; and § 280.104(d), which requires that the chemical composition of all fastener lots manufactured under QAS/SPC must be conducted in laboratories accredited under the FQA. In-process testing and inspection may occur within Registered Facilities.

In the view of the Department, these requirements meet the statutory mandates of the FQA, and protect the public safety.

## 280.2 Definitions

*Comment:* Eight commenters addressed the issue of whether subcontracted processes required final testing by an accredited laboratory or whether they could be performed by another Facility.

*Response:* In § 280.2, the definition of Facility has been expanded to include a facility performing subcontracted

processes such as electroplating and heat treating, provided that they too are listed on NIST's Facilities list. In addition, § 280.807 allows subcontracting to other Facilities listed on the Facilities list.

*Comment:* Eight commenters suggested that Quality Assurance Systems are not equivalent, and that they do not define which characteristics to measure and how to measure them.

*Response:* No changes have been made to the regulations based on these comments because the QAS facilities must meet equally rigorous standards to maintain their registration by an accredited Registrar.

*Comment:* Two commenters requested that the regulations be amended to allow QAS in lieu of metal testing by a metal manufacturer.

*Response:* No changes were made to the regulations because to the Department's knowledge, chemistry of metal is obtained by testing it in a laboratory. Therefore, chemical analysis by QAS is not an acceptable testing method.

*Comment:* Ten commenters suggested deleting references to ISO-9000 in the definition of Fastener Quality Assurance System because it lacks quality details and does not contain the details of ISO-25. In addition, three of these commenters stated that the proposed rule does not satisfy the intent of the Congress and will have a serious effect on the laboratory accreditation, and that a final inspection should be still required.

*Response:* No changes were made to the regulations based on these comments. The regulations are clear on laboratory accreditation and registration of fastener manufacturing facilities. The laboratory accreditation is performed in accordance with ISO Guides 58 and 25, and specific requirements of the Act and the regulations. Registration of fastener manufacturing facilities is carried out in accordance with the ISO Guides 61, 62 and the specific requirements of the Act and the regulations. The revised rule accommodating QAS facilities is fully within the intent of the Act because under QAS, fasteners are produced to stringent standards that yield fasteners of at least as good quality as end-of-line laboratory testing can assure. Since the two programs, accreditation and registration, are treated separately, the Department does not believe that laboratory accreditation will be seriously affected.

*Comment:* Two commenters suggested that the Department specify a level of revision of ISO Guides referred to in the QAS regulations that will assure the Department that the QAS approved

today will remain compliant in the future.

*Response:* No changes were made to the regulations based on these comments. As they currently exist, the ISO Guides referenced in the QAS regulations fulfill the needs of the Act and the regulations. The regulations are sufficiently flexible to accommodate moderate change in these standards.

*Comment:* One commenter remarked that the parameters of a control plan are not discussed in the proposed rule.

*Response:* No changes were made to the regulations based on this comment because the Department has decided that the broad parameters described in § 280.2 are sufficient.

*Comment:* One commenter suggested clarifying the meaning of "documented criteria of a QAS."

*Response:* No changes were made to the regulations based on this comment because the definition of QAS describes specific criteria to be met by the QAS facility.

*Comment:* One commenter suggested adding a requirement that personnel who collect data pursuant to the operation of a QAS be held to the same standards of training, experience and competency as laboratory personnel.

*Response:* No changes were made to the regulations based on this comment. The processes involved in laboratory testing differ from those in a QAS facility. Requirements for personnel performing tasks involved in these processes differ. The requirements for laboratory personnel are described in ISO Guide 25. The requirements for QAS facility personnel are described, in general, in the fastener QAS followed by that QAS facility.

*Comment:* One commenter remarked that QAS plans should be required to measure all characteristics called for in the standard and specification, rather than just those that the manufacturer finds appropriate for product functionality.

*Response:* The Department agrees. Changes were made to the regulations in § 280.2 under the definition of Fastener Quality Assurance System in (2)(v). To improve clarity, this section is amended to read as follows: "a requirement that the in-process control plan include those characteristics specified by the QAS standard, characteristics specifically indicated by the applicable fastener standards and specifications, and those characteristics as designated by the end user for evaluating product functionality."

*Comment:* One commenter asked if a fastener standard does not accept SPC as an alternative to the final testing, then can the SPC be used.

*Response:* No changes were made to the regulations based on this comment. If a fastener standard does not accept SPC, SPC may not be used to meet the requirements of that standard.

*Comment:* One commenter requested amending § 280.5 to confer upon the major end user the responsibility of specifying how a lot of fasteners is to be tested, including in accordance with major end users in-house publication or in accordance with QAS, rather than in accordance with the embedded standards and specifications.

*Response:* No changes were made to the rule based on this comment because section 5(b)(1) of the Act requires that a manufacturer have lot samples tested to determine whether the lot conforms to the standards and specifications to which the manufacturer represents it has been manufactured. The Act does not offer the flexibility of delegating this responsibility to the end user.

*Comment:* One commenter suggested adding a definition of major end user to the rule.

*Response:* The Department has not made any changes to the regulations based on this comment. A definition of major end user is not necessary because the term major end user does not appear in the regulations.

*Comment:* One commenter remarked that NIST overlooked the basis of its Malcolm Baldrige award, and NIST should practice its quality outreach program by reissuing regulations to encompass ISO-9002 and QS-9000 and state of the art quality programs.

*Response:* No changes were made to the regulations based on this comment. ISO-9002 and QS-9000 are used worldwide while the Malcolm Baldrige criteria are familiar only to United States firms. Since fasteners to which the Act and the regulations apply are produced worldwide, international standards are more appropriate.

#### 280.5 Certification of Fasteners

*Comment:* One commenter proposed an amendment to § 280.5 of the rule to clarify that a manufacturer that follows QAS is in compliance with the Act.

*Response:* No changes were made based on this comment because § 280.5(a) states the rule for inspecting, testing, and certification of covered fasteners, and § 280.104(a) brings registered QAS facilities under this general rule, and therefore, in compliance with the Act.

#### 280.6 Laboratory Test Reports

*Comment:* Nine commenters stated that manufacturers registered to QAS should not have to prepare test reports as proposed in § 280.6 (b) and that

requirement would make the QAS program unworkable. These commenters stated that amendments to proposed § 280.6(b) would be necessary. In addition, two additional commenters requested that the Department reduce the contents of the test reports for QAS facilities since it is unnecessary and burdensome, limit requirements to those of the Act and require just a statement that fasteners conform to the QAS plan on the report.

*Response:* The requirement for a test report is mandated by sections 5 and 7 of the Act. However, based on these comments, amendments have been made to § 280.6(b) of the regulations by deleting certain reporting requirements. Also, similar amendments were made in § 280.6(a) to simplify laboratory test report requirements for both laboratories and Facilities. Further, § 280.7 was amended to accommodate amendments made to § 280.6.

*Comment:* Two commenters asked whether imported fasteners produced under QAS must be accompanied by a certificate and laboratory testing report.

*Response:* No changes were made to the regulations because there is no exception that states that imported fasteners produced under QAS need not be accompanied by a certificate and laboratory test report. Section 280.13 describes the requirements for imported fasteners, which include a manufacturer's certificate of conformance and an original laboratory test report.

*Comment:* One commenter suggested that a "synopsis" of the test report would not provide assurances for end user.

*Response:* In response to this comment, the word, "synopsis" has been deleted from § 280.6(b) to clarify that registered facilities must include test results in their reports rather than a synopsis of their test results. The reporting of actual test results will provide assurances for the end user.

*Comment:* Two commenters asked that QAS reports include basic and unique identification information to tie a particular fastener lot with the report and control plan.

*Response:* In response to this comment, the Department has amended § 280.6(b)(2) to require that test reports include: "Unique identification of the test report, including date of issue and serial number, or other appropriate means, including reference to the control plan identification."

*Comment:* Three commenters suggested allowing facilities to make a certified statement that fasteners with a specific lot number are fulfilling the requirements of stated standards and

specifications, in place of a detailed test report as required by § 280.6(b).

*Response:* No changes were made to the regulations based on this comment because a certified statement will not satisfy the requirements of sections 5 and 7 of the Act. An original laboratory testing report and a manufacturer's conformance certificate are required.

*Comment:* One commenter asked how he should report QAS test results in accordance with the regulations.

*Response:* No changes were made to the regulations based on this comment because § 280.6 describes procedures for reporting QAS test results.

#### 280.10 Sampling

*Comment:* Two commenters addressed a conflict between § 280.10, which pertains to sampling, and one of the goals of QAS. According to these commenters, § 280.10 appears to permit a plan provided by a Fastener QAS only when the standards and specifications do not provide for size, selection and integrity of the sample. However, one of the goals of QAS is to have a control plan which describes a sampling plan. Therefore, these commenters requested guidance on which sampling plan should they follow. Another commenter requested allowing sampling plans specified by the customer in a QAS control plan.

*Response:* Section 280.10 has been rewritten in response to these concerns to clarify sampling requirements under the FQA and these regulations. Section 5(b)(2) of the Act restricts the authority of the Department to prescribe sampling procedures for fastener testing to those instances where the standards and specifications relevant to a fastener lot are silent on sampling. This is why revised § 280.10(a) states "For tests conducted either in a laboratory on the Accredited Laboratory List or in a Registered Facility, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which provides for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with that standard or specification".

However, in response to these comments, the Department has included § 280.10(c) to clarify sampling procedures in the QAS/SPC setting. Section 280.10(c) sets out procedures to be followed when § 280.10(a) does not apply: "For tests conducted in a Registered Facility, and not in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or

specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample for inspections and tests by the Facility shall be determined by the sampling plan provided by its Fastener Quality Assurance System or by standards and specifications intended for use with a Fastener Quality Assurance system, as appropriate. Or, a manufacturer operating a Registered Facility may elect to conduct inspections and tests upon all of the fasteners within a specified lot, provided that this election is documented in the control plan of its Fastener Quality Assurance System."

The last sentence in § 280.10(c) has been added because sampling is a concept that will not always be relevant in the QAS/SPC environment. The definition of FQAS speaks about "process inspection embodied in a comprehensive and written control plan for product/process characteristics, process controls (including statistical process control), tests, and measurement systems that will occur during mass production." The Department recognizes that under QAS/SPC, some tests and inspections will be conducted upon every fastener in the lot. That is, the test sample will be one hundred percent of the fastener lot. The last sentence in § 280.10(c), as it has been revised as a result of the public comment process, makes this point clear by stating that "[A] manufacturer operating a Registered Facility may elect to conduct inspections and tests upon all of the fasteners within a specified lot, provided that this election is documented in the control plan of its Fastener Quality Assurance System".

*Comment:* Three commenters remarked that the default sampling plans prescribed in the regulations are overly restrictive. One commenter cited the example of sampling plans restricting lot size to 250,000 pieces while manufacturing lots may be larger.

*Response:* No changes were made to the regulations based on this comment. Section 5(b)(2)(B) of the Act provides that default sampling plans prescribed by the Secretary must, to the extent practicable, use consensus testing standards and related materials. Sampling plans are prescribed by these standards and specifications. NIST does not have the authority to change those standards.

#### 280.12 Applicability

*Comment:* Eighteen commenters stated that the planned implementation date of May 26, 1998 will not allow enough time for NIST to approve Accreditors, for Accreditors to accredit

Registrars, and for the Registrars to register fastener manufacturing facilities. Suggested approaches were: (1) To delay implementation date of the Act until a sufficient number of facilities are registered, (2) to grant provisional approval of current QAS-registered facilities and begin audit in six months, (3) to convene a meeting of all interested parties to establish a reasonable time line for industry compliance.

*Response:* The Department has studied these comments and assessed the registration requirements of the fastener industry. To accommodate the industry needs, the Department has developed the following plan, codified in § 280.810(c)(3), to provisionally approve current QAS-registered facilities so that commerce in fasteners is unaffected as a result of the July 26, 1998 implementation date.

