DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 280

[Docket No: 970724177–7177–01]

Procedures for Implementation of the Fastener Quality Act

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

ACTION: Notice of proposed rulemaking; request for comments.

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, United States Department of Commerce, request comments on proposed changes to the regulations found at 15 CFR part 280 pertaining to implementation of the Fastener Quality Act (the Act). The proposed changes allow accreditation of in-process inspection activities of qualifying statistical process control manufacturing facilities, address the issue of passing laboratory inspection and testing reports along the supply chain to the fastener manufacturer, address the issue of significant alteration by removal of manufacturer or grade identification markings for decorative purposes at the customer's request, address the issue of grandfathering fasteners, and revise definitions and related sections for clarity and to correct editorial error. The proposed changes will facilitate the implementation of the Act and regulations and will better accommodate modern industry practices by incorporating them into the Fastener Quality Act certification process.

DATES: Comments must be received no later than November 7, 1997.

ADDRESSES: Comments on the proposed revisions must be submitted to: 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.

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:

Background

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 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 the National Institute of Standards and Technology (NIST), published final implementing regulations on September 26, 1996, establishing 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, record keeping, 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, pursuant to Section 15 of the Fastener Quality Act, NIST announced a one year extension in the implementation date of the regulations on grounds that there were an insufficient number of accredited laboratories to conduct the volume of inspection and testing required by the Act and regulations (62 Fed. Reg. 19041 (1997)). NIST believes that it will have completed the approval/accreditation of a sufficient number of accreditation bodies/laboratories to implement the Act by May 26, 1998.

Following issuance of the final regulations on September 26, 1996, the automobile industry approached the Department and expressed its concerns that the Act and implementing regulations do not recognize the use of modern manufacturing methods using prevention-based quality assurance systems employing statistical process controls (SPC). During the period of September 1996 to January 1997, the Department worked with the automobile industry (domestic and foreign) to develop further information about the extent of the problem. On February 4, 1997, a Public Workshop was held at the National Institute of Standards and Technology (NIST) to solicit information from the automobile, aerospace, construction, and fastener industries on the use of prevention-based quality assurance systems employing SPC in the manufacture of fasteners. On the basis of this meeting and many discussions with the concerned industries, the Department is proposing amendments to the implementing regulations that will recognize the use of prevention-based quality assurance systems under the Act and regulations. These amendments are discussed in detail in Part 1 of this proposed rule.

In addition to the above, the Department collaborated with industry in conducting eleven Fastener Quality Act Workshops in various parts of the United States, Europe, and Asia during the period from September 1996 to February 1997. The workshops attracted over 2,500 industry participants who asked hundreds of questions of the Department on the Act and regulations. As a result of those workshops and the great deal of information provided by the industry participants on the impact of the Act and regulations, the Department assembled evidence of need for several possible amendments to the regulations. These amendments are discussed in detail in Part 2 of this proposed rule.

Part 1: Summary of Proposed Amendments on Statistical Process Control

Background & Definition of the Issue

Ford, General Motors, and Chrysler Corporation established a Supplier Quality Requirements Task Force in the 1980s to develop quality system requirements (QS–9000) for their suppliers of materials and parts. Initially, each company developed its own expectations for supplier quality systems. In 1988, emphasis was placed on standardizing the requirements, and in 1992 this was largely accomplished. The goal of QS–9000 is the development of fundamental quality assurance systems (QAS) that provide for continuous improvement, emphasizing

defect prevention and the reduction in variation and waste in the supply chain.

QS–9000 employs statistical process control (SPC) in ensuring the quality of parts. Suppliers must demonstrate process capabilities which will yield a given quantity of parts with a minimum specified number of defects. Depending upon the fastener type and auto maker, the maximum allowable defective Parts Per Million (PPM) ranges between 15 and 125 PPM.

The heart of the QS–9000 system is the Control Plan which each company must develop and have approved by Ford, GM, or Chrysler as part of their adherence to QS–9000. The Control Plan is a comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that will occur during mass production. It will normally also specify how much in-process or final testing and inspection will be carried out by the supplier company. This determination is based upon demonstrated process capabilities, experience with the supplier, etc. QS–9000 implies that, through continuous improvement, a supplier company may ultimately be able to demonstrate a capability of producing millions of parts with zero defects by continuously monitoring and controlling the production process rather than relying upon the inspection and testing of the physical attributes of the manufactured product. Given the above, the automotive industry asserts that the Fastener Quality Act's reliance on lot control and final inspection of fasteners does not recognize the reality of modern mass production using statistical process control.