If a Facility intends to be listed in accordance with § 280.810(c)(1) but the registration process will not be completed by July 26, 1998, the Facility may be provisionally listed on the Facilities List by providing the following to NIST on or before September 30, 1998:

1. Certification that: (a) The Facility is registered to QS-9000 or an equivalent by a quality systems registrar; (b) the Facility conforms to all other requirements of the Act and the regulations at the time of certification; (c) if the Facility ceases to be registered to QS-9000 or an equivalent by an accredited Registrar and/or ceases to conform to any other requirement of the Act and the regulations at any time during the provisional listing period, it will notify NIST of that fact within three working days; and (d) if the Facility fails to apply to an accredited Registrar for registration under the FQA within 30 days of the time the Registrar is accredited by a NIST-approved Accreditor, an authorized representative of the Facility will immediately notify NIST. (If the Facility's current Registrar decides not to seek accreditation under the FQA, it is the Facility's responsibility to apply to another Registrar that has been approved by NIST-ABEP.);

2. A list of fasteners produced or processed by the Facility, identified by either a part number or a specification number;

3. A list of standards included in the Facility's registration;

4. A copy of the Facility's registration certificate; and

5. The listing fee established by NIST. The Facility must meet all the requirements of the Act and the regulations by May 25, 1999. If the

Facility fails to receive FQA registration by May 25, 1999, it will be removed from the Facilities List.

*Comment:* Six commenters requested delaying the implementation date (for example, one more year) so that outstanding questions can be interpreted and lead time provided to get ready for implementation of the Act.

*Response:* Changes were made to the regulations based on these comments. As described earlier, the Department has developed a procedure, based on industry input, by which manufacturing Facilities in the QS-9000 system may "self-certify" for one year. The Department is also delaying the implementation date from May 26, 1998 to July 26, 1998, following the Department's determination that there will be an insufficient number of accredited laboratories to perform the volume of inspections and testing required on May 26, 1998.

*Comment:* Three commenters, including a U.S. government agency, requested delaying the implementation date until a detailed regulatory flexibility analysis is conducted and published for public comment. They claim the proposed regulations will have a significant negative impact on fastener distributors and manufacturers because of the cost of inventory scrapped, the cost of accrediting laboratories, the loss of potential market share because of exemption of fasteners in free trade zones, the disruption in supply and resulting loss of business to OEM customers, the disproportionate cost of laboratory accreditation on QAS registered facilities, and the disproportionate cost to certify raw materials.

*Response:* A detailed regulatory flexibility analysis was conducted and published as part of the final regulations on September 26, 1996, which considered almost all issues raised by these commenters. The remaining issues related to QAS regulations were addressed as part of the proposed rule on September 8, 1997. As noted above, the Department has delayed the implementation date until July 26, 1998.

*Comment:* An agency of the U.S. Government commented that the proposed rule does not provide a meaningful regulatory alternative to small businesses because of the short deadline of May 26, 1998, and does not address economic impact on affected sectors.

*Response:* The Department has addressed the issue of the short deadline for registering a sufficient number of facilities before the July 26, 1998 implementation date by adding § 280.810(c)(3), which allows

provisional approval of current QAS-registered facilities if they meet certain requirements.

The Department certified, under 5 U.S.C. 605(b), that the proposed rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification was published with the proposed rule. The Department does not agree with the commenter's conclusion that the proposed rule does not afford a meaningful alternative to small businesses as no preference is given to large manufacturers and registrars over small industry participants. This methodology would be available to any business, large or small, that employs QAS of manufacturing. Moreover, whether small or large, businesses are not forced to adopt QAS. The amended rule would establish a second option for those manufacturers interested and qualified to use the QAS of manufacturing.

On the issue of cost of inventory produced before the implementation date, the industry has long recognized this problem and has had adequate time to react appropriately. This issue has been discussed several times since the 1992 comment process. In its January 10, 1995, report and recommendations for amending the Act, the Public Law Task Force, the fastener industry coalition, recommended that fasteners manufactured before the implementation date not be allowed to be certified as conforming fasteners under the Act. This recommendation was endorsed by the Fastener Advisory Committee in letters to Congress dated February 9, 1995. Other cost elements were addressed in the September 26, 1996 notice of final rulemaking.

#### **280.104 Accreditation of Certain Manufacturing Facilities as Laboratories**

*Comment:* Four commenters stated that the requirement that in-process testing be done by a laboratory on the Accredited Laboratory List would require a costly additional evaluation of the laboratory by an accreditation body. In addition, one suggested that the QS-9000 registration process should include accreditation of the Facility's laboratory.

*Response:* No changes were made to the regulations based on this comment. The requirement that in-process testing be performed by a laboratory on the Accredited Laboratory List is included in the regulations because registration of a QAS facility under ISO Guide 9001 or 9002 or QS-9000 does not include evaluation of technical credibility and validity of test results from an accredited laboratory.

*Comment:* One commenter stated that having to be assessed by a body approved by NIST is just as onerous a burden as getting laboratory accreditation.

*Response:* No changes were made to the regulations because section 6 of the Act mandates that laboratory accreditation be performed by accreditation bodies recognized by NIST. Facilities are brought into the FQA regime under § 280.104(a) of the regulations, which deems registration of Facilities to meet the requirements of laboratory accreditation. Therefore, the Act's requirements for laboratory accreditation apply to the registration of Facilities, as well.

*Comment:* One commenter suggested clarifying the phrase "any in-process inspection and testing," because it does not include all in-process testing at a QAS facility.

*Response:* Based on this comment, the Department revised § 280.104(d) of the regulations to clarify which tests must be performed by a laboratory on the Accredited Laboratory List.

*Comment:* Three commenters suggested making laboratories used by QAS registered facilities meet ISO Guide 25 and proficiency testing requirements so that QAS registered facilities provide consistency in accreditation of laboratories.

*Response:* Since these requirements are already present in the revised regulations, no changes were made.

*Comment:* One commenter suggested that since laboratories must comply with stricter standards (ISO-25, EN-45001, etc) than manufacturers, the Department should allow laboratories owned by distributors to use the same standards as manufacturers.

*Response:* No changes have been made to the regulations because manufacturers follow QAS standards defined under § 280.2 of the regulations to qualify as a QAS facility. Distributors are not manufacturers manufacturing, hence they cannot follow the same standards as the manufacturers. However, irrespective of the ownership of the laboratory, the laboratory has to meet the same requirements.

*Comment:* One commenter stated that recognizing SPC as an alternative to final testing inspection is unlikely to benefit the aerospace industry because aerospace industry specifications specifically do not allow SPC.

*Response:* No changes were made to the regulations based on this comment because the incorporation of fastener specific QAS standards is an essential element of the QAS requirements. If the aerospace industry requires final testing

and inspection, it will not be affected by the addition of the QAS option.

*Comment:* One commenter suggested that if a chemical laboratory is included in the registration of a QAS registered facility, there is no need to go to an accredited laboratory for testing.

*Response:* No changes were made based on this comment. Section 280.104(d) requires that chemical testing be performed by a laboratory on the Accredited Laboratory List. Section 280.104(b) allows that such a laboratory may be located on the same premises as a fastener manufacturing facility if the laboratory is separately accredited pursuant to a provision of the regulations other than § 280.104(a). Therefore, a chemical laboratory cannot be accredited through registration process.

*Comment:* One commenter requested providing clarification as to when a QAS Facility does testing and when an accredited laboratory does testing.

*Response:* In response to this comment, § 280.104(d) has been amended to clarify the requirements for laboratory tests.

#### **Subparts I-L: Accreditation of Manufacturing Facilities; Foreign Accreditors; Accreditors; Registrars**

*Comment:* Two commenters requested amending § 280.800 to allow the use of QAS facilities registration by another agency, in addition to NIST.

*Response:* No changes were made to the regulations based on this comment. NIST is the only government agency allowed to carry out laboratory accreditation under section 6 of the Act.

*Comment:* Three commenters suggested recognizing accreditation bodies that have been recognized by organizations other than NIST. Two commenters mentioned recognizing accreditation bodies accessed under the International Accreditation Forum. One commenter suggested that if one accreditation body is recognized in Europe under the Act and the regulations, NIST should recognize all other bodies that are part of multilateral agreements to which the recognized accreditation body is a party.

*Response:* No changes were made to the rule based on this comment. Section 6 of the Act allows FQA accreditation only by bodies recognized by NIST. Under this regulatory program, each accreditation body must apply to NIST directly and be individually evaluated to obtain recognition. Blanket accreditation under a multilateral agreement or under an international forum would not allow NIST to ensure that each accreditation body meets all

requirements of the Act and the regulations.

*Comment:* One commenter asked if the Registrars will be required to evaluate the substantive content of control plan.

*Response:* Under the definition of a Fastener QAS in § 280.2, one of the elements of a QAS is a requirement that a fastener manufacturer fully document a detailed control plan. Therefore, it is the responsibility of the manufacturer to develop and maintain a detailed control plan. However, as part of the registration process, a Registrar is required to evaluate the contents of the control plan.

*Comment:* One commenter stated that in Japan, a government body approves QAS registered fastener manufacturing facilities as JIS Marking factories. In this situation, the commenter asked, how will the proposed system of registration work.

*Response:* No changes were made to the regulations based on this comment because the system of registration in the current regulations is based on internationally accepted procedures. The system proposed by the commenter is different from the internationally accepted standards procedures. The commenter has two options to comply with the regulations: 1. Separation of registration and accreditation activities; or 2. Use of a private registrar to register facilities.

*Comment:* One commenter asked if the United Kingdom Accreditation Service (UKAS) can accredit Registrars for QAS assessments.

*Response:* No changes were made to the regulations based on this comment because the procedures for seeking recognition by NIST-ABEP are described in the ABEP handbook. If interested in engaging in the accreditation of Registrars, UKAS must apply to NIST-ABEP for recognition.

*Comment:* One commenter inquired whether approving Registrars will require additional resources for NIST. According to the commenter, if NIST approves registrars, it will be perceived as expansion of government into a role previously performed by the private sector. If that is the case, the commenter asked, why not rely on the private sector.

*Response:* No changes were made to the regulations based on this comment because the revised regulations clarify that NIST will not directly accredit Registrars. NIST will rely on NIST-approved private sector Registrar Accreditation Bodies to perform Registrar accreditation. There will be no additional resources required for NIST because section 6(d)(2) of the Act

specifies that accreditation activities performed by NIST will be on a reimbursable basis.

*Comment:* One commenter asked how NIST-ABEP will assure that a manufacturer is competent to conduct fastener testing if the criteria is based on ISO-9000 series.

*Response:* No changes were made to the regulations based on this comment. Registering a fastener manufacturing facility to ISO-9000 does not indicate that the facility is competent to perform laboratory tests. Any laboratory tests performed during in-process inspection and testing must be performed by a laboratory on the Accredited Laboratory List.

*Comment:* One commenter commented that elements (ii), (iv), and (v) in proposed § 280.1010(d)(5) are not related to quality elements.

*Response:* No changes have been made to the regulations as a result of this comment. Section 280.1010(d)(5) details the requirements for a quality manual, which necessarily must contain administrative information as well as quality elements. The same information is required by ISO Guide 61, so these requirements are familiar to the industry.

*Comment:* One commenter asked for clarification of terms used in §§ 280.1010 and 280.1011: "appropriate international documentation" in § 280.1010(d)(5)(xiv); "informed", "corrective action", and "timely and appropriate" in § 280.1010(f); "appropriate international documentation", "technical experts", "assessment of familiarity" and others in § 280.1011. Similarly, this commenter suggested that subparts K and L need to be reworked to eliminate vague terms.

*Response:* No change was made to the regulations. The ABEP handbook will provide guidance for interpreting these terms.

*Comment:* One commenter mentioned that § 280.1010(i)(2), the prohibition on disclosure of information about an accreditation body without its written consent, could interfere with the responsibilities of end-users to control the quality of their suppliers in quality management.

*Response:* No changes were made to the regulations based on this comment. Section 280.1010(i)(2) refers to confidentiality of information obtained by the Accreditor concerning the applicant Registrars. The Department feels that this provision is required to safeguard confidentiality of the information provided by the Registrar to its Accreditor. The regulations do not prevent the end user from getting the quality management-related information

of its Registrar from the Registrar itself or from the Accreditor with the Registrar's written permission.

*Comment:* One commenter stated that there is a high probability of inconsistent requirements under various registration systems. This commenter specifically asked how NIST will assure that NIST and Registrar Accreditation Body recognition requirements are equivalent.

*Response:* No changes have been made to the regulations in response to this comment. Subparts I through L describe the criteria by which Registrar Accreditation Bodies will be approved and by which Registrars will be accredited by the approved bodies. NIST plans to closely adhere to these requirements to maintain uniformity among the Registrars accredited by various bodies.

*Comment:* One commenter asked if auditors will be approved for appropriate standard industrial codes. The commenter also asked if auditors will be required to be experts in both QAS and fastener technology.

*Response:* No changes were made to the regulations based on this comment. Approval of auditors will be the responsibility of accredited Registrars under subpart L, which is based on ISO Guide 62. Auditors will be required to be competent in both QAS and fastener technology. Additional requirements specific to the fastener technology will be described in the ABEP Handbook.

*Comment:* One commenter requested that NIST function as a Registrar Accreditation Body if no accreditation body seeks NIST's approval.

*Response:* No changes were made to regulations based on this comment because NIST does not foresee such a problem. The industry has indicated that accreditation bodies are ready to apply once the regulations take effect.

*Comment:* One commenter suggested that all Registrars currently approved by Registrar Accreditation Bodies should be automatically approved by NIST and all companies with QAS systems accredited by those Registrars should be deemed to have approved QAS.

*Response:* No changes were made to the regulations based on this comment. Recognition of Accreditation Bodies, accreditation of Registrars, and registration of Facilities under the Act and the regulations include meeting requirements specific to the Act and regulations. Therefore, prior recognition, accreditation, or registration, based on different requirements, are insufficient to meet the requirements of the Act and the regulations.

*Comment:* One commenter suggested appointing the major users of QS-9000 as registrars.

*Response:* The requirements for an organization to qualify as a registrar are outlined in subpart L. If a major user wants to become a registrar, it must meet those requirements and must apply to a recognized registrar accreditation body to become an accredited registrar.

*Comment:* One commenter requested that the Act should merely require that certification (recognition of accreditation bodies and accreditation of registrars) be made in accordance with applicable standards because existing certification practices are sufficient to meet the purposes of the Act.

*Response:* No changes were made to the regulations based on this comment because existing practices do not require that accreditation bodies and registrars meet the specific requirements of the Act and its implementing regulations and, therefore, are insufficient for these purposes.

*Comment:* One commenter suggested modifying § 280.1010(e)(1) by replacing "partially or in total, for all or part of the accreditation body's scope of accreditation" with "for FQA."

*Response:* No changes were made to the regulations based on this comment. The regulations apply only to FQA accreditations, not all accreditations. Therefore, the current language of § 280.1010(e) refers only to partial or total suspension or withdrawal of accreditation under the FQA.

*Comment:* One commenter suggested modifying § 280.1012(c)(2)(iii) by replacing "product categories" with "Fasteners."

*Response:* The Department has accepted the suggestion and modified § 280.1012(c)(2)(iii) by replacing "product categories" with "fasteners covered by the Act."

*Comment:* One commenter requested deleting the requirement for accreditors in § 280.1010(b)(17) that they must have a structure where members are chosen to provide a balance of interest, where no single interest predominates.

*Response:* The Department has not made any changes to § 280.1010(b)(17) based on this comment because a balance of interest is required to maintain objectivity in making decisions related to accreditation.

*Comment:* One commenter requested deleting § 280.1010(b)(18), which is a requirement for accreditors that offer other products, processes or services not to compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.

*Response:* No changes were made to the regulations based on this comment because, according to ISO Guide 61, this is a necessary condition that assures a fair decision making process in granting accreditations.

*Comment:* One commenter suggested the following changes to the proposed regulations: replace "international documentation" in § 280.1010(d)(5)(xiv), § 280.1010(b)(2), and § 280.1010(b)(3) with "ISO Guide 10011-1."

*Response:* No changes were made to the proposed regulations based on this comment. The Department deliberately used the term "international documentation" rather than referring to an existing document so as not to restrict the interpretation of that term. The Department notes that §§ 280.1010(b)(2), and 280.1010(b)(3) do not include the words "international documentation."

*Comment:* Two commenters requested changing the reassessment period for accreditors, registrars, and QAS manufacturing facilities from two years to three years to be consistent with the policies of the International Accreditation Forum.

*Response:* No changes were made to the regulations based on this comment. The Department has decided to retain the two year reassessment period in order to be consistent with the laboratory accreditation reassessment period under the Act and the regulations.

*Comment:* Three commenters requested that NIST should have an oversight role on the Registrar activities to assure uniformity.

*Response:* No changes were made to the regulations based on this comment. Detailed descriptions of oversight roles will appear in the ABEP Handbook.

## **Part 2: Summary of Comments Received on Six Proposed Amendments**

Six issues were addressed in the proposed amendments with a request for public comment. A discussion of the comments received, and the actions taken by the Department as a result of these comments follows:

### **1. Significant Alterations of Fasteners**

Of the 125 commenters, 15 commented on the issue of significant alteration of fasteners; eight favored the proposed changes to the FQA regulations, and seven others offered different issues in the area of significant alteration. Of the eight commenters who favored the proposed changes regarding the significant alteration of fasteners, four were trade associations, three domestic and one foreign; two were

fastener manufacturers, one domestic and one foreign; one was a fastener distributor; and one was an other interested party. Of the seven commenters who proposed changes regarding the significant alteration of fasteners, three were government agencies; two were aerospace manufacturers; and two were consultants.

In the notice of proposed rulemaking, the Department proposed changes to the definition of "significantly alter" in § 280.2 and to § 280.11(b) to correct editorial errors in the reference to Rockwell C hardness in these sections. These changes have been adopted into the final rule.

*Comment:* One aerospace manufacturer, one professional organization and one consulting organization commented that other alterations such as application of adhesives, locking elements and cutting off of finished fasteners should be considered significant alterations.

*Response:* Based upon advice from the Fastener Advisory Committee, the Department has determined that application of adhesives, locking elements, and cutting off of finished fasteners are not significant alterations because they do not weaken or otherwise materially affect the performance or capabilities of fasteners as they were originally manufactured, grade or property class marked, tested, or represented. This language appears in the current definition of "significantly alter." Therefore, no changes were made based on these comments.

*Comment:* One distributor commented that clarification is needed as to whether "coating" a fastener with a Rockwell hardness of C32 or above is a significant alteration.

*Response:* The definition of "alter" as contained in the Act lists only through-hardening, electroplating, and machining as forms of alteration. The regulations do not expand upon this definition. Therefore, "coating" other than electroplating is not a significant alteration under the Act and the regulations.

*Comment:* The Department received three comments, two from distributors and one from an equipment manufacturer, requesting that the regulations be revised to allow alterers who electroplate the option of either testing or warning rather than requiring them to test to the plating specifications.

*Response:* Based upon advice from the Fastener Advisory Committee, which deliberated this issue at great length during the initial review of the regulations implementing the Act and recommended the requested option not

be offered for electroplating due to concerns about hydrogen embrittlement as a result of electroplating, the Department has made no changes to the rule.

*Comment:* One distributor suggested deleting all references to adhesives and sealants from the regulations and workshop materials and requested that the Department issue a clarifying statement that these issues are not covered by the Act.

*Response:* No changes have been made to the rule based on this comment. The definition of "significantly alter", as it appears in the regulations, specifically states that "[t]he term does not include the application of adhesives or sealants \* \* \*." The Department feels that retaining this definition clarifies what processes are not considered significant alterations for purposes of the Act and the regulations.

## 2. Removal of Head Markings

Of the 125 commenters, 18 commented on the proposed amendment to allow the removal of head markings for decorative purposes and to meet customer needs; eight favored the proposed changes, and 10 were opposed. Of the eight commenters who favored the proposed changes regarding the removal of head markings, five were trade associations; three domestic and two foreign; one was a foreign equipment manufacturer; one was a foreign fastener manufacturer; and one was a foreign other interested party. Of the 10 commenters who opposed the proposed changes regarding the removal of head markings, four were government agencies; two were fastener distributors; two were fastener manufacturers, one domestic and one foreign; one was a trade association; and one was an aerospace manufacturer. In all of these comments, it was noted that the proposed amendments did not contain the statement, "fasteners are to be manufactured according to the OEM or major end user standard which does not require head marking" though the same was found in the preamble. This statement was included in the preamble in error. Some of these commenters noted that removal of head markings would not have adverse implications.

The proposed rule included a proposed new § 280.11(c) to allow a fastener user or purchaser to special order fasteners covered under the Act and regulations without the required manufacturer or grade identification markings under certain conditions. Based on comments received, the Department has excluded this section from the final rule.

*Comment:* Two commenters suggested that the head marking exclusion be moved to § 280.700(b).

*Response:* No changes have been made based on this proposal. Since the Department has decided not to adopt the proposed change, it will not appear in either section.

*Comment:* Several commenters stated that the proposal to remove head markings is contrary to the intent of the Act, and that markings are vital for informing the user of strength levels and traceability. These commenters emphasized that the removal of head markings does not conform with the purpose of the Act that fasteners conform with standards to which they were represented to have been manufactured. One commenter from a trade association stated that removal of markings promotes unsafe alteration of fasteners. Three commenters (a manufacturer and two trade associations) noted that allowing the removal of markings could lead to misapplication, misrepresented fasteners, entry of substandard fasteners into commerce, and significant equipment failures. These commenters stated that if the end users want fasteners without markings, they can contract to have them made that way. One manufacturer stated that no sales should be allowed without the markings. Two commenters from U.S. Government agencies stated that the removal of head markings would hinder investigations and reduce accountability; therefore, it should not be allowed.

*Response:* Based on comments, the Department has decided not to adopt the proposed change but to retain the existing rule.

## 3. Supplying Originals vs Copies of Test Reports

Of the 125 commenters, 18 commented on the issue of originals vs. copies of test reports; 13 favored the proposed changes, and five were opposed. Of the 13 commenters who favored the proposed changes regarding originals vs. copies of test reports, five were trade associations, two domestic and three foreign; four were fastener manufacturers, three domestic and one foreign; three were consultants; and one was a government agency. Of the five commenters opposed to the proposed changes, two were government agencies; two were fastener manufacturers, one domestic and one foreign; and one was a raw material manufacturer.

The proposed rule included a proposed amendment to the definition of "original laboratory testing report" in § 280.2 to allow metal manufacturers, as

well as laboratories, to certify copies of laboratory testing reports of chemical characteristics. Based on comments received, the new definition has been included in the final rule. In addition, the Department has added a definition of "certified copy" to further clarify the issue.

*Comment:* Two foreign equipment manufacturers commented that the proposed rule does not allow a fastener manufacturer to test his own fasteners rather than rely on the metal manufacturer's chemical analysis of the metal.

*Response:* The Department has determined that the proposed rule does not prevent fastener manufacturers who choose to adopt QAS from obtaining chemical analysis, provided that the fastener manufacturers obtain such analysis from an accredited laboratory.

*Comment:* A manufacturer proposed an approach in which the fastener manufacturer keeps the actual test report of material chemistry and transfers only the data from the raw material test report.

*Response:* The Department has determined that this approach is not consistent with section 5 of the Act, according to which the entire chemical test report is necessary for traceability purposes.

*Comment:* One commenter recommended that the term "certified copy of test report" be explained or defined.

*Response:* The Department concludes that it would be useful to provide guidance as to what constitutes a certified copy. Therefore, this final rule amends § 280.2 to add a definition to read as follows: "Certified Copy (of a laboratory testing report) means a complete and accurate copy of the original laboratory testing report, which contains a statement describing it as an accurate and complete copy of the original and which is signed by an authorized representative of the accredited laboratory issuing the report or, in the case of metal chemistry testing reports, an authorized representative of the metal manufacturer."

*Comment:* One consulting firm recommended that the Department repeal § 280.15(d) of the regulations because it allows the fastener manufacturer to use tests performed on the raw materials by the metal manufacturer; however, the fastener manufacturer cannot prove that fasteners came from the same coil or heat as required by § 280.15(d).