As present, the FQA and implementing regulations, rely on the use of accredited laboratories for inspection, testing, and certification of fasteners to applicable standards and specifications. Sections 5 of the Act and 280.5 of the regulations are very specific that a manufacturer of a lot of fasteners shall cause a representative sample of the fasteners in the lot to be inspected and tested by an accredited laboratory, and a test report must be produced which indicates that the fasteners tested are in conformance with all of the provisions of the standards and specifications used by the manufacturer in the production of the fasteners. The end result, and the cornerstone on which the Act is based, is that every lot of fasteners is certified by the manufacturer as conforming to a given standard and specification, and the paperwork relating to such certification (e.g., certificates of conformance and test reports) is maintained on file and available at the purchaser's request.

In the case of fastener manufacturers supplying the automobile industry, Ford, GM, and Chrysler, as major end users of the fasteners, have established QS–9000 as a means of achieving the same end. Their suppliers are required to: (1) Establish a control plan under which they will produce fasteners to the auto industries standards and specifications; (2) submit evidence in the form of production data that they can produce fasteners under a specified defect rate; and (3) perform continuous monitoring and tests to maintain control of the production process and to assure that the final product will be in conformance with fastener standards and specifications. The difference between the previously published regulation and the QS–9000 approach is that the regulation assures end users that fasteners meet standards and specifications by relying upon the inspection and testing of fasteners by accredited laboratories. Under QS–9000, the end users (Ford, GM, and Chrysler) recognize the fastener manufacturer's entire production process as a means of ensuring conformance to these end users standards and specifications. Consequently, ensuring adherence to standards and specifications, is equivalent under the QS–9000 approach to end product testing. However, the automobile industry believes that reliance on QS–9000, which is based upon continuous monitoring and improvement of the manufacturing process, is more efficient and cost effective than traditional manufacturing regimens of final inspection and testing of the end product, and represents the direction in which manufacturing technology is evolving in this country and abroad.

Parallels to QS–9000 are being used in other countries including Japan, and in other industries. For example, the U.S. aerospace industry employs statistical process control in much the same way that the automobile industry does. That is, major end users of aerospace fasteners are beginning to require their fastener suppliers to comply with comparable quality assurance programs as a condition to supplying them.

When the Fastener Quality Act was signed into law in 1990, QS–9000 was in the early stages of development, and its full implication for the industry was not well known. There is some evidence in the history of the Act that Congress was informed of the need to consider OEM based quality assurance systems for procuring fasteners (e.g., Statement of Donald Keil, Assistant Director of Quality, Caterpillar Inc., during the Hearing on H.R. 3000 before the Committee on Commerce, Science, and Transportation, United States Senate, S.Hrg. 101–509, November 20, 1989). However, the Act did not directly recognize major end user quality system requirements for satisfying testing, inspecting and certification provisions under section 5 of the Act. Similarly, in August 1992, NIST published draft implementing regulations for public comment. As a result of the public comment process, letters were received from General Motors and Nissan Corporation calling attention to quality assurance programs they had in place to qualify fastener suppliers; they indicated that the Act would require some redundant testing. However, no recommendations were made at that time to permit recognition of QS–9000 type systems.

The discussions about the use of statistical process control within the automobile industry, did not lead to specific recommendations for treating SPC under the Act or regulations. However, the issue was raised at a meeting of the Fastener Advisory Committee in May 1996. At that meeting a member of the Advisory Committee raised the issue of problems that fastener suppliers would face in meeting the inspection, testing, and certification requirements of the Act and regulations. Accordingly, a proposal was introduced to exempt from the regulations the automotive fasteners produced to the standards of a major end user such as GM, Ford, and Chrysler. Since May of 1996, the Department has had many discussions of these issues with representatives of the automobile industry (U.S. and foreign) and with fastener manufacturers who supply such industries. On February 4, 1997, NIST held an open meeting to solicit industry views on the use of SPC in the manufacture of fasteners under the Act. The purpose of the meeting, attended by some 150 industry representatives and Department officials, was to determine the impact that inspection, testing, and certification requirements of the Act and regulations would have on fastener manufacturers who use SPC and to identify ways in which the requirements of the Act and regulations might be met by prevention-based QAS using SPC.

A report of the meeting was published in April 1997, NISTIR 6001—''Summary of Public Meeting, Use of Quality Assurance Systems in the Fastener Industry,'' and may be obtained from NIST. The report included proposed regulatory language being considered at that time by the Department for resolving the issues identified during the meeting. As part of the report, the

Department invited industry to provide input on the suggested regulatory approach. Some 30 letters were received by NIST, commenting on the report and the proposed regulatory language. The vast majority of these focused on the SPC issue, suggesting solutions ranging from exempting the automobile industry from the Act and regulations to incorporating SPC in the regulatory scheme. Many proposed specific amendments to the regulations that would incorporate SPC. The Department appreciates the spirit with which the automobile industry has responded and had considered all comments received. It is believed that the amendments proposed in this notice best achieve the incorporation of SPC in the regulatory scheme.

The Proposed Solution to the QAS/SPC Issue

The Director of NIST is today proposing that a fastener manufacturing facility employing a fastener quality assurance system (QAS) as defined in the regulations may be deemed to be an accredited laboratory for purposes of the Act and regulations if such facility has been formally registered by a NIST-recognized quality systems registrar.

NIST wishes to make it clear that recognition of facilities that employ fastener QAS as accredited laboratories within the meaning of the Act and regulations is an alternative to final inspection and testing of fasteners that is still carried out by many fastener manufacturers. Both approaches to meeting the requirements of the Act and regulations are equally valid. Adoption of these proposed amendments will enable the use of QAS in fastener manufacturing in a manner consistent with the requirements of the Act by ensuring that every lot of fasteners is sampled and examined to ensure conformance with applicable standards and specifications. Manufacturers must follow the requirements of the fastener standards and specifications, as published by a consensus standards organization or a major end user. For example, a fastener manufacturer cannot unilaterally decide to replace final inspection and testing with a QAS unless the designated standards or specifications provide for this as an alternative to final inspection and testing.

A definition of ''Fastener Quality Assurance System (QAS)'' is proposed as part of the amendments. In developing the QAS definition, NIST feels it is important to provide guidance to the industry as to the minimum elements a fastener manufacturer's QAS should contain to be eligible for recognition as an accredited laboratory within the meaning of the Act and regulations. These elements have been included in the definition.

The Department believes that the proposed amendments resolve industry's concerns that the Act and regulations should recognize the use of modern manufacturing methods. Proposed procedures for applying for NIST/ABEP recognition of registrar accreditation bodies that accredit quality systems registrars, which are based upon international standards, are included as subparts I through L.

Part 2: Summary of All Other Proposed Amendments

Since September 1996, eleven Fastener Quality Act Workshops have been conducted in seven cities in the U.S. (Chicago [2], Cleveland, Columbus, Houston, Newark, Atlanta, and Los Angeles), and in Taiwan and the U.K. (two were held in London). Over 2,500 industry participants attended the workshops. These included fastener manufacturers, distributors, and importers, and representatives of industries such as automotive, aerospace, construction, heavy machinery, etc., that purchase and use high strength fasteners. At the workshops, representatives of BXA, NIST, and the Patent and Trademark Office (PTO) presented information on the Act and implementing regulations. In addition, members of the Public Law Task Force (PLTF), a nine member industry committee representing fastener manufacturers, distributors, and importers, provided an industry perspective on the impact of the Act and regulations. Over the course of the workshops some 450 questions from the participants were documented by the Department, with the understanding that answers would be published as interpretive opinions of the Department as soon as practicable.

During the course of the workshops a great deal of practical information was exchanged among the participants on the impact of the Act and regulations on daily commerce in fasteners. This information has been analyzed by the Department and translated into proposed amendments which are discussed below. Comments from the public are requested on these proposed amendments.