*Response:* The Department has determined that repeal of this section is not appropriate at this time. Allowing chemical testing of raw material by the

metal manufacturer to be sufficient for meeting the requirements of chemical certification of fasteners was one of several options recommended by a large segment to the industry as part of the 1996 amendments to the Act. The Fastener Advisory Committee supported this amendment.

#### 4. Laboratory Test Reports

Of the 125 commenters, seven commented on the issue of laboratory test reports; all favored the proposed changes. Of the seven commenters, three were trade associations, two domestic and one foreign; two were foreign fastener manufacturers; and one was a consultant.

Based on these comments, the Department has adopted the proposed amendments dealing with a discrepancy in the language used in reporting of alternative chemical characteristics. Following the amendments, § 280.6(b)(5)(ii), which is redesignated as § 280.6(c)(5)(ii), reads as follows:

Test results for such coil or heat number chemical characteristics.

#### 5. New Definition of Lot Number

Of the 125 commenters, 18 commented on the new definition of lot number; four were in favor of the proposed changes, and 14 were opposed. Of the four commenters who favored the proposed changes, two were trade associations, one domestic and one foreign; one was a fastener distributor; and one was a consultant. Of the 14 commenters who opposed the proposed changes, five were fastener manufacturers, four domestic and one foreign; three were domestic trade associations; three were government agencies; one was a fastener distributor; one was a fastener testing laboratory; and one was an other interested party.

The proposed rule included a proposed amendment to the definition of "lot number" in § 280.2 to include a number assigned by a manufacturer, importer, distributor, or significant alterer to the lot. Based on comments received, the Department has excluded the proposed definition of lot number and retained the original definition of lot number in the final rule. Based on the comments, for purposes of the Act and the regulations, there is only one lot number that is assigned by the manufacturer of fasteners or significant alterers, i.e., the lot number is unique to the manufacturer or significant alterer. Distributors and importers may use "tracking numbers"; however, if the tracking number is used for lot identification, both lot number and tracking number must be used. Therefore, the Department has decided

not to adopt the proposed change but to retain the existing rule, under which the "Lot number means a number assigned by a manufacturer to the lot."

The following issues were highlighted by those that opposed the adoption of the new definition of lot number:

- Allowing distributors and importers to designate lot numbers will make it impossible for users to verify that the test report relates to the fasteners they receive, possibly requiring them to engage in costly retesting.
- The proposed rule would thwart enforcement efforts by creating gaps in the paper trail,
- The proposed rule would conflict with published consensus standards,
- The proposed rule would conflict with numerous Federal and State codes,
- The proposed rule would prevent product recalls,
- The proposed rule would make counterfeiting easier.

These commenters suggested that the original manufacturer's lot number and any number assigned by an importer or distributor should be sent to the end user. Otherwise, merely requiring that a subsequent lot number be traceable to a manufacturer's lot number creates too great a possibility that traceability will be lost. These comments suggested that the lot number should be reserved for the number assigned to a lot by the manufacturer; distributors and importers may assign their own inventory number or tracking number or traceability number.

*Comment:* One commenter suggested allowing alterers to deliver only the new lot number assigned by the alterer so long as it is traceable to the manufacturer's lot number.

*Response:* The Department does not consider this to be an appropriate change because traceability would be questionable.

*Comment:* A common theme among those who supported this proposed change in the definition of lot number is that distributors and importers that use their own lot numbers should be able to prove that those lot numbers link to manufacturer's lot numbers all the way back to ladle analysis, and there should be no provision allowing the fasteners to be sold without the manufacturer's original lot number.

*Response:* No changes were made to the regulations based on these comments because importers and distributors can use a trace number to avoid confusion with the lot number that is assigned by manufacturers.

*Comment:* One commenter asked how the two numbers should be identified.

*Response:* The Department recommends that both numbers, the lot number assigned by the manufacturer and the trace number assigned by the distributor or importer, appear on the package and wherever the trace number appears.

#### 6. Grandfathered Fasteners Issue

In response to the notice of proposed rulemaking, NIST received 28 comments on the issue of grandfathering, i.e., representing that fasteners produced prior to the implementation date of May 26, 1998 are in compliance with the Act and the regulations. Of the seven commenters that opposed any form of grandfathering, three were agencies of the U.S. Government, two were domestic fastener manufacturers, and one was a domestic trade association. Of the 21 commenters who suggested that grandfathering of different degrees should be allowed, 10 were fastener manufacturers, nine domestic and one foreign; five were domestic trade associations; three were fastener distributors; one was a foreign automobile manufacturer; and one was an other interested party.

In the notice of proposed rulemaking, the Department proposed amending section 280.12(c) of the regulations by moving the last sentence of that section, which states that fasteners manufactured prior to the implementation date of the Act may not be represented as being in conformance with the Act or the regulations, to § 280.602, Violations. Based on the comments and because as a prohibition on certain specific conduct, the language more appropriately belongs in the Violations section, the Department has included this change in the final rule, with appropriate modification to reflect the changes made to § 280.12 that are described below.

Although the commenters supported the proposed change, the comments NIST received offered a wide variety of alternative grandfathering solutions. The Department considered each of these, as well as other regulatory alternatives.

The first and most crucial "regulatory" alternative for the disposition of pre-existing inventory is found in section 15 of the Act itself, which provides that the requirements of the Act apply only to fasteners manufactured after the implementation date of the regulation, now set at July 26, 1998. Thus, the sale of pre-existing inventory after the regulation becomes effective is legal, and the fasteners may properly be held out as complying with relevant standards and specifications.

Five other regulatory alternatives have been considered by the Department during the current rulemaking. The genesis of the Department's consideration of the pre-existing inventory or "grandfathering" issue, however, predates the promulgation of the final rule implementing the FQA on September 26, 1996. (See 61 FR 50538.) During that rulemaking, NIST sought the advice of the Fastener Advisory Committee on the grandfathering issue, noting that the Act prohibited all parties from holding out fasteners in the pre-existing inventory as being compliant without the various lots of fasteners being retested. The Fastener Advisory Committee responded that fasteners in the pre-existing inventory, if not held out as FQA compliant, could still be sold after the implementation of the Act, meaning that the companies would suffer no economic loss on these fasteners. The Committee, also, however, recommended to NIST that finished fasteners manufactured prior to the implementation date be permitted to be retested to be in compliance with the FQA provided that all the associated requirements of law could be met for the lot of fasteners in question, such as the presence of the original set of certifications. The Committee also recommended a one year moratorium on the retesting of these fasteners to avoid shortages in the pipeline that could occur if pre-implementation material was put up for retesting at the same time as new complying material was put up for initial testing. There also was discussion of placing a time limit, i.e., three years or five years, on retesting of pre-implementation fasteners, but no conclusion was reached on this issue. The Fastener Advisory Committee reemphasized that if the holders of pre-existing inventory did not wish to incur the cost of the retesting after the proposed moratorium, the product would still be saleable in commerce under section 15 of the Act.

Due to concerns about lot integrity and falsification of certification documents for pre-implementation fasteners, and the "bottle-necking" concerns raised by the Fastener Advisory Committee, in the final regulations of September 26, 1996, NIST made no provision for the retesting of the pre-existing inventory. This effectively meant that the fasteners in the pre-existing inventory, when sold after the effective date of the regulations, could not be held out as FQA compliant.

Following the September 8, 1997 notice of proposed rulemaking, the Department has considered the following alternative solutions to the

grandfathering issue, each of which was supported by one or more comments:

(1) Seven of the comments opposed any regulatory change that would permit fasteners manufactured before the effective date of the regulation to be held out as complying with the FQA. The Department views this as essentially a reaffirmation of the proposed change. Among the reasons stated for this position were: The inability of a procurer of fasteners to determine whether the fasteners were manufactured pre- or post-FQA; possible hindrance of the Government's ability to prosecute defective or counterfeit fastener cases currently being investigated; enforcement problems; the additional cost and demand on laboratories that retesting would cause; and the inability to "upgrade" lots of fasteners produced to previous revisions of consensus standards to certify that they conform to the requirements of the current revisions.

(2) One comment suggested that NIST permit new fasteners tested in a duly accredited FQA laboratory prior to the effective date of the regulation be permitted to be held out as FQA compliant. NIST deemed this alternative to be permissible under the FQA since the requirement of testing in a FQA accredited laboratory has been met.

(3) Two comments suggested that the regulation be amended to permit fasteners to be held out as FQA compliant if they are included in lots of fasteners manufactured before the effective date of the regulation but subsequently tested or retested after the effective date of the regulation in FQA accredited laboratories. NIST deemed this alternative to be permissible under the FQA since the FQA requirement of testing in an FQA accredited laboratory has been met.

(4) Eight comments suggested that since fasteners are manufactured to high standards, NIST should permit all fasteners manufactured prior to the effective date of the regulation to be held out as FQA compliant, regardless of whether the fasteners were ever tested in a laboratory, accredited or otherwise. NIST has rejected this alternative because the FQA requires that fasteners must be tested by an accredited laboratory to be deemed FQA compliant. Hence, this alternative is not permissible by law, since it does not require testing.

(5) Six comments suggested that fasteners manufactured prior to the effective date be deemed to be FQA compliant after a "paperwork" review of laboratory records. NIST has rejected this alternative because the FQA

requires that fasteners must be tested by an FQA accredited laboratory to be deemed FQA compliant. Hence, this alternative is not permissible by law, since the tests being reviewed were not conducted by FQA accredited laboratories.

(6) The recommendation of the Fastener Advisory Committee received no comment, but is the sixth alternative considered by NIST.

Thus, NIST was left with four lawful alternatives, options (1), (2), (3), and (6) above. Based upon the public comments, NIST believes that the weight of the evidence supports the view that some form of grandfathering beyond option (1) is appropriate. Accordingly, NIST has decided to proceed immediately with option (2) and has included this option in the final rule in §§ 280.12 (d) and (e). Section 280.12(d) allows that "fasteners manufactured on or after May 14, 1998 may be represented, sold, or offered for sale as complying with the Act and these regulations if they are tested and certified by a laboratory appearing on the Accredited Laboratory List \* \* \* and meet all other requirements of the Act and this part." Section 280.12(e) allows that "fasteners manufactured on or after May 14, 1998 by a Facility listed on the Facilities List may be represented, sold, or offered for sale as complying with the Act and regulations" if the Facility meets the requirements of § 280.810(c)(3).

NIST does not believe that the existing record permits it to endorse either option (3) or (6).

#### *7. Paperwork Reduction Act and Regulatory Flexibility Act*

Various commenters questioned the statements made in the preamble to the proposed rule regarding the Paperwork Reduction Act or the Regulatory Flexibility Act or both. In general, these commenters stated that the Department understated the cost to industry to comply with the Act and regulations and the impact that those costs would have on small businesses. The costs cited in these comments included the costs of scrapping inventories and disruptions to supply because customers would not accept preimplementation fasteners on or after the implementation date, the costs of obtaining laboratory accreditation or using an accredited laboratory, the costs of testing small lots, the costs of added paperwork and storage of records. Two specific proposals were made in regard to this issue. One proposal was to form a joint government-industry task force to measure the costs of compliance. The other proposal was to conduct an in-

depth analysis of the negative impact on distributors and manufacturers under the Regulatory Flexibility Act and publish it for public comment. Several commenters recommended delaying implementation of regulations because of the costs to industry. The Department notes that all of the concerns cited above relate to the cost of complying with the existing rule. The final rule creates an option for fastener manufacturers to use, in certain instances, instead of the existing rule. Any costs associated with developing a registered fastener QAS would not be affected by the costs of complying with the existing rule. Therefore, the Department is not delaying the implementation of the regulations due to this issue.

**Comment:** Two trade organizations commented that the cost of raw material analysis obtained by coil analysis is disproportionately high for small producers.

**Response:** No change is made based on this comment. The requirements for raw material analysis and reports under the Act are the same for large producers and small producers. Under the revised regulations, small firms may obtain raw material analysis reports from either the laboratory that conducted the tests or from the metal manufacturer.