1. Significant Alterations of Fasteners

Under section 280.2 of the regulations, ''significantly alter'' means to alter a fastener in a manner 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 specified Rockwell C hardness of less than 32, or cutting off of fasteners. In the reference to Rockwell C hardness, an editorial error was made in the September 26, 1996 issuance of the final regulations in that the word ''minimum'' was to appear before the word ''specified'' so that it reads ''minimum specified Rockwell C hardness of less than 32 * * *'' in section 280.2 and in section 280.11 (b) of the regulations. The Department proposes amendments to these sections to correct this error.

2. Removal of Head Markings

Questions were raised during each of the workshops about specialty fasteners and the practice of shaving or polishing of fastener heads to remove all markings for decorative purposes. The cases mentioned were of manufacturers of motorcycles and pianos which frequently special order fasteners that will be subject to the Act and regulations without any head markings on them because they do not want the markings to show in the final product. However, the Department also recently received a letter from the Association of International Automobile Manufacturers (AIAM) indicating that some of its members produce company standards which may reference consensus standards for certain requirements for fasteners but which do not reference requirements for including the manufacturer's insignia on the head of the fastener. AIAM asserts that such practice is consistent with the Act and regulations and that the manufacturer of the fastener may supply the fasteners to these automobile manufacturers without any head markings. The issue is whether a fastener manufacturer is in violation of the Act and regulations if he/she fills such an order from a customer. Put another way, how much flexibility does a customer have in requesting that covered fasteners be supplied to them without the required headmarkings if they are going to use the fasteners in their products and possibly even sell them for repair and replacement parts?

The Department has studied this issue and is proposing to amend the regulations by adding a new section 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. The existing sections

280.11(c) and (d) are proposed to be redesignated as sections 280.11(d) and (e). The new section 280.11(c) requires that: (1) The fasteners be manufactured to an OEM or major end-user standard which does not require such markings; or (2) the customer request in writing that manufacturer or grade identification markings be removed for decorative purposes and certifies that such fasteners will not be held out or sold as meeting the requirements of a consensus standard which requires manufacturer or grade identification markings.

3. Supplying Originals vs Copies of Test Reports

In all of the workshops, especially those held in Asia and in Europe, concerns were expressed about the potential paperwork burden on raw materials manufacturers in meeting the requirements of section 280.15 of the regulations. Raw materials manufacturers (domestic and foreign) assert that the requirement for ''originally signed'' test reports to accompany shipments of raw materials and finished fasteners will be a significant burden to them.

In the case of raw material suppliers, the raw material purchased by the fastener manufacturer typically goes through as many as four processors, each performing a different operation that does not affect the steel's chemical characteristics. In addition, distributors may be involved in these transactions. Under one scenario, the following successive processors/distributors transform the ingot/bloom to fasteners:

Steel mill or melter or ingot producer ⇨rod producer⇨ wire or rod producer⇨ distributor⇨ fastener producer

Current industry practice is that the steel mill is the primary source at which the chemical characteristic certification is produced and passed down to the first processor or distributor to whom it sells the steel. All other subsequent processors, distributors and fastener manufacturers in the above mentioned chain, produce their own certification based on the results contained in the original chemical certificate of the steel mill. This certificate consists of relevant information such as the name of steel melter, steel mill identification, heat number, and chemical analysis data. Therefore, current industry practice is for everyone in the chain except the original steel melter to reference the original chemical certification data instead of passing on a certified copy of the chemical characteristics certificate down the chain to the fastener manufacturer. The primary reason for this practice is that from a single heat number of steel, thousands of lots of fasteners can be manufactured by an unknown number of fastener manufacturers. Moreover, the steel mill would not know in advance the name of fastener manufacturers who would purchase steel from a given heat number or the number of certificates required from a heat number of the steel.

To comply with the Act and current regulations, either copies of the laboratory report of chemical characteristics, certified by the laboratory, must be passed down the supply chain ''through the metal manufacturer'' or the fastener manufacturer must be responsible for contacting the laboratory that performed the chemical tests to obtain a certified copy directly. Since the metal manufacturers do not know how many fastener manufacturers will acquire part of a particular heat or coil, they do not know how many certified copies to request from the laboratory at the time they obtain the original test report. The fastener manufacturers feel it is burdensome for them to obtain certified copies from the laboratories, and it is extremely burdensome for the laboratories to have to retrieve reports and create certified copies whenever requested by fastener manufacturers.