### Part 3: Comments Received Regarding Issues Not Presented for Public Comment in the Notice of Proposed Rulemaking

The Department received many comments on issues that were not presented for public comment in the notice of proposed rulemaking. These issues included: Repeal the Fastener Quality Act, amend the Fastener Quality Act, deem compliance with other regulations to be compliance with the Fastener Quality Act, create exemptions to the coverage of the Act and regulations, and define more terms. The Department will not respond to these comments at this time because they were not presented for public comment in the notice of proposed rulemaking but will retain these comments for possible action at a later date.

### Additional Information

#### Executive Order 12866

This rule has been determined not to be significant under section 3(f) of Executive Order 12866.

#### Executive Order 12612

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

### Regulatory Flexibility Act

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. NIST received one comment, addressed above, regarding this certification. This comment did not cause a change in the determination regarding the certification. As a result, no final regulatory flexibility analysis was prepared.

### Paperwork Reduction Act

Notwithstanding any other provision of the Act, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number.

This rule contains collections of information subject to the requirements of the Paperwork Reduction Act that have been cleared under OMB Control Nos. 0693-0015 and 0693-0026. The public reporting burden for the self-certification of QAS fastener manufacturing facilities is approximately four hours: The provisional registration is estimated at three hours, and one hour for the associated recordkeeping requirements. Send comments regarding these burden estimates or any other aspect of the data requirements, including suggestions for reducing the burden to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20230 (Attention: NIST Desk Officer) and to NIST (Attention: FQA Program Manager, NIST, Building 820, Room 306, National Institute of Standards and Technology, Gaithersburg, MD 20899).

### National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

### List of Subjects in 15 CFR Part 280

Business and industry, Fastener industry, Imports.

Dated: April 3, 1998.

**Robert E. Hebner,**

*Acting Deputy Director, National Institute of Standards and Technology.*

Dated: April 3, 1998.

**William A. Reinsch,**

*Under Secretary for Export Administration.*

For reasons set forth in the preamble, Title 15 of the Code of Federal Regulations part 280 is amended as follows:

### PART 280—FASTENER QUALITY

1. The authority for part 280 continues to read as follows:

**Authority:** Sec. 13 of the Fastener Quality Act (Pub. L. 101-592, as amended by Pub. L. 104-113).

2. Section 280.1 is amended by adding paragraph (d) to read as follows:

#### § 280.1 Purpose/description of rule.

\* \* \* \* \*

(d) *Delegations of authority.* The Secretary of Commerce has delegated authority to the Director, National Institute of Standards and Technology to promulgate regulations in this part under sections 5 through 8 of the Fastener Quality Act (15 U.S.C. 5404-5407). In addition, the Secretary of Commerce has delegated concurrent authority to the Under Secretary for Export Administration to amend the regulations issued under sections 5 through 7 of the Act, regarding enforcement. The Secretary of Commerce has also delegated concurrent authority to amend the regulations issued under section 8 of the Act, regarding recordal of insignias, to the Assistant Secretary and Commissioner of Patents and Trademarks.

3. Section 280.2 is amended by revising the definitions for *accreditation*, *consensus standards organization*, and *original laboratory testing report*, and adding the remaining definitions as set forth below:

#### § 280.2 Definitions.

\* \* \* \* \*

*Accreditation* for purposes of the Act and this part means accreditation of a testing laboratory or the registration of a fastener manufacturing facility employing a quality assurance system (a Facility).

\* \* \* \* \*

*Accredited registrar* means a registrar, as defined in this part, that is accredited by a recognized accreditor and appears on the Registrars List described in section 280.810(b).

\* \* \* \* \*

*Accreditor* means a Registrar accreditation body that meets the requirements of subpart K of this part.

\* \* \* \* \*

*Authorized representative* means an employee of an organization who is authorized by that organization to speak on its behalf for purposes of the Act and this part.

\* \* \* \* \*

*Certified Copy* (of a laboratory testing report) means a complete and accurate copy of the original laboratory testing report, which contains a statement describing it as an accurate and complete copy of the original and which is signed by an authorized representative of the accredited laboratory issuing the report or, in the case of metal chemistry testing reports, an authorized representative of the metal manufacturer.

\* \* \* \* \*

*Consensus standards organization* means the American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI), American Society of Mechanical Engineers (ASME), Society of Automotive Engineers (SAE), or any other consensus standards setting organization (domestic or foreign) publicly identified by NIST as having comparable knowledge, expertise, and concern for the health and safety in the field for which such organization purports to set standards.

\* \* \* \* \*

*Facility* means a fastener manufacturing facility, or a facility performing subcontracted processes for a fastener manufacturing facility, implementing a fastener quality assurance system as defined in this part.

\* \* \* \* \*

*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 quality planning;  
(ii) Monitoring and control of the manufacturing process;  
(iii) Process inspection embodied in a comprehensive and written control plan for product/process characteristics, process controls (including statistical process control), tests, and measurement systems that will occur during mass 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 § 280.7 of this part,

regarding the inspections, tests, and measurements required by or performed pursuant to the control plan.

(2) A Fastener Quality Assurance System contains the following elements at a minimum:

(i) A documented quality management system that satisfies the requirements of ISO-9001 "Quality Systems—Model for quality assurance in design, development, production, installation and servicing," ISO-9002 "Quality Systems—Model for quality assurance in production, installation and servicing," or other quality system standards that incorporate ISO-9001 or ISO-9002 (e.g. QS-9000, AS-9000, etc.);

(ii) A requirement that raw material certification supplied to the fastener manufacturer shall be traceable to that of a mill heat of material that has been tested by a laboratory on the Accredited Laboratory List;

(iii) A requirement that subcontracted processes, including plating and heat treating, are controlled by the manufacturer, to avoid product lot contamination, and that finished lots of fasteners shall be traceable to subcontracted processes performed by a registered Facility on the Facilities List described in § 280.810 of tested by a Laboratory on the Laboratories List described in § 280.101;

(iv) A requirement that the fastener manufacturer fully document fastener sampling and inspection points and an in-process control plan that emphasizes defect prevention, relates frequency of inspection, corrective action for nonconforming characteristics, and sampling frequency and sample size; a requirement that the control plan be made available to the customer upon request and shall identify those standards and specifications upon which the plan is based; and

(v) A requirement that the in-process control plan include those characteristics specified by the QAS standard, characteristics specifically indicated by applicable fastener standards and specifications, and those characteristics as designated by the end user for evaluating product functionality.

\* \* \* \* \*

*Original laboratory testing report* means: (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 § 280.15 of this part 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.

\* \* \* \* \*

*Recognized accreditor* means an accreditor, as defined in this part, that is recognized by NIST and appears on the Accreditors List described in § 280.810(a).

\* \* \* \* \*

*Registered facility* means a facility, as defined in this part, that is registered by an accredited registrar and appears on the Facilities List described in § 280.810(c).

\* \* \* \* \*

*Registrar* means a quality systems Registrar that meets the requirements of subpart L of this part.

\* \* \* \* \*

*Registration* means evaluation and certification of a manufacturing facility as competent to carry out and conforming to the applicable requirements of a Fastener Quality Assurance System when such evaluation and certification is performed by a Registrar as defined in this part.

\* \* \* \* \*

*Significantly alter* means to alter or take any other action which could weaken or otherwise materially affect the performance or capabilities of the fastener as it was originally manufactured, grade or property class marked, tested, or represented. The term does not include the application of adhesives or sealants, locking elements, provisions for lock wires, coatings and platings of parts having a minimum specified Rockwell C hardness of less than 32, or cutting off of fasteners. The cutting of finished threaded rods, bars or studs to produce individual smaller length threaded studs for resale is not a significant alteration. However, cut threaded studs, rods, and bars offered for sale shall be individually marked with the grade or property class identification marking appearing on or accompanying the original threaded studs, rods, and bars from which the fasteners were cut.

\* \* \* \* \*

4. Section 280.6 is revised to read as follows:

#### **§ 280.6 Laboratory test reports.**

(a) When performing tests for which they are accredited under this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall issue test reports of its work which accurately, clearly, and unambiguously present the test conditions, test set-up,

test results, and all information required by this section. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

- (1) Name and address of the laboratory;
- (2) Unique identification of the test report including date of issue and serial number, or other appropriate means;
- (3) Name and address of client;
- (4) Fastener Description, including:
  - (i) Manufacturer (name and address);
  - (ii) Product family (screw, nut, bolt, washer, or stud), drive and/or head configurations as applicable;
  - (iii) Date of manufacture;
  - (iv) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);
  - (v) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load indicating washer); thread form and class of fit;
  - (vi) Product standards and specifications related to the laboratory in writing by the manufacturer, importer or distributor;
  - (vii) Lot number;
  - (viii) Specification and grade of material;
  - (ix) Coating material and standard and specification as applicable;
- (5) Sampling information:
  - (i) Standards and specifications or reference for sampling scheme;
  - (ii) Final manufacturing lot size;
- (6) Test Results:
  - (i) Test results for each sample;
  - (ii) All deviations from the test method;
  - (iii) All other items required on test reports according to the test method;
  - (iv) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (a)(10) of this section.
  - (v) A statement that the samples tested either *conform* or *do not conform* to the fastener standards and specifications and identification of any nonconformance, except as provided for in §§ 280.13 and 280.14;
  - (7) A statement that the report must not be reproduced except in full;
  - (8) A statement to the effect that the test report relates only to the item(s) tested;
  - (9) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;
  - (10) The name of the body which accredited the laboratory for the specific

tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(b) When performing tests for which they are registered under this part, each facility registered under subpart I or J of this part and currently listed in the Facilities List shall issue test reports of its work which accurately, clearly, and unambiguously present test results, and all information required by this section. In addition, the facilities shall attach reports of chemical characteristics and any report of the tests conducted in a laboratory under the accredited laboratories list. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a temper resistant system, and contain the following information:

- (1) Name and address of the facility;
- (2) Unique identification of the test report, including date of issue and serial number, or other appropriate means including references to control plan identification;
- (3) Name and address of client, if applicable;
- (4) Fastener Description, including:
  - (i) Manufacturer (name and address);
  - (ii) Product family (screw, nut, bolt, washer, or stud), drive and/or head configurations as applicable;
  - (iii) Date of manufacture;
  - (iv) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);
  - (v) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load bearing washer); thread form and class of fit;
  - (vi) Product standards and specifications related to the facility in writing by the manufacturer, importer or distributor;
  - (vii) Lot number;
  - (viii) Specification and grade of material;
  - (ix) Coating material and standard and specification as applicable;
- (5) Sampling information:
  - (i) Standards and specifications or reference for sampling scheme;
  - (ii) Final manufacturing lot size;
  - (iii) Identification of control plan governing production of the lot to which the test report is applicable;
- (6) Test Results:
  - (i) Test results of actual tests required by applicable fastener standards and specifications, and characteristics designated by the end user;
  - (ii) All deviations from the test method;
  - (iii) All other items required on test reports according to the applicable

fastener standards and specifications, and characteristics designated by the end user;

(iv) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory/facility and accreditation/registration information listed in paragraph (b)(9) of this section.

(v) Where all processes under the applicable QAS were found to be in accordance with the inspections, tests and measurements required by the standards and specifications and the QAS and characteristics designated by the end user, a statement that the samples tested conform to the applicable fastener standards and specifications;

(vi) Where any process under the applicable QAS was found not to be in accordance with the inspections, tests, or measurements required by such QAS, a statement that the samples tested do not conform to the applicable fastener standards and specifications and identification of any nonconformance;

(7) A statement that the report must not be reproduced except in full;

(8) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(9) The name of the registrar which registered the facility, and code number assigned to the facility by the registrar, and the expiration of registration.

(c) For alternative chemical tests carried out under § 280.15 of this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall provide to the fastener manufacturer, either directly or through the metal manufacturer, a written inspection and testing report containing all required information. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

- (1) Name and address of the laboratory;
- (2) Unique identification of the test report including date of issue and serial number or other appropriate means;
- (3) Name and address of client;
- (4) Coil or heat number of metal being tested;
- (5) Test Results:
  - (i) Actual tests required by the standards and specifications;
  - (ii) Test results for such coil or heat number chemical characteristics;
  - (iii) All deviations from the test method;
  - (iv) All other items required on test reports according to the test method;

(v) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (c)(9) of this section.