A solution that works for both fasteners of foreign origin and domestically-produced fasteners is to allow copies of laboratory testing reports of chemical characteristics only to be certified by either the laboratory or the metal manufacturer. The definition of ''original laboratory testing report'' in section 280.2 is proposed to be amended to allow metal manufacturers, as well as laboratories, to certify copies of laboratory testing reports of chemical characteristics.

4. Laboratory Test Reports

Several steel producers raised another issue with respect to the chemistry certificate during the workshops. It deals with a discrepancy in the language used in reporting of alternative chemical characteristics, as follows:

1. Section 5(d)(3)of the Act requires reporting the, ''chemical characteristics of such coil or heat number;''

2. Section 280.6(b)(5)(ii) of the regulations requires, ''test results for each sample;'' and

3. Section 280.15(b) returns to the requirement for reporting, ''chemical characteristics of such coil or heat number.''

The chemical characteristics data required to be reported in section 280.6(b)(5)(ii) is not the same as the other two sections mentioned above. Currently, steel manufacturers use test reporting methods that conform to section 5(d) of the Act, and section 280.15 of the regulations. The reporting of the ''heat number analysis'' is well defined in existing steel making practices and consensus standards. A ''heat number analysis'' consists of derived values for each element from one or more samples taken from either molten metal or solid steel. Overall, this method best describes the chemical characteristics of the steel.

If section 280.6(b)(5)(ii) is not changed to make it in agreement with other sections of the Act and regulations, several problems may occur:

1. Steel suppliers will be forced to use their best judgement in interpreting the Act, and proper methods of reporting of chemical analysis;

2. Variations in interpretations will lead to serious disputes between steel suppliers and their customers; and

3. Steel suppliers will be forced to change reporting methods to those described in section 280.6(b)(5)(ii), which will result in unnecessary costs to the industry.

Accordingly, the Department is proposing for public comment an amendment to section 280.6(b), which is proposed to be redesignated as section 280.6(c), which requires the reporting of test results for such coil or heat number chemical analysis.

5. New Definition of ''Lot Number''

It was pointed out during the workshops that ''lot number'' as defined in section 280.2 of the definitions means a number assigned to the lot by a manufacturer, and that it is fairly common for distributors and importers to assign their own unique lot number to fasteners in addition to the number assigned by the manufacturer. Further, section 280.11 of the regulations dealing with significant alterations requires that significant alterors assign their lot numbers to significantly altered fasteners. Accordingly, the Department is proposing to amend the definition of lot number found in section 280.2 to include a number assigned by a manufacturer, importer, distributor, or significant alterer to the lot. The amendment further stipulates that a lot number assigned by an importer, distributor, or significant alterer shall be traceable to a manufacturer's single, unique lot number.

6. Grandfathered Fasteners Issue

Section 15 of the Act provides that the Act is applicable only to fasteners manufactured after the implementation date of the Act. Section 280.12(c) of the

regulations further states that nothing in the Act or in the regulations prohibits selling finished fasteners manufactured prior to the implementation date of the Act, or representing that such fasteners meet standards and specifications of a consensus standards organization or a government agency. Additionally, this section of the regulations 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.

It is clear that Congress, in enacting section 15 of the Act, intended only to cover those fasteners produced after the implementation date of the Act so as not to impose a hardship on the industry by having existing product retested and certified. However, representatives of the fastener industry met in January 1997 with representatives of NIST and proposed that section 280.12(c) of the regulations be amended by moving the last sentence of the 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 section 280.602, Violations. This sentence is moved to the violations section because as a prohibition on certain specific conduct, it more appropriately belongs there.

Request for Public Comment: Persons interested in commenting on the proposed regulations should submit their comments in writing to the above address. All comments received in response to this notice will become part of the public record and will be available for inspection and copying at the Department of Commerce Central Reference and Records Inspection facility, room 6228, Hoover Building, Washington, DC 20230.

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

Regulatory Flexibility Analysis of Procedures for Implementation of the Fastener Quality Act

This proposed rule has been determined to be not significant for the purposes of E.O. 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy, the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The proposed rule includes changes that allow accreditation of in-process inspection activities of qualifying statistical process control (SPC) manufacturing facilities, address the issue of passing laboratory inspection and testing reports along the supply chain to the fastener manufacturer, address the issue of significant alteration by removal of manufacturer or grade identification markings for decorative purposes at the customer's request, address the issue of grandfathering fasteners, and revise definitions and related sections for clarity and to correct editorial error. The proposed changes will facilitate the implementation of the Fastener Quality Act (FQA) and regulations and will better accommodate modern industry practices by incorporating them into the FQA certification process. However, of all these proposed changes, the major change covered here is that which allows accreditation of in-process inspection activities of qualifying statistical process control manufacturing facilities. The remaining changes are relevant to the existing regulations that became effective on November 25, 1996, and their impact on the fastener industry already has been presented. Therefore, in this analysis, the issues relevant to manufacturing of fasteners using only SPC or quality assurance systems (QAS) are covered.

As presently constructed, the FQA and implementing regulations, rely on the use of accredited laboratories for inspection, testing, and certification of fasteners to applicable standards and specifications. Sections 5 of the Act and 280.5 of the regulations are very specific that a manufacturer of a lot of fasteners shall cause to be inspected and tested a representative sample of the fasteners in the lot by an accredited laboratory, and a test report must be produced which indicates that the fasteners tested are in conformance with all of the provisions of the standards and specifications used by the manufacturer in the production of fasteners. The end result, and the cornerstone on which the law is based, is that every lot of fasteners is certified by the manufacturer as conforming to a given standard and specification, and the paperwork relating to such certification (e.g., a certificate of conformance and test reports) is maintained on file and available at the purchaser's request.

In the case of fastener manufacturers supplying the automobile industry, the industry has established QS–9000 as a means of achieving the same end. That is, they qualify their suppliers by requiring them to: (1) Establish a control plan under which they will produce fasteners to their standards and specifications; (2) submit evidence in the form of production data that they can produce fasteners under a specified defect rate; and (3) perform continuous monitoring and tests of the production process to maintain control of the process and to assure that the final product will be in conformance with fastener standards and specifications. The difference between the regulation as it exists and the QS–9000 approach is that the regulation assures end users that fasteners meet standards and specifications by relying upon the inspection and testing of fasteners by accredited laboratories. Under QS–9000, the end users (Ford, GM, and Chrysler) recognize the fastener manufacturer's entire production process as a means of assuring conformance to their standards and specifications. The end result, that of assuring adherence to standards and specifications, is the same under the QS–9000 approach as with end product testing. However, the automobile industry believes that reliance on QS–9000, which is based upon continuous monitoring and improvement of the manufacturing process, is more efficient and cost effective than traditional manufacturing regimens of final inspection and testing of the end product, and represents the direction in which manufacturing technology is evolving in this country and abroad.

To the extent the FQA permits flexibility in developing these draft regulations, the Department has sought advice from the fastener and end-user industries (automotive, aerospace, etc.) to maximize the cost-effectiveness of the proposed rule. Those recommendations presented by the industry at the February 4, 1997 meeting and at site visits to industry have been incorporated in this proposed rule to assist industry in implementing this rule, if accepted, in a cost-effective manner.

It is difficult to estimate the total number of fastener manufacturers in the U.S. because there are too many that do not belong to any professional organization and operate very small shops. Some estimate this number to be in excess of one thousand. However, based on an estimate from the Industrial Fastener Institute, 80% of the U.S. fastener production capacity is served

by approximately 120 major manufacturers. Of these, nearly 50%, or 60 manufacturers, supplying fasteners to the auto and aerospace industries could be using the QAS included in this rule. A large majority of these 60 manufacturers could be classified as small businesses employing less than 750 employees (as defined at 13 CFR 121.201).