(vi) A statement that the samples tested either conform or do not conform to the metal standards and specifications and identification of any nonconformance;

(6) A statement that the report must not be reproduced except in full;

(7) A statement to the effect that the test report relates only to the item(s) tested;

(8) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(9) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(d) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g., "Supplement to test report serial number \* \* \*." This document must specify which test result is in question, the content of the result, the explanation of the result, and the reason for acceptance of the result.

(e) For tests carried out by a Facility registered pursuant to subpart I or J of this part, the Facility shall maintain laboratory test reports in the forms of electronic, photographic, or paper records, available for inspection during the periods required by section 10 of the Act and § 280.7 of this part, regarding the inspections, tests, and measurements required or performed pursuant to the QAS control plan.

5. Section 280.7 is amended by revising paragraph (a) to read as follows:

**§ 280.7 Recordkeeping requirements.**

(a) Each laboratory accredited under subparts C, D, or E or § 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 this part. 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 personnel performing the testing. Procedures for storage and retrieval of records must be documented and

maintained in the laboratory's quality manual.

\* \* \* \* \*

6. Section 280.10 is revised to read as follows:

**§ 280.10 Sampling.**

(a) For tests conducted either in a laboratory on the Accredited Laboratory List or in a Registered Facility, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which provides for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with that standard or specification.

(b) For tests conducted in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with the sampling plan provided by ASME/ANSI B18.18.2M, Inspection and Quality Assurance For High-Volume Machine Assembly Fasteners; ASME/ANSI B18.18.3M, Inspection and Quality Assurance for Special Purpose Fasteners; or ASME/ANSI B18.18.4M, Inspection and Quality Assurance for Highly Specialized Engineering Applications—Fasteners.

(c) For tests conducted in a Registered Facility, and not in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample for inspections and tests by the Facility shall be determined by the sampling plan provided by its Fastener Quality Assurance System or by standards and specifications intended for use with a Fastener Quality Assurance System, as appropriate. Or, a manufacturer operating a Registered Facility may elect to conduct inspections and tests upon all of the fasteners within a specified lot, provided that this election is documented in the control plan of its Fastener Quality Assurance System.

7. Section 280.11 is amended by revising paragraph (b) to read as follows:

**§ 280.11 Significant alterations of fasteners.**

\* \* \* \* \*

(b) If the significant alteration is only electroplating of fasteners having a

minimum specified Rockwell C hardness of 32 or above, the requirements set forth in paragraphs (a)(2) and (a)(3) of this section shall not apply, but the alterer shall assign a new lot number as set forth in paragraph (a)(1) of this section and shall test the electroplated fasteners as required by the plating standards and specifications.

\* \* \* \* \*

8. Section 280.12 is revised to read as follows:

**§ 280.12 Applicability.**

(a) The requirements of the Fastener Quality Act and this part shall be applicable only to fasteners manufactured on or after July 26, 1998.

(b) Metal manufactured prior to July 26, 1998 may not be used to manufacture fasteners subject to the Act and this part unless the metal has been tested for chemistry pursuant to § 280.15 of this part by a laboratory accredited under the Act and this part and the chemical characteristics of the metal conform to those required by the standards and specifications.

(c) Nothing in the Act and this part prohibits selling finished fasteners manufactured prior to July 26, 1998 or representing that such fasteners meet standards and specifications of a consensus standards organization or a government agency.

(d) Fasteners manufactured on or after May 14, 1998, may be represented, sold, or offered for sale as complying with the Act and these regulations if they are tested and certified by a laboratory appearing on the Accredited Laboratory List described in § 280.101, and meet all other requirements of the Act and this part.

(e) Fasteners manufactured on or after May 14, 1998, by a Facility listed on the Facilities List may be represented, sold, or offered for sale as complying with the Act and these regulations upon NIST's acknowledgment of receipt of the items required in § 280.810(c)(3).

9. Section 280.104 is added to subpart B to read as follows:

**§ 280.104 Accreditation of certain manufacturing facilities as laboratories.**

(a) Subject to the limitations contained in paragraphs (b), (c), and (d) of this section, registration of a fastener manufacturing facility employing a fastener quality assurance system shall be deemed to meet the requirements of accreditation of a laboratory for purposes of the Act and this part. The independent third-party Registrar registering such facility under this section shall comply with all procedures set forth in subparts I through L of this part. Records

documenting the inspection and testing of a lot of fasteners performed by such an accredited laboratory shall be maintained by the facility in accordance with the requirements of §§ 280.6, 280.808, and 280.809 of this part.

(b) In any instance where a Facility accomplishes any in-process inspection and testing by performing laboratory tests on a sample of fasteners at any stage in the manufacturing process, those tests must be conducted by a laboratory on the Accredited Laboratory List. Such a laboratory may be located on the same premises as a fastener manufacturing facility if the laboratory is separately accredited pursuant to a provision of this part other than § 280.104(a).

(c) Any laboratory tests performed outside the Facility's in-process inspection and testing must be conducted by a laboratory on the Accredited Laboratory List.

(d) Chemical and raw material testing must be performed by a laboratory on the Accredited Laboratory List.

10. Section 280.602 is amended by revising paragraphs (e)(2), (h), and (j) and adding paragraphs (k), (l), (m), (n), and (o) to read as follows:

#### **§ 280.602 Violations.**

\* \* \* \* \*

(e) *Misrepresentation and concealment of facts.* \* \* \*

(2) In connection with the preparation, submission, use, or maintenance of a laboratory test report, certificate of conformance as described in §§ 280.5 and 280.6 of this part, or any quality assurance system document required by this part or;

\* \* \* \* \*

(h) *Falsification of documents relating to accreditation of laboratories or registrars or approval or recognition of accreditors or accreditation bodies.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to laboratory accreditation or approval or recognition of accreditation bodies, Accreditors or Registrars as required by section 6(a) or 6(b) of the Act or this part.

\* \* \* \* \*

(j) *Falsification of laboratory accreditation, accreditation body or accreditor.* No person shall falsely claim to be an accredited laboratory or approved or recognized accreditation body or Accreditor as described in section 6 of the Act or subparts B, C, D, E, I and J of this part.

(k) *Sale of fasteners manufactured prior to the implementation date as compliant with the Act.* No person shall

represent, sell, or offer for sale fasteners manufactured prior to July 26, 1998 as being in conformance with the Act or this part except as provided for in § 280.12(d) or (e) of this part.

(l) *Failure to assign lot number traceable to manufacturer's single, unique lot number.* No importer, distributor, or significant alterer shall assign a lot number unless the assigned lot number is traceable to a manufacturer's single, unique lot number.

(m) *Falsification of documents relating to the registration of fastener manufacturing facilities as accredited laboratories, accreditation of registrars or recognition of accreditors.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to the registration of Fastener Manufacturing Facilities as accredited laboratories, accreditation of Registrars or recognition of Accreditors as required by subparts I, J, K, and L of this part.

(n) *False claim of registration of fastener manufacturing facilities as accredited laboratories, accreditation of registrars, and recognition of accreditors.* No person shall falsely claim to be a registered Fastener Manufacturing Facility, an accredited Registrar, or a recognized Accreditor as described by subparts I, J, K, and L of this part.

(o) *Falsification of documents relating to the certification of FOA compliance required for provisional listing on the Facilities List.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to the certification of FQA compliance required for provisional listing on the Facilities List pursuant to § 280.810(c)(3).

11. Subparts I through L are added to read as follows:

#### **Subpart I—Special Rule for the Accreditation of Certain Fastener Manufacturing Facilities, Whose Implemented Fastener Quality Assurance Systems Meet Defined Requirements, as Laboratories**

Sec.

280.800 Introduction.

280.801 Application.

280.802 Review and decision process.

280.803 Criteria for recognition.

280.804 Maintaining recognized status.

280.805 Voluntary termination of recognition.

280.806 Involuntary termination of recognition by NIST.

280.807 Subcontracting.

280.808 Reports.

280.809 Record keeping.

280.810 Listing of recognized accreditors, accredited Registrars, and registered facilities.

280.811 Removal from a list.

280.812 Appeal.

#### **Subpart I—Special Rule for the Accreditation of Certain Fastener Manufacturing Facilities, Whose Implemented Fastener Quality Assurance Systems Meet Defined Requirements, as Laboratories**

##### **§ 280.800 Introduction.**

(a) This special rule applies to those fastener manufacturers, employing a fastener quality assurance system (QAS) as defined in this part, who wish to seek accreditation of the particular manufacturing facility employing the QAS as a laboratory within the meaning of the Act. This rule consists of this subpart, and subparts J, K and L of this part. The rule adopts the view that a fastener manufacturing facility is deemed to be an accredited laboratory for purposes of the Act and this part if such facility employs a fastener quality assurance system (QAS) that has been formally registered by a NIST-recognized quality systems Registrar. The rule applies only to facilities manufacturing fasteners; raw materials for fastener manufacture must be tested and certified by a laboratory listed on the Accredited Laboratory List. This Subpart sets out the full process that NIST requires for the accreditation of a fastener manufacturing facility employing a QAS in the United States: A fastener manufacturing facility employing a QAS (a "Facility") will be deemed to be an accredited laboratory if it is registered by a Quality Systems Registrar (a "Registrar") that in turn has been accredited by a Registrar Accreditation Body (an "Accreditor") that has been recognized by NIST. Subpart J provides for foreign Accreditors to be recognized and to recognize Registrars under the same procedures.

(b) A chain is thus established to assure the proper regulation of Facilities: NIST recognizes Accreditors that meet the requirements of subpart K of this part, which is based upon ISO Guide 61; the NIST-recognized Accreditors may in turn accredit Registrars that meet the requirements of subpart L of this part, which is based upon ISO Guide 62. The Registrars, in turn, may register Facilities that satisfy the elements of a fastener quality assurance system (QAS), as defined in this part.

(c) Within this subpart, §§ 280.801 through 280.809 contain the procedures that NIST uses to process requests from Accreditors for recognition by NIST.

Section 280.810 establishes three lists that NIST will maintain: Section 280.810(a) provides for a list of Accreditors that have been recognized by NIST; § 280.810(b) provides for a list of Registrars that have been accredited by Accreditors listed according to § 280.810(a); and § 280.810(c) provides for a list of Facilities that have been registered by Registrars listed according to § 280.810(b). The remainder of this subpart, §§ 280.811 and 280.812, contain procedural provisions related to the lists established by § 280.810.

#### **§ 280.801 Application.**

(a) Application must be made by Accreditors to NIST for recognition to accredit Registrars under the Act. Upon request, NIST will provide application forms and instructions. The applicant shall complete the application in English and may provide whatever additional enclosures, attachments or exhibits the applicant deems appropriate.

(b) Application packages may be obtained from: Manager, FQA Accreditation Body Evaluation Program, NIST, Bldg. 820, Room 282, Gaithersburg, Maryland 20899. Requests may be made by mail or by FAX to: (301) 963-2871.

(c) The applicant shall reimburse NIST for all costs incurred in the evaluation of its accreditation program and subsequent costs incurred in ensuring the continued compliance of its program. Reimbursement shall be in accordance with the fee schedule established by NIST for this purpose.

(d) An application may be revised by an applicant at any time prior to the final decision by NIST. An application may be withdrawn by an applicant, without prejudice, at any time prior to the final decision by NIST.

#### **§ 280.802 Review and decision process.**

(a) Applications submitted by Accreditors will be accepted by NIST and their receipt acknowledged in writing. The applications will be reviewed by NIST against the criteria specified in this subpart and in subpart K of this part. NIST may request additional information as needed from the applicant.

(b) NIST shall conduct on-site assessments of the facilities of the applicant including all of the applicant's organizational units and locations covered by the application.

(c) If the applicant's program is deemed by NIST to have met the requirements for recognition, the applicant shall be notified by NIST in writing. The recognition notice shall include the date when the recognition

begins and the scope of the recognition. The recognition period shall be for as long as the Accreditor continues to satisfy the requirements of § 280.803. As part of maintaining its approved status, each Accreditor shall agree to be reassessed by NIST every two years following its initial notice of recognition. NIST will maintain and make available to the public a list of recognized Accreditors.