We believe the overall effect on the fastener industry of adopting this proposed rule will be highly beneficial. No negative effects are envisioned at this time. In fact, as we look into the future, we believe market forces (improved quality and decreased cost) will push the remaining manufacturers not currently using QAS to adopt the QAS standards. This proposed rule, if adopted, would allow these manufacturers to do so without incurring additional costs to comply with the FQA. We believe this proposed rule, if adopted, would benefit the industry in, at least, the following ways:

1. Ability to use modern manufacturing technology to conform with the law without a need to make any changes;

2. Ability to use just-in-time delivery and other advancements to avoid production delays and reduce inventory costs; and

3. Overall improvement in the fastener quality at a lower production cost.

Registration cost per facility will vary with scope (the number of procedures and products, the number of sampling locations, etc.) as in the case of laboratory accreditation. Based on the laboratory accreditation carried out by NVLAP during the past nine months, we estimate the annual cost of registration will run between $5,000 and $15,000 per facility which is the same as the cost of laboratory accreditation. Since most facilities are likely to adopt one of the approaches, this will not be an additional cost. Moreover, most facilities seeking registration have already obtained registration under either ISO–9000 or QS–9000. Therefore, additional cost savings may result because fastener manufacturers do not have to spend resources solely for conforming with the FQA.

It is not expected that any manufacturing facility practicing QAS will cease to operate; suffer a significant loss in gross revenue; or have increased compliance costs because of this proposed rule, if adopted.

We seek public comment providing data on impact for use in determining the appropriateness of this certification for purposes of a final rule. Moreover, within one to two years of the initial implementation period, if adopted, we should have sufficient data to assess impact for purposes of determining the necessity for review under 5 U.S.C. § 610(c).

The requirements for laboratory accreditation and registration of manufacturing facilities under this rule are in accordance with the established international standards, thus promoting uniformity in the evaluation process. The rule allows the fastener manufacturer and testing laboratories to decide which approach to choose for seeking accreditation.

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act. However, that requirement involves paperwork already being produced by fastener manufacturers. The only additional requirement is to prepare a synopsis of the testing and inspection results in the form of a test report. This requirement is proposed to facilitate enforcement actions of the Bureau Of Export Administration (BXA), which has the enforcement authority granted under the Fastener Quality Act.

As a result, no initial regulatory flexibility analysis has been 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 proposed rule revises an existing collection of information subject to the requirements of the Paperwork Reduction Act that was previously approved by the Office of Management and Budget under the control number 0693–0015. The revision is applicable to persons requiring approval of the Accreditation Body Evaluation Program (ABEP) at NIST to register quality system registrars who would in turn register fastener manufacturing facilities.

The collection of information requirement is applicable to persons requiring approval of the Accreditation Body Evaluation Program (ABEP) at NIST to accredit quality system registrars who would register fastener manufacturing facilities. The public reporting burden per respondent for the collection of information contained in this rule is estimated to average 4 hours annually. This estimate includes the time for reviewing instructions, searching existing information, gathering and maintaining the information needed, and completing and reviewing the collection of information.

Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of NIST's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Comments should be addressed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503; and to NIST (Attn.: ABEP 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: August 13, 1997.

Robert E. Hebner,

Acting Director, National Institute of Standards and Technology.

Dated: August 21, 1997.

William A. Reinsch,

Under Secretary for Export Adminstration.

For reasons set forth in the preamble, it is proposed that Title 15 of the Code of Federal Regulations be amended as follows:

PART 280—FASTENER QUALITY

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

Authority: Section 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 had 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, lot number, original laboratory testing report,* and *significantly alter* 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).

* * * * *

Accreditor means a registrar accreditation body that meets the requirements of subpart K of this part, is recognized by NIST, and appears on the Accreditors List described in § 280.810(a).

* * * * *

Facility means a fastener manufacturing facility implementing a quality assurance system as defined in this part, that has been registered by a Registrar and appears on the Facilities List described in § 280.810(c).

* * * * *

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, ARD–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, and performed by a Facility on the Facilities List described in § 280.810 or tested by a Laboratory on the Laboratories List described in § 280.101, to avoid product lot contamination, and that finished lots of fasteners shall be traceable to subcontracted processes;

(iv) A QAS plan, requiring 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 or specifications (consensus or major end-user standards as defined by the Act and this part), or those characteristics appropriate for evaluating product functionality.

* * * * *

Lot number means a number assigned by a manufacturer, importer, distributor, or significant alterer to the lot. A lot number assigned by an importer, distributor, or significant alterer shall be traceable to a manufacturer's single, unique lot number.

* * * * *

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.

* * * * *

Registrar means a quality systems registrar that meets the requirements of subpart L of this part, is accredited by an Accreditor as defined in this part, and appears on the Registrars List described in § 280.810(b).