(d) If the applicant does not meet the requirements for recognition, the applicant shall be notified in writing, listing the specific requirements from this subpart and subpart K of this part which the applicant's program has not met. After receipt of such a notification, and within the response period provided by NIST, the applicant may:

(1) Submit additional information for further review. Reviewing the new submission may involve additional on-site visits by NIST personnel. Additional fees may be required. Or,

(2) Submit a request that the original application be reconsidered, including a statement of reasons why the applicant should have been recognized.

#### **§ 280.803 Criteria for recognition.**

An applicant for NIST recognition must demonstrate the ability to operate a registrar accreditation program consistent with the requirements of this subpart and subparts A and K of this part, and accredit registrars of Facilities to requirements set out in subpart L of this part.

#### **§ 280.804 Maintaining recognized status.**

(a) Accreditors shall continue to satisfy all the requirements of recognition during the recognition period.

(b) Upon request, recognized Accreditors shall make available to NIST and/or BXA all records and materials pertaining to the program.

(c) NIST has the right to participate as an observer during any on-site visit to a Registrar being audited by a NIST-recognized Accreditor, or a Facility being audited by an accredited Registrar, or it may perform its own surveillance visit of such bodies at its discretion.

(d) Neither the Accreditor, nor any Registrar it accredits, nor any Facility registered under the Act and this part shall take any action which states or implies the approval, or endorsement by NIST or any other agency of the U.S. Federal Government of any product or report pertaining to a product associated with any activities carried out under the recognition. None of these entities may take any action which states or implies that they are recognized or authorized

by NIST to act or perform in any area(s) beyond that which was specified in their recognition under this part.

#### **§ 280.805 Voluntary termination of recognition.**

An Accreditor may voluntarily terminate its recognition by giving written notice to NIST and to all Registrars accredited by that body under its accreditation program. The written notice shall state the date on which the termination will take effect.

#### **§ 280.806 Involuntary termination of recognition by NIST.**

(a) NIST may terminate or suspend its recognition of an Accreditor if such an action is deemed to be in the public interest.

(b) Before terminating the recognition of an Accreditor, NIST will notify the Accreditor in writing, giving it the opportunity to rebut or correct the stated reasons for the proposed termination. If the problems are not corrected or reconciled within 30 days, or such longer time as NIST in its sole discretion may grant, the termination shall become effective.

(c) An Accreditor may appeal a termination to the Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, hold in abeyance the termination action pending a final decision by the Director. Within 60 days following receipt of the appeal, the Director shall inform the Accreditor in writing of his or her decision.

(d) Registrars and registered organizations which have been listed by NIST in accordance with this Subpart, based on their accreditation by an Accreditor whose recognition has been terminated, shall be removed from the list, unless an exception is granted by NIST.

#### **§ 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.

#### **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.

#### **§ 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 § 280.7 of this part.

#### **§ 280.810 Listing of recognized accreditors, accredited registrars, and registered facilities.**

(a) *List of Accreditors.* NIST shall prepare and maintain a list of Accreditors recognized under this subpart and subpart J of this part.

(b) *List of Registrars.* NIST shall prepare and maintain a list of Registrars accredited by Accreditors listed in accordance with § 280.810(a).

(1) Names and information regarding accredited Registrars may only be included on the list from information submitted to NIST by an Accreditor listed in accordance with § 280.810(a) that submits the listing fee established by NIST and the following information, in English:

(i) The name of the Accreditor which granted the accreditation;

(ii) The name and address of the Registrar affected by the accreditation action;

(iii) The nature of the accreditation action (e.g., initial accreditation, renewal of accreditation, etc.);

(iv) A copy of the Registrar's accreditation certificate and a scope of accreditation which states the quality system standard(s) for which the Registrar has been accredited for purposes of assessing and registering a fastener manufacturer's Facility; and

(v) The name and telephone number of the accredited Registrar's authorized representative(s), and information concerning the physical locations of all organizational units involved in the accreditation activities.

(2) All Accreditors listed by NIST in accordance with § 280.810(a) shall promptly notify NIST of each accreditation action taken. Accreditation actions include initial accreditations, denials of accreditation, renewals, suspensions, terminations, and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards

and Technology, Gaithersburg, Maryland 20899.

(c) *List of Facilities.* NIST shall prepare and maintain a list of Facilities registered by Registrars listed in accordance with § 280.810(b).

(1) Names and information regarding registered Facilities may only be included on the list from information submitted to NIST by accredited Registrars listed in accordance with § 280.810(b) that submit the listing fee established by NIST, through their Accreditors, and the following information:

(i) The name of the fastener manufacturer and the address of the registered Facility;

(ii) The name of the authorized representative of the fastener manufacturer whose Facility is registered;

(iii) The scope of the registration, stating the quality system standard(s) to which the Facility has been registered; and

(iv) The effective dates of the registration.

(2) All Registrars listed by NIST in accordance with § 280.810(b) shall promptly notify NIST of each registration action. Registration actions include initial registrations, denials of registration, renewals, suspensions, terminations, and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

(3)(i) If a Facility intends to be listed in accordance with § 280.810(c)(1) but the registration process will not be completed by July 26, 1998, the Facility may be provisionally listed on the Facilities List by providing the following to NIST on or before September 30, 1998:

(A) Certification that:

(1) The Facility is registered to QS-9000 or an equivalent by a quality systems registrar;

(2) The Facility conforms to all other requirements of the Act and these regulations at the time of certification;

(3) If the Facility ceases to be registered to QS-9000 or an equivalent by an accredited Registrar and/or ceases to conform to any other requirement of the Act and these regulations at any time during the provisional listing period, it will notify NIST of that fact within three working days; and

(4) If the Facility fails to apply to an accredited Registrar for registration under the FQA within 30 days of the time the Registrar is accredited by a NIST-approved Accreditor, an authorized representative of the Facility

will immediately notify NIST. (If the Facility's current Registrar decides not to seek accreditation under the FQA, it is the Facility's responsibility to apply to another Registrar that has been approved by NIST-ABEP.);

(B) A list of fasteners produced or processed by the Facility, identified by either a part number or a specification number;

(C) A list of standards included in the Facility's registration;

(D) A copy of the Facility's registration certificate; and

(E) The listing fee established by NIST.

(ii) The Facility must meet all the requirements of the Act and these regulations by May 25, 1999. If the Facility fails to receive FQA registration by May 25, 1999, it will be removed from the Facilities List.

(d) These lists will be readily accessible to the public. Only entities listed by NIST are authorized to offer services which comply with the Act and this part. NIST shall revise as appropriate all listings when notified of applicable actions and shall take appropriate steps to make changes promptly available to the public.

#### **§ 280.811 Removal from a list.**

NIST may remove from a list any listed entity if NIST deems such action to be in the public interest. An entity may appeal the removal or proposed removal from a list to the Director by submitting a statement of reasons why it should remain on the list. NIST may, at its discretion, hold in abeyance a removal action pending a final decision by the Director. The Director shall inform the entity in writing of the decision within sixty days following receipt of the appeal.

#### **§ 280.812 Appeal.**

An applicant Accreditor, Registrar, or fastener manufacturer whose Facility has been registered may appeal the removal or proposed removal from the Accreditors list, the Registrars list, or the Facilities list, to the Director.

#### **Subpart J—Recognition of Foreign Registrar Accreditation Bodies**

Sec.

280.900 Introduction.

280.901 Recognition of foreign entities.

#### **Subpart J—Recognition of Foreign Registrar Accreditation Bodies**

##### **§ 280.900 Introduction.**

In accordance with section 6(a)(1)(C) of the Act, this subpart sets forth the conditions under which the recognition of foreign entities by their governments,

by organizations acting on behalf of their governments, or by organizations recognized by the Director shall be deemed to meet the requirements of the Act.

#### **§ 280.901 Recognition of foreign entities.**

Foreign Accreditors wishing to be recognized to accredit Registrars must submit an application for evaluation to NIST according to subpart I of this part. NIST recognition is limited to bodies that accredit Registrars which register Facilities producing fasteners covered by the Act. To be recognized by NIST, Accreditors must meet conditions set out in subparts I and K of this part and accredit Registrars of Facilities to conditions set out in subpart L of this part.

#### **Subpart K—Requirements for Registrar Accreditation Bodies (Accreditors)**

##### **General**

- 280.1000 Introduction.
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#### **Subpart K—Requirements for Registrar Accreditation Bodies (Accreditors)**

##### **General**

##### **§ 280.1000 Introduction.**

This subpart sets out organizational, operational and other requirements that must be met by all Accreditors recognized by NIST under subpart I or J of this part. This subpart also sets out the requirements against which an Accreditor assesses the competence of an applicant Registrar.

##### **§ 280.1001 Scope.**

These are general requirements for an Accreditor to follow if it is to be recognized as competent and reliable in assessing and subsequently accrediting Registrars.

##### **Requirements for Accreditors**

##### **§ 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.

(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 of 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;

(11) Have a quality system, as outlined in paragraph (d) of this section, 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

(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:

(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 complies with the applicable provisions of this part, including section 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; 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, and the quality manual shall contain or refer to at least the following:

(i) A quality policy statement;

(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 functions;

(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;

(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.

(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.

(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 § 280.804(d); and

(vi) Information on procedures for handling complaints, 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.

#### **§ 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 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.

(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 Act and this part, 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 fulfill 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;

(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.

#### **§ 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) Fasteners covered by the Act.

(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.

#### **§ 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 an 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 § 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.

#### **§ 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.

#### **§ 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.

#### **§ 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**

#### **§ 280.1020 Application for accreditation.**

(a)(1) As specified in § 280.1010(g)(1) of this part, the Accreditor shall maintain up-to-date 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 § 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.

(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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

#### **§ 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.

(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.

### **Subpart L—Requirement for Registrars**

#### **General**

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### **Subpart L—Requirements for Registrars**

#### **General**

#### **§ 280.1100 Introduction.**

This subpart sets out organizational, operational and other requirements that must be met by all Registrars accredited under subparts I or J of this part.

#### **§ 280.1101 Scope.**

These are general requirements that must be met by a third-party body registering Facilities.

**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.

### Requirements for Registrars

#### § 280.1110 Registrars.

(a) *General provisions.* (1) The policies and procedures under which the Registrar 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 applicants other than as specified in this part.

(2) The Registrar shall make its services accessible to all applicants. 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 registration be conditional upon the number of Facilities already registered.

(3) The criteria against which the quality assurance system of an applicant is assessed shall be those outlined in the quality system standards or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific registration program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the Registrar.

(4) The Registrar shall confine its requirements, assessment, and decision on registration to those matters specifically related to the scope of the registration being considered.

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

- (1) Be impartial;
- (2) Be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of registration;
- (3) Identify the management (committee, group, or person) which will have overall responsibility for each of the following:
  - (i) Performance of assessment and registration as defined in this part;
  - (ii) Formulation of policy matters relating to the operation of the Registrar;
  - (iii) Decisions on registration;
  - (iv) Supervision of the implementation of its policies;
  - (v) Supervision of the finances of the Registrar; 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 Registrar, 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 registration system;

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

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

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

(9) Have the financial stability and resources required for the operation of a registration system;

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

(11) Have a quality system, as outlined in paragraph (d) of this section, giving confidence in its ability to operate a registration system for Facilities;

(12) Have policies and procedures that distinguish between registration and any other activities in which the Registrar 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 registration process;

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

(15) Ensure that activities of related bodies do not affect the confidentiality, objectivity, or impartiality of its registrations and shall not offer or provide, directly or indirectly, those services that it registers others to perform, consulting services to obtain or maintain registration, or services to design, implement, or maintain quality systems;

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

(17) Have a structure where members are chosen to provide a balance of

interests, where no single interest predominates; and

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

(c) *Subcontracting.* (1) When a Registrar decides to subcontract work related to registration (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflicts of interest, shall be drawn up. The Registrar shall:

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

(ii) Ensure that the subcontracted body or person is competent and complies with the applicable provisions of this part, including § 280.7, and is not involved, either directly or through its employer, with the design, implementation, or maintenance of a quality system in such a way that impartiality could be compromised; and

(iii) Obtain the consent of the applicant or fastener manufacturer whose Facility is registered.

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

(d) *Quality system.* (1) The management of the Registrar 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 Registrar 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 Registrar.