* * * * *

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 amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d) respectively, adding new paragraphs (b) and (e), and revising redesignated paragraph (c)(5)(ii) to read as follows:

§ 280.6 Laboratory Test Reports.

* * * * *

(b) When performing tests for which they are registered under this part, each facility registered under Subpart I or J of these regulations and currently listed in the Facilities List shall issue test reports of its work which accurately, clearly, and unambiguously present a synopsis of 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 tamper 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;

(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, if any, 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) Production lot size and the number sampled;

(iii) Name(s) and affiliation of person performing the lot sampling;

(6) Test Results:

(i) Actual tests required by the standard and specification;

(ii) Test results;

(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/facility and accreditation/registration information listed in paragraph (b)(10) of this section.

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

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

(c) * * *

(5) * * *

(ii) Test results for such coil or heat number chemical characteristics;

* * * * *

(e) For tests carried out by a Facility registered pursuant to subpart I or J, 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, 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 involved in sample preparation and 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.

In the event that the standard or specification to which a manufacturer represents the fasteners in a particular sample to have been manufactured does not provide for the size, selection or integrity of the sample to be inspected and tested, inspections and tests under section 5 of the Act shall be carried out using 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,* or a sampling plan provided by a Fastener Quality Assurance System or by standards and specifications intended for use with a Fastener Quality Assurance System, as appropriate.

7. Section 280.11 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e) respectively, adding new paragraph (c), and revising paragraph (b) and redesignated paragraph (d) 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.

(c) If the significant alteration is only the removal of manufacturer or grade identification markings for decorative purposes at the customer's request, the requirements set forth in paragraph (a)(2) 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 either test the fasteners or provide a written statement disclosing the alteration as set forth in paragraph (a)(3) of this section. Along with such an order the fastener manufacturer must require a written certification from the customer stating that fasteners from the altered lot will not be held or sold as meeting the requirements of a consensus standard which requires manufacturer or grade identification markings.

(d) Any person who knowingly sells a significantly altered fastener as described in paragraph (a) of this section, and who did not alter such fastener, shall provide to the purchaser a copy of the statement required by paragraph (a)(3) of this section; unless the significant alteration is only electroplating of the fastener, as described in paragraph (b) of this section or removal of manufacturer or grade identification markings, as described in paragraph (c) of this section.

* * * * *

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 May 26, 1998.

(b) Metal manufactured prior to May 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 May 26, 1998 or representing that such fasteners meet standards and specifications of a consensus standards organization or a government agency.

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 and 280.7.

(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 testing 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), and (n) to read as follows:

§ 280.602 Violations.

* * * * *

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

(2) In connection with the preparation, submission, use, 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 May 26, 1998 as being in conformance with the Act or 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.

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.

(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. 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, which is based upon ISO Guide 61; the NIST-recognized Accreditors may, in turn, accredit Registrars that meet the requirements of Subpart L, 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: § 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.

(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 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.

(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.

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. 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 and accredit Registrars of Facilities to conditions set out in subpart L.

Subpart K—Requirements for Registrar Accreditation Bodies (Accreditors)

Sec.

General

Requirements for Accreditors

Requirements for Assessment

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 to committees or individuals, as required, to undertake defined activities on its behalf.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 § 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 function;

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

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

(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 Fastener Quality Act and its implementing regulations, accreditation procedures and accreditation requirements;

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

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

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

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

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

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

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

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

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

(i) Name and address;

(ii) Affiliation and position held in the organization;

(iii) Educational qualifications and professional status;

(iv) Experience and training in each field of competence of the Accreditor;

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

(vi) Performance appraisal.

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

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

§ 280.1012 Decision on accreditation.

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

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

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

(1) The name and address;

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

(i) The type of registration scheme;

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

(iii) Product categories.

(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) The Accreditor shall maintain up-to-date as specified in § 280.1010(g)(1), detailed description 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—Requirements for Registrars

Sec.

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 § 280.1110(d), 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 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 section 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 paragrphs (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, im plemented, 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 dis closed 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 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 Fastener Quality Act and its implementing regulations, 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) The Registrar shall maintain up-to-date as specified in § 280.1110(g)(1), 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 section 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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