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

(4) The Registrar 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 Registrar 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 and the quality manual shall contain or refer to at least the following:

- (i) A quality policy statement;
- (ii) A brief description of the legal status of the Registrar, including the names of its owners, if applicable, and, if different, the names of the persons who control it;
- (iii) The names and qualifications, experience, and terms of reference of the senior executive and other certification/registration personnel, affecting the quality of the certification/registration 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 taking decisions regarding registration;
- (v) A description of the organization of the registration body, including details of the management (committee, group, or person), its constitution, terms of reference and rules of procedure;
- (vi) The policy and procedures for conducting management reviews;
- (vii) Administrative procedures including document control;
- (viii) The operational and functional duties and services 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 registration body personnel (including auditors) and monitoring their performance;
- (x) A list of its subcontractors and details of the procedure 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 registration process, including:
  - (A) The conditions for issue, retention, and withdrawal of registration documents;
  - (B) Checks of the use and application of documents used in the registration of quality systems;
  - (C) The procedures for assessing and registering fastener manufacturers' quality systems as employed in particular Facilities; and
  - (D) The procedures for surveillance and reassessment of registered Facilities.

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

(xiv) The procedures for conducting internal audits based on the provisions described in appropriate international documentation.

(e) *Conditions for granting, maintaining, extending, reducing, suspending, and withdrawing registration.* (1) The Registrar shall specify the conditions for granting, maintaining, reducing, and extending registration and the conditions under which registration may be suspended or withdrawn, partially or in total, for all or part of the Facility's scope of registration. In particular, the Registrar shall require the fastener manufacturer to notify it promptly of any intended changes to the quality assurance system or other changes which may affect conformity.

(2) The Registrar shall require the fastener manufacturer to have a documented quality system which conforms to applicable quality system standards or other normative documents.

(3) The Registrar shall have procedures to grant, maintain, withdraw and, if applicable, suspend registration; to extend or reduce the scope of registration; and to conduct reassessment in the event of changes significantly affecting the activity and operation of the Facility (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the registered fastener Facility no longer complies with the requirements of the Registrar.

(4) The Registrar shall have documented procedures which shall be made available on request for:

- (i) Initial assessment and for the surveillance and reassessment of a fastener manufacturer's quality assurance system as employed in a particular Facility;
- (ii) Continuing conformity with relevant requirements; and for verifying and recording that a fastener manufacturer takes corrective action on a timely basis to correct all nonconformities; and
- (iii) Identifying and recording nonconformities and the need for corrective action by fastener manufacturers on a timely basis for such items as incorrect references to the registration or misleading use of registration information.

(f) *Internal audits and management reviews.* (1) The Registrar shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality

assurance system is implemented and is effective. The Registrar 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 recorded.

(2) The top management of the Registrar 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 Registrar 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 Registrar operates;

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

(iii) Information about the assessment and registration process;

(iv) A description of the means by which the Registrar obtains financial support, and general information on the fees charged to applicants and fastener manufacturers whose Facilities have been registered;

(v) A description of the rights and duties of applicants and fastener manufacturers whose Facilities have been registered, including requirements, restrictions, or limitations on the use of the Registrar's logo and on the ways of referring to the registration granted;

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

(vii) A directory of registered Facilities, including their locations, describing the scope of registration granted to each.

(2) The Registrar shall establish and maintain procedures to control all documents and data that relate to its registration 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 Registrar or of the fastener manufacturer whose Facility is registered, when

required to perform any function relating to the activities of an applicant or registered Facility.

(h) *Records.* (1) The Registrar shall maintain a record system to suit its particular circumstances and to comply with this part. The records shall demonstrate that the registration 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 registration. 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 Registrar shall have a policy and procedures for retaining records for a period of five years. The Registrar shall have a policy and procedures concerning access to these records consistent with paragraph (h)(1) of this section.

(i) *Confidentiality.* (1) The Registrar shall have adequate arrangements, consistent with applicable laws to safeguard confidentiality of the information obtained in the course of its registration 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 product, quality assurance system, Facility, or fastener manufacturer shall not be disclosed to a third party without the written consent of the fastener manufacturer.

#### **§ 280.1111 Registrar personnel.**

(a) *General provisions.* (1) The personnel of the Registrar involved in registration 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 registration process shall be maintained by the Registrar. 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 Registrar.

(2) Auditors shall meet the requirements of the appropriate

international documentation. For the assessment of a quality system, the relevant guidelines for auditing and the criteria for auditors are those defined in 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 by the appropriate international documentation.

(c) *Selection procedure.* (1) The Registrar shall have a 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 assessment and subsequently monitoring the performance of auditors and technical experts.

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

(i) Be familiar with the Act and this part, registration procedures and registration 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 registration is sought and where relevant with associated procedures and their potential for failure (technical experts who are not auditors may fulfill this function);

(iv) Have a degree of understanding sufficient to make a reliable assessment of the competence of the Facility to provide products, processes or services in its registered 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 fastener manufacturer whose Facility is registered which compromise the registration process and decision; and

(B) In accordance with the directives of the Registrar, the audit team members shall inform the Registrar, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the fastener manufacturer whose Facility is to be assessed.

(d) *Contracting of assessment personnel.* The Registrar 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 Registrar, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior and/or present link with the fastener manufacturers whose Facilities are to be assessed. The Registrar shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for assessment personnel outlined in this Subpart.

(e) *Assessment personnel records.* (1) The Registrar shall possess and maintain up-to-date records on assessment personnel, 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 Registrar;

(v) Date of most recent updating of records; and

(vi) Performance appraisal.

(2) The Registrar 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 Registrar.

(f) *Procedures for audit teams.* Audit teams shall be provided with up-to-date assessment instructions and all relevant information on registration arrangements and procedures.

#### **§ 280.1112 Changes in the registration requirements.**

The Registrar shall give due notice of any changes it intends to make in its requirements for registration. It shall take account of views expressed by the 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 fastener manufacturer whose Facility is registered carries out any necessary adjustments to its procedures within such time as, in the opinion of the Registrar, is reasonable.

#### **§ 280.1113 Appeals, complaints and disputes.**

Appeals, complaints and disputes brought before the Registrar by fastener manufacturers or other parties shall be subject to the procedures of the Registrar. The Registrar shall keep a record of all appeals, complaints and disputes, and remedial actions relative to registration; take appropriate

corrective and preventive action; and document the actions taken and assess their effectiveness.

#### Requirements for Registration

##### § 280.1120 Application for registration.

(a)(1) As specified in § 280.1110(g)(1) of this part, the Registrar shall maintain up-to-date a detailed description of the assessment and registration procedure, the documents containing the requirements for registration and documents describing the rights and duties of fastener manufacturers whose Facilities are registered, and shall provide them to applicants and those fastener manufacturers. The Registrar shall require that a fastener manufacturer whose Facility is registered:

(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 its Facility is registered with respect to those activities for which it has been granted registration;

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

(v) Upon suspension or withdrawal of the registration (however determined), discontinues use of all advertising matter that contains any reference thereto and returns any registration documents as required by the Registrar;

(vi) Uses registration only to indicate that the quality assurance system as employed in its Facility is in conformity with specified standards or other normative documents, and does not use the registration to imply that a product or service is approved by the Registrar, as required by § 280.804;

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

(viii) In making reference to the registration in communication media such as documents, brochures, or advertising, complies with the requirements of the Registrar.

(2) When the desired scope of registration is related to a specific program, any necessary explanation shall be provided to the fastener

manufacturer. If requested, additional application information shall be provided to the fastener manufacturer.

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

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

(2) The applicant agrees to comply with the requirements for registration and to supply any information needed for its evaluation.

(c)(1) At least the following information shall be provided by the applicant prior to the on-site assessment:

(i) The general features of the applicant, such as corporate entity, name, addresses, legal status and, where relevant, human and technical resources;

(ii) General information concerning the quality system and the activities it covers;

(iii) A description of the systems to be registered and the standards or other normative documents applicable to each; and

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

(2) The information gathered from the application documentation and the quality manual review may be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

##### § 280.1121 Preparation for assessment.

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

(1) The requirements for registration are clearly defined, documented, and understood;

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

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

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

(c) The Registrar 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 Registrar's team as advisers.

(d) The fastener manufacturer 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 to by the fastener manufacturer. The mandate given to the audit team shall be clearly defined and made known to the fastener manufacturer, and shall require the audit team to examine the structure, policies, and procedures of the Facility and the quality assurance system it employs, and confirm that these meet all the requirements relevant to the scope of registration, and that the procedures are implemented and are such as to give confidence in the products, processes, or services of the Facility being evaluated.

##### § 280.1122 Assessment.

The audit team shall assess the quality assurance system, employed in the Facility being evaluated, covered by the defined scope against all applicable registration requirements.

##### § 280.1123 Assessment report.

(a) The Registrar 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 fastener manufacturer's management prior to leaving the premises, at which the audit team provides a written or oral indication regarding the conformity of the quality assurance system, as employed in particular Facility, with the particular registration requirements and provides an opportunity for the fastener manufacturer to ask questions about the findings and their basis;

(2) The audit team provides the Registrar with a report of its findings as to the conformity of the quality assurance system, as employed in the particular Facility, with all of the registration requirements;

(3) A report on the outcome of the assessment is promptly brought to the fastener manufacturer's attention by the Registrar, identifying any nonconformity to be discharged in order to comply with all of the registration requirements;

(4) The Registrar shall invite the fastener manufacturer 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 registration

requirements identified during the assessment of its quality assurance system, as employed in the particular Facility, and shall inform the fastener manufacturer of the need for full or partial reassessment of its quality assurance system 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 the Facility audited;  
(iv) The assessed scope of registration or reference thereto, including reference to the standard(s) applied;  
(v) Comments on the conformity of the quality assurance system, as employed in the particular Facility, with the registration requirements, with a clear statement of nonconformity and, where applicable, any useful comparison with the results of previous assessments of the quality assurance system, as employed in that particular Facility; and

(vi) An explanation of any differences from the information presented to the body at the closing meeting.

(b) If the final report authorized by the Registrar differs from the report referred to in paragraphs (a)(3) and (5) of this section, it shall be submitted to the fastener manufacturer 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 body to give confidence in the quality assurance system, as employed in the particular Facility; and

(3) The actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.

#### **§ 280.1124 Decision on registration.**

(a) The decision whether or not to register a fastener Facility shall be taken by the Registrar on the basis of the information gathered during the registration process and any other relevant information. Those who make the registration decision shall not have participated in the audit.

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

(c) The Registrar shall provide to each fastener manufacturer whose Facility is registered, registration documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These documents shall identify, for the fastener manufacturer and the particular Facility covered by the registration:

(1) The name and addresses;  
(2) The scope of registration granted, including as appropriate:

(i) The quality system standards and/or other normative documents to which quality systems are registered;

(ii) The product, process, or service categories; and, if appropriate,

(iii) Regulatory requirements, product standards, or other normative documents against which products are supplied.

(3) The effective date of registration and the term for which the registration is valid.

(d) Any application for amendment to the scope of a previously granted registration shall be processed by the Registrar. The Registrar shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.

#### **§ 280.1125 Surveillance and reassessment procedures.**

(a) The Registrar shall carry out periodic surveillance and reassessment

at sufficiently close intervals to verify that its registered Facilities continue to comply with the registration requirements. The period involved cannot be greater than one year.

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

#### **§ 280.1126 Use of certificates and logos.**

(a) The Registrar shall exercise proper control over ownership, use and display of its quality system registration mark and logos.

(b) If the registrar confers the right to use a symbol or logo to indicate registration of a Facility, the fastener manufacturer may use the specified symbol or logo only as authorized in writing by the Registrar. This symbol or logo shall not be used on a product or in a way that may be interpreted as denoting product conformity.

(c) The Registrar shall take suitable action to deal with incorrect references to the registration system or misleading use of certificates and logos found in advertisements, catalogs, etc. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

#### **§ 280.1127 Access to records of complaints to fastener manufacturers.**

The Registrar shall require each fastener manufacturer whose Facility is registered to make available to the Registrar, when requested, the records of all complaints and corrective action taken in accordance with the requirements of the quality system standards or other normative documents.

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